

The Institute of Medicine

**A Workshop to
Obtain Input on the Gulf Long-term
Follow-up of Clean-up Workers Study**

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Proceedings by:

**CASET Associates, Ltd.
Fairfax, Virginia 22030
(703) 266-8402**

NOTE: This is an unedited verbatim transcript of the IOM Workshop to Obtain Input on the Gulf Long-Term Follow-Up Study for Oil Spill Clean-Up Workers and Volunteers held on September 22, 2010 prepared by CASET Associates and is not an official report of National Academy of Sciences, the National Academy of Engineering, the Institute of Medicine, or the National Research Council (the "National Academies"). Opinions and statements included in the transcript are solely those of the individual persons or participants at the workshop, and are not necessarily adopted or endorsed or verified as accurate by the National Academies.

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P R O C E E D I N G S (8 : 3 0 a . m .)**Agenda Item: Welcome**

DR. FINEBERG: Good morning everyone. I am Harvey Fineberg, the President of the Institute of Medicine. It is my great privilege to welcome all of you to today's workshop. This is an opportunity for all of us to come together to focus on the question of the health effects of the oil spill in the Gulf of Mexico. The Institute of Medicine is the health arm of our National Academy of Sciences. Our job, in general, is to bring the best that we can of science and evidence to bear on questions of health and health policy and health practice. Our work is intended to help inform and advise government agencies, institutions, members of the profession, and the public about what can be done and should be done to improve health.

In this instance, the Institute of Medicine has been invited by the Department of Health and Human Services and specifically by the National Institute of Health to assist in thinking and refining the ideas, if I may use that verb. To improve our ability to understand and to intervene on health effects of the Gulf oil spill. While the oil was still flowing early last summer, the institute of Medicine convened a first workshop in the Gulf area -

this one in New Orleans - to examine, broadly, the questions about how the assessment could, in general, be carried forward. That effort, that workshop is summarized in a report called Assessing the Effects of the Gulf of Mexico Oil Spill on Human Health that came out earlier this summer after the workshop and represents, I think, a good backdrop to the general proposition that we are going to be considering through the course of this day.

In that effort, more than 40 experts from a range of fields of public health, of environmental health, of occupational health, toxicology, medicine, exposure assessment, risk communication - from all dimensions, came together to look at the entire array of possible effects and how one could approach assessment and understanding about them. It is true that the oil is no longer flowing. Perhaps, as a consequence the intensity of media scrutiny and public attention has waned, but the consequences and the health consequences, particularly, remain as real and as potent as they were while the oil was, in fact, pouring forth. Indeed, as we will see in the course of this day, long-term, as well as intermediate and short-term effects are critical as parts of the agenda.

As a workshop, our job is not to produce recommendations out of the discussion. Our job today, with

everyone's participation, is to increase our understanding, expose ideas, raise questions, make sure there is clarity in everyone's mind, and that the National Institutes of Health, especially the NIEHS that is leading the proposed study that is at the heart of our discussion today, has the benefit of everyone's best question and thinking as the study protocols will take shape. In parallel to this, there will be an ongoing Institute of Medicine activity to help in providing periodic advice to the Department of Health and Human Services on emerging concerns, on research priorities, on recalibration of direction. Indeed, the committee that will be carrying out that work is assembled here, today, to help in participating and to learn from the discussion today, and, indeed, will be carrying forward on its work tomorrow.

I was joking with the committee this morning that it is rather unusual for the NIH to have others look at its protocols and we thought that was a rather delicious turn of events. I suggested that it would be entirely appropriate for the first report - the letter report of the committee to be printed on pink sheets. The members of the committee will be introduced a little bit later this morning, but I do want also, specifically, to thank Dr. Nicole Lurie. I do not know if Nicole is here this

morning. I know she will be here a little bit later today. She is the Assistant Secretary for Preparedness and Response in the Department, who has been so instrumental in helping to guide the overall response and in initiating some of the work earlier with the Institute of Medicine. We will hear from her and see her later.

At this point, it is my great privilege to introduce a colleague and friend, who is the Director of the National Institutes of Health, Dr. Francis Collins. Dr. Collins distinguished himself as a scientist and as a leader in advancing discoveries around gene tracking methodology that catapulted him into a leadership responsibility as Director of the National Human Genome Research Institute. In that role, he earned a reputation as an individual who was not only scientifically astute, but also able to deliver results ahead of schedule and under budget - a talent that in his current position as Director of NIH, undoubtedly he will be called upon to replicate time and time again. We will all, I know, benefit tremendously from Dr. Collins' perspective on this critical problem and I look forward very much, as I know you do, to hearing. Please join me in welcoming Dr. Francis Collins.

Agenda Item: Remarks

DR. COLLINS: Thank you, Harvey, and good morning to all of you. I am delighted that we have gathered here on the shores of the Gulf of Mexico to talk about this important project and all of the information that we hope will flow from in, in term of understand the health effects of this unprecedented environmental disaster that began some months ago and which, as Harvey has pointed out, may now be acquiring less press attention because the well has been capped, but, of course, the health effects remain undefined and need to be defined. This is a challenging task, indeed, but one that I believe the assembled scientific brain trust that has put together a plan is well positioned to be able to carry out. We are grateful, indeed, for the Institute of Medicine's role, here, in your somewhat delicious opportunity to do this input of ideas and review of the design that has been already assembled and vetted a few times. Today and tomorrow are particularly important steps before launching this enterprise, which we hope to do in the relatively near future.

I thought what I would do is first walk through a timeline of how we got to this point because there have been a lot of activities, stemming back to April. Then I

will say a bit about a particular issue that I thought would be good to get on the table right at the beginning, which is the question of how will data be accessible from this study given the broad interest and the potential here for maximizing the value of the study by having as many bright minds able to look at the information as possible.

Let us begin with this timeline issue. Of course, all of this dates back to the Deepwater Horizon explosion on April 20th. Certainly, as the seriousness of this impact grew, many state, federal, local government agencies, as well as volunteer organizations, and with much leadership from the Coast Guard, joined in the effort to begin this clean up. NIOSH, led by John Howard, initiated the Health Hazard Evaluations and, importantly for what we are talking about today, developed quickly a roster of clean up workers to be able to identify those individuals for future follow up. The National Institute of Environmental Health Sciences, led by Director Linda Birnbaum, were early involved in the effort to train tens of thousands of clean up workers about potential health risks and ways to minimize that risk. So NIH was involved very early in that part of the process.

On June 15th, recognizing that the health effects were going to require a longer-term study, over perhaps

several years and that this kind of a study would require resources, NIH announced the additional support for a cohort study. I decided to utilize funds from the Director's discretionary fund and also from what is called the common fund, which is a part of the NIH budget that is utilized for kind of scientific issues that, perhaps, no single institute could support. Clearly, the consequences, here, of the spill do stretch it to many different potential areas so it seemed a valuable opportunity to do that. Together with funds from NIEHS' base budget, it was then announced that we would be able to go forward with this ambitious cohort study and Dale Sandler, who is here and you will hear from in a little bit, stepped forward as the principal investigator of this study and probably has had very little sleep ever since.

As you have heard from Harvey, in late June, the IOM convened a very important meeting in New Orleans to assess the possible health implications. That report, released August 20th, is very much an appropriate guideline that has been assisting the process of designing this study. Certainly, the study and the need for it was endorsed, as well continued surveillance efforts and the importance of communication with the affected community, given the ways in which this study could benefit, but also,

perhaps, be misunderstood.

Because of the complexity of this enterprise and the multiple agencies involved within HHS, Nicole Lurie and I and others, including the Secretary, herself, decided we needed a coordination function. Harold Jaffe from CDC and Teri Manolio from NIH, who is here, were appointed as the coordinators for HHS, in order to try to be sure that the various agencies with a stake in this coordinated their efforts and did not fall over each other. That has been, I think, a very helpful addition to the management of the program. I just want to say publicly how much Harold and Teri's participation has meant, in terms of the organization of things leading up to today's meeting and no doubt beyond.

There was a meeting at NIH involving NIOSH and CDC to try to coordinate those functions - a very helpful one, understanding more the perspective from the three partners here - and then a much broader interagency meeting held a week later at NIH, which involved a wide variety of government agencies, including the Coast Guard, including the US Geological Survey, including EPA, NOAA, and other agencies, as well. This was an extremely valuable exchange of data, which brought agencies together that had not been as aware of each other's enterprise, as it relates to the

spill. That is a network that, I think, at that meeting, everybody agreed should be sustained and there is a plan for that group to gather again in the not too distant future. Some of those representatives are also here at this meeting. This is an enormously complex area and there is great potential here for missing possible connections. This meeting was a wonderful antidote to that risk and much credit to people who dropped everything to come to that meeting - some of them with one day's notice.

Meanwhile, community input is being sought on the potential design of the cohort study. There have been conference calls and, maybe most importantly, webinars held twice with more than a hundred participants having a chance to put their ideas forward and react to the proposed study, which you will be hearing about later this morning from Dale. There have been meetings with state health departments as recently as last week. To get this enterprise underway, NIOSH, having done a lot of work here to roster the clean up workers, have shared that roster with NIEHS as a starting point for enrolling participants in the cohort study - another good example of agencies working well together.

Also, just to make the point that not everything that is going to be important to study as part of the Gulf

oil spill is going to be covered by the cohort study. There are special circumstances that ought to be looked at, such as, perhaps, children and pregnant women, which will require additional analyses. This is what is now called the consortium study. A release was put forward, which you are urged to look at, if you want more data about this. This is a notice of intent to publish a RFA for Gulf oil research consortia, particularly impacts on health of residents. This was issued September 3rd. Again, this is an attempt to solicit applications, particularly from organizations that are in the Gulf area, to study some of these special areas that the cohort study, alone, will not adequately touch on. This will be an additional NIEHS driven enterprise that will be connected to the cohort study, in terms of its scientific goals, but will be separately managed. Again, if you want more information about that and many other things we are going to be talking about today from NIH's perspective, the NIEHS website is a very important place to go and see the information that is there.

After considerable discussions back and forth between HHS and BP, we were delighted that BP agreed, then, to contribute ten million dollars to this research effort on health effects of the oil spill. Part of that is

actually supporting the IOM effort, including this meeting. Part will go to the consortium effort. And part to the cohort study. So the combination of support systems is now judged to be sufficient for a five year cohort effort, as Dale will describe later. The funds are in hand. And, I think it is fair to say the cohort study was planned to go forward back in June and it has been very helpful to have BP come onboard as a partial supporter of the effort, but, frankly, most of the funds will be coming from the government because of the cost of this. Although, we certainly hold out hope that BP might decide that this is such an important effort to make future contributions as well.

The design of the study continues to be refined and that is why we are here, in Tampa - is to try to look closely, with much assistance from our IOM-sponsored colleagues about the details. Before I sit down, I do want to emphasize one particular point about this discussion we might have today because, from NIH's perspective, this has often been a thorny one, but often, I think, is an opportunity for us to set things up from the get go in order to maximize the benefit of the study. NIH has been increasingly interested in pushing forward plans for data sharing to maximize the access by qualified investigators

to study data. And perhaps, one particular model we might look at, because it is the one where I think NIH spent the most time and effort collecting public input about data access policies and ultimately settled upon a proposal that has weathered pretty well over the course of the last two or three years, and that is the policy that was developed for genome-wide association studies, GWAS studies as they are called.

Obviously, the Gulf oil cohort study is not intended to be a GWAS study, although, I suppose there is some possibility that genetic data may get collected, so I do not want you to think that I am trying to put this particular study into a format that it does not quite represent, but I think the data access issues actually map across pretty well. The argument with GWAS studies was that these were expensive, a lot of public money went into generating the data, and the greatest public benefit ought to be sought by making the data available to the largest possible number of investigators, as long as this is consistent with the informed consent and the protection of individual privacy. So how has this been done for GWAS and what are the similarities and differences?

Similarities, there is substantial public investment, there is going to be a very complex and rich

data set, and, yet, there are also concerns about privacy because of detailed individual data. The differences, certainly the Gulf study is connected to intense public concern by those who live in this area and have potentially been exposed and may be concerned about their health consequences. There is public skepticism about a study run by the government of this sort. And there is this potential for litigation that needs to be thought about so that individuals involved in the study are not putting themselves at jeopardy by the participation, especially if it means access to individual data that might potentially be used against them.

The way in which data management is handled in the GWAS model and, again, I think there is a lot of ways in which this could be done similarly for GuLF, is research participants grant informed consent, but have there direct interaction with submitting investigators. Data is collected, then the identifying information is removed and all of the data is coded. Then that goes into a data repository, which does not contain any of those individual identifying bits of information. For the GWAS data, that is dbGaP, a database run by the NCVI of genotypes and phenotypes. I think, actually, this might be a reasonable database to also be the repository for the GuLF study

because it has already in it a very large number of studies, many of which have no genotypes at all, but have phenotypes in a standardized way that investigators are getting quite used to querying. NCVI also provides a lot of resources, here, to take complex data and organize it in a way that makes it searchable.

Once that has been put into the data repository, then recipient investigators have to apply for data access. I will say a little more about that in a minute. If approved, then they have access, but only to the data that is in the repository, which has had the personal identifiers stripped away. That means that you need to pay close attention to what the data use limitations might be based on the informed consent. Certainly, for the GuLF study, it is critical right now to be sure we think about that, in terms of what the consent does say, because everything will follow from that. So if for the GuLF study, a proposal would be that this model could be followed, that NIEHS would then certify approval of submission to the data repository, deciding that the data had been validated sufficiently. You do not want to put things into the repository that have not been cleaned, but that has to be done in a timely fashion. The data would then be provided in accord with laws and regulations and,

of course, an IRB needs to be involved in the submission plans. An IRB will be looking at the GuLF study quite closely.

The responsibility for removing personal identifiers and retaining the key code rests upon the PI and the informed consent, in order to make this a feasible argument, should be constructed to permit data sharing beyond the primary investigators. Any limitations on data use ought to be clarified up front. The HIPAA identifiers, in case you do not remember the list of 18 of them, is this. That has been, generally, the mode followed in the GWAS studies and could be here, as well.

The way this, again, just to blow it up a little bit more, the way in which this has worked in practice for GWAS data is genotype and phenotype data going into the dbGaP database. There is, by the way, public access without any restrictions to overall descriptions of the study protocol, the questionnaires and so on, just so that people who are interested in knowing how the study was conducted can do so without having to go through an application process. But if one is interested in individual data, even though it is de-identified, that is what is going to be called controlled access. That requires a request from a user about what they want to do

with this and that has to go through a data access committee. The data access committee then has to decide whether the requested use is consistent with the original consent. If that is then carried out, investigators and their institutions then have to follow all of these other guidelines. The data access committee will be, in general, operated by people who are not, themselves, in some way in a conflict.

The way we have done this with GWAS studies is to use federal staff because that means you do not have to set up a whole complex arrangement that follows the Federal Advisory Committee Act. This has worked quite well, but the federal staff ought not to, themselves, have a stake in this, in terms of openness of the access. This ought to be an objective view that can determine whether or not a particular application is appropriate. Then there should be annual reporting factored into this from the users so people can find out what they have done with the data.

The user application, the data use certification agreement, has to include certain terms and conditions. So this is not the sort of thing where you just go on the web and take the data. You have to be responsible for compliance with policies, only use data for a research use that you specify because you have to be clear whether this

fits the original consent. You are prohibited from identifying or trying to identify or contact study participants if you are a data user of a secondary sort. You are not allowed to transfer the data because, obviously, that would defeat the whole purpose of having this data use certification. Notify the data access committee if any security breach occurs. Submit annual updates. Be identified on the website as an approved user, including posting your research use statement so that other users can see who is using the data for what purpose and you can avoid duplication that might otherwise be kind of frustrating to everybody and acknowledge other policies.

In this instance - this is based on a conversation that Teri and I have had with Linda and Dale and some lawyers - that we ought to be clear, here, that in this special instance where there might be a concern about a participant having this data used against them, should they happen to be involved in litigating against some harm that has come to them - that this data from this study shall not be used in any litigation procedure against the participants. I think that can be added as a data use certification agreement contingency that we had not thought about for GWAS, but might be reassuring and important in this case.

There is always an anxiety with this kind of open data access about, well, what about the principal investigators? They do all the work. They collect all this data. Do they get scooped with their own data? Do they open up Major and realize that somebody else has just published their conclusions?

There has to be some understanding there that there is a responsibility on the data users to respect the rights of the principal investigators to be the one to, perhaps, make the first publication about their own work. The way this has usually been done is that the contributing PIs have an exclusive right to submit publication for a protected period, after a data set has been made available. Now, a protected period for GWAS is traditionally a year.

That includes any form of public dissemination, including speaking at meetings or abstracts submission. The contributing PIs have the sole right to do that for that protected period. But, during that protected period, other users may download the data, may work with it, may come up with other hypotheses, may start other studies. They can do all kinds of things. So you are not ending up with a blackout period of access. It is just a blackout about publication for that time period. That has worked really well for GWAS.

Over the course of the last two or three years there has been one violation of that, which resulted in quite a hubbub and I think the violator was quite chastised and the person whose data was published in advance of their own ability to do so actually was nicely recovered from the experience by the intervention of a journal editor. We have a good track record here.

I just want to finish with this quote because I am very fond of this and it fits particularly nicely here. Probably none of us planned to be here in Tampa at this moment a few months ago. The idea that we would need to gather to have a conversation of this sort about a study of this sort would probably not have occurred as a high priority. Abigail Adams, writing to her son - so here is Abigail, who is both the wife of the second president and the mother of the sixth president - this is in the sort of waning days of the Revolutionary War, but things are pretty tough. Her son is off in Europe with his Dad. I am not sure what exactly she was responding to, but maybe people were feeling a bit down and despondent.

Abigail says, "These are the times in which a genius would wish to live". This is like the Rohm Emmanuel never waste a good crisis idea. "It is not the still calm of life, or the repose of a pacific station, that great

characters are formed. The habits of a vigorous mind are formed in contending with difficulties. Great necessities call out great virtues. When a mind is raised, and animated by the scenes that engage the heart, then those qualities which would otherwise lay dormant wake into life and form the character of the hero and the statesman."

Certainly, this is not a still calm or life in the Gulf over the last few months and yet, it is an opportunity, I think, for all of us to rise to the occasion and people have been in really remarkable ways. I am delighted to be here today to participate in the continuation of that conversation and hopefully soon the initiation of a study that will do a lot to try to understand the potential health risks of the Gulf oil spill and provide for the public the information that they very much want and deserve. Thank you very much.

DR. FINEBERG: Francis, thank you very much, both for your general introduction and setting of the perspective on this question and especially for the insights you have provided, already, on the data access questions, which are going to be so important to ensuring the fullest use of the available knowledge and information. Your personal leadership makes a huge difference in this and we are very grateful to you for that and for all that

you are doing to make this study the enterprise that it is becoming.

I am very privileged now to introduce the Chair of the Institute of Medicine committee that planned this workshop. As I do so, I cannot pass up the opportunity to extend my personal note of appreciation and thanks to our staff, who did so much to prepare for this workshop. I want, especially, to single out Abby Mitchell, for her extraordinary efforts in preparation. Abby is a real stalwart at the Institute of Medicine. She is part of the Board on Population Health and Public Health Practice that is led by Rose Martinez. She has some very able colleagues, but Abby has done the heavy lifting for this effort and I really am grateful to you, Abby, for all of that.

The Chair of the Committee is a dear friend and a very experienced leader in public health in government and academia, in many dimensions of work connected with the environment. Dr. Lynn Goldman is now also the Dean of the School of Public Health and the full title is and Health Services - is that right, Lynn? - the School of Public Health and Health Services at George Washington University. She is really extraordinarily qualified to lead this effort for the Institute of Medicine as a trained pediatrician and

epidemiologist, who is familiar both with the issues that are confronting us substantively and with all of the necessary talent and skills to manage the effort throughout the coming months and perhaps even years. Now, Lynn it is a great privilege for me to welcome you and I invite others to join me in expressing our appreciation to you for your leadership. Dr. Lynn Goldman.

Agenda Item: Welcome, Introductions and Overview of Workshop

DR. GOLDMAN: Good morning. I have to, in turn, thank the two who preceded me here. It is a rare event when you see both the Director of the National Institutes of Health and the head of the Institute of Medicine together in an enterprise. I think that it underlines the importance of this to those institutions. Also, I should say that it is highly unusual to see both of these institutions in a mode of responding so quickly to an event such as we see here.

Normally, events at the NIH play out over many years and reports by the Institute of Medicine are done over the period of many years. We are all challenged by this, but we also, I think, all appreciate the importance of moving forward quickly, but with sound scientific advice to try to form a framework that will last for a long time.

I also need to thank the staff. Abby Mitchell has been wonderful. China Dickerson, as well, who really did a lot of the work to bring us together, just making the arrangements. Rose Martinez, who heads the board, and perhaps, if all the staff would stand up just so people in the audience will know who you are and if you need anything, these are the people who can help you. They are just fantastic. The members of the committee - these are all volunteers, who are helping with this effort. We have assembled, with the help of the staff, a fantastic committee. They have very busy lives, but I think they also understand the importance of this and also the urgency of being able to provide good advice. I am so grateful to all of you. I am going to just ask you each to stand and give a brief introduction - very brief because we do not have much time.

(Introductions of committee members.)

DR. GOLDMAN: There are two others who could not be here this morning, Roberta Ness from the University of Texas and Larry Palinkas from the University of Southern California.

This committee has been given two separate but related tasks that we are going to be accomplishing over today and tomorrow. The first, which has already been well

explained by Dr. Fineberg, is to provide feedback to the NIH on the GuLF study, the Gulf long-term follow up study for oil spill clean up workers and volunteers. The second task, which is our goal, really, for tomorrow, is to begin to provide periodic advice to the Department of Health and Human Services about research priorities and emerging concerns related to health effects from the oil spill. Tomorrow's session will start out with a public session at 9:00 AM and you are all invited to attend that one.

In terms of reviewing the session for today, basically the day is structured around a number of panels that have themes. Our first panel is going to have the theme of looking at the study goals and design. We are going to have a second session on data collection and cohort surveillance and maintenance. There will be more to kind of go through what we think that means in this context.

A third session on relating to the community, enrollment, trust, transparency, and communication issues. Then a fourth session having to do with the interagency collaboration on this, which, as I think you heard from Dr. Collins, is already well underway and a very important part of this, given the fact that different agencies bring different resources to the table that are critical to the

accomplishment of this study. The final session will be a summary of these discussions that will be led by Dr. Fineberg, prior to and then at the end of the day, a public comment session. It is going to be a very packed day. It is going to be conducted, hopefully, on schedule. It is going to be challenging to stay to the schedule. I am saying right now, for the benefit of all the speakers, that the time limits that you have given are real and will be strictly enforced. I do not know if I need to say more about that at this point.

There is another person that I should introduce, who is here, Dr. Linda Birnbaum. If you could stand up - is the Director of the National Institute of Environmental Health Sciences and is the Institute under which this study is being conducted. So, without further ado, I want to introduce Dale Sandler and her colleagues, who are here. Dr. Sandler is going to take the next session. She is the principal investigator for the GuLF study, probably one of the busiest people around the National Institute for Environmental Health Sciences, over the last few months. She is accompanied today by her study team, Richard Kwok, who is with the NIEHS, Lawrence Engel, Aaron Blair, who is with the National Cancer Institute, and Aubrey Miller, who is also with the NIEHS. Welcome to you all.

Agenda Item: Overview of NIH Gulf Long-Term**Follow-up of Clean-up Workers Study**

DR. SANDLER: While we are getting the slides up, thank you. This is an interesting opportunity for me. I want to thank everybody who has taken the trouble to download the protocol and read all hundred or something pages of it. It looks like a real protocol because it is long, but there are still plenty of opportunities to modify our design, hear what you have to say, and take that into account. Please, do not be intimidated by the number of pages or appendices that we sent out.

I am here to talk about the study and hear what you have to say. As Dr. Collins said, we have been working on this for what seems like forever, but is really a very short time. Our primary objectives are, as you know, to assess the short- and long-term health effects that are associated with the oil spill clean up. We also want to create a resource for future collaborative research that might focus on specific hypotheses related to health effects of working in the Gulf and focused on specific subgroups with unique concerns.

From the last time we were all together here, at an Institute of Medicine meeting focused on this topic, you are all well aware that there have been at least 38

supertanker oil spills in the past 50 years, but only eight of them have been followed for human health effects. And with notable exceptions, such as the Prestige spill, which has been well studied, from Spain, research has typically been cross-sectional or short-term. As you also know, the Deepwater disaster is larger than any previously studied spill so we think it is very important that the potential health effects be investigated.

Our scientific hypotheses are pretty broad. We are not designing a study to go after one specific key health effect, but the basic idea is that, controlling for other factors, exposure to oil, dispersants, and oil dispersant mixtures would be associated with adverse health effects. That there would be a dose-response relationship between exposures and health effects and, as you will hear, we will be relying on qualitative and semi-quantitative measures to think about dose-response. That biomarkers of potentially adverse effects are associated with chemical effects, as well. An important other hypothesis or concern in the study is that workers from the Gulf region, who are exposed to other social and environmental stresses will be at greater risk for mental health outcomes than workers and controls from other regions.

The outcomes of interest in this study are based

on whatever research there has been on previous oil spills. It is also designed - we are also focused on what health complaints have already been reported in relation to this particular spill, which are similar to complaints in other spills - dermatologic effects, respiratory effects, dizziness, and so on. We are also basing our research on studies of other groups that have had exposures to compounds that are in oil or dispersants or other disaster-related stresses. This is a wide list.

We are talking about our study as the GuLF Worker Study, a health study for oil spill clean up workers and volunteers. The population that we are focused on are adults over the age of 18. Initially, we are looking at those who can communicate in English, Vietnamese, and Spanish, for translating our study materials because this is how the worker training was done. All of the materials were available in those three languages. But we are well aware that this excludes some groups, who may have participated, so we are working on developing accommodations for people speaking other languages. We are defining exposure, initially, very broadly, which is anybody who worked one or more days in any clean up task, whether it was paid or volunteer. The unexposed group, which you will realize is a challenge to identify the

appropriate comparison group, but for unexposed workers, we are starting with the idea that there were many people who completed safety training with the idea that they would then be hired for work, but were not hired, largely because they were not needed. It was difficult to estimate how many people would be needed at any one time. So we will be, initially, starting with those individuals - people who trained but did not get hired. We are also, because some of the workers are from federal groups, including the Coast Guard, there is the possibility of studying individuals who were told get ready you are going to be going to the Gulf, but then were never called. If we are not successful with this plan, we are thinking about other strategies, including enrolling community members, who are friends or relatives of the participants.

We are beginning with the NIOSH roster that Dr. Collins mentioned, to identify potential participants. There are about 50,000 individuals, who voluntarily signed up and said they might be interested in being a participant in future research. They provided a little bit more information than was available through the training documents. But, there are also many other lists, including the list of anybody who trained. A contractor ran this program, the Petroleum Education Council, and there are

more than 100,000 unique names on this list of people who took some training. We are aware that some groups did not go through the PEC training. They had their own training programs. There were certain parishes in Louisiana, who had their own lists of workers and we are exploring opportunities for obtaining all of these other lists so that we will have a complete enumeration of the potential worker cohort.

After merging all of these lists to create a master list and eliminating individuals without contact information and duplication, we expect that we are going to need to approach about 75,000 or 80,000 people from this master list to identify our cohort. We are hoping to be able to maximize the inclusion of individuals from the Gulf States. About three to five percent of the individuals on the NIOSH roster come from Texas, but there is much larger representation from the other states. We would also try to maximize the inclusion of people who had jobs, which, in theory, would give them higher exposures to chemicals or chemical byproducts - and also individuals who had jobs that were associated with health complaints.

Our design calls for an initials enrollment questionnaire that will take no more than thirty minutes. We will begin trying to do this by telephone. We have been

having, as you will hear later, meetings in the Gulf region with various community groups and it is clear that in certain circumstances the telephone is not going to work and so we are exploring other ways to obtain the enrollment information.

This questionnaire will collect some basic information on general health, lifestyle, their usual occupation, some socio-economic factors and demographics. It will focus extensively on clean up activities, including their living accommodations while they were working in clean up activities and then also collect information on spill-related effects. Timing is such that we will not be focused on acute effects, but we will be able to collect information about what people experienced at the time they were involved in clean up and their health symptoms now. Because of the special circumstances in the Gulf of Mexico region, we will also be assessing stress, depression, anxiety, and perceived risk using standardized instruments.

We are expecting, optimistically, a cohort size of about 55,000 individuals, if we have a 70 percent response rate. From this group, we are going to select or to recruit a group who will be our actively followed cohort. That would be approximately 27,000 individuals, who will be followed more closely for the long-term

clinical study. This active cohort will include all job categories and we hope to enroll about 20,000 individuals who were doing clean up work, again, over sampling for higher exposures and also for smaller job categories so we fully represent the range of activities that were being done in the Gulf region. We also will enroll 7,000 people, who were unexposed to serve as a control group. This is tricky to do.

Looking at the distribution of where people lived, about 75 percent of the initial workforce, when we had access to just 15,000 records, initially - 75 percent came from nearby, from communities close to the Gulf and 25 percent further away. We are hoping to enroll non-exposed individuals, about 4,000 from the local community, 2,000 from further away, and then we have this special category of federal workers. We will include in our cohort federal workers, who may not come from the Gulf States - Coast Guard were called from all areas.

If we can, we would maximize the Gulf region, but we are not going to exclude people because some of those people might be the most heavily exposed individuals, who were called in for specific jobs. So we will have a thousand federal workers as a composite comparison group, as well. The rest of the individuals who have done

screening will be followed passively through record linkage, looking at linking to cancer registries and vital statistics.

For baseline data collection in the active cohort, we will be conducting a home visit. At that time, we will collect much more detailed information on their medical history, prior jobs, and current jobs, if they are no longer involved in clean up, recreational activities, opportunities for residential exposure to oil, either through the spill or because of where they live, living next to a refinery, or other sources of exposure. We will collect additional information on mental health and social and behavioral factors and we will also include some questions about the consumption of local fish because this is a community concern.

We will collect biospecimens during this home visit - blood, urine, toenail clippings, or hair. Then, if we can not get a blood sample, we will collect saliva so they will have DNA available for gene environment studies. We will collect some environmental samples. We are trying to do something that is quick and can be accomplished in a relatively short home visit so we will be collecting household dust wipes and tap water. We will be making physiologic and anthropomorphic measurements. Height and

weight and waist circumference will be measured. We will be measuring blood pressure and we will measure lung function, focusing on FEV1 and Force Vital Capacity, using a standardized technique. We will report back to participants some information of clinical relevance to them - their Body Mass Index, their blood pressure, and whether their respiratory function is outside of clinical norms.

For those of you who need to see this visually, I thought we would try a flowchart, but I am looking at this now and I am not sure this is going to be large enough for any of you to see so we will dispense with that and save some time. The flowchart is in the protocol materials so I hope you had some time to memorize it.

The active cohort, by definition, will be followed actively. They will receive an annual newsletter, at a minimum, as well as other communications, to maintain participation and at that time, we will collect information to update their contact information. We plan a telephone questionnaire to follow up on changes in their health status and, initially, we are planning to do this in years two and four, but dot, dot, dot means that if this proves to be both feasible and productive, we hope to be doing this more into the future. This group will also have passive surveillance by linkage to cancer registries, vital

statistics, and other electronic medical records or other records that might become available. We will be taking advantage of other supplemental information to describe the health of the community relative to the health of the cohort, such as looking at poison control data, more at baseline, but any health surveillance data from the communities. We also are planning to include in our questionnaire instruments that are modeled after the Behavioral Risk Factor Survey, the BRFSS, and other surveys so that we will be able to have comparisons to regional and state data.

For the passive cohort follow up, they, too, will get an annual newsletter and we will update their contact information. They will be told, up front, that there is a possibility that other people might call them for studies so it is important to keep in touch with them, as well. Then they will be followed with the same passive surveillance methods as for the active cohort. We are planning now - we are saying now that the cohort will be followed for ten or more years. Realistically, if we are interested in cancer outcomes, a much longer follow up will be needed. The cohort is relatively young. Hopefully, we will be able to sustain at least passive follow up, even beyond the ten years.

We have planned to identify a sub-cohort of about 5,000 people from the active cohort, who will be studied more intensively. We have alluded to what we would like to do in the protocol, but we believe that this is something that will be important to do in collaboration with researchers from the local community.

So the final protocols and selections of tests have not been designed. We envision doing this clinical assessment either in the home or using a mobile van or some other method to be proposed by our collaborators in years one and three. We would collect additional biological and environmental samples. We would do, at that time, more comprehensive pulmonary function testing. We would do neurological and neurobehavioral testing. Additional mental health screening is warranted. There may be opportunities to study reproductive function in the men. By the way, about 20 percent of the workforce appear to have been women so there will be opportunities to study women, as well, in the workforce. And there will be some specific laboratory tests that are included as part of this cohort where samples will be analyzed as they are collected, as opposed to in the active cohort where samples may be banked for later use.

The overall collection schedule, here, was also

in the protocol, but basically there is something that happens every year. For the passive cohort, this is simply the enrollment questionnaire and a newsletter and a one page update and the active cohort will get a questionnaire in years two and four and beyond and the biomedical surveillance will come in between.

The issue of statistical power is one that is difficult to deal with when you have broad hypotheses and you are not really sure what you expect to find. We based our assumptions on what has come out of the Prestige spill in the short-term and in occupational cohorts with individuals with similar exposures. We believe that we will have sufficient statistical power to detect some potential effects. This table shows the minimal detectable odds ratios under various assumptions, if we assume that about ten percent of the control population has the outcome of interest. The relative risks that we can detect are consistent with the risks that have come out - the reported risks, for example, for respiratory effects that have come out of the other studies, studies of other oil spills. We will obviously have greater statistical power for continuous outcomes and less statistical power, if we start focusing on unique subjects within the cohort.

In terms of the biospecimen collection, we have

modeled what we are doing on two ongoing cohort studies - current cohort studies. We had access to the protocol from the UK Biobank and then the Sister Study, for which I am the PI. This is a study that we just finished enrollment of 50,000 women. We will be collecting blood. We will encourage people to fast, but we realize if we need to do all of these interviews in a really short time frame that is not going to be possible. So we will be doing home visits at any hour of the day. We will request fasting, but we will ask when the last meal occurred, most likely.

We are planning minimal field processing. We will be collecting the samples so that we could store a whole array of blood components. We will perform, up front, some hematologic assays, such as a complete blood count on a fresh sample for a subset. This will be the subset of individuals, who will have been tagged for invitation to the biomedical cohort - so a much smaller group because of cost and feasibility. But that would allow us to follow up on some observations of specific hematologic effects from the benzene cohorts, for example. We will be collecting urine.

Again, we want to assess the feasibility of collecting their first morning void. There has been some discussion of whether we can collect the full void or just

the smaller amount that we need to collect and store. Those things are still being worked out. We will perform a dipstick urinalysis, just to get a quick measure of individuals who may need to be referred for further study, specifically focusing on glucose urea. Then I mentioned the hair and toenail clippings that will be collected for studies of trace metals and then the saliva, if we can not collect blood.

Our biorepository is conveniently located right a mile from us in Research Triangle Park, North Carolina. It is called EPL. That is not an acronym. That is its name. It has got a long history of report for the National Toxicology Program. It has been our contract biorepository for many, many years. It has supported epidemiologic studies for the past ten years, including the storage and handling of the samples that we have for our 50,000 person Sister Study cohort. It is well coordinated with other study contractors that will be involved in this study. I mentioned it is in close proximity so we have regular meetings with them. And we use a common database for sample tracking. We will, of course, follow guidelines for the best practices for biorepositories, including rigorous quality control.

We are planning a phased rollout period. We will

start in one area, yet to be selected, first and expect to do that for about for to five weeks and we will consider this sort of a mini pilot study for the protocols and the approaches. Unfortunately, we are not working on a timescale where we can have a deliberate year-long pilot study before we get into the field.

Then, if we start when we think we are going to start, then we will come smack up against the Christmas holidays. So there will be sort of a break for us to reassess and redesign, if we need to and getting started in earnest again in January. We are planning on having the enrollment and baseline data collection completed in a 12 to 18 month period, starting very optimistically in late October, probably slipping into November.

We hope to complete the enrollment process in 9 to 12 months and then the home visits within 12 to 18 months. We are hoping to enroll any individuals who are still working first - that would be our priority - to collect information on exposures, while memory is still fresh - this is one of the reasons for working to get this into the field so quickly - to enroll the cohort while their contact information is still valid - many of the workers gave cell phone numbers, which change frequently, although we just learned that more than half of the cohort

gave email addresses, which also change but gives another opportunity for us to locate people. I think that enrolling quickly will maximize community support. If minimize delays then we show we are serious.

One key aspect of the study is going to be our ability to reconstruct exposures. We are working this in parallel and the information was not as well along as - the design for the study, at that time, the first draft of the protocol came out, if you had a chance to look at the revision that was sent to the Institute of Medicine just a few days ago, many more details are coming into the picture. We plan to - we are working to identify a collaborator or consultant for the study - an industrial hygienist.

We have been in discussion with several people. I am not going to name names, but we will have an industrial hygienist on our team. We will shortly convene an expert panel that will draw on government and industry expertise and we would also be including local experts. We want to include industrial hygienists, chemists, toxicologists, statisticians, and individuals with GIS-type expertise. Their task will be to complete industrial hygiene assessment, to look at exposures by time, task, location, and consider all of the data that we can bring to

bear, including information on the use of personal protective equipment and the hazard evaluations that have been completed by NIOSH and other groups.

There is a lot of available data. It just needs to be pulled together. My team has been talking with all of the holders of the data and we are working to assemble this and it is really falling into place nicely. One of the tasks for the committee will be to evaluate the quality and usefulness of the existing data - the exposure measurements that have been collected by OSHA, NIOSH, the EPA, BP, the Coast Guard, and other groups.

We will also take a look at information on weather patterns, which may impact health. We have other GIS-based information such as the size, location of the spill, of the oil, and where fishing areas may have been closed. We can take into account residential proximity to the crude oil burning and waste sites, as well as individual worker proximity to the potentially more hazardous areas.

At this point, we are aware of personal sampling measurements that have been collected across a number of jobs, as many as 80,000 samples, we believe, have been collected, maybe more, as we finish talking with other groups who have done some of the collection. We are

exploring possibilities of accessing information, such as time cards, security badge information, payroll records. Not necessarily to have information on everybody in the cohort, but to provide supplemental information to validated self-reported exposures.

If we had timecard information, we would know how well people are able to report how many hours they worked and where they did it. Then we will incorporate all of this quantitative and qualitative information and hopefully be able to create a series of job-exposure matrices and some GIS-based exposure measures that we will use. We anticipate the need for multiple exposure metrics, depending on what the exposure of interest might be.

It is important to note as we think about the timeframe for how far along we are with thinking about the cohort design and the blood collection versus the exposure reconstruction is that the quantitative exposure data will not change. Our ability to access it needs to be secured upfront. But what will change is peoples' ability to recall what we did. So we believe that enrolling the cohort should be our first priority.

There will be many opportunities for scientific collaboration, as we create the study. You heard about the open data policies. You taking advantage of the data that

we collected is certainly a possibility, but we think that there are opportunities for more active collaboration early on and further into the process. We already know that we are going to need help with certain special populations, enrolling Vietnamese fisherman, for example. We will need to be collaborating with NGOs or other local groups, who have expertise in dealing with these communities - the various recruitment challenges. And this would be an opportunity to focus on any unique needs or research questions for those communities in collaborative research.

We have been in discussions about the possibility of a collaboration that would enroll family members of clean up studies. This would be an opportunity to look at health effects in the general population by capitalizing on the enumeration that we will be doing. I mentioned that 15 to 20 percent of the cohort are women, so there will be opportunities for collaboration on studies of reproductive health. There is also the possibility that we will identify specific groups with initial symptoms that merit more intensive follow-up, such as what has happened from the follow up of the World Trade Center cohort might focus on reactive airway diseases or neurological symptoms.

Data sharing - we have already heard about this. We are with the program. I am at NIH and NIH is interested

in promoting uses of the data so I will move on.

One thing that is very important in this study - in all studies, but in this study, particularly, is to make sure that we maximize community involvement. It has been sort of difficult to do that in the usual way because we needed to get going quickly and have a protocol. We did not start in the community, but we still have plenty of opportunities and we are taking advantage of that to engage the community in what we do. It will be important to have community involvement at key points throughout the study.

This will facilitate community involvement and ownership, to foster trust and mutual understanding. We will take advantage of every opportunity to educate the community on the rationale for collecting data, which will empower them to make informed decisions about participating. This also - talking with various community groups has allowed us and will continue to allow us to refine our design and protocols based on their input.

We will be convening a Community Advisory Board. This board will be actively involved. This will include community members from the Gulf States, primarily, that are participating in the study, as well as representatives from special interest groups. As I mentioned, we need to directly engage specific community groups to facilitate the

recruitment and follow up of special populations within the cohort. We believe this will foster opportunities for community-directed research, either as add-on or companion studies to what we are doing or to encourage us to answer specific questions of concerns through what we are doing, ourselves.

We have had some initial outreach already. My team has been very busy flying back and forth down to the Gulf region from North Carolina or Washington. We have been in Mississippi and Alabama. That was the week of September, 12th, talking to local health departments and various community groups. We were in Florida the week of the 19th. We will be in Louisiana next week - I think it is next week - the week of October 3rd. And we have yet to schedule Texas. We had the two webinars that you have heard about that had both scientists and community members listening in and offering advice about the study. We have had presentation to something called the NIEHS "Partners". It is groups that are interested in environmental health, who have special concerns and have been advising our Institute for many years. We will continue to have ongoing outreach to address concerns that come up as we do the study and to communicate results when we get there.

Informed consent. We need to mention that just a

bit. We plan - our initial recruitment, we will send out a letter and a brochure that include the elements of informed consent and allow for an opt-out process if people do not want to be called.

NIOSH has already done that for us by sending us the names of workers, who have agreed to be contacted. There will be telephone consent for the enrollment questionnaire and some adaptation for those groups that we enroll in person. Written informed consent will be collected at the home visit for the actively followed cohort and then there will need to be additional consent for participation in the biomedical surveillance subgroup, which, again, all of these things are voluntary. The consent will allow for add-on studies and data sharing. It will address issues of record linkage and long-term follow up and long-term storage of samples. We have already begun to develop answers to frequently asked questions from our experiences here, meeting with the community, and our experiences doing other studies of this sort, and a consent summary document.

So those of you who have seen an NIH consent form lately know it is very hard to write something that is understandable to the average person. The summary documents, we found, are very useful and people could have

it and look at it and understand what they agreed to. And we will be applying for a certificate of confidentiality.

The issue of compensation keeps coming up in our meetings with the community. At this point, we were not planning on compensating participants to be in the passive cohort - that is to do the enrollment questionnaire. There are precedents that we have to consider. Our work has to be reviewed by the Office of Management and Budget and things like the behavioral risk factor survey, they do not compensate people. But community groups think that there will be special pockets of the population who will not do this with something.

These are ongoing discussions and I will be interested to hear what you have to say about that. But we will compensate people who participate in the home visit, which is a much more extensive contribution. It will not be coercive - something like 25 or 30 dollars for doing all of that, but at least a token of our appreciation and compensating them for the time they have given up. For the biomedical surveillance, then, we have the opportunity for greater compensation in proportion to the greater amount of work.

We talked a little bit about communications. We are working on developing a comprehensive community

strategy. Obviously, we have the opportunity to do things that we did not do in our other studies by taking advantage of social media and the web and all these technologies that I do not use, but others in my group do. We will be generating reports to participants, to the local communities and other groups, partner organizations, larger scientific community, as part of the process. We already planned newsletters, a study website, electronic communications - since a large proportion do have e-mail addresses - and we will be holding scientific and community meetings throughout.

We have been concerned about several issues related to high stress levels in the community and what do we do when we identify concerns, whether these are mental health concerns or health concerns in a community that might not have access to care? Part of our training or getting ready to go is to have extensive training for our interviewers, providing them with resources, helping them to identify signs of distress, having people to call. That is part of the purpose of our visits now to the local communities and to meet with local health organizations is to identify what some of the options are if people need to be referred out. We will provide clear written messages and education materials on the meaning of any individual

results that they get indicating when there is the need for action. We are, again, trying to line up information in local areas about where people can go if they have a blood pressure level that is of concern, but they do not have a doctor or they do not have health insurance. And, as I mentioned, working with local communities to identify these networks.

There is a lot of oversight of this study and there will continue to be. The peer review of this protocol has been unprecedented so far and it will continue. We have just recently completed our standard NIEHS process, which is to send this out to four - actually, three to five extramural experts for review. This process is blinded so somebody here, in the room, may have provided extensive written comments already.

I thank you and we have tried to address them. We, of course, will go to the IRB and we, as feds, have the opportunity to be reviewed by the Office of Management and Budget. We have shared our protocol with many, many federal agencies and committees and with the public with our protocol published on the NIEHS website and the Institute of Medicine website. We will be forming a study advisory board. In order to do this quickly, in the context of the federally appointed something advisory

committees, the FACA committees - Dr. Collins had it right and I forgot to write it down. We are planning to do this as a subcommittee of an existing federal committee, which is the NIEHS Board of Scientific Counselors. Andy Liu has agreed to be the Chair of that. The Committee will include one or more other members of our Board of Scientific Counselors, other experts, community representatives and federal agency liaisons. We, of course, will have this ongoing oversight by the Institute of Medicine and, I am sure, other federal panels.

To date, we have had the intra-agency meetings on August 19th, where we shared the protocol and got some feedback. We have had our webinars where we got extensive feedback, answered questions. The comments that people had and questions are summarized - they are on our website, if anybody is interested in what the community had to say. I mentioned the protocol has been posted. Some comments have been coming in. The protocol was circulated to federal agencies and to something called the Intra-agency Gulf Oil Spill Committee or GOS. We have so far gotten written comments from OSHA, EPA, several investigators at EPA, the CDC, and others. I mentioned our peer review.

So what other concerns have come up so far? Some of them have already been addressed in the revision that we

submitted a few days ago. The issue of completeness of ascertainment of eligible workers came up and we are working diligently to make sure that we have access to information on all of the potential workers in the workforce.

Questions about the availability and quality of the exposure data. Availability, we have determined what is available and that there is a lot of it and we believe we will have access to it. The quality of those data will need to be assessed by our committee. Everybody has pointed out the challenges of exposure reconstruction. We will form an expert committee to do this. It is not going to be done by me.

They have raised concerns about the timeframe, but we really, as I mention, believe that it is important that we enumerate the cohort, first, and deal with that in parallel or second. Several people mentioned the need to include other collaborators or consultants with subject matter expertise and we are working on that. We agree. We specifically will be adding investigators with expertise in mental health and social epidemiology and I already mentioned adding an industrial hygienist. There are issues of confounding by other occupational and residential exposures, which we will deal with as best we can by

collecting lots of information in our questionnaires and then the need for alternate enrollment strategies for some groups has been mentioned.

There are some concerns that cannot be addressed. We are getting started late. We know this. The workforce is quite small now, relative to what it was at its peak. The heaviest exposures have thankfully ended. Good for the community, not so good for us, where we would have loved to have been able to collect biosamples as people were being exposed.

The other thing that we cannot respond to is that, in an ideal world, we would have extensive pilot testing, we would have preliminary data collection, we would classify exposures before we start. If we do that, the opportunity to do this study and be responsive will be lost. In the same vein, there are other limitations. We do not have pre-exposure biologic samples or health assessments for the vast majority of the workforce, but there are subgroups for whom there are such data, such as the National Guard, the Coast Guard, maybe BP workers. We are working to obtain that information.

I should have mentioned that we are, in fact, already collaborating with the Coast Guard and so we will have active participation from them in our study.

There is not an ideal unexposed comparison group. No matter how you look at this, at the end of the day, our best shot is going to be we have this cohort of people with various ranges of exposures and for whatever question we have, we can compare the most exposed to the least exposed, however we end up defining exposure. But in thinking about this, it is important to think about what the questions are that we want to ask. If we think about unexposed, local community members, they are similar, but they also are exposed to all of the stresses that are related to having an oil spill in your backyard and having it affect your livelihood.

There are certain questions that cannot be addressed with local community members. Persons far away from the spill do not have those stresses, but they may differ in other ways - health and economically. That certainly adds to the complexity and cost of the study the further away we go. It is not a typical worker cohort. Some have suggested that we find another occupational cohort. This is not an occupational cohort. It is a unique cohort, all by itself. There is not an obvious choice of who to compare the group to. As I mentioned, within cohort comparisons will probably be the best bet, but we have gone out of our way to make sure we include

various types of unexposed individuals, who come from different locations.

We do not have quantitative exposure measures. Other disaster research and other cohort studies have identified risks - health risks - despite this limitation. We will, we hope, end up with semi-quantitative job/task exposure matrices, but we also have qualitative rankings - the most to the least exposed based on assessment of how close you were to oil or burning oil or handling dispersants. We have distance from the spill or burning sites and there are bunch of other ways to think about exposure.

We will be relying on self-reported data. In fact, in many settings, self-reported data is the best you can do. If you think about a biomarker of something that is only around for a short amount of time, you need this historical, self-reported information to quantify how long people have been exposed and what they actually did over time. There are some persistent compounds, if they prove to be relevant, such as metals, that can be measured in the biosamples that we are collecting. We also have the opportunity to look at some specific biomarkers of effect.

Another limitation is that the available data that has been reported so far suggests that individual

exposures are, in fact, very low. I just want to point out that the Prestige oil spill study and other oil spill studies have shown molecular effects of possible concern and persistent clinical effects so it is important that this group be studied, as well. Other studies have shown health effects or biomarker effects at surprisingly low levels of exposure.

Given the impact of spills and community concerns, there is definitely a need to assess the consequences, even if any of you believe in your heart that the exposures are too low to see effects. We do not know if there will be effects and it is important for us to take a look. We also need to further evaluate the exposure assessment that was done. There may be limits to the assessment that was done that contributes to it having shown up as being low or unmeasurable. So are the exposures truly low or are there monitoring limitations that explain the findings? That remains to be seen.

Some of the cohort members will have petrochemical and other exposures, either through previous or subsequent jobs or through hobbies or because they live close to a source of exposure to oil or to oil byproducts. We will be taking these into account through the questionnaire and our statistical analysis of the data.

I did not do this by myself. In fact, there are many people who have been working around the clock. I would especially like to acknowledge Larry Engel and Richard Kwok, who really have done the heavy lifting in putting together the protocol that you had to read. There have been a number of other NIEHS investigators, who have been involved in the study - Aubrey Miller will be involved, Stephanie London for respiratory expertise, Christine Parks for immunologic effects.

We have had the advantage of a number of consultants - Aaron Blair, retired from the NCI and is spending some quality time with us, John Hankinson, who is an expert in respiratory function measurement is a consultant to the study. I want to give a shout out to Chip Hughes, who has been involved in NIH's efforts in the Gulf since the spill happened, involved with the worker training, and he knows everybody and without his contacts we would not be able to do this study. Thanks.

DR. GOLDMAN: Thank so much. Time is limited, but we do have time for a question or two and I would like to actually just ask you one question. As all of this is emerging, in terms of developing the study protocol, I am aware that there are other efforts underway, as well, to try to understand actually what the identification is of

compounds that might have been involved in this and the dispersants and so forth, looking at the toxicology. And then all of you, as you are doing your exposure matrix, may then stumble on things that might be useful to the people who are doing that work. Just if you can talk a little bit about how that works or how you would hope that might work, in terms of the back and forth transmission of that kind of information within even your own institute.

DR. SANDLER: Thanks. I should have mentioned that because we do have opportunities within my very own institute. The NTP has been actively involved in obtaining samples and measuring compounds. We are aware EPA is doing things. In part through the federal meetings that Teri and others have organized, we are keeping abreast of what is being done. We will include toxicologists and representatives from the NTP in our exposure assessment panel so that the information will go back and forth. More than that, I cannot give you specifics, but it is important to know. And Linda would like to say something about NTP's work.

DR. BIRNBAUM: The NTP - Frances also provided NTP some additional funding to look at the issues, especially focusing on some of the analytical issues about what really was in the crude oil, what was in the crude oil

plus dispersant, what has been in the weathered crude oil, what has been in the weathered crude oil plus dispersants, what are in the tar boils, et cetera, to get a clean handle on that. I should say it took a while to get appropriate samples. We are getting them now and our folks are working very, very hard at this. In addition, we are collaborating with the NTP part of NIOSH, who are conducting some - well, especially inhalation, but also some dermal studies in rodents of the crude oil and the crude oil plus dispersant, and the weathered crude oil plus dispersant. We are providing the analytical support for that, as well.

DR. GOLDMAN: Thank you. I think we have time for, perhaps, one more question. Yes.

DR. FINEBERG: Thank you so much for the overview. Just a very brief question. You did not say very much about the recruitment of the field staff to carry out this work. Do you want to make any comment on that?

DR. SANDLER: Yes. Thank you. It is a challenge. We need a lot of field staff. The field staff that we recruit will be local. We are doing our study through - in order to do this quickly, we are doing this through an existing contract for support of clinical research at NIEHS. It is a company called SRA - this is the initial. This is just to get the first year and get us off the

ground and then there will be an RFA out for other contractors to propose that they might do a better job. But the first year we are starting with SRA. SRA has had meetings with various groups that have staffing capability in the Gulf. They invited - I'm blanking - Labcore and EMSI and all these various groups, who can provide different arrangements for doing the home visits. The questionnaires - the telephone part will be done local with our staff.

The facilitated enrollment of special groups will be done by us developing arrangements with either local researchers or local community groups to help facilitate that enrollment. That will take place using field staff, who are in the various communities where we are doing the enrolling. For the home visits, we envision - one model is this sort of distributed model where we hire home examiners from a company like EMSI that does insurance physicals when they are not doing scientific support. They use local work staff. But there are other models for us to do this and we believe it is important to at least make sure that we have a mix of our own employees, who are working there, who are the local community coordinators of then some sort of distributed staff. There are companies like ClinForce that provide staffing. There are lots of ways to gear up

quickly without increasing the size of the government workforce, which is something that we cannot do because they become permanent very quickly.

DR. GOLDMAN: Thank you so much. That was a wonderful overview and I would say a model for the rest of the presentations time-wise, as well, I am going to say. It was really so much packed into the last hour. We are now going to move into our first session on study goals and design. That will be chaired by Dr. Bernie Goldstein with the University of Pittsburgh School of Public Health. Without further ado, I am going to turn the platform over to him.

Agenda Item: Session I - Study Goals and Design

DR. GOLDSTEIN: Thanks, Lynn. Can I ask the panelists to come up?

As you have heard over and over again, this has been an incredible effort in a short time, and time is the essence here. So I am going to start by trying to save each of the panelists some time.

Scientists tend to be very polite. These are very polite folks here. There has been a superb presentation of the really excellent study being done by folks who have had to put this together very quickly. Not only do they know that, they also know that they are people that they greatly

respect, Dr. Sandor and colleagues, and their boss is here, and their boss's boss is here. So their tendency is going to be to take their 12 minutes and to spend the first ten or 11 saying very nice things about this protocol, then the last minute or two, slip in something that they think may need to be fixed.

I am going to absolve you of that first ten or 11 minutes. You have all said these wonderful nice things now, and let's make sure that our focus is on how to improve this study. As Dale has told you, they have been through a lot of thought processes of what to do, how to do it better. They have asked for help. That is why we are here today. So let's see if we can do that.

I would caution you and ask you to keep to Dr. Tucke's old rule about distinguishing the difference between a blemish and a scar, that as you point out ways to improve this, we do focus on what are crucial problems, but what are also perhaps minor but still correctable approaches that could be taken.

I am going to introduce all three of our speakers. I say three; we have four people here. Larry Engel, who has already been introduced to you as someone who has participated in this, is here to react to what is said and to be responsive in that way. Larry, I ask you to keep your

facial gestures to a minimum as they say things about your project.

Our three panelists are Robert Wallace, who is Director of the Irene Emsminger Stecher Center for Aging at the University of Iowa College of Public Health. He is also a professor of epidemiology; Stephen Cole, who is a professor of epidemiology at the Gillings School of Global Public Health at the University of North Carolina, who is particularly interested in quantitative epidemiological methods, and David Kalman, who is professor and Chair of the Department of Environment and Occupational Health Sciences of the University of Washington School of Public Health, who is an expert on exposure assessment and toxicology, among others.

So, 12 minutes. Robert.

DR. WALLACE: Good morning. It is a pleasure to represent the Institute of Medicine. I am daunted. I am probably the 300th person to comment on this protocol, and it is still interesting and rich, and I will do what I can.

I am going to take my few minutes to just talk about things large and small with respect to the protocol and the background communities from which these workers came. I wanted to make a case first of all to use wherever possible archival data that might not have been thought of. Some of

this is very important to understanding the cohort, crime rates, unemployment claims, children's emergency room visits, adult protective service calls as older people and families get stressed by all of this, community mental health center visits. So I think there is a substrate of all of this that becomes very important.

I think it is even possible to go back and look at some of the exposures such as food. FDA of course is always in the Gulf, has been for many, many years, testing foods, and has data. There may be locals who can test their foods, and that can be analyzed. And there are some air pollution sites.

Another area that I would like to talk about is, if possible, I think it would be important to try to get the community context of who does this cohort also represent. So it is an occupational cohort, and that is fine, and it ought to give excellent information, but it also represents probably millions of people in the Gulf area who have also been exposed one way or another, even with small jobs, recreational activities. I just listed several activities that Gulf area residents might do.

It would be great just to get some kind of a sense about the larger community and larger population and what this cohort represents, so that when all is said and done,

one could say to the community at large, this is where you fit in terms of what we found in terms of health effects or not, and that is very important to me.

Dale did a great job of talking about the control groups. I know you have considered lots of study designs, and I really don't have too much to say. I thought about possibly siblings who were not exposed to the Gulf, because that controls for a lot of the hereditary things that go on, if there are enough siblings. Community residents at large, you covered that in the protocol.

I would also like to mention large simple occupational cohorts which I will come to in a moment. Then, if you have a problem getting into certain corners of this very large complex culturally diverse community, to think about network sampling. That is, start with some people and let them guide you into the rest of the community. I think that could be important.

So the large sample cohort that I am thinking of, and I am not an environmental scientist, is basic working populations that have nothing to do with Gulf exposures, but do have something to do with oil products, refined and not refined. I have listed some of the jobs where this is the case, enrolled and followed for mortality, just as a way to put boundaries around what one might expect in terms of

excess risk for morbidity and mortality. I think that would help understand the data as it becomes available.

I also thought about, are there other data sets that could help you one way or another. These are just a few things that came to mind, including one of my own studies.

The SEER program, NCI's great cancer surveillance program, does the whole state of Louisiana, so that becomes important. I'm sure in the Gulf the health interview survey and health and nutrition examination survey from CDC are in the Gulf a lot. There was the Bogalusa heart study, which studied a lot of Gulf residents again in Louisiana, that might have stored specimens over a number of years that might be of interest.

Then there is my own health and retirement study, which is a nationwide study of older people, sponsored by the National Institute on Aging. We have hundreds of participants who have been followed for a number of years in the Gulf area and might be able to provide insight.

I wanted to make a point about the primary outcomes. The protocol is written, and I think correctly so, as going in a large number of directions and being encompassing and looking at a wide variety of health outcomes. I would argue that there might be value in taking a cue from clinical trials and to declare what you think the

primary outcomes might be, and what you will consider not statistically significant, because everything will be statistically significant, it is a very large sample size, but to consider what would be an important difference between the groups. Then you can take care of everything else with secondary and tertiary outcomes.

So I think whether you are looking at biochemical or physiological or genetic factors, I think they should be defined in clear terms, and declare yourself. I think that would be a useful exercise if you have time.

I think the biggest problem is going to be recruitment. You have heard thoughtful and rigorous approaches to all of this. I don't know that I really have too much to add.

As I read the protocol, much of the pretest was about logistical things. My own suggestion would be to try to pretest different cultural groups and to pretest different communities to see if you can recruit, over and above handling the paper and collecting the data. If you don't know from the top how well you are going to do, at least with an estimate, then I think going further will be difficult if the study stumbles a little bit.

I have listed some distractions that I think could impede recruitment. It is a younger, most mobile, mostly

male population, very, very difficult in survey research to recruit and to maintain adherence. As was well described in the protocol, there are lots of health and economic effects. There may be some foreign nationals and other undocumented workers who may be afraid to come forth; you may have heard about that. That may be an issue.

I think there needs to be some investigation in a small sub-sample of health literacy and scientific illiteracy, so that you know that people can understand the consent form and what the study is at any level.

There are lawyers out there, you may have heard that. Some of these workers may already have been gathered by lawyers. Some of them may have claims against BP or maybe the government, and I think may be an impediment of some sort. But I think pretesting of the recruiting is a critical part of this, even though time is short.

The only other thing -- the questionnaire isn't there yet, and the only other thing that occurred to me that I didn't see in the protocol was whether or not protective clothing and other devices were issued to the workers, and did they use them. So I think that is very, very important to all of this.

So just a series of thoughts. Thank you.

DR. GOLDSTEIN: We are going to go through our three presentations and then go to questions. So, Stephen Kalman.

DR. COLE: I will take the time while the slides are coming up to say thank you to Dr. Goldstein for releasing me from the first minute of my talk, but not the other 11.

I have three points to make. I will be able to make two and maybe touch the third. I have a bunch of minor points that I left on a slide at the end that you will have.

The first point is that *sans* randomization, our effects in this study are going to be assumption identified. What I mean by that is, we don't get to estimate a point estimate to get at the difference between the five-year risk of end stage renal disease in those heavily exposed versus those unexposed. We don't get to identify that as we would in a randomized clinical trial.

To wear that up front means a few things. First, that we need to structure the eligibility criteria to maximize the comparability of participants on non-exposure issues. I think the study protocol attempts to start to do that, but one of the tricks here is to think about this as a randomized trial. You are not going to conduct a randomized trial, but to think about the study as a randomized trial and what would you do there differently than you are doing now.

There may be insights that are gained from that thought experiment.

Second, we need to collect extensive, detailed and accurate outcome determinants that may influence the exposure. This is important, to collect the confounders.

If we link back to Dr. Sandler's slide on controlling for other factors, it is almost slipped in there, but it is the key issue here to get the identification of this effect. The factors that we control for will differ when the outcome differs. So there is not one set of factors. This is the key assumption.

I think probably the biggest danger in this study is around getting the comparability of the exposed and the unexposed. In the occupational setting, people sometimes call it the healthy workers selection effect. This is a huge issue.

We will never do it right. We should say that out front, that we will have bias remain in the study most likely. So rather than report a point estimate and say this is what we know to be the truth, we have to do formal sensitivity analysis to this assumption.

Just like in a lab, if you couldn't identify something, you would vary something over a range to see what

the results would look like, if you couldn't identify that piece of information. You do the same thing in our analyses.

The adage here is, you can't get there to causation from here, observation. In particular there is a nice example that we had in HIV, where we know we can't identify in this observational cohort, similar to the Gulf worker cohort, the effect of these anti-HIV therapies on changes in CD4 cell count among treated versus untreated patients in an observational setting. Randomized trials were conducted for short term effects, but we want to know the ten-year effects of these drugs. What would typically be reported would be a point estimate assuming there is no bias. The analyses in the protocol are those that assume that there is no bias. What we want to do is, we want to vary the amount of bias that might be present, and look at the sensitivity, the slope of this effect, over the range of plausible unmeasured confounding.

So the one-year effect of change in CD4 was very strong, but it was also very sensitive to the unmeasured confounding. The per year after one year effect of these therapies on CD4 cell count was not as strong, but it was also not as sensitive. This is helpful in thinking about making policy, not just having the point estimate, but the balance of what can happen.

So that is point one, this healthy worker selection effect and the unmeasured confounding. Everybody knows it is a problem. But the thing that I saw was missing from the protocol is to lay out front formal sensitivity analysis for this issue.

Point two. We know that random sampling imparts portability. If we randomly sample from a population, then we can make inferences back to that population. Partial random sampling imparts partial portability.

Is the biomedical cohort that is planned comparable to the active cohort, full cohort, which I combine the active and the passive, for the U.S. population? We may want to envision this Gulf study as a four-stage design. Two-stage or K-stage designs have existed for decades in epidemiology and biostatistics, but they are under used. They are under used because it is planned missing data. Everybody revolts and has a gag reflex when we think about missing data, but planned missing data shouldn't induce the gag reflex, it induces the salivary glands.

So that is what we should be thinking about here up front, is how can we map these Chinese boxes of the biomedical cohort to the active cohort to the whole thing.

This speaks to the issue that Dr. Sandler raised about the power. You saw that there was a lot of power in

the full thing, less in the active, much less in the biomedical. What we want to do is just leverage that biomedical to capture some of the power that we have in the full cohort. There are approaches to do this.

As an example here with a colleague at Johns Hopkins, Lynn Stuart, we took results from a trial in HIV that was the first trial to demonstrate that these triple therapies really were effective, the ACT-320 trial back in the late '90s. We applied those results, we put that as a Chinese box into the 2006 HIV infected population of the United States.

The bias depends on a lot of things, but it is not complicated, it is just algebra. On the left is the trial results, on the right is the results for the 2006 population. The results still maintains. It is a little attenuated. But what we typically do, just like in epidemiology now, we typically just report the results under no bias. We don't talk about that function. We typically report the results on the left and don't talk about the application of our study results in the larger context.

My third point is that we want data analytic influenced design. Design should be driven in part -- not totally, in my world it would be great if it was totally, but in part by aspects of the data analysis. We should be

thinking about the analyses that we need to do in the design of the study and the forms.

So how will the ten to 30 percent dropout be accounted for? And is extra information needed to do so? We are thinking about the confounders from point one that we need to measure to identify an exposure of health effect.

We should also be thinking about the set of variables that are common causes of dropout from the study and the outcome of interest. That might be a different set. If you think about Venn diagrams, there might be some overlapping covariants that are there and confounders, but this is potentially a different set of variables that we need to be thinking about. There are methods to not only do sensitivity analysis as we saw, but to make accounting for informative dropout by things that we have measured, but we have to have measured them to do the accounting.

Originally I thought the health worker selection effect, the initial confounder was a big deal, and the healthy worker survivor effect wasn't playing out there. What we have is a bolus exposure, and if we are going to follow them for cancer, it is going to be quite a long time.

The more I thought about it, the more worried I got that early heavy exposure made immediate changes in their work exposure. So susceptible individuals who had an

immediate respiratory problem after being on the water in heavy exposures for a day or two may have backed off the water, but still helped out and volunteered. Those kind of changes could threaten the study results. It is something that I didn't really have time to fully think out before coming here, but I think it is something that needs to be thought about in more detail.

I didn't say my little adage for the last one, did I? Well, I will skip it. It is there on the slides.

I am going to skip over the fact that there are multiple time axes going on that we should probably pay attention to. For particular analyses, survival analyses, whether age or time since exposure or time on study, is the real time scale that we should be paying attention to. So the adages come back.

So in summary, without randomization our effects are assumption identified. We should wear that proudly. We don't have to hide it as I think has happened in the past in a lot of observational research. You can't get from causation to observation without relying on assumptions. Let's list them, let's explore them.

Partial random sampling would impart partial portability. The real point here, the catch here, is to get into that biomedical cohort, it would be great if you

randomly sampled from the active cohort. If you can do that, you can be in targeted random sampling, but to do that will give you power and leverage unheard of.

Originally when people took the training, if one in 100 would have been randomized to go to exposure or not, your study would have been 100 times more powerful. Just one in 100, if you flipped a coin, you would have had this leverage we don't have there; hindsight.

So the study is not the target, the map is not the terrain, but we can create that map if we think about this.

Finally, we should measure twice and cut once, or think about our design twice before we make our decisions.

There are a bunch of additional points that I will leave here. There is two that I wanted to quickly say. Take saliva on a small proportion of those who do provide you blood. Always do that. We have disjoint information; always get a little coverage on both pieces.

In a recent paper we had in *Biostatistics* with a colleague, Haitao Chu, at Minnesota, we went into this as an occupational database where we had self reports, expert assessment and a job exposure matrix. We were looking at the exposure misclassification, how to correct for it.

We went into that process thinking, we are over identifying. We have got three reports we can totally

triangulate. We found out that when you do the math, you need a fourth. I think the innate reaction before I did that work was, get two measures of your exposure. Always try to get two measures of the exposure, so you can compare. In fact, now I think we need four for the math.

Thanks a lot.

DR. KALMAN: I have nothing for you to look at, for which I apologize. But at the same time, had I developed slides in the few days I had, I would have thrown out three-quarters of them after receiving the revised study protocol. So it is probably a wash.

I would like to thank everybody for inviting me here. I have a number of general observations, but mostly I wanted to share some comments specifically about exposure.

Before I get to that though, I would like to begin taking the longest view in terms of the study goals and approaches, and to echo something Bob Wallace said, which is, the study is conceived as kind of an open architecture study with respect to end points and potential relationships between observations of health effect and what the exposures might have been.

I have no quarrel with that. I think that a study of this scale and in these circumstances that didn't have that open quality to it would be a big missed opportunity.

But I also echo what Bob said about the desirability of having a few things that you think are likely testable questions related to health effect, and to put those out there as a way of giving people something concrete to think about, and also as setting a benchmark for beginning to interpret your findings as they come in. So I think that would be a point worth considering.

The other thing I wanted to say of a general nature is that one aspect of this study is kind of on a realm of an exposure registry or a repository of exposure information linked with bio samples, linked with other biomedical information. We have seen a number of enterprises over the years of this sort, some of which have been very successful, some of which have not.

I think that the presentation this morning talking about the study design and the way in which thought is going into how to engage new investigators in the communities from which the samples come, is an important element in determining whether or not that kind of, you build it and they will come, approach is going to work or not.

I think that the early engagement of potential users and giving thought to a transparent and predictable process for accessing the information is really important. Outreach in general is really important, so the more that

this kind of planning can go forward in terms of how will the lines of communication be established and how will people be able to come and go from this, what I hope will be a very rich set of information and samples, I would encourage that. I think that is well thought of.

Turning to exposure. Obviously other people have looked at these emerging plans and had the same reactions I did, one of which is that exposure is oftentimes the Achilles heel of large scale population studies, especially retrospective ones or ones that are being done in an emergent way. I think that is a fair characterization here. There are a lot of reasons to be concerned about exposure misclassification or simply lack of discrimination in terms of the exposures that occurred.

The constraints that were described are real, and probably unavoidable. The majority of the exposures have happened, and there is no magic biomarker that I am aware of that is going to fix that. So there is going to be some uncertainty, more than some. There is going to be uncertainty.

So as I understand it, and I should have prefaced anything I say about exposure by pointing out that I have not been involved in the planning of this work. I acknowledge up front that I could well have not gotten it right or not known

things that I should know, so we will have a chance to get that corrected later on.

But as I understand it, there are three sorts of information that can be brought to bear to achieve the exposure dimension. The first is information that comes out of what you would otherwise call an employer. That is to say, the circumstances under which the person worked, when they started, when they stopped, where they were, what their job assignment was, that kind of stuff. That can be achieved through the enrollment information, although the linkages between the individual participants and how they got onto the beach or whatever they did and what their employment situation was, need to be thought about.

For example, it may turn out that it is very important to know who was organizing the activities on a given day. So if there is an issue about, did you use dispersion A or dispersion B, or did you use it or didn't you use it, or what were the practices that could be better quality of information coming not from the worker, but from something the worker -- some other source of information about the circumstances for that workplace. So that is point one.

Point two is that we have in addition to what we can glean from that information, there is the information

from the participant themselves. This is an area where I have more questions than reactions. The materials that I have looked at so far suggest that that information will be collected in either the baseline questionnaire, which is a 30-minute interview that covers a wide range of topics. So clearly a detailed workplace collection of information is probably not going to be achievable at that point.

The second opportunity is the home visit, which is about an hour, as I understand it. Again, a number of things are covered, and the actual questionnaire related to exposures was not available yet.

There was something that looked kind of like a calendar, where I presume there will be some vehicle for collecting information. I don't know how well developed that is.

It was commented during the presentation that we are going to have to rely on worker recall for a lot of stuff, and that that drives the priorities in terms of timing to get the study started. I agree with all of that.

I would also though point out that the further down the road the enterprise is in having its exposure classification system conceived and thought of and commented on, the better, because that will inform what you ask people. What are going to be the kinds of details that are going to

be useful in terms of not only helping assign people to categories, but even refining the categories, if necessary. I don't have a quarrel with the issue of priorities, but I think the parallel effort should be encouraged and supported and pushed forward as much as possible.

The third source of information will be the body of measurement data and industrial hygiene assessment that will be created out of the extensive but so far not unified chunks of activities that have already gone on under the various groups that have been monitoring their workers or monitoring activities in general, the Coast Guard, the health hazard evaluations that NIOSH did, BP looked at its own work sites.

I don't know whether all of you have had a chance to look at the summary notes from the August 19 meeting, which was focused on that. This is encouraging to me, that the study designers are aware that this is a pressing issue, because even convening such a meeting shows a lot of foresight.

I was kind of blown away by what was described there. There is a ton of stuff. If it can in fact be brought to bear on this study in an ideal way, I think it will help a lot with the lack of real time measurement during the time when exposures were current. For one thing, there is the opportunity to enroll people who were being measured,

and for whom there could be extensive environmental and personal samples and biological sample information that could be used for a variety of things, not only for setting the bar in terms of what were the worst exposures, but for validating assumptions about how to classify people or what were the relationships, looking at the potentially looming issue of non-occupational exposures that were ongoing and were elevated during this time period, because this is an ambient impact as well as a personal impact.

So I think that on the exposure assessment side, I am encouraged by what I have heard, that care and priority is being given. I do think though that there is a real time line issue here. Without achieving a certain level of conceptualization of how this is going to go early in the process of enrolling people, the opportunity to get recall information ideally will be lost. You can go back and ask later, and if I had to make a prediction, it would be that there will be follow-up questionnaires down the road about details of exposure. But at first contact when there has not been any kind of random effects going on in terms of what do you remember about this and what is going on about that, is your best opportunity to get the information that is just as it is recalled. The more that that process can be informed by the development of the industrial hygiene approach, the

better. So that is a pitch for trying to encourage the subset of investigators who are working this issue to be thinking that their product needs to be coming online synchronously with enrollment to the greatest extent that it can be.

Clearly there is going to have to be validation down the road. That brings me to a second time line issue. To the extent that there are still cleanup activities going on and still people doing things on the beach, this represents an opportunity for further validation of approaches to exposure classification or even just gathering more data.

Again, this is a door of opportunity that is closing. So if it were a tradeoff between getting it perfectly six months from now or getting it mostly right six weeks from now, I would vote for the latter thing, because there will be improvements down the road, but I think that the quality of the exposure information and the quality of the classifications that come out of it, are going to be critical in terms of how broadly useful the whole data set becomes down the road, at least as it relates to Gulf cleanup workers.

So those are basically my comments. Thanks.

DR. GOLDSTEIN: Larry, you can respond to anything that you heard if you want to.

DR. ENGEL: I'll give it my best shot.

DR. GOLDSTEIN: Let me point out that Dr. Engel is at Sloan-Kettering.

DR. ENGEL: Thank you. There is a long list of items to respond to, and I will do my best to address them.

We have made a good effort in the protocol to address them to the extent possible. One overarching issue that we have confronted in this is the lack of information that we have had going forward, and the fact that a lot of pieces of information, for example, the kind of exposure information that is available. The monitoring data has been collected has dribbled in, some that we have only obtained in the last week or so.

We recognize that we have been less specific than we would otherwise prefer to be in any protocol, and less so than we typically are. A lot of that is based on the fact that the information simply has not been there, and in an ideal world, as Dale pointed out earlier, we would spend a year to three years figuring out all these details and filling in the blanks and putting everything together in as solid a way as possible.

In this case, the urgency precludes that. Our goal has been to work with what we have, make some assumptions about what we don't have, and try to fill in those blanks as we go, but to keep things moving as quickly as we can, so we don't miss the opportunity altogether. We don't want to have the perfectly designed study that is then too late to carry out.

So that said, I appreciate the comments that have been made today, and all the ones that have preceded these as well.

The idea of using archival data and materials is a good one. There is quite a bit of information available on residents of the Gulf, and we will do our best to obtain that information and figure out how we can relate that to the subjects in this cohort.

One of the difficulties of course is that most of those data are anonymized, and so it becomes more of a general comparison, as opposed to being able to take direct advantage of that information for our particular participants. But it does give us a general picture of what the context is in which we are working, and so in that sense it is a very valuable resource.

I might mention in that regard that, as was mentioned in Dale's presentation, we will have some data on

health and also some specimens on a subset of the workers, in particular some of the federal workers like the Coast Guard, who do have sera stored over time as part of routine military specimen collections. There are also health data that precede their deployment to the Gulf. So for a certain admittedly small subset of our cohort, we will have some additional information which we can draw on to fill in some of those blanks. But for the majority of the people that we will be studying, that simply is not an option.

The issue of control groups is a problematic one, as has been raised numerous times. There have been some interesting suggestions raised today that I guess we will have to go back and think more about. I don't have any immediate reactions. I think there are pros and cons to the different -- all of the possible control sources that have been discussed, and I think we need to weigh them both from a scientific perspective, and also from a feasibility perspective. We are trying to get the study done quickly. We have limited resources, and we do need to figure out how to balance the science and the feasibility together. But those are some good suggestions that I would like to give some further thought to.

One of the other issues that was raised was in regard to existing studies in the region. We are very

interested in pursuing this angle further. In fact, we have already been in some discussions with other investigators who do have ongoing studies in the Gulf. We would be very interested in talking with them and with anyone else who do have such studies and who would be willing to work together with us.

To the extent that it is feasible, it would be ideal to be able to link data, since many of these studies will have data that predates -- in fact, most of these studies would have data that predates the Gulf spill, and so there is a lot of opportunity there. Then the issue is the extent to which there is overlap between the populations in those studies and the study that we are looking at.

But this is an issue that we are aware of and that we are very interested in pursuing further, and we have already made some preliminary efforts to pursue. So if anyone is aware of any other studies that are ongoing or that have occurred in the Gulf that might provide relevant data for our study, please let us know and we will be happy to pursue those further.

The other issue was in relation to exposure assessment. Well, there were a number of issues in relation to exposure assessment, but one of the first ones raised was

in regard to what we were asking about the potential for exposure among the subjects.

The questionnaire does include not only the types of tasks that people were doing. We also ask about specific exposures that may have or did occur. We ask about for example whether they had contact, dermal or contact on their clothes, with oil or dispersants.

By the way, it is in the preliminary questionnaire, which you haven't seen yet because it is still very much a work in progress, but this is what we are working on now, and these things will be remain in the final version. We do ask about other exposure opportunities in relation to the particular tasks that the people are engaged in, and we do also ask about the use of personal protective equipment and what type of equipment was used, how frequently it was used, reasons for not using it. So we do try to get at this issue of not simply classifying someone based on their job title, but trying to further refine that so we get a better estimate of what their likely exposure was, given the other parameters of their particular situation within the limits of the job exposure matrix. But we will be taking those exposure modifiers into account.

Some of the methodological issues raised in regard to analysis and design of the study are also very important.

I guess we as a study team need to think through these issues more.

We have been very concerned about comparability of the exposed and the non-exposed workers, and that has been a big part of the challenge we faced in coming up with a suitable control group. As was pointed out in the presentation, one of our primary analyses will be comparing the least exposed to the most exposed among the workers, which to a certain extent addresses this issue of bias with unexposed controls. But some of the other issues that come up do need to be considered.

The idea of sensitivity analysis is certainly a good one. It is one that we don't explicitly address in the protocol, but I think is one that should be considered. We can certainly discuss that in some detail in the protocol, and it certainly would be included in any analyses that we do. I think it should be included in most analyses that we do in general. So that is something that we need to consider more, and figure out how best to implement that.

As far as the issue of accounting for loss due to dropout, we will have some information at different levels on who the people are that we are losing in our study. We will have for the people who we aren't able to contact at all or who refuse, we will have some information from the NIOSH

roster. We will have information from the Petroleum Education Council lists, very limited information, but some information that we can use to assess comparability.

Those information are quite limited, so to the extent possible we are hoping to collect some additional information from people too, but obviously we can only do that in people that we actually reach. One of the motivations for getting to the field as quickly as possible is so we lose as few people as possible, given that a lot of these workers do use, we are told, disposable cell phones and so on. So there is a certain urgency in getting to them before we lose that opportunity. But those things will be taken into account when we are conducting our analyses, to figure out if we are looking at a biased sample, how we might account for that.

As far as random sampling, we would like to do random sampling for our subjects. We considered different options for best to enroll in particular the biomedical surveillance cohort. Part of it is driven by the task that they did and the likelihood of exposure and the likely level of exposure that they received. So as Dr. Cole pointed out, we would probably be doing if anything a target or a stratified sampling, because we do want to make sure that we over sample the groups that have the highest exposures, the

groups that are small that otherwise might be under represented if we did a strictly random sampling. But we are attempting to get a representative sample of the larger cohort within that biomedical surveillance cohort, but again, over sampled for groups that of particular interest.

I might point out that this in itself is not a simple question, because we are not talking about a single exposure. We are talking about a whole range of exposures that people will have received, and the nature of the exposures will differ not only by the task that they did, but when they did the task. So we are looking at volatile compounds, we are looking at metals, we are looking at dispersants.

So we have a matrix of exposures that we need to take into account. So to the extent possible, we are trying to get a solid representative sampling of these different groups, but recognizing that it is a complicated mix that we are trying to assess, and we are trying to capture that to the extent possible.

I might mention also that as far as collecting the saliva sample goes for DNA, that is a good suggestion. I think we will look into incorporating that into the protocol.

The plan had been to collect DNA from persons via saliva who did not provide a blood sample, who we could not

otherwise get a blood sample from in the active cohort. But it is certainly feasible and desirable to get a sample from a small proportion of the other people who do give blood samples as well.

Our primary focus has not been on genetic factors, although clearly that will be an important issue. But our driving interest has been on measures of exposure to the extent that we can do that within the samples that we are collecting at this late date, and also on markers of effect. But we will be collecting a large amount of DNA via the blood, so we will be able to do some comparisons with saliva that we collect.

I will try to wrap this up soon.

As far as the exposure misclassification goes, this obviously has been one of the more pressing issues and has received quite a bit of attention, and justifiably so. We are collecting information from employers to the extent that it is available. Let me back up a moment. We are trying to collect information from employers to the extent that we can. There are certain legal issues that we need to overcome, and there are limitations to what those data contain as well.

But this is something that has come up only very recently, the opportunity to do this, and so there is still a lot of unknowns about what data are even available, and what

legally we will be able to get. But that is certainly a good point, and we will attempt to do that. In other occupational studies this can be an invaluable tool for figuring out exposures that the workers themselves may be unaware of. So we are cognizant of that, and we will attempt to get information we can, not only on the dates and the amount of time that the workers were engaged, but to the extent that it is available, particular tasks or exposures that the workers may have experienced.

The issue of what data to collect in the questionnaire is problematic. We are trying to keep this short in order to maintain the good will and the cooperation of the participants. Like I said, this is probably a challenge for every epidemiologic study. We always end up with a long list of what we want to do. We say we will start off with a half hour interview, and we will put some questions in, and you have four or five hours of questions, and you need to figure out which ones you are going to cut.

We have been going through that now. We have been going through on a very abbreviated time scale, so we are very much aware of the need to collect the right information and to collect it now. We are attempting to get as much detail as we can on the tasks and the exposures that these workers experienced, on the personal protective equipment

that they used, on the amount of work that they did in these different tasks, and again trying to do this within the limited time frame that we have, recognizing that there are also other issues that we need to assess, like for instance lifestyle factors, other occupational exposures and health questions.

I would be happy to discuss this further with anyone here about what other suggestions people have for doing this as economically in terms of time and efficiently as possible, but as I think we are all aware, this is a challenging task, to do this in a time efficient manner, in a way that doesn't burn out the participants and lose their interest and focus.

We are attempting to get this wealth of monitoring data that is available from the various government agencies and from BP. To the extent that we can, it would be very desirable to link those to individuals. There are some questions about that, about whether because of the manner in which the data were collected, we will be allowed by the IRBs or by the individual entities to actually do this linkage.

It may be that these data will only be usable within the legal limits for validity testing, for doing validation on the exposure estimates that we make, but to the extent that we are allowed to use them for individual

assessment, I think that would be a valuable opportunity, and we need to investigate that. But I suspect that will be largely beyond our control, our decision to make.

The last point I wanted to respond to is as far as validating our exposure assessment among the currently exposed. That is something that we are very much interested in doing. When we first started on this project, we had very ambitious ideas of how we were going to collect exposure information on the various worker groups. As time went on and as the well was capped, that obviously became less and less of an option.

There are still a fair number of workers employed, primarily doing beach cleanup in the Gulf right now. We have discussed doing some validation among those workers. Such information will be useful, but it will also be very limited.

We need to keep that in mind as we go forward with this, that their exposures we expect will be much, much lower than other exposure groups such as persons who were at the source or who were applying dispersants and so on. So while it has value, it will be applicable largely to a small subset of our subjects.

In some respects it will be relevant to the least interesting in terms of their exposure opportunity, of the subjects. But we recognize that this is an important and

perhaps our only opportunity to validate our exposure assessment, so we will take advantage of that opportunity.

DR. GOLDSTEIN: Thank you very much. That is really very, very valuable.

Well, this is a reaction panel. You are now part of the panel. In other words, what we do from now on in, and we have got almost an hour and a quarter, is to all react. Larry, you might want to defer occasionally to Dale, because in a sense we are reacting to the presentation that Dale Sandler gave to this lightweight document we have here, and to what you have heard so far. You can also comment obviously on what the panelists have said so far.

I am going to start by first a couple of ground rules. You have got to use a microphone. We are recording everything, so we really do want to hear from you, so everyone who does comment in any way, please use the microphone. You are going to have to line up over there.

But first, before you do that, we are going to start with the IOM committee being the first ones to do that. Since I am a committee member, I thought I would make a comment first, and then speak for one of the committee members who I don't think is here.

The comment is one of some degree of stress over the fact that that it has been 25 years since the Academy had a

committee on biological markers that talked about how important these were for exposure assessment.

Obviously we are pretty late, as Dale started off by talking about this, for a lot of the biological markers which have been developed through this great investment in toxicology that have come out of the National Toxicology Program at NIEHS and the academic community.

At the very least, one hopes that all of the work that you are doing now, will be usable for the next one like this that occurs. It would be nice to think that none will ever occur again, but given any reasonable scenario about the demand for fossil fuels and the tension of industry at all times to the best safety practices, one comes out with some degree of likelihood that something like this will occur in this area, or something like the World Trade Center. We need to be prepared in advance. We need to be able to take advantage of this. So I hope that the NIEHS will go beyond just this to think about how to be immediate responders.

Is Larry Palinkas here? He is coming tomorrow. Let me make the point that he would make, and in a sense, Bob Wallace made it. Bob talked about the legal issues and the difficulty there. Dale presented something that basically said that there is going to be a promise that there won't be a problem, and you can release the information, that anyone

participating need not worry about information being released.

Dr. Palinkas did some superb studies on the Exxon *Valdez* issue, some of which documented the increase in psychosocial stress and mental health problems and violence in Native Alaskan communities. He did this under providing promise of full confidentiality. It got to the ports in the various lawsuits that occurred, and the judge, in what the judge felt was the interest of justice, insisted that Dr. Palinkas release this information. Obviously this impacts on whether he can follow further.

I would hope that real effort goes into being sure that confidentiality can be maintained, and that we look at it not only from a federal point of view, but from all the different state courts.

I will tell you that from the Exxon *Valdez* experience, which is now 20 years ago, it was only a few years ago that the lawsuits got settled, the major ones, having to do with providing funds. In fact, there still are lawsuits going on about it, although in this case it is the plaintiffs' lawyers suing other plaintiffs' lawyers as to their share of the pot, the money that got released.

So with that, let me open this, first to the committee members. I guess, Dr. Fineberg, you can be part of the committee.

DR. GOLDMAN: That topic of confidentiality, two points. When Dr. Kalman talked about the ways that you will have to go about reconstructing the exposure, a lot of that, even if it isn't the individual sampling results that might be difficult to obtain because of confidentiality concerns.

I think we understand that. When NIOSH might have been out there doing a health hazard investigation, nobody was consented into a study to collect those samples, and so that is a complication. But even the other data that might be used in the reconstruction, such as in the data set that will be the height and the weight. So a five foot three, 200-pound person who is on a certain beach on a certain day doing a certain activity, may actually identify that person to an employer, the employer may be able to see who that person is.

I think it is admirable that there will be data access and that there will be data made available, but how that kind of data will be stripped as being identifying data, when it might be data on people who are in relatively small work groups, doing very specific activities that need to be

understood to do the job exposure matrix. So that was one question that I had.

The other one, which is also just something I didn't understand in the protocol. It is three sub-cohorts that will be followed, the so-called passive group, the active group, the biomedical group. But whether there will be a conscious effort to collect common information on all three, so the telephone questionnaire for the passive group, will that be given to all.

It goes back to Dr. Cole's point about nesting. If you are going to do that, which I think ought to be done, to have that common core of data collected so that you can tie together the information that is collected at those three different levels.

So those are my questions.

DR. SANDLER: I just want to respond in reverse order. That is where that flow chart would have helped, if we had had a chance to make it bigger; I apologize for that.

Everybody gets the same baseline questionnaire that documents what their work experience was, and some minimum amount of health data. Then from that we divide it into those who contribute more data and those who don't.

I want to say that the two-stage, multi-stage design is a great idea. We should have said it explicitly,

because that was what was in the back of our minds, that we would be able to do this in a randomized way, being mindful of the need to maximize certain groups, so that we can scale it back up. I have been thinking about using a multi-stage design since 1993 when we designed the agricultural health study, and when these papers had first come out. So that is important.

The issue of the confidentiality and how many data points do you need to identify a person is something that is of deep concern to me. We are having ongoing discussions about the balance between protecting the confidentiality and the need to make the data useful.

I think we have -- this has been vetted for a long time in the context of the GWAS studies, and Teri Manolio may want to speak to that. We have other concerns because of the employer relationship. In fact, just Friday we had lovely conversations about this, what is the target, how are we going to do this. So we will welcome peoples' thoughts on how we can maximize the data access while preserving the confidentiality. There are certain things in here that it wouldn't be too hard to find people if you really wanted to do it.

There was one other point, but I have already forgotten it, so I'll come back.

DR. MANOLIO: Teri Manolio. Just to respond on the issue of small cell sizes and how one deals with that. I think what we are talking about here are not public use data sets in the classic sense. So these are not tables that are put up for anybody to access from the Internet and download and that sort of thing. It is very different from that approach.

Really what we do in these studies is to provide a data file that has everybody in it, with everybody's individual level information and assurances that the people who receive those data and their institutions who have to consign these agreements will not attempt to identify anyone or to contact them or to use the data against them.

I think we recognize that a court of law doesn't need a data user and a data use agreement to compel disclosure of that information. It can compel that information from the P.I. So whether we are doing data sharing or not, those issues remain. But in terms of small cell sizes and that sort of thing, we are not talking about public use data sets here.

DR. GOLDSTEIN: Just to follow up on that, if I think I heard what you said, you cannot then go to the public and say, once you have given us your information, we can promise that it will never become public.

DR. MANOLIO: That is correct. I think we all need to recognize that in this day and age, and most people out there do recognize that. In fact, when we try to say we will keep it confidential, they say, you can't possibly, don't be silly. So we need to do our best to put the protections that we can on the data and then make it clear to participants what those limits are.

DR. LE: Hi, Mai-Nhung Le. Thank you so much to the panelists for your comments. They were very helpful. I want to acknowledge the P.I. for including in other languages in terms of doing the study, because that is really an important criteria.

I have a question. My question is, what instrument -- you said a standardized instrument for the psychological measurement. What instrument are you going to use? And have they been used for non-English speaker or people who are not from the U.S.? It is really important to be mindful in terms of the questions that you ask and the interpretation of these responses.

For example, in terms of some of the psychological measurement, a question like health is a matter of luck, and then is assessed as fatalism. But for a lot of Vietnamese people, that is not fatalism in their culture. In terms of looking at culture meanings behind the psychological

measurement is really important, and it is not just for the Vietnamese community, but it is for other groups as well.

It seemed like since you have language as a component, I was wondering whether or not you are going to look at the effects of workers by the health effects, variation by race, ethnicity and gender, since you are going to have that sample. It would be very interesting to look at the variation of the health outcomes, physical as well as psychological.

Then in terms of the question of confidentiality, it is very hard if your sample size within a certain group, like let's say the fishermen. How you cannot pinpoint if that person have a certain kind of adverse health outcome like cancer? Cancer is still taboo within a lot of Asian groups. So how could your data, when you report that in this study, in this area, we found X number to have cancer or certain kinds of health effects? How could you not identify that individual?

So a possible way of doing that may be to try to have a very representative sample of that population, so that you don't really have such small number that you can pinpoint, and that that individual within that community will be a scapegoat.

DR. GOLDSTEIN: Is there a dose response? You are suggesting over sampling when you have a small homogenous community.

DR. LE: Right.

DR. GOLDSTEIN: Is that something that has been considered, Larry or Dale?

DR. ENGEL: We are looking at over sampling targeted groups, including the highly exposed workers, but also smaller populations. So we will be over sampling certain ethnic groups as well.

The difficulty that we are going to run into is, if we are presenting aggregate data, then that solves the problem. The difficulty that we need to resolve is, when you are presenting a lot of information on people, on their age, on their sex, on where they worked, where they live, personal health information, it becomes increasingly difficult to keep those people anonymous.

So that is the issue that we are trying to grapple with. That is one of the problems of making the data as open as it will be. But to the extent that we can, we will have large enough representative groups so that people at the aggregate level should not be individually identifiable.

DR. LE: Can I ask one more question?

DR. GOLDSTEIN: Go ahead, if you have a specific question. But how about an answer to the instruments specifically?

DR. SANDLER: We haven't selected exactly which scales we are using, but we are using standardized scales, like the CESD and various things that are used in the behavioral risk factor surveys that are done.

We have the advantage in behavioral health in that a lot of the scales have been standardized. I am embarrassed to say that I don't know what is available yet in other languages and how comparable they are. So that is an excellent point. We will need to work with specific communities to make sure that we are using culturally appropriate instruments in special populations for the translation. So I thank you for bringing that to our attention, and I will come back to you.

DR. ENGEL: I want to respond to the last point about conducting analyses within certain subgroups. We had every intention of doing that. We will be looking at health effects among women, among specific racial groups, ethnic groups.

We run into issues of power as soon as we do that, because some of these groups will be relatively small, and

even over sampling some of these groups, the underlying population is still relatively small for us to draw from.

So for example we know that approximately 20 percent of our workers are women. We will attempt to recruit them all into the study, but for some outcomes we will have limited power to assess the facts. But we do have every intention of looking at effects within these subgroups.

DR. COLE: There is a tension here between the statements that the data is going to be made available and usable to scientists on a broad scale, and the ability to identify individuals.

So we are talking about both of these things. We are not talking about them at the same time. I think that that issue is -- maybe we are not talking about it at the same time because it is a thorny issue, but I think it is something that is going to have to be faced. If the data is high dimensional, it is likely that you are going to be able to identify people.

So the NCI pooling project of cancer studies, I was asked to go give a talk there about a year ago, and they had their GWAS on the Web, downloadable as a de-identified data set on the Web. Two biotech students from a California university had mapped everybody, and had published this in like an engineering journal.

Schlom Walkholder gave a talk about how they replicated what these people had done. They brought them out to NCI, and they pulled everything off the Web. They had assurances that you couldn't figure out who these people were in this huge pooling project. I think it is something that we need to think about here.

DR. WALLACE: Can I just weigh in for one second? I don't think it is that big of a problem that people are suggesting. There is a lot of very personal data out there that has been shared by a lot of people.

I am involved in studies where we share Medicare data, for example. There are ways to do it, and they work. There are also ways to mask data sets. There have been a lot of investigators who spent their time working in this area, and we are farther along than a number of people are suggesting.

DR. COLE: But the example I just talked about happened in the last 12 months at NCI. Schlom Walkholder is one of the brightest methodologists in our field, and they ended up having to pull it in.

DR. MANOLIO: You are absolutely right, that happened. And actually, even before that happened, there was a group in Phoenix that showed that you could use individual level. If you had somebody's SNP genotype data, 500,000 SNPs

are very rich data. You can basically tell that somebody is in a particular cohort.

When that became clear, those authors actually shared that paper with us, unlike the engineering students. We pulled the data down from public websites. They had been available in summary form, so not individual level data, but summary form. I think that is what the CJEMS project had been doing, too.

So we recognize that there are constantly going to be advances in how one could potentially identify someone. We do the best we can. I think what we really need to do is be up front with people and say, we will continually monitor this and when there are problems, we will take every step that we can. But we can't guarantee you that you won't be identified.

DR. GOLDSTEIN: I would make one more comment to bring it back to the legal stuff. In the Alaskan experience, Native American groups, lawyers coming and asking them to be plaintiffs against Exxon. I expect the same thing is happening in the Vietnamese fishing communities here and on the Gulf.

Not explaining that in the American jurisprudence system they would have to name names. So that when the chief of the village went into a deposition and had claimed that

there was alcoholism, that children left home, that there was interpersonal violence, that they were going to have to say, who is an alcoholic? These are small, tight-knit communities.

The report back, I don't know this first hand, but the report back was that some of the village leaders said, if we had known that we had to do that, we never would have sued Exxon, because it was so important to them not to release this kind of information. Dr. Parker.

DR. PARKER: Thank you. I get to stand up again, which I like to do. I think this highlights for me, this last several minutes -- I actually had two comments that I wanted to bring up. They are both very different, but I want to follow up with the one that relates most to this.

I think our own lack of clarity will only get magnified when we try to communicate it. So I think the more that we take time to decide what the absolute essential information is, the closer we will get to being able to communicate it.

I think we already know that we are reaching out to a needy underserved group of people with literacy challenges, with language challenges. So whatever it is will only go through lenses, and on the far side become that much more

complex, less clear. So the more we can do to come to our own clarity about what matters.

One of the problems I think is that we think we know what matters, but it is really a study about people who have been affected. So they are the real experts. It is really hard to partner with the real experts. It is a huge challenge. That is why it is on health agendas around the country forever, how do we understand the most disadvantaged, the disenfranchised, the vulnerable, and how do we bring their voice to the table in creating something that truly does decrease disparities.

So the challenge is right in front of us, but I think the more that we figure out how we put their voice at the table and partner with them, in understanding what matters to them and why up front, the closer we will get to doing something that will really have meaning for everyone.

So that is number one, just taking stock of our own lack of clarity and the lens that will go through, and the magnification that will be on the other side, and how that relates to recruitment, informed consent and retention. So I applaud the efforts, but I also would like more insight into how the voice of those real experts have been informed how we will go about recruiting and who will we recruit.

Which leads to my other point, which is a little different, but what I understand people want to know, who lived there and who have been exposed, is, is the seafood safe, is the water safe, is the air safe.

That means different things to people who live there than it does to those of us who are looking at the data and trying to line up the science of it. So we have to come to common meaning about what we mean about that. We have to be honest about it, and we have to figure out how we are going to communicate it.

So in light of that, I heard the goals of the study for this session, exposure to oil and dispersants is associated with adverse health effects, and there is probably a dose response relationship. I get it.

My question is, I heard repeatedly that there is probably not ongoing exposure, but that doesn't make great sense to me, when people who are living in Dauphin Island and on the coast won't eat the seafood, because they are worried that there is an ongoing exposure.

So I just want to make sure that we understand and can communicate with people who are asking questions like that what that means, in a very practical sense, as we try to enroll them and recruit them in a study that hopefully is to improve the health and understand the consequences.

DR. GOLDSTEIN: Dale, would you like to respond, in terms of how you are going to -- you spoke a bit about how you are enlisting folks in the community, but you also pointed out that because of the short time frame, you had difficulty doing what you would normally do in terms of enlisting community participation.

DR. SANDLER: We have been making up for lost time. Our goal is to be down there listening to people. I feel like Hilary Clinton; we have had our little listening tours and we have been going around and meeting with NGOs. Thanks to other things that were going on, some of our team have been involved in what are called dockside chats, talking to workers, so we are getting a sense.

I think there is much more we need to learn. This issue of what people are really worried about is not what I as an epidemiologist am worried about. So we are learning, and we will take that into account, surely. I think the comments about the clarify of the message -- it is important, and we are working on it. But any help that people want to give us, we are going to take it.

DR. GOLDSTEIN: Let me ask you and push just a bit on that, how are you going to distinguish very clearly in the public's mind that you are not really responding to the question of the health effects in the community, you are

responding to the health effects in the worker. For instance, the issue of, can I eat the fish, I live here.

DR. SANDLER: That is complicated, because the workers are the community. So in some ways we will be, but our answers are years off. That is the problem with epidemiology. It just takes so darn long to get to the end.

But there is other stuff going on. I am hoping that later on today and tomorrow, you will hear what are some of the other opportunities. I think certainly what our Institute is planning to do with these community participatory research grants, the consortia, will address more directly what the specific health concerns are and social concerns in the community.

We are not the only game in town. There are other opportunities for funding research for people doing this. I have been receiving calls from people interested in the food safety at FDA, what is the FDA doing, how can we build some of that into our study. As an epidemiologist we have limited tools, but we certainly are going to ask about what people are eating and when they are eating it in relation to the food in the area. But the testing of the food safety, we have to partner with FDA to get to the end of that. So it is a bigger problem.

DR. DOMENICI: I have a question which is more specific to the issue of data linkage. You mentioned the linkage of the monitoring data, hair quality, hair sampling from the EPA, information collected by NOAA, from BP.

What are the major obstacles in terms of linking all of the information to the individual health data that will be collected in the population to get a much richer estimate of individual level exposure? That is question number one. It wasn't clear to me what are the major limitations in being able to achieve that.

Second of all, assuming that all of these limitations and all these challenges can be overcome, is there information on what will be the percentage of the population for which we will have enriched individual level exposure data? It said that we could possibly have additional information for a subset of the population, but it wasn't clear how big will be that chunk. Also in this Appendix N there are tables and tables and tables of potential very, very useful information about how many monitoring stations and how extensive. So I was wondering if anyone can help me clarify that.

DR. ENGEL: I think there are two answers to the question. One is in terms of any legal barriers. These data were not collected for research purposes, so I believe there

are issues about whether we can link them to the individuals, to other data that we collect on the individuals, given that they were not collected for this purpose.

Again, we would find great value obviously in linking these and being able to identify specific exposures for individuals. So I think this issue was largely outside of our realm. So, I am not putting it off, but I am saying that we are not the ones who are going to be deciding whether we can link those data or not. I think we would like to link those data.

DR. DOMENICI: Some of these data were collected by EPA and NOAA. There was this meeting on August 19 where all of the federal agencies -- that is my understanding -- were around the table. So I don't understand what type of legal issues there are for you, for your study group, to access to that data. I don't understand that.

DR. MANOLIO: There is an issue called the Privacy Act, that has to do with the way that the government uses individual level data. Essentially, if data are not collected for research use, there are very strict restrictions on how those data can be shared and provided.

Within an agency, there are certain exemptions to that, so that there can be sharing within an agency. So if there is an emergency or a public health need or whatever,

sharing is possible, as between NIOSH and NIEHS, where these data were not collected with IRB approval, but we were able to share them for that purpose.

We are talking about data from OSHA, which is a different department and a different agency, and data from the Department of the Interior. It is not clear to us how we can do that. We are still trying to explore that.

I think everybody wants to share them and usually when there is a will, we can find some way to deal with that. But at the moment, we really need to look into what is the best way to do that.

DR. SANDLER: A large chunk of the data was collected by BP contractors, so there will be other issues. We have had very positive conversations with the collectors of those data and about the will to share.

I think one other piece that is a challenge that maybe Larry was going to get to is the idea that we don't have an area exposure measure on all the 55,000 people who were going to enroll in a cohort. What we will have is measurements that were taken to assess the potential hazard with a specific task or stationary monitoring that was done in a specific location that we can link to where a worker was.

Then the added complexity is that the data collected by different people and analyzed by different groups with different methods all needs to be assessed for comparability. In fact, I am aware that BP has a contract with somebody with an industrial hygienist to pull together many of the sources that are publicly available on the Web. The biggest job Task E faces is to put it all into a common language, about what the jobs were that were being measured and what the circumstances are of that measurement.

So I don't think that these are insurmountable. I don't think we are going to end up with a unique data point that comes from an individual worker. But we will be able to have something that we can assign back to an individual worker. It is just going to take a lot of minds and a lot of time, and it will take a lot of administrative bureaucratic hurdles to overcome.

I think we are going to be able to do it, but don't quote me.

DR. ENGEL: I do want to respond to the last point about the proportion of workers. Dale alluded to this, but we actually have no idea. I'm not sure any of the people who collected this data have any idea what percentage of the workers they have data on. That is one of the tasks that we are trying to identify now.

In fact, that lengthy list that was included in the protocol, we only received that last week. We have been working on this for months, but this information dribbles in slowly. It takes months and months to get some of this. So we are moving as quickly as we can, but there continue to be unknowns.

So again, it gets back to the fact that these data will probably be primarily useful for assigning exposures to a group, and then we can modify that based on the particulars.

DR. SANDLER: It is important to think about the circumstances under which these data were collected, and how fast decisions were made about data that needed to be collected.

The data that were collected by the generate were collected at the request of BP and contractors. We have this group, and they are doing this and we need a hazard evaluation, and we need to run in and collect information.

So it was done not with the thought of, we are going to have a cohort and we are going to need to capture the entire workforce, but I think at the end of the day it may capture a large percentage of the workforce. But it is like with all those other data that are collected for other purposes; it wasn't collected for this.

One of the things that somebody mentioned -- I think, Bernie, it was you -- we will know how to do it better the next time. I think at this government meeting that we had, it was clear that we made advances since the World Trade Center. NIEHS was on the ground immediately with training for workers. This next time, if there should ever be another disaster like this, we will be prepared to collect samples in a more systematic way.

PARTICIPANT: Thank you, everyone, so far for your comments. I have a couple of comments and a couple of questions. Some of those relate to things Dr. Parker has already mentioned.

There are a couple of opportunities that I heard that are of interest to me. One was about community directed research. I am wondering if funds have been set aside for that. I think that will be important for community members for communication and enrollment.

Related to that, there was a comment made about incorporating and addressing health concerns and complaints of the local community, and specifically wondering, are there examples that you could indicate of the types of things that have been incorporated. I believe fish consumption was mentioned as one. Thinking towards enrollment and communication. The more specific we can be about how the

community's health concerns and complaints were built into the design of the study. It is important for building trust, transparency and ultimately getting people enrolled and keeping them enrolled. So those are two thoughts.

Incentives were addressed. I am wondering whether or not there has been input from any of the community groups or NGOs or people that you have talked to in listening sessions about how the current incentive structure will work to either facilitate or impede enrollment, recognizing that of course incentives shouldn't be coercive, but will it be sufficient for a population that perhaps didn't have work for long periods of time, who had already been economically distressed. So how exact and taking into consideration for the incentive structure.

Then the last question has to do with the comment made about the importance of communicating clear written messages on the need for action. I am particularly interested in hearing how that might relate to things other than blood pressure, glucose.

For example, household samples in particular, I would be interested in hearing a little bit about that, because I think that is going to be an area where people are going to want to know what that means and what does it mean to them in particular.

Last but not least, I think we end up with an inherent dilemma just when we name the studies. As soon as people hear acute and long term health effects, they assume it answers the question of, what does it mean to me.

So a possible thing to consider and suggestion is where in the materials that I have looked at so far, it talks about what the study will do. There is some talk about what it won't, but being very, very explicit about what this study will not address will be something I would suggest you might want to consider.

DR. GOLDSTEIN: Those are good comments. Dr. Birnbaum wanted to respond to the first point.

DR. BIRNBAUM: I would like to address the opportunities for others to participate. Dr. Collins mentioned in the introduction the fact that NIH is developing a cross-Institute effort to put funds out there for universities and community groups to partner to form a consortium to address health issues that may not be the top focus of this study.

We are still in the process of gathering all the funding for that. We are very pleased with the additional amount that BP has given to us this year. Our Institute has ponied up a substantial amount of funds to that, so has National Cancer Institute, the National Center for Research

Resources, the National Institute of Arthritis and Musculoskeletal Diseases, and several other Institutes have told us they will participate, but they haven't put their money on the line yet.

By the time that the FOA goes out, within about two to three weeks, we expect that we will have an information to let people know about the total amount of money. We are hopeful that there will be enough that we can form several consortia that can apply for five-year grants in this area to address issues.

The other point that I think maybe Dale could address more is now local -- she did talk a little about the biomedical surveillance sub-cohort, and how that will involve local communities and universities in terms of design of some of those studies as well.

DR. GOLDSTEIN: We have two more committee members and Dr. Fineberg, then Dr. Suskey, then Dr. Lichtveld.

PARTICIPANT: No, we want responses.

DR. MILLER: I will provide some additional information. I am Aubrey Miller with NIEHS. We have been working already with the communities, and we are getting out to meeting with both state and local public health officials in the states and with the NGOs. In terms of trying to understand their concerns and being prepared, what we are

hearing clearly is that we have to get our message out there about what the study is and is not, and start communicating that well in advance of when we begin the study and the enrollment, to already be using the local media, the local NGOs and the local health infrastructure to prepare the people about what the study is and isn't.

The Department of Health and Human Services has additional things going on, and this is part of that context and part of that fabric that is being woven. SAMHSA is going to be additional BRFSS work, and additional work will be happening in the states with their mental health additional assets that they are getting. So we are trying to collaborate and coordinate those messages. That is what we are hearing clearly.

Also, in terms of the incentives which was mentioned, we are getting feedback from them on what works for those communities in terms of incentives. One thing that has been suggested is a Walmart card. We are hearing it not just from the health officers, but from the workers and the worker representatives, about what things will work with them in terms of those kinds of incentives that the people would actually find useful in that.

So I think the baseline of getting way ahead of this and being in those communities and starting to talk to

their health infrastructures and understanding what the messages that we need to communicate consistently, not just one time, but really getting in there and having an ongoing conversation is really going to be key to the participation and retention of this group.

DR. GOLDSTEIN: Thank you, and thank you particularly for bringing up the state and local health authorities and infrastructure. I think that is a very important point.

DR. COLE: Can I make one reaction to that? I'm not really certain whether these are incentives to the study participations or to defer their time lost and effort. If it is a deferment of their time, then it should be uniform like it is and set up. If it is an incentive, then our friends in economics would say a one in ten chance at \$250 costs the study the same as giving ten people \$25, but the human reaction to that unfortunately is much more participation. The incentive of a one in ten chance of \$250, you are going to get a lot more participation.

So we have to think about the goal. If the goal is to defer costs, then we should give \$25 to everybody. But if it is to make an incentive, then we should borrow from economics.

DR. GOLDSTEIN: Thank you, that is a great comment.

DR. KASS: I am Nancy Kass. I am a member of the committee. I have two comments that are very different from each other.

The first one, which is very specific, is, I would love to hear a little bit more about the plans with regard to pregnant women. There was a little bit in the protocol that I read. I thought that I read something about some deferral of biological sampling, and I would love to know -- I may be wrong about that, that is the first thing I will say, and if there is something correct about that, I would love to know why, because for things like blood draws and urine samples and saliva, that is not an issue. I would almost wonder if one might want to over sample pregnant women. So that is one set of questions.

My second set of questions I will try to make really short, because I think it echoes on what Dr. Parker started in this whole dialogue about community. I will just underscore that it was something that I was also thinking about in reading the protocol.

I am wondering, to try to add to the comments and not duplicate them, if -- and again, my guess is the answer is yes, there is a point person on your team, to add expertise in mental health. Is there someone who may even

have the same expertise as other people, but it is their designated job to think about the community engagement.

It is so time consuming, everybody here knows that, but it is really, really time consuming. It is also a piece that benefits from having a protocol, even though the responses have to be really flexible, but there is a lot of language about, people are there to represent other peoples' views, but they may not know that. That means they have to go back and they have to get input, and come back, and there needs to be some protocol about giving people information back. Having a point person helps to learn from other experiences, including how large community based studies internationally have done really cool creative things to try to let communities know that research is coming their way.

My other thought about this whole potential disconnect that would make all of us anxious about what community members might think is the purpose of the study, like we are going to find about all of this broad based exposure, rather than me having been a cleanup worker exposure, is something I need to worry about or not. It is not only making sure that people know where else those questions are being addressed, but that a little bit of that dialogue can happen in informed consent.

I do some work on informed consent. I am a big advocate for at the end of informed consent discussions insuring that there are really discussions. It is standard protocol in informed consent to give people information and say, do you have any questions.

There is growing evidence that at the end of informed consent disclosure, we ask them a couple of really generic questions like, can you tell me in your own words what the study is and why we are doing it. We hear all sorts of remarkable things. It is a great opportunity, at least with the 27,000 people who are going to be the most important, having a moment of discussion.

DR. ENGEL: In regard to the pregnant women, that is an interesting question. We now have information. The most current information is that approximately 20 percent of the workers are female. A large proportion of them are of reproductive age.

We have no idea, because there is no current information on this, how many of them were pregnant during the cleanup or are pregnant at the present. We do intend to ask questions about that. However, given the time constraints and the limits of what we are trying to do, we have decided that that would not be a specific priority of the study.

We really want to focus on the health characteristics of the cohort as a whole, which is not to diminish the importance of adverse reproductive outcomes, but that we feel that -- what we would like to do is to get other researchers involved to help address these issues. We recognize that this is important, and that it needs to be addressed. But we feel that through some of the funding mechanisms that NIEHS and others are putting forward, that we will be able to tackle these issues, but we will do it in concert with other investigators.

DR. KASS: I would like just to comment that that is one of the areas that is targeted in the NOT and will be targeted in the FOA. We are guardedly optimistic that one of the consortia will decide to focus on that.

DR. SETYA: Just a few quick questions on the methods. I need some clarification on the enrollment questionnaire, whether there is a plan to validate that. That is one of the eligibility criteria is excluding subjects who are medically ineligible. So is there a plan to validate that?

Then the other issue is with the sub-comparisons. Is that a part of comparing with some national comparisons? For example, mortality is an end point, so looking at the state mortality rates versus the cohort.

Although the study is prospective, there will be some baseline cross-sectional analyses done for example at baseline. So it will be useful to look at for example the biomedical surveillance cohort, looking at the CDC. The CDC has done about 20-plus chemicals from the general population, so it may be useful to look at that as well.

With regard to vital status tracing, special procedures may be required for certain cultural groups, particularly with regard to names. The concept of first name and last name may be quite different. So multiple combinations will have to be sent for vital status procedures when you send for linkage, because they are interchangeably used. We have found that with certain groups. So that is also important to remember.

The other comment I had was with age. Age 18 and above, certain states may require parental consent, for example Alabama, 18 to 21.

DR. COHEN: I am David Cohen. I am one of the panel members. I know you clarified a little earlier your question about personal protective equipment and whether it was used and how it is used. Will there be questioning about personal hygiene?

I certainly know from my own practice, when you are dealing with oil or pitch or things like that, whether you

shower right after work, whether you are laundering your personal protective clothing, really matters on the kind of exposure you had. Were boots issues to these workers, and if so, can the soles and heels be used as surrogate exposures, because you rarely tend to wash your boots.

Some of the larger issues. Will there be one IRB reviewing and approving this? It seems like there are a lot of people involved in this. For example, will Sloan-Kettering's IRB be looking at this and approving it? Will there be local university IRBs who may have insight into local sensibilities be reviewing and approving these?

DR. ENGEL: I will take the last question first. The NIEHS IRB will be primarily responsible for this study. The Sloan-Kettering IRB will not be reviewing this.

When other investigators get involved in the studies and want to do add-on studies, then there will be additional IRBS involved, clearly. We are currently talking with investigators in the Gulf, for example, at local institutions who want to do companion or add-on studies, so we will have multiple IRBS involved at that point.

But the NIEHS IRB is the primary IRB review, although I would point out that we have gone through many, many levels of review in other contexts.

As far as the personal hygiene, it is a good question. We need to consider how best to ascertain that information. Again, getting back to the issue of balancing all of the very important questions that need to be addressed.

I recognize that that one is very important. I have seen from other studies that I have been involved in that how frequently clothes are washed, or whether protective clothes are used over regular work clothes and so on, and how frequently you bathe, can have an important impact on the exposure that one receives.

So we will give some thought to that. But everyone's difficulty always is trying to balance the multitude of questions that we need to ask.

DR. KALMAN: There is a slightly larger question that yours fits within that I have, as well as maybe others.

My biggest previous experience was with the cleanup in Prince William Sound after Exxon Valdez. In that situation, the cleanup activities were very clearly centrally directed. Pretty much 100 percent of the cleanup was following central protocols that came from Exxon. The materials that people used, the procedures they followed and the cleaning products that were used, it was relatively easy to know what the diversity was, and what was used where.

In a case like that, there was a definite protocol for protective clothing and for decontamination and washing of boots, and of replacement of garments and that kind of thing.

In the slides that we have seen in the various presentations today, it looks like people are dressed uniformly. It looks like they are wearing supplied clothing. In some cases all you can see are outer garments that are shells. In some cases they are wearing T-shirts, and they all look uniform.

So it is somewhat of interest to know to what extent we can talk Gulf wide about cleanup practices or even things like detergents or dispersants or other chemical mixtures that might have been used for specific purposes, like cleaning booms, for example. Do we have good knowledge of the exact comparability, or are there a range of different versions of the same kind of stuff? And if so, are those being captured in an archive so that there is always a way to find out exactly what was used in a certain place. These get folded into the larger task of structuring the exposure evaluation.

DR. GOLDSTEIN: A very effective way of removing tar from your skin or your clothes is by benzene or gasoline.

DR. KALMAN: Yes, it works great.

DR. GOLDSTEIN: And people will find it out pretty quickly, unless it is some sort of uniform control.

DR. COHEN: And apropos to that, when you consider using family members as controls, they may be unanticipated exposed individuals. You come and throw your dirty laundry into the hamper or on the floor of the closet, you have exposed your kids and everyone else.

PARTICIPANT: Will the informed consent be administered -- I thought I saw it as written. Will it be given to subjects to read and answer, or will it be orally administered?

DR. ENGEL: It will be orally administered.

PARTICIPANT: To everyone?

DR. ENGEL: Well, the entire cohort, the 55,000 will all undergo a telephone interview. It will be a verbal consent given there. For the approximately 27,000 workers who are included in the active follow-up cohort, we will have a lengthier oral consent. But because those people are being asked to do a lot more, they will be -- the consent is more elaborate.

This gets back to the issue of the multi-stage approach. We have the biomedical surveillance cohort, which is within the active cohort, and they will undergo all the same procedures as the active cohort, including the consent,

but they will also have additional consent that they will undergo, because they will be undergoing additional testing at later dates.

DR. SANDLER: There will be a written document that will go out to people in advance, along with a smaller sheet. Then because of literacy issues we will need to go over this with people we will have trained for our home visitors, to do this.

And I loved your idea about conversation afterwards. I think it is important, too.

PARTICIPANT: Just one other thing. The documents that we received are pretty hard to understand. So doing whatever we can to make those as understandable, going through whatever process to try to make them understandable. They can be improved upon, and there are some good methodologies that the NIH has out there that can be applied to those, that we use regularly.

DR. SANDLER: (Comments off mike.)

DR. FINEBERG: I just wanted to make a very practical suggestion that gets back to the fundamental question, at the end of the day what will we be able to say about health effects. This is about the power calculation, Dale, that you showed us as well.

As I recall, you used a ten percent baseline as the comparator. In a study where you are surveilling a wide range of possible effects, so you don't know which effects you are going to be trying to test at the outset, but you have some ideas, two features will dramatically affect your ability to make a statement from what you have already said, which is, you are not going to look at subpopulations. You are going to let others dive into the question of the pregnant women and possible effects, for example.

Those two are first, the initial cumulative incidents of whatever the effect is. The second, which I think Stephen referred to in his comments, is the misclassification problem on exposure. Even a relatively small misclassification can have dramatically deleterious effects on your power. A sensitivity analysis in advance can reveal that, but the practical impact of that is that you can know at this time how long is this study going to have to be for example to be able to have a certain probability of finding an effect of a certain size in a population of the size that you are hoping to have.

It will also tell you whether certain neurological effects will be imaginably detectable, compared to say respiratory effects, which will be much more common, et cetera.

So this kind of more in-depth initial projection I think would be very valuable as you get started.

DR. SUSKEY: The comments have been very, very helpful, as always. I just want to spend a minute, because I promised Morgan Ford yesterday that I would not use my PowerPoints this afternoon, since some of them do relate to our ongoing studies. But I think it is worth mentioning that we are in the midst of --

DR. GOLDSTEIN: Dr. Suskey, perhaps you would like to say who we is.

DR. SUSKEY: The Department of Psychiatry at LSU Health Sciences Center has received a grant from the state Department of Social Services to do the mental health needs assessment in the most impacted parishes in our state. It was originally for four. Just yesterday I received a call from Jefferson Parish, a fifth one, because of their experience with Barataria Bay, would we please add them into our mental health needs assessment.

We have had immense cooperation. We were supposed to be giving out gift cards. Somehow because of a clause in the Department of Social Services, that has been delayed. As we have gone through and promised people what we hope to give them, they said that is not even important. You are doing the right thing. We want to cooperate with you.

I would just mention the following domains were using our demographics, including the Katrina experience. The oil spill experience has an impact with the Sheehan disability scales being used. Physical health adapted from the PHQ. Mental health, we have always used the CEST. Since Katrina together with Ron Kessler, Dori Reissman and other experts we are now using the K-6.

We recognize that it has not fully been standardized for the Vietnamese population, and are working carefully in that area. We are looking at self harm substance abuse, including alcohol, drugs and smoking, anger and conflict. We are using the PCL for stressful experiences. Quality of life, the World Health Organization BREATH and children, the SDQ in the family member assessments.

We try to be careful because of one of the issues that has come up here, and that is with protected health information. Given what happened with Alaska, we are very careful. We do written consents. We are very careful to mention in addition to our efforts to protect, knowing that there has been at least one case where the information was made public by the federal court.

We have also been careful on that point, more careful than this study will be, not to obtain past protected

health information which could be utilized against the individuals in litigation. We are also careful with the current protected health information to stop at a certain point.

For example, if we are assessing anger, aggression, how one handles it in the family situation, we stop short of asking the specific question, are you abusing your child. That would need to be reported. Just as we are very careful with the question of suicidality, in our written assessments, our person to person assessments, we do include that because we immediately can step in, since this is being done with mental health professionals, our faculty, our trainees, and take it to the next step, as well as providing information.

With our phone interviews we do not include a question about suicidality. We certainly deal with depression, but we try see where the limits are in a phone interview. Though we give out information about referrals, we are very careful with some of this.

What we have found, we seem to have the opposite reaction. Maybe it is because of being well known, being at the university in the various roles since Katrina and before Katrina, we have immense cooperation. Yesterday I mentioned one of the parishes. I got a call from one of the parish presidents -- this was from Terra Bonne -- wanting to know

how he could cooperate more fully with us and make sure it is carried out carefully.

We work with each of the communities. We have tried to make sure our questions are ethnically appropriate. In Terre Bonne, for example, in which there are five distinctly different fishing communities, we have had the interest from other departments of psychiatry in working with us, and we are working with the Gulf Health Consortium in this line.

We do not find the same degree of resistance. We find appreciation more than resistance. But I would be delighted to discuss this further. As I say, it has been a panel of superb people. I have been very appreciative to Ron and Dori and others on a national level. I know Bernie and I have talked about it at great length as we have tried to put together the most careful mental health and substance abuse needs assessments.

DR. ENGEL: I appreciate that feedback. We would be very happy to talk with you further about this to learn more from your experience, because I think it would help us immensely going into this population.

I do have one question. What languages are you currently working with?

DR. SUSKEY: We generally do it in English. What we do for example in Vietnamese, we have had excellent Vietnamese doctors go over the wording to make sure that it would be acceptable for the translators, who then can work in administering it in Vietnamese, so that it fits and makes sense.

The same thing would be true in Spanish. We have everything translated into Spanish. For example, we did this with much of our work when we were helping with Chile. So it is all available.

What we have decided would be most helpful in Vietnamese communities is working with, whether it is regional or some of the other groups, the groups out in the community, to have translators present during the interviews.

DR. GOLDSTEIN: We have about five minutes left. I know Dr. Lichtveld had a comment, and there were two hands raised in the back. So, if you could all come forward and want to ask something, so we can be sure to get everybody who wants to ask a question online, and see how many we can get in in five minutes.

DR. LICHTVELD: In one, then. Maureen Lichtveld, Tulane University. First I want to thank you for being here. I won't spend a half second on that, but I particularly want to thank you for demanding clarity and clear speech. So this

afternoon I will model that. I will be very direct and apologize beforehand.

First on the issue of ongoing studies, actually there is a unique cohort of Vietnamese that we have both pre-Katrina and post-Katrina data for now over five years. So we would be happy to share with you this unique baseline.

Secondly, with respect to instruments, we have instruments that have been used specifically in that community, and funded by NIH. So we would be happy to share that with you. I couldn't agree with you more on the issues of cultural appropriateness.

It is really important to come at it from yes, as scientists, but as scientists in the skin of communities. I will do that this afternoon.

It is very critical to look at the comparison population, because some of them will look too similar to be compared. I really appreciated Dr. Cole's comments on that. It is also very critical to separate -- although we want to address the community's concerns, to separate what truly is a worker study versus what truly will become community based participatory research. So you can't do both in one umbrella.

I will come back to the issue of incentives because there are camps on multiple sides, and I would love to share with you that this afternoon.

There is a clouded field of consortia. You will hear some about them today or tomorrow, but just so you know, the field is crowded and to make sure that it is an even playing field.

Lastly, I want to mention that although we all understand what the study is, these are communities that have historic health disparities and historic lack of services. So how we explain what a study is versus services will become critical not only for enrollment, but particularly for retention.

DR. GOLDSTEIN: Thank you, Dr. Lichtveld.

DR. TREPIDO: I am Ed Trepido from the LSU School of Public Health and the Gulf Health Consortium. First of all, I want to thank you. I know how hard it is to put together a study by committee. It is a major task.

Have you considered for the 20,000 who are still employed using these GIS and air sampling monitors that are personal, so that you can use it as a way to correlate what is reported, even though there are obviously less exposures now, what is reported to what is actually recorded? It would have been nice of course to have had that early on. They can

take measurements every few minutes of GIS as well as air, and then you can get some way to correlate those, too. It might be just a good way to do some validation studies.

DR. ENGEL: Of the remaining workers?

DR. TREPIDO: Yes.

DR. ENGEL: That is a good point. We had very detailed procedures early on, and we discarded them all as the opportunities were lost. But that is a good point that we will discuss further.

DR. YUCHEVSKEY: Hi, I am Jennifer Yuchevskey of the U.S. Coast Guard. Thanks for the opportunity to comment on this very comprehensive and important study. The Coast Guard had about 3,000 responders, so naturally we are very interested in the successful execution of the study.

I am joined here today with Commander Erica Schwartz. We had just a few comments on the inclusion of federal workers, in particular U.S. Coast Guard workers, in issues to think about, and I will describe these really quickly.

The Coast Guard and the federal workers in general -- I will talk from the perspective of Coast Guard workers -- comprise a pretty unique population within this larger cohort. So it may be worthwhile considering having some separate sub-protocol for those federal workers. I don't

mean to give you more work, but I think this would naturally happen as we go forward with the study.

For example, separate questions that may make more sense to federal workers that are more applicable to them. For example in the initial enrollment questionnaire, instead of asking what is your usual job, a Coast Guard worker may just say, I am with the Coast Guard. So it may be rephrased to something more applicable to them, within the Coast Guard what has your usual occupation been.

Additionally, communicating with the community with respect to inclusion in the study. You have had dockside meetings with the community in the Gulf. It may be worthwhile to have some of those similar type of meetings with potential Coast Guard workers. Having separate brochures for the federal workers or Coast Guard that would be more applicable to them.

The other thing I wanted to bring up, as you know, the Coast Guard is a very mobile population. In addition to that, you are going to have Coast Guard workers all over the country. I know that a lot of your interviewing staff is going to be located in the Gulf. I'm sure you have probably thought of this already. We had responders coming from Alaska, from the West Coast, from the Northeast, so they are

all over the place. That is one thing you should think about.

People will get out of the Coast Guard. While they are in the Coast Guard it is pretty easy to track them, but once they are out it is something we have to think about, how to follow them up.

I just want to make a little comment about the comparison group. You also have Coast Guard people who are local people, who are suffering not probably to such a great extent as other local people have been, because they still have their jobs and health care, but this is another potential control group that we would want to think about.

Just two quick questions. We discussed at the NIH meeting a month ago about inclusion of the National Guard. I was just wondering where that stands, if they have been contacted.

The other thing was, in the abstract you mentioned potential adverse long term effects from heat stress. We are particularly interested in this, because the Coast Guard felt like one of its greatest exposures was heat stress. I was just curious what those long term adverse health effects you think they may be.

Thank you.

DR. GOLDSTEIN: Good questions. Comments, response?

DR. ENGEL: It is a long list. Those are good points. We will think about how we can modify the questionnaires and the material to accommodate the different populations that we have. In fact, any help that you can provide and other representatives of federal agencies would be very helpful in helping us to figure out how that should be done.

Some of your other suggestions are very valuable, the idea of having these quote dockside chats with Coast Guard members would also be very helpful. I would say I am reluctant to commit to anything further now, since we are already working about 25 hours a day. So we will do our best, but I think these are very good suggestions.

The issue of where the Coast Guard members are from is a challenging one. We now have the enumeration of the NIOSH list, which again is not a complete list of the workers, but it does show that we have people from all over the country. What we do know at this point is that within that list, about 93 percent come from the immediate Gulf states or from Louisiana, Mississippi, Alabama and Florida, and a few percent come from Texas, and then the remaining four percent or so are scattered across the U.S.

We would like to target people with high exposure outside of the Gulf states. The dilemma is that they become very, very expensive and very challenging to recruit. At some point we have to decide how much information we get from those people, given the expense and the effort required to recruit them.

So that is an ongoing discussion that we are having. We are well aware of the value of those people, but we are also very much aware that we don't want to spend half of our study budget on a few percent of our cohort. So that is an issue that we are discussing and trying to figure out the optimal strategy for.

In the interest of time, Jennifer, I would prefer to talk with you afterwards about some of the remaining questions, unless people have specific interest right now.

DR. FORD: Good afternoon. Tamanda Ford, with the Administration for Children and Families. My question focuses on the human services aspect.

We recognize that the primary focus is health effects, but we wanted to ask that when we look at health effects and we look at all the modular outcomes such as mental health needs, we wanted to make sure that human services has a specific bucket. The impact not just at the individual, but the individual as a family unit, the

individual as a member of the community, what is the human services impact as a result of this event.

What we are trying to get at is, what are we able to say about the health effects, we want to make sure what are we able to say about the health effects that include specifics for human services.

DR. ENGEL: Can you expand on that?

DR. FORD: Yes. For instance, in the human services, we know that people were unemployed. We know that the downstream effects of a family on unemployment would be more poverty, loss of income, that family would need more social services, because they would need support because they have lost their jobs. They may have lost the industry of seafood as well as the industry of oil.

So we are looking at more of the systemic effects, I guess you could say the socioeconomic effects, but particularly though the effect of the human being. They are unemployed, they now have to be re-employed. They may even be relocated.

DR. ENGEL: We do have questions that we are currently refining that address the socioeconomic impact of the spill on the workers and on the controls, so we are very concerned about that issue. Mental health issues also go along with that.

One question I have for you is, are you particularly interested in elucidating the need for human services or the subjects' access to human services?

DR. FORD: I think it is both. We are looking at making sure that human services is not ingested in mental health. It is stand-alone area that you speak specifically to what are the human services impact of the populations that are the cohort.

DR. GOLDSTEIN: Thank you for bringing that up. I think it is a pretty fitting way to close our session for today. It has been an excellent session. Applause to all of you who have all been reactants.

(Applause)

We will convene until this afternoon. The committee will meet again in its location.

(Whereupon, a luncheon recess was taken.)

A F T E R N O O N S E S S I O N

DR. GOLDMAN: We're running a little bit behind coming out from lunch, and what we're going to do now is move into Session Two on data collection and cohort surveillance and maintenance, chaired by Francesca Dominici.

Agenda Item: Session 2 - Data Collection and Cohort Surveillance and Maintenance

DR. DOMINICI: Good afternoon. So I will be chairing this section, which is entitled Data Collection and Cohort Surveillance Maintenance. We have three panelists. The first one is Professor DeJuran Richardson, who is Associate Dean of the Faculty and a Professor of Mathematics and Computer Science at Lake Forest College, then we're going to have David Tollerud, who is a Professor and Chair of the Department of Environmental and Occupational Health Sciences of the School of Public Health and Information Sciences at the University of Louisville. Then we will have Leslie Wolf, Associate Professor of Law, Georgia State University College of Law.

As a GuLF study investigator representative, we are pleased to join us Richard Kwok of the Epidemiology Branch of the National Institute of Environmental Sciences.

DR. RICHARDSON: Good afternoon. If you don't mind, I think I'll just sit right here; I won't take the podium, and I'll make my comments pretty much focused on the data collection components of this study, and I'll try to be concise and brief.

The GuLF Worker Study will investigate short and long-term health effects associated with the clean-up activities of the Deepwater Horizon Disaster. This observational prospective cohort study will provide an important contribution to our knowledge of human health, as there is a dearth of research as to human health consequences of all spills.

The effective gathering of accurate and comprehensive data is essential to the study successfully achieving its stated objectives. The cohort to be enrolled will be sizable, requiring that the study leadership form and maintain many collaborative components, including designed laboratories, telephone callers, specimen couriers, home visit professionals and a rather sophisticated data acquisition and management system. These disparate parts must not only fulfill their individual responsibilities efficiently and effectively, but they must all work in concert to ensure overall success of the project.

The study leadership has done an excellent job of attending to necessary details in the areas of data, analysis and management. Enlisting the aid and assistance of an experienced data management consultant group is noteworthy and well-advised. The data capture strategy appears well-conceived and designed to maximize the chance of obtaining accurate and timely data. Training protocols for research staff at all levels of operation seem comprehensive and reasonable.

My concern in the areas of data analysis, management and oversight are few, but worthy of consideration, in my opinion.

First, there is an absence of detail with respect to how the overall study will be run. The study leadership is well-defined, of course, but it is not clear how this team will interact with each other and the various key study components, such as interactions with SRA, the study laboratories, specimen repositories, et cetera. Just these details were not highlighted in the proposal document.

How they will oversee the various scientific paths outlined in the proposal, such as the very important exposure reconstruction effort, is also not clear. Will there be an executive or steering committee that will be responsible for day-to-day functions? How and how often

will investigators interact with groups such as the SRA, which has considerable responsibilities with respect to the acquisition and maintenance of the study data?

Such details are extremely important and key to making sure this quite large effort is kept on course. Moreover, there are many areas in which decisions must be made based on the accumulating data itself, and experience conducting the study.

There should be protocols in place, written and agreed upon, for ensuring timely feedback of information to those who can use it, so that adjustments to study operations can be made when needed.

There will be a lot of laboratory data generated by this study, and quite likely, use of several different labs during the years the study is open. It is common for any incompatibility issues, with respect to data formatting, to arise unexpectedly during the course of long-term cohort studies such as this. I encourage, whether it's SRA or the study leadership, if they have not already done so, to be sure that the study labs agree upon preset, predetermined formatting and structure for the storage and collection of their data, as well as how they will transmit it to the central group for maintenance and analysis.

It is not clearly stated how data queries will be handled. No doubt SRA is very experienced in these operations, but such details need to be written out clearly and spelled out clearly. That is, how are corrections to be solved when suspect data is encountered, say, subsequent to a subject interview? Given the size of this cohort, this is not a minor consideration and should be considered very carefully.

There is frequent mention of study staff using laptops to conduct their work, particularly during the home visits. I assume the word "laptop" in the document presented is used generically here, as smaller and more manageable computer tablets will be much more efficient and manageable, especially those visiting households.

Last point. The protocol states that considerable input will be solicited from community groups in designing study materials and determining the training regimen for study staff with respect to recruiting Vietnamese participants, in particular. This outreach will include inviting community leaders to observe and possibly participate in staff training, as a means of facilitating engagement and commitment within this community. I think this is a very effective strategy, and I recommend

extending it to other special populations as well, such as Creole-speaking, Hispanic and African-American populations.

Such outreach activity, that is, involvement at the earliest stages of development and in planning and training, such outreach activities can combat the traditional and well-noted resistance to participation in health outcome studies within such communities and populations.

In summary, the details are very well-presented, especially given the rather short timeline the study leadership had to kind of assemble all these disparate parts together. They are to be commended for such a large effort, but I think the comments that I've made here are well worth considering, that can make a very good study proposal even better. Thank you.

DR. TOLLERUD: My time is already up - Hopefully we will catch up a little bit of time with my presentation.

I wanted to make a couple of suggestions, just reacting to some of this morning's comments, before I get into my part of the presentation. The first is to echo Bernie's plea that if nothing else, what comes out of this is the design for future disaster responses going forward. And I wanted to reflect back on my history with the Agent Orange series of reports.

I was on the first Agent Orange and the Veterans of Agent Orange committee, and did that for about a decade, and when the first committee report came out, one of the charges to the committee was to design an epidemiological study that could actually look at the Vietnam veterans, of which there were some three million, and look at their health effects.

Well the one problem with that was the military and the Veterans, VA, had absolutely no way to come up with a comprehensive roster of who went to Vietnam because of the way the records were kept, the way the deployment records were kept and the way the VA records were filed. They were filed by Social Security number, not by war. So among the 30 million or so records that might be housed in a warehouse, if I came with my father's Social Security number, they could tell me whether or not he was in Vietnam and what war he was in, but there was no way to come up. That report came out shortly before Gulf War I, and the military got it, and they developed a strategy to be able to identify everyone who went into that theater of war, and actually to do some actual testing and keep a record of that.

By the time Gulf War II came around, I'm on another committee now to look at the burn-pit exposures.

Not only do they know who went there, but they've done a health evaluation, they've collected biological samples before they were deployed, and they're doing in-theater, in-combat air monitoring to look at air toxic exposures and particulates.

So I guess my point is, if the military can do it, anybody can do it, excuse me - so I would argue that one of the charges of the committee, and I'm thinking of sort of the NIOSH Health Hazard Evaluation, the way EPA does their monitoring, that procedures could be put into place to be a little bit more proactive rather than reactionary, and when NIOSH, or the Coast Guard, or EPA, is responding to a disaster of this magnitude, that one of the things that clicks in is oh yes, this may be used as a way of looking at health effects of workers or populations, and kind of move beyond the traditional reactive response.

So I just lay that as a paradigm because it really has seemed to have worked with the military in wartime.

The second point was brought up about the complexity of IRBs. That had recently been dealt with quite effectively, I think, by the National Childrens' Study, and I would suggest that you look to the NCS as an example. They have set up a confederation of structure for

IRBs, where local IRBs can completely cede all authority to the NIH, the NICHD in this respect, or there are ways of sharing that responsibility. So you might want to sort of put that in the works going forward to ease the issues for IRBs.

And the third may be a bit heretical, but it's been my observation in whatever organization I've worked in that especially with things that need to be done over a very short time frame very quickly, that the most efficient way and easiest way is to reach out within your organization for expertise and bring them on board, and there's a concern that potentially that gets siloed, and with this study in particular, with all of the interagency conversations, I would suggest actually bringing on people from other agencies, or people with individual expertise, to specifically be a part of the project, rather than giving comments. You'll never get the dedication for somebody, no matter how well-meaning, to give comments or input, as you will if they're actually on the study team, so I just think expanding the core study group to include other individuals from outside of NIEHS may be useful.

Now, quickly, one of the things that I did was to try and read this as an interested party. This protocol has already been widely disseminated. It will continue to

be widely disseminated, and so if I got annoyed three pages into it, it seemed to me that probably that was worth passing on, because I probably wasn't the only one.

So for example, the first mention of the number of controls, my first reaction was there's not enough, there's just not enough to do what you need to do, and just a simple reference to the very well-done power calculations, modified according to the suggestions that were made this morning, would help the reviewer to say oh yeah, that's coming, I don't have to worry about that.

I think the Exposure Assessment Workshop have just completed a project with a very detailed job exposure matrix, looking at a workplace that had been employed for 50 years. It's very difficult, I applaud the idea of the workshop and expanding the different expertise that will be participating in that. And just some internal things with spoken languages - the inclusion section and exclusion section doesn't refer to languages at all, and so that is just an element of confusion, potentially, to the reader.

Data collection - it's already been talked about the intent to have these data be available, and again, I'm probably flavored by the FISMA compliance stuff that we have to go through for the National Childrens' Study because that's a contract and it has a whole different

level of compliance issues, but I have learned that data security is not - goes way beyond keeping things locked behind doors and limited access and all that. I would suggest a fairly robust section at the beginning of the data section that actually talks about data security explicitly and how that's going to be maintained. I think it will raise questions that you'll have an opportunity to work your way through.

The computerized telephone interviews and computerized personal interviews - again, it wasn't really defined until well back into the protocol, and just simply referring to those as you first start talking about the interviews and how they're going to be done, would lead the readers to be reassured that that had already been thought through, and I think they did a great job with sample processing.

My interpretation of cohort surveillance and maintenance was ongoing contact and retention of the cohort. I had to throw out two slides because the most recent protocol had a really nice additional section on special populations and how they were going to be managed, so I applaud that.

I would consider, however, that the evaluation of retention materials and approaches, as you begin to

thinking about this, it's fine to go to community leaders and to community representatives, and again, this reflects our work on the National Childrens' Study - you won't get the same answers as you get with a half a dozen actual community members who are sitting in a room for half an hour, an hour, talking to you and talking back and forth directly.

They can be suggested by these community organizations that you're going to be a part of, but I really think it would be worth your time in a number of settings to actually go through some focus groups, describe your approaches, describe your materials, describe how you're going to do this, and actually get some fairly direct feedback. I think it would be very helpful.

The remuneration issue has been talked about before, and that will just simply have to be dealt with within the restrictions of the NIH, but I like the conversation earlier on, that remuneration may need to be different in different populations, and how you justify that will be up to you, but for some of the groups that we've dealt with over time, those numbers were pretty small, for keeping - 50 dollars over five years isn't very much, or 100 dollars, whatever it was, over five years, is not very much.

I know NIEHS has this expertise in-house, but for other readers looking at this, I think explicitly acknowledging existing expertise in groups that have spent many years working out community outreach and education, subject retention, those all should be referenced and acknowledged, and making sure that you actually have team members who are specifically - I think it was mentioned this morning - specifically charged with the idea of retention, with the idea of community outreach - somebody where the buck stops here, because it is very time-consuming and it is very complex, and it is a fairly specialized area of expertise.

And similarly, I think making reference to, and perhaps drawing on the experience of ongoing cohort studies, the Nurses' Health Study, the Normative Aging Study, Healthy Eating, Activity and Lifestyle Study. You already mentioned the sister study, which I assume is the same kind of thing, but I think for the general readership, just acknowledging that yes, these are out there, we're going to tap into their expertise, we'll inquire among them, it will again dissuade the reader from having the impression that this is an NIEHS project with sort of ancillary input from other institutes by explicitly

acknowledging this, and that's it! Thank you for the opportunity.

DR. WOLF: Good afternoon. My name is Leslie Wolf, and we've talked about the lawyers are coming, so here I am.

I was asked to talk about ethical considerations of the data collection and maintenance plans, and I come at it in a couple of different ways. I come at it as somebody who does work in research ethics and thinks about these things from that perspective. I come at it as a researcher myself, as well as, in this case, thinking about it as a former practicing lawyer, and how I might, particularly in this context, have access to information that might actually have an impact on how you think about this study.

I think it's clear, if there are a couple of features about this study that make it very clear, we need to think very carefully and there's been a lot of thought already about what data is collected and how it is secured, because it's longitudinal - everything has to be identifiable throughout this at some level, and you are of course asking about sensitive information, information that you need. Certainly we want you to be asking about mental health effects and other sensitive issues, that's an

important component, but it also heightens the confidentiality concerns that participants may have.

And as was already alluded to, we can really anticipate there will be litigation. I can imagine probably more types of litigation than you can, but as was already mentioned as well, there may be ways in which somebody who is participating in the study may become involved in litigation that has nothing to do with your study, and yet the information in your study, if somebody learns about their participation, may be relevant to them, and they might want to get access. So it's about thinking through these processes early on.

So the first question I think that's important, and as I say, just listening to the morning session, there's a lot of work already going on in this, but it's thinking very deliberately about what information are you collecting and why. What do you really think it's going to involve, and there was a comment made earlier - Dr. Izevsky(?), I think it was, who mentioned how there are questions they don't ask in their study because they don't want to be placed in a situation of having to report, and so thinking about do we need this information - if you need it, fine. Justify it, that's great. But if you don't, and it might put somebody into a situation or might put your

research people in a situation in which they would have to report, then just be deliberate about what you do and do not include, and just - I checked, I've done some research in the past about mandatory reporting.

I don't have information on all the five Gulf states, but I can tell you, in Florida and in Texas, everybody is a mandatory reporter of child abuse, so if you have people going into the home, as you do, who witness something, they could be a mandatory reporter, so again, you just need to think about those issues and what it means for how you deal with this data.

The next question, I think, is what are we going to do to protect the data? And when I looked at the protocol, obviously, there are already some very standard approaches that are in there that are totally appropriate. Some of the details may need to be worked out, and often are worked out in other documents rather than in the protocol, but in your operations manual, especially, as you're dealing with so many people, you're dealing with SRA, you want to make sure everybody is on the same page in how you deal with this, the things that stand out to me are, when you're coding, is it truly non-identifiable, especially as information is going to be downloaded to those laptops or tablets or whatever, the I-Pad, whatever

is being used, so what information, what identifying information, may be downloaded onto something which may then compromise your ability to secure it, or how is that being handled, just to think about those things.

I think entirely appropriately, there is a statement that you're going to get, the Certificate of Confidentiality. Given the anticipated litigation, I think it's incredibly important, and for everybody in the room - not everybody may know what this is - it is something that is given to researchers who are collecting sensitive information that allows you to protect against compelled disclosure.

And under the statement, it is compelled disclosure in any local, state or Federal level, administrative, legislative or court proceedings, so by its terms, it's very, very broad. But it covers identifiable information, and so there, also, you need to think about how are we actually going to continue to protect that? Just applying for the certificate may not be enough, and having good practices in place for making sure that you don't disclose some information in some way that might prevent that protection from having its maximal effect.

So given good plans for sharing of data, to make sure you get maximum use of this data and maximum information, you need to think about how that is shared.

Certificates are given on a project basis, and so that means you have to think about whether or not those subprojects are covered, or do you need to require people who are going to use your data to get a certificate of their own, so that data continues to be protected and they can assert it? You want to think about if we do get a request, what information are we, in fact, disclosing?

If it can be rendered non-identifiable, some information may be gotten through a lawyer's request, so exactly what is non-identifiable here, and think, I know it was stated in the protocol, we don't necessarily know what other databases may be out there. As I say, as a former litigator I can tell you if it is a litigation involving BP, for example, they would have information from employers for their employees. Certainly, if somebody was making a claim that I was injured, my health was injured, they can get medical records and other things, so there may be information that when combined with other information they can look and say, with this data, we know who it was.

So just thinking about those combinations and where that information may come from, so again, when you're

sharing with others, how can we limit that so it's not too identifiable, as well as what other ways can we do this? And having a plan so everybody knows, whoever's getting this, if we get a request, how are we going to respond? So someone doesn't inadvertently say, "Yes, they're in our study but I can't give you the information" - and now you've given out identifying information.

I've seen court cases that that identification, in some cases, may be enough. So you really want a protocol that really is maximally protective, and everybody at every level understands that. And sort of relatedly, I'd like to suggest that you think about adverse events as even just a request. If there's a reporting mechanism, so that again, from the main study you're aware of anybody's interested in your data, and you can help coordinate and making sure you maintain this protection going forward.

In the limited time I have left, I did want to raise - I thought it was fascinating that you're thinking about using social media here. It's also another place that raised a concern for me, and some of it really is how do you use it? And I'm influenced here by reading in my local newspaper and other places about people putting in some information that they think is going to their friends, and actually, they've added a bunch of other people, and

depending if they're not controlling their privacy settings, it's going down to a whole lot more people.

So again, if people who are participating friend the study, that could identify them, again, as participants in the study. So just think carefully about how can we use the social media to keep people informed without unintentionally identifying them in particular ways that is not what they would have wanted in the first place, and may also compromise the ability to protect the rest of the data in other ways.

I think I'm going to go ahead and stop there. One other point, and that is whatever you decide you can promise, and I did hear earlier that we understand we can't guarantee, but we need to have a consistent message throughout. I did notice in the Frequently Asked Questions document, which I think is a fabulous approach, I think giving people information is so important.

But there was a statement that suggests that no one else except for research team members can see that, and in fact, that's not actually true. There may be auditing purposes, the IRB may be able to look at it, so it's just being very consistent about the message and not overpromising without also underpromising, because you are taking strong efforts to try to protect.

DR. DOMINICI: Thank you for all your comments. I am taking the initiative, asking one or two questions, and then inviting the committee members to ask questions, and then the rest of the audience.

So as I was listening to all your comments in addition to this morning's comments, that are ranging from data security, data management, and also how to provide more details about how the study will be conducted, it reminds me maybe to go back to the usual framework of when we submit a project grant, where you have an administrative core, you have the data core, and you have a biostatistics core. And it seems to me that the administrative core is where you provide all the details about how the study will be run - is there a steering committee, who is responsible for what - the data core actually - it seems to me that probably 80 percent of the conversation has been around the data core.

I mean, very broadly speaking about data security, data maintenance, data quality, linkage of data sets, which it seems it's going to be, and how you're going to make it accessible, and then, this is my own bias in terms of the biostatistics core, and naturally Steve Cole mentioned this morning, in terms of thinking a little bit more specifically about what type of analysis we wanted to

conduct and what are going to be the types of the statistical expertise, so then it could inform back of what type of information we want to collect.

Now I understand that you've put together this amazing project in a very short period of time. So anyway, this is a very long question, so I was wondering if you could share with us a little bit of your thought of how would be the template for your data core and the administrative core?

DR. KWOK: I just want to thank the committee for very helpful suggestions, and these are wonderful comments and feedbacks. We're not operating in a vacuum. We have been working very closely and have a lot of experience with the other large core studies; for instance, our PI Dr. Sandler, working with the sister study. So we're using that as a template in terms of how to move forward, and looking at other successfully-run studies that have incorporated, of similar size and complexity, adding these administrative oversights for further data collection aspects.

But obviously, the protocols are being refined, and we are still in meetings with the states and the community groups, and as we discover additional information, we are working to incorporate those into our

protocol. So obviously, none of these are final, and we're still working, but we have the template, for example, to the sister study, and we've been refining it based on those things, to tweak it to be more specific. Does that make sense?

DR. DOMINICI: Questions from the committee, or would you like to add something?

DR. SANDLER: I just wanted to respond directly to the overriding structure. You know, we haven't had an opportunity to invite who's our steering committee, who's the executive committee that's going to be working on all the various aspects, but SRA, the contractor, they're a mile from us. We have regular staff meetings once a week, we're in daily contact, and we'll continue to have these sort of regular meetings. I envision a steering committee from NIEHS with other governmental agencies that deal with day-to-day decision making. In my previous studies, we've done this. We find that over time, you need to meet less frequently, but early on, it's a really close working relationship.

There will be - the advisory boards will meet regularly, of course they don't deal with the day-to-day, but the structures and establishing those and writing them down, I think was a wonderful suggestion, and it's not that

we haven't thought about it, it's just we didn't put it in the protocol, so I will assure you that those things will be paid attention to.

And the idea of thinking about this as a program project grant, that's a great idea. But there are all those components, and they all have different details, and what goes into the protocol that goes to scientific review as opposed to operation, some of that style of thinking, where to put that information. But I hope we don't have to move forward until all those things are figured out.

DR. RICHARDSON: Just a response. I assumed that was the case, because the study team's definitely experienced with these kinds of studies, it's just that having seen the studies that work well and the ones that don't, that are large like this - one of the components of them failing is not having sufficient up-front attention paid to these administrative details, because when you have so many - as you know, better than I do, when you have so many disparate pieces, that all are really important, but there are so many of them, and the level of complexity involved in what they're doing, the levels are so deep that decisions get made and the study leadership, the ones that get derailed, the studies that get derailed, the study leadership finds out only about these things far down the

road because of the communication - the communications structure is not emphasized early enough on, because these things are so large.

DR. SANDLER: I think this is a really important point, and I spend a lot of time in the trenches, and it's silly, but the thing that we found that's the most useful is we have this mega-spreadsheet with sort of tiers to other pages, and we start every single study meeting with okay, here are the decisions that are made, here's whose hands it's in. It took us a while to figure that out, but that one overriding organizational structure, it seems simple in retrospect, but it is really key, and the last time I wish I'd thought about it up front.

DR. DOMINICI: Any questions from the committee?

DR. WARNER: I'm Charles Warner from the Alabama Department of Public Health. I have a question for Ms. Wolf. Is there a convention about the right of a participant to access his or her data for their individual benefit or purposes? For example, some folks who are interviewed and enrolled in a study may not have sought medical care, but yet may feel that they've had an adverse effect, and when it comes to litigation, their documentation as being a participant in the study and the

data that they've provided into that study may be their sole source of evidence of a claim.

DR. WOLF: I'm not aware of there being a convention - in part because there are times when there are reasons that if it's a controlled trial where you don't want to be giving the information, and it's one thing when somebody shows up in the emergency room and needs to be unblinded for that purpose versus somebody who comes in because they have a litigation concern. So I've not seen it.

Certainly, we know part of what HIPPA has been about is giving that control to patients, because patients would sometimes seek to get their medical data, and their doctor wouldn't give it to them! So I think that would be one of those things where the researcher would have to think about it, and to the extent it doesn't destroy the study, would want to give the support - but that also involves potentially the researcher and litigation, which I can tell you is not fun. Nobody wants to go in and get deposed, nobody wants to - it's a time suck for one thing, you just - it was mentioned how long the Exxon Valdez cases go, the litigation runs very long and things are often delayed, and you can sit, for the time you're supposed to go in for eight hours and still not - and things will be

postponed, so there are questions about how involved people want to be in that case.

Did I answer your question?

DR. SEGER: Hi, I'm Russ Seger with the Florida Department of Health, and I'm going to continue on the same theme and ask the same speaker - this was a question I was wanting to ask this morning, but for time, I didn't.

It's my understanding that in settlements, class action settlements or settlements with individuals, there's often a requirement imposed on the plaintiff not to disclose information, and if that's the case, and especially in a long-term study like this, could that impact the study in a negative way, so that people enrolled in the study who now are party to a class-action lawsuit can't give information in surveys or questionnaires or interviews, et cetera?

DR. WOLF: That's a matter of what the agreement is about. And it is very typical to have a confidentiality agreement in a settlement, because the company settling the claims doesn't want people going around and saying, well I got a million dollars from ABC Company, and people then deciding that they can go after it for a similar reason, as well as they don't want to be admitting liability in any way, shape or form.

That's different from being - usually it would not cover whether or not I can tell you I've been to the doctor, what I was working on, those specific details. It is about the settlement dollars and the settlement fact, is often what that's really talking about.

DR. SANDLER: Can I ask that question again?

Because we were told that there have been similar instances where individuals were told that we're going to sue on your behalf, and in order to make that happen, you should not participate in research because you shouldn't disclose your information, and so it may happen, there's nothing I can do about it, but are there things that we should think about?

DR. WOLF: That would be a different portion. The settlement - confidentiality agreements in a settlement comes after you've been litigating, you've done discovery, you've done all this stuff. You're talking about plaintiffs' lawyers trying to gather up plaintiffs - and I did do - the plaintiffs' work that I did was not that kind of work, I represented individual inventors in patent litigations. The lawyers can recommend it and certainly that's what they're trying to do and trying to promise that the only way you're going to get any dollars at the end of the day is by doing this. It wouldn't be a legally binding agreement, although they may try to make it as part of

their contract of services. I don't know that it's necessarily the best way to practice law, but it's not an experience that I have, so can you prevent that? I think you can talk to people and explain - talk to them, ask them to ask their lawyer about it.

A lot of times in these cases, the plaintiffs don't have a lot of contact - individual plaintiffs will not have a lot of contact in a class action suit with a lawyer, I mean they'll have some, but it's not like an individual whose being represented by an individual lawyer, to have that contact. But otherwise, just explain what you're trying to do, what protections, and just try to persuade them.

DR. FINEBERG: Just two points. This discussion makes me wonder, and again, Leslie, you may be in the best position to answer this, but others may know too - Is there anywhere a set of guidelines, a protocol or a more elaborate description of best practices in epidemiologic, long-term cohort studies, to protect and preserve the privacy interests of participants, and if not, is that a task that needs to be done? That's one question. And that would apply, obviously, not just to this study, but any number of studies.

The other questions are really thinking about this issue of ensuring participation over a long period of time, which is another real concern as the flip side of this. It grows out of a recent study that I was just hearing about, which happened to be a study of obesity and diabetes, and what was interesting about this study wasn't the findings particularly, to me, but what was really interesting was the fact that this study involved certain group activity over web-based interaction. That was the model of the intervention.

And what was striking was that when the study ended, the participants did not want to stop. They wanted to continue with the interaction and the communication and the group identification beyond the time of the settlement. Nothing to do with what the interests of the investigators were, it was what the participants found valuable for them. So the question in connection with the study at hand is have you given thought to the possibility of using social networking as a vehicle locally to encourage and support longer-term participation, and a kind of parallel set of thoughts around the community advisory activity that you're contemplating - could that be coupled or even utilized as more of a continuing advocacy and outreach activity that

goes beyond simply advising you, but being also ambassadors for the program in an ongoing way?

So those are two disparate, but I think, both prompted by this discussion.

DR. WOLF: So in terms of the best practices for epidemiology, I don't know of - the one thing I can hand you is, this is it - I've seen pieces of talking about it, and I think there's probably at least some suggestion out in the literature. In terms of - with respect to the certificate, legal component to it, I am currently doing an NIH-funded study on certificates of confidentiality that has a legal analysis component, and although we're very preliminary at that, I'm beginning at least to form some ideas about best practices, given what we've seen. That's one of the things I hope we will contribute, but we're very early in trying to identify those things.

But I do think, that is certainly the approach to take, is thinking what are some of the best practices so that everybody knows throughout the study and can do it from the beginning.

DR. SANDLER: There is a lot of guidance that's been recently developed in best practices - on best practices for biorepositories, that's been ambiguous

whether they're biorepositories or data repositories, and so some of the committees are dealing with all of that.

Not down to the nuts and bolts yet, that I've seen, about what's the best security, what's the best computer system to store your stuff and what kind of, how many layers of passwords do you need in order to protect the data, but certainly the elements of the things that you need to think about have been in discussion, and it includes data.

DR. KWOK: In regards to the Web 2.0 resources, we have thought about it, and in our initial discussions with the community, we are aware that it is underutilized in certain populations. I know that some of the shrimp boat operators don't use the internet at all. On the flip side, as Larry mentioned this morning, over fifty percent of the population in the NIOSH roster area provided an e-mail address. So presumably, they are more connected. So we're exploring those avenues right now, in light of privacy and confidentiality concerns. NIH doesn't have a specific policy in terms of 2.0 resources like Facebook and Twitter, and so we're trying to balance the privacy issues on one hand and then the community engagement, advocacy on the other, to be appropriate on both sides, so we're still exploring that.

DR. FINEBERG: Even as an experiment it would be very interesting, sub-experiment, if you want.

BOARD MEMBER: I just wanted to make a quick follow-up comment to what Dr. Fineberg had said. I'm aware of a similar kind of experience happening not through the web, and just to put that out there as well, particularly if you have people where either you're concerned about privacy concerns or you have people where that's not the right medium for them. But I think it's another way of saying something that came up this morning, which is you want the people to feel like their participation is valuable to them, and basically in research, we're generally going around and asking people to do us a huge favor, for some payoff that happens in the future and often not to them.

And to the extent to which we can get them to understand that, but then also we actually really have something that we can offer them, even if it's not the health information they wished that they could receive, and I think it can be low-hanging fruit, since it's probably more for the panel we're about to have next on community, rather than data, but there really are some, I think, fairly easy ways to get people together to talk about their experiences, to do all sorts of things that are nice for

them, and lo and behold, it actually really does enhance their commitment to the study.

DR. TOLLERUD: Just to come back to Dr. Fineberg's opening remark about how delicious it is to suggest things to the NIH, one of the things that the many grants from the NIH now require is, particularly in things that involve community involvement, is a plan for sustainability at the end of the funding period. And I would actually encourage you to think about that as well, because you don't know after five years, or whatever.

But these are communities that are incredibly engaged. They got hammered by Katrina, they got hammered by this bill, they're tough, they're resilient, they've come back before, they'll come back again, and I think this would be a real opportunity to provide them with the funding you have, to provide them with actually some assistance in organizing around environmental issues that will perhaps give them the momentum to be sort of more structured and to carry the thing forward, as opposed to ad hoc groups who have already sprung up who don't need your help because they're already going.

You're going to be going into a lot of communities that don't necessarily have that underpinning of a grass roots organization, and I think there's a real -

you're going to need to do it anyway to get your enrollment and to sustain your cohort, so there's just an opportunity, I think, to kind of think about that in the sustainability metric, so that you sort of give them the tools and figure out who can actually carry this forward going into the future.

DR. DOMINICI: I am taking the opportunity to ask a question, then. Just as a clarifying question, moving forward, and that was something that was brought up by David, I think there is no doubt that this is a very huge task, and that you have been putting this project on in a very short period of time, and I think everybody agreed that you need a lot of expertise and a lot of help.

So, David pointed out, as a general suggestion, that in addition of just getting advice, as has been the frame of today, to basically have more complete involvement, basically expanding the number of investigators that would be working the study. Have you thought about this, and what would be the process? I would like to know if you have some thought of moving forward, how you are going to include more expertise, basically more people that can help you by doing this.

DR. KWOK: It has not been a formal process per se, in terms of engaging the investigators, I think. We've

reached out, in terms of identifying the areas that we are deficient, in terms of expertise, to get this efficient process, but I think we welcome the opportunity to collaborate with other investigators. Dale, do you want to speak more about that?

DR. SANDLER: I think we've been researching the researchers. We've been looking - who's writing, who has the best chance of actually contributing something that we need to the study, and we started talking with people, and we will continue to do this. Our plan, all along, has been to bring in more collaborators. There's going to be more data, more tasks and more disparate areas, health areas, to focus on, and we don't have that expertise in-house. So we will do this through several mechanisms, defining collaborators or consultants, and then through these other add-on studies, there will be opportunities for co-investigators, so whoever responds to our requests for proposals for the biomedical sub-cohorts, they will need to be collaborators, so that everything we do is coordinated in one arm to service the purposes of the other arm.

I think it's something that we need to do, and we wish we had time to have done that up-front, but I think there will be opportunities. And we've also reached out to

our Federal partners. We hope to get Federal collaborators on the study as well.

DR. DOMINICI: Just as a general thought and one thing to think about, is to be able to, and that was something that was discussed this morning - to what degree defined the primary scientific questions, a little bit more specific way, that will be conducted by this particular study, and then, what would be the additional questions that will be addressed through the biomedical cohort or to additional RFA, because I think that right now, at least as it sounds, it is a very generic, a very broad array of outcomes, a very broad array of exposures, and so it's hard to get.

DR. SANDLER: So I think that the outcomes actually - so maybe it was too subtle? Or are there too many other things - but I think that it's clear that respiratory health is a key component, and mental health is a key component.

The respiratory health, we know who our collaborators are. Mental health, we don't, and so that's clearly a need that needs to be filled. We believe that neurobehavioral function is a key component, and we will be reaching out to do that through the biomedical sub-cohort, because it involves more intensive study. It's not really

something you can do well through a questionnaire. So anything else that we would collect on general health is secondary. I think people have pointed out, there's an interest in reproductive health and I see that as something that we would do. It's an opportunity for somebody else to partner with us to do that, and we are trying to make sure that we capture enough information so that we will make that possible.

PARTICIPANT: I have a question regarding data in terms of the finding. It seemed like the recruitment that you're going to get involved in with certain population, vulnerable population, it would be community leaders. So if there's an understanding between the PI and some of these community leaders, that in good faith, they think that there are certain findings that you're not going to report, have nothing to do with workers and the (54:06.9)?, but it has something to do with their community personally.

Let's say if you present your report to these community leaders, and they say "I do not want you to document it" - so what are some of the legal ramifications? Because I know that certain communities feel that trust is a matter of your word, it's not in writing. So in certain communities, maybe the community leader, these faith-based community-leaders, think that "Well I trust this PI, this

PI is going to do us well - this PI is going to protect my community." So there are certain data findings that might construe negative images of that particular community. What are some of the legal ramifications, in the heads of some of these community leaders, that is your responsibility, that we give you this population, we're sharing, we trust you.

Reciprocity means that you don't report certain things that might be damaging to us. So how are you going to deal with that?

DR. WOLF: So you asked about legal ramifications, so there, I mean, there's not necessarily an obligation to report certain things from the legal perspective, and more it's a matter of what do the researchers feel, and what did they tell, the communities that they were going to do? And so, you know, just sort of a backdrop in the biodepository context, where that has recently come to light, was the Havasupai tribe in Arizona, where specimens were collected, they were told it was for diabetes research, which was something that the tribe identified as a health concern of the tribe, and they were willing to participate.

Unbeknownst to them, although legally permitted, perhaps, they were used for other purposes, including

schizophrenia research information, research on inbreeding, and most importantly, at least in some ways, from the tribe's perspective, research on migration, which suggested that they came over the Bering Strait, instead of being born in the blue waters of the Grand Canyon. The tribe brought suit against the researchers, saying that this was not what we agreed to, recently settled the case.

Importantly, Arizona State returned the materials to them, but it didn't change the fact that the research was done. So there, I think it's more a matter of trust. The law doesn't really support their claims in many ways, but I think the University recognized, it's a changing area right now, in terms of what peoples' expectations are, and also some of the implications, so it's beginning to move and I think that's part of why they backed off.

PARTICIPANT: What about undocumented - (off mic).

DR. WOLF: You're asking about undocumented status. Well, that goes back to my point earlier of do you need the information? If you don't need the information, don't ask the question, then there's no obligation, the community feels protected, that's the stuff that I think needs to be thought about. Do we need this information or would it be harmful to somebody and yet not tell us

something important in terms of the health outcomes? If you don't need it, don't ask it, and that way, you're in a good situation.

DR. TOLLERUD: Let me ask you a very specific question. If you're going to use passive long-term follow-up of mortality, you need a Social Security Number. Right? I'm not aware of another way to do it. With NDI - Can you get NDI information without a Social Security Number?

DR. SANDLER: You do a better job of linkage if you have Social Security. You need a certain amount of identifying points. There's been a move toward IRBs asking you not to collect Social Security, but to collect the last four digits, and so then you're dealing with other issues related to probabilistic matching, but you do need some information for tracking, which we wouldn't have, for somebody who didn't have a Social Security Number, and so they would not be contributing to the tracking, because we wouldn't be able to find them.

But I like the idea of don't ask if you don't need the information. One of the things that we've discovered in our other settings is people were worried about illicit drug use, and we know that this is a concern in a stressed community - if there's more drug abuse, there's more alcohol abuse. We asked about alcohol and

tobacco. We're not going to test for illegal substances. Somebody else can do that research. It's not really directly related to this question.

DR. TOLLERUD: Especially in a worker population, I will tell you that any time you get a urine sample, their assumption is you're doing a drug test, so that's some education that you'll need to do right up front.

DR. KWOK: And it really is engaging the community. I think what they're doing, and I think Dale and Aubrey will be able to talk about it in the next panel, in terms of really doing the necessary community outreach, doing the necessary stuff in terms of is educating them, why we're collecting this information, what we're collecting, how we're collecting it, and really working collaboratively with our community partners to make sure that they are understanding of what we're trying to do.

But we're not planning to ask about undocumented status. There's no plans in the study to do so.

DR. RICHARDSON: I would just say, this is another example of why it should be a partnership, as opposed to, we are just going to inform you of what we've done. When folks are involved early and often, then these things are identified early before they have a chance to really - because quite frankly, those are deal-breakers in

community eyes, and it's hard to recover from that. And when you have this sort of interactive relationship early on, then these questions of "Do we really need to ask this?" will come up and be identified early and eliminated early.

DR. KWOK: Which is why we've been in the states, and we'll continue to do so.

DR. FARFEL: Hi everybody, I'm Mark Farfel, from the World Trade Center Health Registry in New York City. Thank you for the invitation to attend. I wanted to congratulate the study for, at least from my point of view, getting off to such an early and strong start. There's obviously questions to answer, but at least from the point of view of the Registry, learning this summer how much had already gotten off the ground is quite amazing.

I just wanted - Leslie, you mentioned being aware of what we're asking and reporting requirements, and you mentioned adverse event reporting, and I just wanted to mention the need to have very strong distress management protocols as part of the study.

As we know, there are going to be interactions in the home, and some of those interactions may trigger actual reporting if there's child abuse, but more likely, it's going to be a situation where the study participant or a

family member will be in distress, and that also may occur during the course of the telephone interviews. So I'm just urging you, based on the experience of the Registry, to pull together a very strong protocol - it's an IRB issue, it's protection of your staff and also protection of the study subjects and something that needs to be drilled and practiced, particularly since you have five states you're dealing with to coordinate calls, or some way to facilitate a three-way connection into something like we use in New York City, which is LifeNet, or some mental health resource that can come right on the line. Then of course, how do you handle the 911 emergency calls in different areas?

DR. DOMINICI: Can I ask to clarify for me, because I couldn't hear - so you say a three-way connection?

DR. FARFEL: Yes, we found when certain, what we call the middle level of distress, is detected either by the telephone interviewer or by staff member, when we have an inbound call, with someone enrolling in the registry, asking a question or wanting to give us information, and that person meets the criteria for a certain level of distress, we offer to connect them via three-way call, so all of our staff stations, people that have direct communications with our enrollees have the ability to do

three-way calling feature, and if the person agrees, then we connect them right away, make the connection and our staff gets off the line and they have the conversation privately with LifeNet. It's something I can't say that we've used very frequently, but it's something that staff need to be very familiar with and to be able to drill that so it happens smoothly, so of course then there's also the IRB reporting of those events.

And then the follow-up to anything that involves 911 calls being made is important, too.

DR. KWOK: That's an excellent suggestion, thank you.

We're currently developing the ROBs and SOBs for the protocol itself, so we do plan an intensive training and comprehensive training of all of the field interviewers to incorporate these aspects.

DR. DOMINICI: Well I would like to thank you again, panelists, for the comment, and we are moving to the next session.

DR. GOLDMAN: We want to go ahead and invite up the panel for Session 3, Relating to the Community: Involvement, Trust, Transparency and Communication of Study Results and Susan Santos is here to chair it.

**Session 3 -Relating to the Community: Enrollment,
Trust, Transparency and Communication of Study Results**

DR. SANTOS: Okay, so we're going to move right along. I'll just introduce folks as they're coming up to the table, to keep us on track, and it's going to be the same format. We'll have three panelists who will each have about 15 minutes and then we'll open it up for questions.

So the first panelist is Roxane Cohen-Silver, Professor, Department of Psychology and Social Behavior, the Department of Medicine at the University of California Irvine. Our second panelist will be Maureen Lichtveld, who is Professor and Freeport McMoran Chair of Environmental Policy and Associate Director of Population Sciences for Louisiana Cancer Research Consortium at Tulane University, and then lastly, Howard Osofsky, the Kathleen and John Bricker Chair, Professor of Psychiatry, The School of Medicine at Louisiana State University.

And I should clarify that it's twelve minutes, not fifteen minutes, and also we have Audrey Miller and Dale Sanders from NIEHS to comment on the study itself.

DR. SILVER: I'm honored to have this opportunity to comment on the proposed study this afternoon, and there is much to be commended in the study - the design, the measures, the methods, the procedures are state of the art

and sound. But this is a challenging study, to be sure, for several reasons.

As has been already acknowledged, there is some skepticism and mistrust about the government's role as the disaster has unfolded, and although it is enormously impressive how much has been done thus far, this effort is basically starting later than is ideal. So doing it right is critical, and this is also, I believe, the opportunity to consider the broader health impacts, beyond primarily physical health effects, as well as an opportunity to consider the broader community impacts, beyond cleanup workers and beyond the study of health.

So how do we do it right? Well, there are a number of challenges and I'm going to just take a couple of minutes to reflect on what I see as challenges in enrolling participants.

We've mentioned that it is important to maximize public engagement and participation. So I ask, what factors can ensure a high response rate? I read the number 70 to 75 percent; that's an extremely high number, and I think it's achievable, but there are some things that need to be done in order to achieve high cooperation and public engagement.

And I think one very important one is encouraging a sense of personal responsibility for participation among eligible respondents. Am I special? It doesn't matter if I say yes or no. I think focusing on large numbers, fifty-five thousand people, minimizes a sense of individual importance, and I think in order to get people to be engaged and willing to participate, they have to feel special.

I would also encourage the researchers to consider random sampling from eligible lists. I understand the challenges of completely randomly sampling, but given that enrollment will take approximately twelve months, I think one can articulate how enrollment will be conducted over time, and consider seeking representative cohorts, perhaps monthly.

In addition, I think we've mentioned this briefly earlier, but I think that providing an effective incentive to participate, why me? - is extremely important, and I think articulating why the individual respondents' participation is crucial - rather than seeing the value of the study as a whole, identifying why this person is somebody that you want to engage in this research.

I also think it's very important, and I know it was mentioned a few times in my proposal, but I think that

this should be addressed very clearly and perhaps up-front - countering public skepticism or suspicion amongst both the workers and community sample. Coming in from a University, University of California at Irvine, is one thing. Coming in from NIH is another, and I think that these kinds of issues should be tackled up front.

I think we've discussed previously, but ensuring diversity of participants, special populations, means that one must recognize that there are differential reasons for participation amongst different potential groups, and a one-size recruitment strategy might not fit all.

There are a number of research challenges once you get people involved, and a very important one is minimizing attrition, so it's one thing to get 70 to 75 percent of people to say yes up front, but it's another thing to get 70 to 75 percent of people to give you hair samples or toenail samples, and I think fostering commitment to the research enterprise is critical, so if I'm one of 55 thousand, does it really matter if I drop out?

Having large numbers can actually trivialize the importance of individual participation, and I would encourage continuing to focus on the importance of the

individual, to feel some commitment to the research enterprise.

I noticed the mention of contact information, and I think I would have to say that it was inadequately attended to, I believe, in the protocol, because I would recommend collecting information early, during the initial contact, and repeatedly, more than just annually, even if it's done by sending an e-mail to see if the e-mail address actually works, or a phone call or letter to see if the address is still valid.

I have seen people do incredibly impressive research with individuals who are homeless, and they get 90 to 95 percent retention rate because they collect incredibly effective re-contact information up front, and I would argue that this is a critical piece that has not yet been got through.

I think that we've talked about, at least alluded to at some point, the importance of being sensitive to respondent burden, but again, respondent burden impacts attrition, and one should not only think about the kinds of questions, but the frequency with which it's appropriate to re-contact people in order to minimize attrition.

I also want to comment, as a person who conducts this kind of research nationwide, I'd like to comment

specifically on the notion that there is a comparison group of unexposed individuals, perhaps family members, individuals who were trained but didn't actually go out and do the work. From a mental health standpoint, which is my angle, I think one should not assume minimal impact on the indirectly exposed; in fact, work that I conducted after September 11 made clear that direct exposure and indirect exposure share some very clear commonalities.

I also think it's very important to distinguish the worried well from the truly ill, and if one is using self-reports, one needs to think about peoples' tendency to report not only exposure, but impact, and I have to say that over time, more people said that they actually witnessed the attacks of the twin towers - as months and years went on, more people actually claimed that they were directly exposed, and so I think that the longer you wait, the more people choose to - and I wouldn't say this is malicious, but the more peoples' memories are in fact reconstructed, and distinguishing the worried well from the truly ill, I think, is an extremely big challenge here.

I, as a researcher, pay enormous attention to ensuring ethical sensitivity in disaster research that I conduct, and I think that non-core of subject recruitment must be balanced against highlighting the importance of

participation, and I would suggest revisiting the consent form, which spends a lot of time up front, saying how much people can drop out, and doesn't actually highlight the importance of them staying in.

I think well-trained interviewers are extremely important, and I was very happy to hear a discussion in this last session about the ways in which interviewers are going to be trained, but one can also train the interviewers to convert refusals - that is, people who are not quite sure whether they're going to participate or not, and figuring out the ways in which you can engage them and get their cooperation.

I do also think it's extremely important to provide opportunities for refusal as well as initial contact of consenting, of specific questions of ongoing data collection, but again, this must be balanced against the importance of continuing one's participation.

And I think, and this is something that was mentioned briefly, and I have a great deal of experience with this particular next point, I think that one needs to prepare and coordinate responses to anticipated respondent questions, like "Am I normal?" - "Have you heard these concerns from others?".

My respondents in my studies always ask these questions of the interviewers, and the interviewers have to have a way to respond.

Avoiding potential pitfalls, I think it's really important, again, to acknowledge the political realities and mistrust regarding the consequences of this disaster, and it's extremely important to recognize the importance of not having conflicting messages about the study and its findings. I think there were some extremely important points in the previous session about how community advocates may have a different message than the researchers actually want, and these kinds of conflicting messages can blow up in one's face.

I think it's really important to recognize that trust is shaped through repeated actions, and once it is lost, it is very difficult to regain, focusing on the importance that people understand what they are being asked to do, and agree to only that.

I also would like to strongly encourage the monitoring of field workers carefully, especially if these are contractors. I would encourage perhaps monthly, or maybe even weekly, stress release meetings. Recognize and address the strain of the job of the workers, particularly

if they are members of the community themselves. These interviews may be stressful for the interviewers.

I would like to mention that I was very pleased to see the community advisory board. I think it's critical that part of the study enlisting community leaders who can encourage and support ongoing cooperation is extremely important, but I also would encourage the continued involvement of outside experts. The insiders have also been directly impacted themselves, and guidance offered by individuals who are outside the impacted community can actually serve as a reality check on ongoing decision-making, post-disaster.

I think it's extremely important that the public for these five states be educated about the importance and value of creating a historical record. I didn't see any mention of the value of actually recording what people have been through, and that just telling your story, seems to be a big motivator for people in this kind of research. Coordinating the message with media, schools or workplace, primary care physicians, mental health agencies, faith-based organizations, can all serve to encourage cooperation and continued participation. We've noted that there is mention of providing access to information, phone numbers to call in, hot lines, web sites, even putting that on

buses, in grocery stores. These kinds of things can encourage peoples' engagement in the project over time, and recognize that the public often cooperates with trusted individuals, but again, maintaining that trust is critical.

I haven't heard very much discussion about the media yet today, but I would argue that the media are crucial members of this project, and openness with the media breeds trust, trust is necessary for successful cooperation, and so I would encourage considering partnering with the media, planning for and coordinating with print, TV and radio in advance, and therefore recognize the potential negative consequences of releasing early results before they are solidified and recognize that if one is not open with the media, rumor and disinformation will be dangerous and can erode trust and potentially blow up in one's face.

I just want to take a couple of seconds to talk about releasing the findings. I think that one should recognize that the release of the findings for the non-scientific community must be clear and understandable, concise and consistent, but I think that one needs to plan for bad news, and therefore, the message should be rigorously pre-tested in advance - focus groups, meeting with individuals - before the data go "public".

The message should be sensitive to the age, cultural, ethnic and educational diversity of the audience, and one should recognize that ambiguity and uncertainty can be acknowledged as long as it is honest and believable.

As a researcher, I just feel compelled to mention some additional research needs. I think that one needs to think about clarifying the time course of symptoms, which argues for the continued and the importance of longitudinal research, at what point do normal responses actually become pathological and warrant intervention, can we identify early predictors of long-term difficulty, identify ethnic and cultural differences and response, and can we clarify the differences between the impact on the directly and indirectly exposed, and just I'd like to remind everybody that the public is not a monolithic entity. Some individuals are more vulnerable than others, and all should be part of the research sample individuals who had prior Gulf disaster exposure, or people who had prior psychiatric illness or pre-existing health care, health conditions - these individuals probably were more vulnerable to the impact of the spill. They should all be included in the research.

I'll skip this point, and just again mention the importance of preparing for the next disaster. Ideal

research is prospective and longitudinal. It uses representative samples, and doing little mini-shot studies is not going to be as beneficial as something like we're seeing after this spill, where we have a comprehensive assessment and therefore, I would argue for using this opportunity to coordinate researchers, services and agencies prior to the chaos of the next disaster. There will be one, I've been studying disasters for 30 years, and I am always busy.

I think one should have a sort of on-call research team, with preapproved ethics board protocols that can be activated quickly, clear roles identified in advance, pre-establish relationships with the media and identify evidence-based strategies for the communication message. Thank you.

DR. SANTOS: And it is a challenge to get all the information in and I know we are only giving you a short period of time. Maureen?

DR. LICHTVELD: Good afternoon. I come to you not only as a scientist - I come to you as a victim. As a victim from Hurricane Katrina, I lost everything. I joined Tulane three weeks before Katrina. I come to you in the skin of our communities - there are more than one. I also come to you as one who can show the scars of having done

almost 20 years of environmental epi studies nationwide at hazardous waste sites.

So in that context, I particularly come to you in the name of our Director of Emergency Services in the New Orleans Department of Emergency Services, in the city of New Orleans, who asked me point blank, why are the lessons not learned? And so, I pose that as perhaps the most difficult question for the IOM panel.

This is how I started. In June, when you asked us to participate, these were the four points I made. They're still valid, and I didn't want you to forget them. Regardless of how we call it, it is a disaster experienced by communities. There is no substitution, you've heard it now, for local knowledge and expertise. Families suffer when workers are hurt, and the health of the environment, no matter how broadly we define the environment, not only the ecosystem, is inextricably linked to the health of people.

This is what it is about. And we can't say it clearer. We have a historic burden of health disparities. We can't just mention it and move on. There are existing and continued environmental threats, and we deal with existing and continuing disaster, so all inherent

formidability comes exactly from the intersect of this Venn diagram.

There is a true need to decipher much better currently, and it's a challenge for all of us, both the proximal and the distal factors of health disparity, and how those factors influence, in turn, the either expected, anticipated or perhaps not so clear health effects, and so emphasis on this kind of research will help bring us answers to some of the questions we still have.

There are many consortia, as I mentioned - this is one of them. It's an NIH-funded consortium across the Gulf states, and one particular study that I am involved in is creating assets within the community in a research-driven sense in the form of disaster navigators.

I want to share with you some early results that are coming out of our focus groups, and these are quotes from our community members, and yes, I do support focus group research - there's enough of rigorous software to be able to make sense of it, but these are two quotes -

"Yeah, because a hurricane is regular water, we've been through that before. But now we've got oil-laced water and winds. So really, what does it look like?"

The second one; "Our beach life, our sea life, which is a protection against hurricanes. But it's also

this food, this house for all our food, that we love so much. I am not sure that that will be repaired."

And so this is the backdrop against which we are going to operate.

Rather than reading to you, you can read much faster than I can. I just wanted to put in front of you the nine principles of community-based participatory research, and then ask whether indeed we are engaging in true community-based participatory research. We don't have to, but we have to recognize that, and so the issues of using community resources and relationships, equal partnerships in all phases of research, co-learning - and co-learning cannot be by informing of outreach - it has to be at least both ways, a balance between research and actions - communities often expect services, not research. And the need for looking at multiple determinants of health.

Ongoing assessment of success - How am I doing? It's a long study, it's critical to do that.

Disseminating information to all partners in languages that are not only understood, but that is particularly respectful. I think that's often more important than just understood - and that long term commitment.

And so what are communities' markers of success, at least the communities that I know in the Gulf? First is, what's in it for them must be what's in it for us. That's a challenge for us.

Secondly, outreach neither creates education nor communication, and so let's not confuse those three concepts. There has to be a true commitment to education and communication. Education is a prerequisite to engagement, and so having a seat at the table doesn't mean I'm going to participate at all, if I'm not educated about what's going on.

And lastly, transparency fosters trust, and transparency begins from Day One.

And so the first question we need to ask ourselves is, what level of community engagement will the study adopt? I think if you throw out inform and consult in that manner, and often, research studies of this kind will not allow for true empowerment, where we give all decision-making to the other party whether the other party is community - you're left with involve and collaborate.

If you look at involve, the commitment here is that you work with the public to understand and consider the options. That doesn't mean you're going to adopt the options. If you look at collaborate, though, it says

"Collaborate to develop alternatives", whether it's alternatives to enrollment or alternatives to retention, and identify solutions. The study, as it is currently designed, actually hovers between the two, and I would advocate that we go more to the collaborate side than the involvement piece.

And so I bring to you for consideration two portfolios. The first one is to elevate community engagement as a study objective. Just be bold. Be upfront, be bold, do it. Secondly, to avoid an inconclusive by design outcome, this is not my terminology, this is - and I look at Elena, and you remember this - this is a report that came out over 20 years ago, when I was in my former career, to us from very frustrated community members, because all the studies we designed at hazardous waste sites, because of particularly the denominator, they were, in their eyes, inconclusive by design. So I'm simply using this terminology to bring up some issues.

And so in terms of community engagement, if we truly are serious about community engagement in the study, just make it an objective. Make it an overarching study objective.

Let's try to lead with the community engagement component. I value the establishment of a community

advisory board, but like the previous speaker, I think it's critical to make that board be active, and yes, provide an honorarium. They can get it too. If the scientific advisory board can get an honorarium, community advisory board can get that too.

In addition, or perhaps as an alternative to funding individual community organizations, try to synergize that power and that asset by creating really, funding a community network across the Gulf states that can learn from each other, work with each other and help each other across the states.

I would be one to say that the incentives are to the left of normal when it comes to being sufficient. And I'm very pleased to see that in the revised protocol, the incentive, there is thought around giving the incentive at the completion of the activity, rather than two to three weeks in, and from my experience with my current study, as well as the previous study, Wal-Mart gift cards is the way to go.

And so, the other questions, and this is not being facetious at all, but there really is a need to better define what this is. Is this truly a worker study? Then let's treat it as such. That includes looking at should we really do in-home measurements? Is it rather a

broad-based tracking registry with more rigorous nested studies? Is it truly a community-based participatory research effort or not? And so here are some thoughts.

As we know, exposure reconstruction will make or break the study, because we don't have a true baseline available anymore, and so it becomes critical to look at duration, whether it's a rare event or intermittent, what the burdens are; all the things that we do as environmental health scientists. There is great worry locally about the selection of controls, and from again, as a scientist, in the skin of our communities, there is worry about using the Federal workforce outside of the Gulf coast.

There is worry about using friends and families, because it might contaminate a future true community study, and so I've heard a lot of support for Gulf coast fishermen and workers who have not gone outside of the affected area.

Biological exposure measurements - you've heard about the urine analysis, obviously not looking at contaminants, because those would not be there. Genetic analysis may actually very much we might learn the most out of that. The current selected equivalent for pulmonary function testing is okay for screening, would not be for comprehensive nested studies, I'll just lay it out there.

It's very critical for us to look at pregnant women, and I highly encourage, based on my experience, to document every birth outcome since the spill, for all that are in the cohort, and to look at, explore, the collection of biospecimens because it's not invasive during the time, rather than postponing it post-partum, to do that post-partum.

There is mention of wanting to collect endotoxins and mold. Seasonality greatly affects that, and if the measurement is only baseline, I am not sure what meaning there will be for that. Perhaps it's more like the home evaluation, best done in a community setting, in a community study setting, where the whole family kind of participates.

We know that residential proximity to point sources is one of our lowest preferred measures of exposure, so let's be careful not to over-interpret that if the study ends up doing that. I talked before about strengthening the role of health disparities and the role that health disparities play in the outcomes of interest.

We spent a lot of time talking about psychosocial health. I like to use the term psychosocial health above mental health for a number of reasons, but an explicit focus on that is critical, as well as doing biological

measurements. I know there was a question that came, critical to add referral mechanism, extremely critical. Addressing that to have more explicitly as a potential risk, and adding professional support, real-time professional support, and I really am encouraged by what the World Trade Center representative mentioned.

Examine the literacy level for all the documents, including the consent form, the frequently asked questions and the intro letter. One of the things we hear often is I can't find my glasses today - a clear sign that you need to read.

Use culturally appropriate reference values. Lung capacity is one of those. Uncontrolled asthma - there will be people not able to have medication. We talked about special populations and the need for stratified analysis.

I'm going to skip just quickly and talk about the HVAs. Home visits in pairs is really critical. It's not an option. Though the local workforce is preferred, take extra home visit kits with you. They might not be there when you arrive. And the duration of the visit may be more than two and a half hours. I know I'm going to be kicked out of here.

Engaging locally practicing health providers is critical. I support local media as an important stakeholder.

And I'll leave you with what I left you with in June. Thank you.

DR. SANTOS: Our last panelist, please. Dr. Osofsky?

DR. OSOFSKY: I hope I did not goof yesterday. After a response from our excellent staff, the staff here, questioning whether my PowerPoints were dealing more with my current work than my comments on the proposed study, we agreed that I would not show them. But they are available to everyone, and they do go through the needs assessment, they go through the types of symptoms we're already beginning to see, and actually, what I didn't include even then because I felt they were too long, we have qualitative data on the focus groups that preceded the formal needs assessment, and I'd be glad to share them as well, with the types of specific questions that people are bringing up.

First of all, I want to thank you. I want to thank you for including me. I also want to pay my respects and say that I think that what is being developed is not only an extraordinary study but one that is going to have such positive long-range ramifications for our country and

the state of our knowledge, and I think we should all salute the efforts that have put it together to this point.

My own background, as you may know, since people have been relating their backgrounds, in addition to being Chair of Psychiatry, I headed up for a number of years an international consortium on the psychosocial needs of families and children following disasters, terrorism and acts of mass destruction. Initially questioned why is this being centered from New Orleans - nobody asked that after Katrina. We didn't know we were going to have Katrina, though.

I've involved with training for preparation in this area. We helped after 9/11 with training on the World Trade Center area, we've helped in other countries with training in Taiwan, China, I've done some for Haiti, most recently had wonderful collaborative data from our work in Chile following the earthquake, and that goes on.

I would also say that after Katrina, as many of you know, I was asked, in addition to my regular work, to head up the clinical effort, Clinical Director for our crisis response efforts for the state, and in addition, then was asked by our mayor and other parishes, to give the services for first responders. We've continued that, and also worked with reopening schools, and have this

longitudinal data on the children in two of the parishes most impacted by the oil spill, because we've been following every one of them since their return following Katrina. Our department has won a number of collaborative awards from our State Department of Education from the social workers. We're getting one that I cannot mention, the top award from the American Psychiatric Association. And our SAMHSA site visitors for one of our studies, asked would we write a book on collaboration, since this seems to be something that we seem so attuned to.

But this brings me to today. If I think of the words that would be going on today, they all start with "Co". Collaboration, cooperation and compliance. And I think this is what is being referred to in many ways.

In the buy-in with the groups of stakeholders you describe, much of it is buy-in, there'll be some input. Our preference, if there is time, is to have the stakeholders, when we have community advisory boards, participate actively with us, not only in learning about what our thoughts are, but giving their input and shaping what we're doing, and then meeting repeatedly to go over what's happening, what they see going on, what they see not going on.

But I think even with all this, this is such an

important study that I don't think there will be trouble gaining buy-in for the importance of this, and how the communities can be of use in helping the data collection, which will be crucial for the communities as well as for the United States. I think if we look at it, we can also say they're as much collaborative in the cooperative sessions as they are with listening sessions, for the investigators to listen to the communities, but for the communities to listen to the investigators, and to understand the purposes and the importance.

I think we can say there is some mistrust. Certainly there is mistrust of BP, there is mistrust of other aspects of the oil industry, there is mistrust about whether there can be full recovery, whether people have control. There is some mistrust of the Federal government, but I also point out the corollary, which is there is a lot of trust that agencies of the Federal government will do what is best for the people, are working in everyone's effort.

And building on this type of trust can be extremely important. There will be so much confidence in that way.

I emphasize one of the things that Marina emphasized, that one of the things is we go around, we hear

always, are we going to be getting sent in a bunch of national experts, people who come in and leave as opposed to the people who are there with us and understand us? In our work in developing the practice directorate, which is serving as a model nationally for crisis response, we work together as the Louisiana experts, but also with the national Child Traumatic Stress Network and the National Center for Post-Traumatic Stress, working together, and the people who are being trained in receiving the consultations could see the benefits of both, and the real importance of it, but they stress over and over again the importance of having people who understand them, who care about them, who are going to be with them for the long haul.

In this role, I think there could be greater involvement of the universities - not only our University in Tulane, but throughout the Gulf South, and as I say, not only am I pleased to be in the consortium that Ed will be speaking about tomorrow, but we've had the department chairs from each of the universities involved in the Gulf South talking with me about their wish to work together with us.

From the point of view of feedback, I think one has to consider the question of what one provides to individuals, and I think it is a broad type of question,

but I think you'll find that people will want to be in the study if they feel it benefits them and it benefits their community in gaining knowledge that will be of help, but also if it benefits the entire country in a way that will be of help. People really are idealistic, and that brings back to the point - at least it's our experience, that people do say yes, and say yes repeatedly and welcome us, and I'm sure you will have the same experience, and if we can work together, we're going to do it.

We're also questioning if people need referrals, and I brought this up earlier. One has to be sensitive in the questions that are asked, and who asks the questions, and what one does at the time when one is learning about things that require referral. And if there's going to be referral, to whom? Are we going to have individuals who are well-trained to receive the referrals? For example, can you use something like the SCID - the Structured Clinical Interview for DSM-IV, soon to be DSM-V, but in helping to determine people getting their best quality of care, they can also be used from a research perspective in also trying to say whether people avail themselves of the care and how successful it is.

I think that there are many confounding variables here. We don't have as much baseline data as we should

have. What people are telling out in the field is they'll say to me, "Doc, if you think there may be some symptoms now, wait two or three months from now, when BP is no longer funding the jobs, and then when people don't have this good employment, what's going to be happening to them" and it sinks in more and more. I can't tell you often this is raised by workers, by parish council members, by parish presidents, by mental health professionals.

And so it would be nice if we could have a rolling type of collection of data, so that one is taking into account the various variables that occur that may impact on people - is there a hurricane in the midst of everything, is there another economic crisis?

I think it is important that as one looks at the individuals, not only to consider ethnicity and age when one considers employment, and when one considers the surveys and the response, but also even among the people who take jobs, remember that of the people who didn't apply, a given percentage - we've gone over this parish council presidents - didn't apply because they felt they would have a positive screen for marijuana, and of those who did apply, there were a significant percentage, and I am aware of it, I don't know that we should be citing - but it was quite high, who were turned down because of testing

positive for marijuana when they didn't think they would test positive for marijuana or other drugs. They thought it was out of their system.

So if we're taking a look at comparison groups, what are maybe some of the differences in the comparison groups? Of the individuals who come to work from other states, are there differences in education or in motivation, or what do they do during the months that they're stranded in a small community where there is very little outlet for recreation and certainly not for family?

The disparities that existed before the oil spill - we don't have as much baseline data on some populations as we wanted. There's some data, but the disparities that existed before certainly have been magnified.

We take a look, in mental health, at the direct contributions to health, or health symptoms, that the health symptoms have contributed to mental health symptoms, the issue of toxicology, but also the perceptions - the perceptions of health symptoms, the perceptions of toxicology, the perceptions of their environment and their future and how these contribute to mental health symptoms, and the opposite being true of the patients who are seen for health symptoms.

As I was saying, I would emphasize what Marina

did, if there is any way of doing it, and it may not be possible here, of doing a collaboration that involves some of the local people, who are seen as experts nationally and internationally too, but also who have the trust of the individuals in these regions of the country.

I would also state, and I mentioned this, this morning briefly, that we're having the opposite of what's been referred to here when we have communities asking for help, and as we do try and take a look, for example, with the Vietnamese community, is the K-6 appropriate, should we be going back to the Center for Epidemiological Studies depression scales, is there a way of modifying it to make things appropriate, and trying to look at each measure in the complex group of measures that we have involved and trying to see what is most appropriate, realizing that in some communities it's not just Vietnamese.

Older people don't talk to their sons or daughter. They don't talk to their wives about symptoms. It may be more likely to occur over a drink or two, and even then, it may be around the worries or something that isn't going right or wrong, and it may be above what we traditionally consider mental health.

But how do we build all of these in? I know my time is up. I want to thank you again. It's funny, when I

leave this weekend, together with Dr. Galloway and Dr. Palinkas, we're putting together an editorial for the Journal of Disaster Health. I know Dr. Goldstein and Dr. Lichtveld are working to complete another article, but whatever assistance we can provide we will. In any case, I thank you for what's going to be an extraordinary study.

DR. SANTOS: I want to thank all of our panelists for clearly the challenge of addressing such a wide area with such a rich and diverse level of expertise, and having that in such a tiny amount of time. So I appreciate that difficulty.

I just want to touch on one or two things that have been raised, again, under the theme of this panel this afternoon, and then open it up to questions. The first is that the issue of trust has been raised several times, and just a question as to whether or not there has been any explicit work done around assessing how trusted NIHS will be in terms of conducting this study in the community. Has any of that been done at this point? I would direct that to -

DR. MILLER: I am going to start. First off, I want to thank the panel for their excellent comments. Fortunately, we also had the benefit of some of your comments from the previous IOM meeting, and it goes to some

of the efforts that we have already started, and I think we really did take it to heart, this issue of both trust and community engagement, and to move beyond involvement into a collaborative mode, and so in that vein, and let me just outline what we've kind of started and kind of getting us to this point - and I really appreciate kind of taking it to the next level and moving this forward -

In terms of our understanding from the previous IOM and some of our own personal experiences in the past, was to try to - while we were also developing and everything was kind of moving and parallel to each other, developing the protocol and ideas for how we were going to do the study, but the concerns about implementation and getting the community's understanding with respect to what we are going to try to do, and in terms of their participation, their retention, their understanding, engagement and hopefully, support. And also in terms of the local public health infrastructure and state health infrastructures, and also including mental health in that discussion.

So we have started actually going and having meetings now with state health departments and local health departments, and NGOs, community representatives, both faith-based and worker representatives from the Gulf, and

there was more planned, but we've done Mississippi and Alabama at this point, we're starting Louisiana in about two weeks. The end of this week we're going to Florida and we'll continue working along these lines, and really getting some very good feedback, both in terms of having them look through the study and get their kind of personal feel in terms of their communities, their cultural sensitivities and issues of concern that are unique to the specific states and localities.

Certain states work on a countywide kind of system, some have district-wide systems, but really thinking it through a little bit what might work and may not, and the more local dimensions, both in terms of flexibility of what we're going to try and implement, and how we might use multimodalities. So as Dale has outlined, both in terms of trying to focus on having the telephone system, but that may not work for all groups - it was really stressed that a lot of the workers may have phones, but they change their numbers fairly frequently. Or the fact that they have phone cards and they pay for those minutes, and they are not going to give us 30 minutes of that time very easily, so we'll have to think about strategies which will, in terms, be effective.

So in terms of some of those elements, we've

started along those lines, and we've actually - you know, part of the questions that we kind of sat down with them was, who else should be at the table? Who do we not have here, what are the other points of contact in the communities, both in terms of NGOs and health infrastructures that we need to be contacting, so we're getting an expanded list of a network, and it will continue to grow and work with.

The other question is really for them, and going back to the referral elements, because we recognize the fact that as we go into peoples' homes, we may identify acute psychosocial situations, we may identify individuals with primary health care needs that need to be addressed either acutely or things that we all identify subsequently because we have taken some lab tests, or whatever we've done.

And we really want to have a network and a referral infrastructure that makes sense, that is community-sensitive and that will work, so in that vein, we have been talking with the states about that, and the communities - Who do they use? What might work? What about fee for services or sliding scales or community health centers, and how might we be able to accomplish this in a really meaningful way. While we are not bringing

health care, we certainly want to make it work in coordinated fashion with the resources that are currently available, and also, in terms of the other efforts that will be going on, mental health efforts are going on, both in terms of SAMHSA, and in terms of the state level, and it was good to hear about the effort that you're undertaking, but how do we tie these things together? It will be a challenge, I mean clearly we have to move forward on that, but we also want to make sure that - one group is referring to one area, and we want to make sure that that's not happening, that it's a system that's working and the referral networks are consistent and the message that people get is also consistent and clear and helpful.

We've talked about, in terms of what we've been hearing, in terms of having available contacts with your 1-800 number that can be called, handing out literature that the state wishes to hand out about public health, so that's kind of a value added right there, so you go in and engage people, you can provide them information, whether it's mental health or primary care information.

One thing that was brought up, I think it was from Alabama too - that they saw it as a real asset that if we are going into individuals' homes and measuring some parameters like their blood pressures or getting urinary

glucose, we can identify those with hypertension or potential diabetes and get them referred in, and that's a real good asset for us, is identifying those groups and getting the health care and the primary services that they can get, so we saw it as a real plus. Also distribution of some of the useful literature as well.

So we're excited about this. Clearly this activity has to go on, you can't just get in there and do it once and then leave. We have to really get down there and have a consistent and focused building off of what's been mentioned in these community advisory boards, but other types of modalities, the media was one, I think. In Mississippi they offer that the local health officer would get on the media with us to advocate on behalf of the study and the need for the community to participate and be involved in the study, and then along with representatives from the study to be doing that in concert together.

So I think those kinds of things are really helpful and will be really useful, and I think it behooves us to put the time and energy in up front before we even make this, to start doing all this leg work and can be consistent about it. But that's kind of where we're coming from right now, and I can kind of go back and address some of the different things that were raised.

DR. SANDLER: I don't know how much there is left and I don't want to steal time from the group who have questions. I just want to - I heard some really important things. Some of the things that have come up were sort of general things that we thought about, some things resonated particularly because we'd used it in other studies, and why didn't I write it down to use it here - other things were new.

I think the idea of staying in touch with the cohort more frequent so that we don't lose them is a terrific idea. We certainly will do that. Using the media - in this last study that I did we were just shameless in taking advantage of the media. Now if we have something that would sell - and this is something that would sell, I think there's a lot of interest in the Gulf and what's happening, so I think it can be very useful.

I was interested in the comments about the consent form, and you know, when I draft a consent form that I like, and it goes back to the NRB and they say we've got five new things you have to add. And currently, the concern in IRB-land is how do you drop out, what are your rights, what happens - so there it is, front and center, so we don't get dinged by the IRB. But I'm going to go back and reorder this. I think that was a terrific idea,

because it's informed consent that this is your - the consent forms scare people away, so as long as the messages are there, why not turn it on its head? So I love that idea.

I wanted to come back a little bit to - I was aware of the secure consortium, and I've talked with folks from the National Center for Minority Health and Health Disparities. So how we can tap into those grantees as we move forward, and Laura, you and I had a conversation that what we need to do has to be open, and everybody has to have the same opportunities to participate and NIEHS has grantees who are doing community participatory research, and so there will be separate grant opportunities, and then within our context of those, we'll have a fair process.

Getting the community advisory board lined up is key. One of the mandates to the teams who have been going in and meeting with people is to figure out okay, who's the best one? There's so many people to choose from. Fortunately, we're not going to sign people up for a ten-year, twenty-year commitment, and so we'll be able to rotate people on and off as things move, but if any of you working in the area have people who have been particularly terrific, useful, insightful, understand research but understand the community - We will, of course, be looking

to our grantees as well for that type of information - it's really important to choose the right people, and not the people who are going to be yes people, but the people who get it, who understand what the give and take needs to be in responding to the community.

The issue of who the control group is - there's sort of a misunderstanding. The Federal works are a comparison for the other Federal workers, and they obviously do not look anything like the community. It's interesting to think about the impact we might be having on other research opportunities if we were to choose the family members as the comparison group, and I heard that - we'll come up with something else - and in fact, we've also been in conversations with others who are interested in studying the family members, so including them as household members, as participants, as opposed to comparison group, is something that we're thinking about.

The pregnancy thing is interesting, so I went to some very well-respected reproductive epidemiologists at the beginning, and they did some calculations, if we had 5 percent of the workforce, but now we know it's a little bit higher - or 10 percent of the workforce are women, and how many of them were pregnant at the time, and would there really be an opportunity to do a really fabulous pregnancy

outcome study, collecting urines from women and tie them to pregnancy-type stuff, or prospectively documenting pregnancies among women who were attempting. The answer was, I'm not sure this is going to work, but it's still worth thinking about, and in our context, I admit I was thinking about pregnancy as a time that would change the measurements. You know, if we're thinking about towards the long haul, if somebody's pregnant now, they weren't pregnant at the time of the spill, if you get them now when they're pregnant and you want to look at various hormones or anything else, the values will be different, and so I'm not really sure what the answer is to whether we collect their samples now or we collect them when they're not pregnant.

If we were designing a pregnancy study, obviously, we would want the samples while they were pregnant, so that's going to take some more thought.

DR. SANTOS: Great and I will open it up to questions, but I will ask that one question again. Any specific research or looking or asking people to try to probe on the issue of trust?

DR. SANDLER: You know, not specifically. I faced this in my last study, and I did something that didn't make the powers that be at NIH happy, is where my

web site is a dot org, it's not a dot gov, and we had a study logo and there's all kinds of issues about one government, and we're the government, and we should be proud - we need to balance that. I think the mistrust is there but it's less because we're not a regulatory agency, and so our ability to communicate that that's not our world has helped us.

DR. OSOFSKY: Our sense over time, is - I really want to support this - we haven't done a formal research study on this, but on this I would echo that I think you'll find that there is trust in the National Institute and the DHHS, and in the groups that are trying to provide information - I would think that you would see the people be open.

DR. MILLER: And that's somewhat echoed by our conversations right now with the state and the NGOs, is that in general, we ask that kind of question - is there a lot of mistrust, do we have a lot of resistance to overcome because of past Federal government perceptions and the current media atmosphere, and they said no, in general, if you can get out and make a good case and communicate clearly and effectively with this community and consistently get your message out, you can overcome a lot of that - and work closely with the local networks to help

you get your message out, not just come in - but really be down there and start working.

PARTICIPANT: I would like to ask the panel a little bit more about how you set up an appropriate community consultation, so that you have really achieved your goal? It's already been pointed out, this is not a monolithic community, not at all. There are rare instances, I suppose, where research studies of this sort, you have a structure that you can tap into, for instance, in the Native American community, and you have a tribal council that you can work through, but that's certainly not the case in this situation, and the communities could be thought of in various collections of shared views, and you could be either a lumpner or a splitter, in terms of how many different communities you want to consider on your list that are involved in this study.

And then within each of those communities, depending on how you define them, you have to figure out who speaks for that community, and does your choice actually resonate with the people who are there? Do they think of that person as representing their views, or do they think of that person as a bit of an outlier, either too negative or too positive, compared to where they want to be?

So we talked a lot about how critical it is going to be to have a community advisory board and how to do this ongoing consultation and communication, but I'd like, from your experience from other studies, to hear whether you have, in your mind, sort of a way of deciding whether you've done it right. How do you assess that? It's not enough to simply say, I have this list of people - How do you decide whether that is the appropriate list to genuinely represent, not in a perfect way, because that's probably not possible, but in a way that is at least going to raise confidence both in the community and in yourself, that you are hearing the appropriate input and giving the appropriate communication back?

DR. OSOFSKY: Can I just say one controversial thing and then I'll let all these - I think there's another part of this that if it could be thought through in a sensitive type of way, would be worthwhile. There are some groups that look as though they're logical groups, but since Katrina, there's been disappointment and mistrust by the communities in which they exist, so I think that might be important to know as well, as you're setting up either community advisory boards, determining the normal chain with which you would do things, recognizing the people felt very let down by some major groups following Katrina. I'm

impressed how much you still hear that when you go into communities.

DR. LICHTVELD: So a few thoughts - yes, it's not perfect at all. This is hard, this is difficult. There are organizations who have a track record in delivering for the community, not necessarily delivering for research, but who are a trusted point. There are organizations who have become the go-to in terms of touch points. The old, I guess, rubric, would be the watering holes, where people always go to get things done or to make things happen, and so that is - it's kind of that needs assessment that stays there.

Secondly, I personally like to refer to them more as community assistance panels, rather than community advisory panels. Advisory connotes something passive, and I think here, assistance may be something more active, where community representatives come together to assist and have a track record of assistance.

The third, I would perhaps say criterion, if we can use that loosely, would be looking at community members and individual organizations, who have a set of assets that have proven to be used by that community, whether it's post-Katrina or post-some other disaster, and so those three efforts, combined with people - there are also a lot

of volunteers who say "I want to be on that panel just to have my name on it", and that's not the idea, the idea is to really work, and I have seen a tremendous coalescing and differences within communities, and I work a lot in the Vietnamese community, that the young people may not necessarily speak for the elderly, and vice versa, and so not only do you have to be mindful do you have the ethnic rainbow, so to speak, but do you have the age strategy as well? So not an easy thing, but my preference is a fundamental research component must be the community assistance panel, that is assessed over time as part of the research, hence my recommendation for it being a study objective, and making sure that you do the best you can in terms of representing those that truly have delivered in terms of asset rather than need, so I prefer to call things an asset assessment rather than a needs assessment. Just some thoughts.

DR. OSOFSKY: In fishing communities, something that is striking, that quite often in our parish leaders, the difference between fishermen of different ages and their attitudes, and even their attitudes about what will happen if they need to find new jobs and their views towards their current jobs. So Maureen and I would echo each other on the need to have representation that connotes

the different parts of the community.

DR. KASS: Nancy Kass, again. I just want to build on what Maureen was saying a little bit, on Dr. Kahn's question. So I want to address both what I think we're talking about directly, which is how do you get what you are hoping to get out of the community advisory board, and then one step broader, which is how do you get the kind of community involvement you want, and underscore what I think we all know, which is that those are not synonymous? So the first, about a community advisory board, just I was thinking about well, we know we have to expand our investigator team, we don't just say well, who's a good investigator - we say, well what do we need.

Like I need a mental health person, or I need something - and then I find the people. And I think it's interesting to think through very specifically whenever a study wants to develop a community advisory board - what, at least from the investigator side, they're hoping the community advisory board will do, and that will lead to really different kinds of people, I think, even if one still tries to ensure that they've been effective at doing whatever that thing is.

And there's some groups that try very explicitly to be advocates, and they can be really good at that, and

it isn't even necessarily how they view their identity to go back to their constituency in a structured way, but they advocate for children, or they advocate for immigrants, or whatever, and there are other people who, because of the way they network, and the way their personality is, are amazingly great at truly representing the views of certain different kinds of people. Those aren't the same things, anyway. There are different purposes to which community advisory boards have been put - some people who have done theoretical work on that, but you end up with different kinds of people, and then even ultimately, I think it's really important to talk through with a community advisory board what you, from the investigator side, and what they, from the CAB side, see as the purpose, and even write a little bit of a job description, because I think it can help people to take on roles that they might feel comfortable with, like going back to people that they might not otherwise have done if they thought they were there just to represent their own expertise.

The second comment, I probably don't have to say much more about than just stating it, but a CAB is a fabulous shorthand way to get a lot of input, but it does represent just a handful of people, and obviously, if I were here to represent people who were female, or people

who are faculty members, I would do a really poor job, and it's important to think of all sorts of - even quick and dirty - ways to -

DR. SANDLER: So as I was listening, it occurred to me that I need more than one, that at the larger study level, which covers five states, and people who come from out of the states, and a whole range of people, I need a community advisory board that will come to me, that will come and meet, however often we need, or beyond phone calls, tracking, and those would be some gatekeepers to populations, people who have actually already been negated as partners in research, and can advise on the best recruitment tools.

And that's sort of a national study community advisory board, and it's clear that I need some other, more local, pockets of ongoing rolling focus groups or other kinds of more local advisory groups to get broader input, and so I don't know exactly how the structure - how we're going to do this, and how we're going to pull it all together, but I suspect that by adding more local partners at the research end, it will come together.

DR. COLLINS: I've had a notoriously bad record through my years of being able to predict the outcome of research, but there's at least some distinct possibility

that given the inherent problems with exposure, misclassification, starting late, given inherently the fact that you don't have the most optimum control group, as good a job as you're trying to do with it, that you're going to end up with at best hypothesis generation, some associations, nothing really definitive that you can say to the community. At the end of that time, with all of the points, and excellent points, that we've heard, you will have, by doing a good job, by saying 'look, here's why you should participate, it's the National Institutes of Health, these folks are the best', you're going to end up with a very disappointed community, unable to quite understand whether or not - did you really find that association between left-handed people and prostate cancer or whatever it is - or didn't you?

And I just wonder, as we go through this process with the community that's been suggested and that you describe, and that you also have to be able to do it in a way that doesn't raise expectations that you're going to have a definitive answer.

DR. SANDLER: I think that's an excellent point, and we've been warned all along that we are going to need to manage expectations. I think we could sort of say "well, we're going to have a mushy study and we should go

home", but I think there are a lot of reasons why we just have to do this, but we do need to make sure that it's clear what an epidemiologic observational study can do, it's not a clinical trial, it's got its limits.

DR. SEIFERT-MARGOLIS: Hi. I'm Vicki Seifert-Margolis from the Commissioner's Office at the FDA, one of the untrusted regulatory agencies. I just wanted to share some experiences that I think will be very important moving forward with this effort, because we've certainly been down there, and dealing with the community at the level of trying to ensure trust in their food supply.

And in trying to explain why, so far, we haven't found anything, yet people saw images of oil spewing out in to the Gulf, and are we doing enough, and what are we doing versus what is EPA doing versus what is NOA doing.

And a few key points I think we've learned - one, in terms of trust, the media can be your friend or they cannot be your friend. And they certainly are going to go out and find detractors, and we found it very important to publish all methods, to allow people to poke holes in them, before you go forward with saying any conclusions or have any discussions about potential results.

I think one of the other things we have been learning is that we are one government, and if you're out

talking to the community, they're going to ask you about fish and they're going to ask you about water and they're going to ask you about closures and they're going to ask about reopenings, so I'd encourage you to work with us and other agencies to make sure that we are one communications team. This has turned out to be incredibly important for us to work closely with NOAA and EPA, and in fact, we're currently working with the White House, on a strategy for displaying all the data in a map, so that there's fish, water samples, there's a clear understanding of the whole picture as opposed to each given agency's role.

So I think that's another really important thing to bring to the table and to bring to the community, and then I think one other point is that the town hall meetings have really turned out to be an important venue for us in terms of doing a lot of Q&A and getting feedback from the community, because many people don't have the internet, and while we've been posting all of our data and posting information on the web, they aren't reading it, it's not sinking in, and we've really been trying to spend much more time talking to people, consumers, different constituents, different environmental groups about what's going on and what our efforts are.

So I think, this is very complicated, it's very

complicated information, it's complicated to communicate, it's complicated to gain trust and when I'm talking to people, they see me as the government person from Washington, they don't see me as NIH, they don't see me as FDA, necessarily, so I think that's just something that I would encourage, that we all try to work together.

DR. SANTOS: Thank you. I am going to ask for the last question from the committee, then see if there's a quick response, and then it will be time to adjourn.

PARTICIPANT: I just have one comment, Dr. Miller brought up that I thought was very interesting. We spent a lot of time here talking about the psychosocial issues involved and we've spent time discussing not asking certain questions because they'll require a certain degree of follow-up, but you brought up a very important point. You're going to have people in peoples' homes, and you're going to find blood pressures of 240 over 160.

Now if I was doing a clinical trial in my hospital, we would hand walk that person to the emergency room, and unlike Manhattan in the middle of 9/11, you can't go 200 feet in Manhattan without hitting a doctor's office or a clinic. It's true, it's absolutely the case. But some of these people may be hours from the nearest medical care, and these people are in real medical danger. We're

not talking about something abstract or something in the future. They could die imminently from things you might discover during your evaluation. How far do you go to ensure that follow-up is made? Do you just say - in the protocol it says 'you know you should see a doctor immediately because you have malignant hypertension, and have a nice day, we'll talk to you in a year' - how do you follow up on that and how do you ensure, how do you work with communities to make sure that that person can actually get care that may not be there?

DR. SANDLER: That's what we are working on.

DR. MILLER: It really is. And it is a large concern, whether it's a primary health care finding or a mental health situation or just a household situation that demands some sort of intervention rapidly. We're trying to build that network. We're collecting what we think is that local infrastructure to be able to access that quickly, for those things that need either urgent attention or later attention. One thing, too, we've been talking about, which was raised, is having a local coordinator or something for the state, we're going to see how it's going to play out, but that person could then do individual follow-ups and to help make sure that this system is working.

We're going to have to have a lot of oversight on

this thing, in terms of both the identification - I referred him to X, did he really get there - was X responsive, you know - to put this together. But that's the challenge right now, and to really stay on it.

DR. SANTOS: Thank you. I want to thank all of our panel members. We're going to take a 15-minute break and we'll start back at 3:30. Thank you.

(Break)

Agenda Item: Session 4 - Interagency

Collaboration on Studies of Health Effects from the Gulf Oil Spill

DR. GOLDMAN: We already had a nice segue into this session with one of the comments in the last session about the fact that when any representative of the government in the community, the community feels that they are speaking to the entire government and for that and many other reasons including the success of this study protocol the issue of interagency collaboration is very important.

I happen to be chairing this session and I am going to quickly run through the list of those who are speaking. It is a lot of speakers in a relatively short period of time, but I think we really wanted to be able to hear from the full array of agencies who might be involved.

We have Tracy Collier who is Advisor on Oceans

and Human Health and Shelby Walker from the Office of Planning, Policy, and Evaluation with NOAA. We have Michele Conlon who is an Assistant Laboratory Director at the National Exposure Research Laboratory at the USCPA Office of Research and Development. We have Scott Deitchman who is the Associate Director for Terrorism Preparedness and Emergency Response at the National Center for Environmental Health at the CDC ATSDR. We have James Galloway who is with the Department of Health and Human Services who is the Representative to the National Incident Command for the Deepwater Horizon Oil Spill. He must have had an interesting summer. We have Princess Jackson who is the Supervisory Public Health Analyst at HRSA. We have Erica Schwartz, Preventive Medicine Officer and Clinical Epidemiologist at the Coast Guard and Jennifer Rusiecki who is an Officer at the US Coast Guard Reserve and also is an Assistant Professor of epidemiology at the USUHS. And we have James Spahr who is the Associate Director for Emergency Preparedness and Response, the director's office at NIOSH.

I want to welcome you all and we are just going to have you move forward in order. Because there are a lot of you, I don't want to take up a lot of time in between each of you and then of course have a response and

discussion. Let's move forward.

MS. WALKER: Good afternoon. My name is Shelby Walker. I am tag teaming today, NOAA representation with Tracy Collier. My goal here really is to briefly highlight some of the NOAA activities and data that we have available that would be useful to inform this study.

NOAA has been heavily engaged in the Deepwater Horizon event. And here is probably a bit too dense of a slide highlighting a lot of the activities that have gone on and I am really going to focus on three areas here. The first really focuses more on seafood safety, and a couple of things that I wanted to highlight here is working in coordination with FDA and the states. NOAA has been working through seafood safety protocols for testing and using that information for reopening of closed fishery areas.

And one of the things I would like to point out here is that to date none of the fin fish samples have actually registered any detection levels above the levels of concern that had been established through the protocol.

But one of the other things I just wanted to highlight here that might be useful for this study is in fact you do have a pretty active survey ongoing to collect all of these samples, to bring them back to the lab. You

have a lot of workers exposed. And this has been ongoing throughout the entire spill. A lot of individuals who had been out in the midst of areas that have had surface oil potentially in the vicinity of in situ oil burns and that is also true for a lot of the sub-surface sampling that has been going on.

And while folks may be aware of a sub-surface monitoring effort that really has ramped up recently, we have had vessels out there working in coordination with the Coast Guard, with EPA, with BP to look at the extent and magnitude of the sub-surface oil, oil in dispersant and really try to get a handle on where this is all going. And again this has been going on since the early days of the spill. There has been a lot of commitment in terms of people power, vessel deployments, getting out into areas that have been actively burning or in close proximity to them or areas with surface oil.

The third area that I really wanted to highlight here is one that I had mentioned in the interagency meeting that I was fortunate enough to attend at NIH in August. And this really focused on the air quality aspect of this. Now NOAA's purview is not so much determining whether or not the air is good to breathe or be exposed to, but we do have the capacity to provide a lot of information to those

agencies that can make that determination such as EPA, OSHA. And we were able to bring to bear some of the assets that we have in hand including deployment of a P-3 aircraft which is equipped with a lot of in situ sensors as well as air canisters that can be conducted -- that can be analyzed off site.

In addition, we used those same canisters to deploy on vessels that went out at varying times throughout the course of the spill. One was on a charter fishing vessel in the early days of the spill in May and then the other two times occurred in June; one on an academic research vessel and one on one of the NOAA research vessels.

As you can see here, we have been able to take a look at a wide variety of compounds. The P-3 was able to do a more extensive mix looking at in addition to hydrocarbons and organic material, particulate matter, ozone, carbon monoxide whereas the air canisters really focused on the hydrocarbons.

This is really just a preliminary shot of some of the data that we have gathered from the air canisters. And you can see that we have both the charter fishing boat, the P-3 flights and the two research vessels shown up there. And maybe a little bit hard to see for the folks in the

back, but I also wanted to direct folks to the fact that all of the data that has been analyzed to provide this shot is actually available on the NOAA web page.

The other thing that I really want to emphasize here is getting back to the earlier point is that this is truly an interagency effort. All of these efforts that have gone; the seafood sampling were being conducted in coordination with FDA and the states, the subsurface monitoring certainly has been a very interagency effort, Coast Guard, BP, academic groups, the air quality work here being conducted in coordination with NSF, EPA, OSHA. None of these things could be done by any one particular agency. I just happened to be fortunate enough to be able to provide you some information at this point.

Just a little bit more information about the P-3 results. I am not going to go into a lot of detail here. Again, we do have all of this information that may be useful to inform this study in terms of degrees of exposure. I think in particular one of the things that I wasn't able to report on earlier but maybe of particular interest is the air canister data from the research vessels because those are reflective of the actual conditions in which people were conducting sampling.

Trying to keep on schedule and within my five-

minute time limit I just wanted to direct folks to the web page that is here. I am delighted to learn that there continues to be a larger effort to coordinate all of the data from the federal agencies into one central repository. I know this has been a particular challenge since the beginning of the spill. I look forward to seeing how much we, NOAA, and the other federal agencies can contribute to this particular study. Thank you.

RADM DEITCHMAN: Hello. I am Scott Deitchman from Centers for Disease Control and Prevention in Atlanta. I won't have a PowerPoint presentation which for someone from CDC is something like an acrobat working without a net. I am sure my colleague will catch me if I fall.

Focusing specifically on what CDC could contribute to sort of an interagency collaboration to support this study, I consider the data that we have been collecting and those data sources. The first one, of course, is the state-based health surveillance and that would be in two categories. One is the specific surveillance systems that the states have set up in response to the oil spill and which CDC has been collecting from the states aggregating and displaying on the CDC website.

That is probably not a resource that is going to

be around much longer. We have been hearing from the states that most of them are looking at timelines for phasing that process out because they have not -- as they have been conducting this, they have not been seeing trends indicating a public health problem and the number of reports that they are getting is steadily diminishing. We will be continuing to collect case reports from the National Poison Center database system as well as from the BioSense network of hospitals: primarily federal hospitals, Department of Defense and VA hospitals in the states. And certainly those case reports could be shared with the study investigators to the extent that we have personal identifiers that allow linkage and this is going to be a recurring theme in my presentation. I think linkage as we heard earlier today is going to be a problem in making these kinds of associations.

The other study that we will be having ongoing is the standalone Behavioral Risk Factor Surveillance Survey looking specifically at mental health needs. This is going to be a telephonic survey. I think since the last time we have met, a lot of the uncertainties have been resolved. It has now been decided that this will be a survey in four states: Louisiana, Mississippi, Alabama, and Florida. Texas will not be participating. It will be 90 questions

of which 60 have been derived either from the existing BRFSS or from a few other existing survey systems. Thirty will be new and will have to undergo cognitive testing to ensure their validity.

It will be conducted for at least one year if we can obtain sufficient funding. It will be carried on for a second year as well. It will not involve the use of geographic controls comparing Gulf Coast counties with non-coastal counties. Funding did not permit that expansive of a survey. Instead since I mentioned that it will use partially existing BRFSS questions. It will allow for the use of what you might call chronological controls looking at how the responses compared to responses from the same or comparable areas earlier in time.

Again, these data can easily be shared with the investigators in the study that we are talking about, but making linkages will be a challenge. We won't have personal identifiers. You might ask could we get the phone numbers and make linkages that way. That would be a possibility but the problem is that you don't know whether the respondent who answered the phone and thereby answered the questions in the BRFSS survey is the same member of the household who participated in the NIEHS study. Then one has to ask the question whether there will be utility in

making sort of geographic linkages. This responded or these respondents in the NIEHS study came from an area in which the telephonic survey found these conclusions. And I will leave that to the investigators to decide.

We will be continuing to help with the interpretation of the environmental data that EPA collects and certainly those interpretations are public and are available to the NIEHS investigators.

And finally, although this isn't necessarily a data sharing issue. CDC has extensive health communications networks, ways of reaching out to various professional and other health associations, ways of communicating through our partners at ASTHO and NACCHO with state and local public health providers. In fact, we had already worked with the BRFSS survey because the local health officials told us they really wanted to know when the BRFSS survey would start making phone calls because people in these communities get that phone calls and they call their local health department to say hey, is this real or is it bogus.

That is a resource that we can help make connections with so that when the NIEHS folks begin their surveys, all the providers on the ground who are likely to get these same kind of phones calls from their

constituents, from their patients asking doc, what do you know about this or calling the health department. We can help grease those skids using our systems. And likewise think about how -- in this morning's discussions there were an emphasis on the importance of communications thinking about how the communications resources that we can help make available to the investigators can be used to announce when different aspects of the survey will begin when it is time to communicate results to the larger community and whatever other needs that you may think of.

Certainly when we get to the question and answer session, I will be available for other questions. But off the top of my head I think those are the CDC resources that may facilitate your work.

DR. GALLOWAY: Good afternoon. I will be brief. It is late in the afternoon. First of all, I should acknowledge my conflict of interest as we start off and that is as an internist and a cardiologist my research experiences have really been focused on clinical evaluations, quality measures, and prevention measures in particular populations primarily Native Americans. And that will influence the way I look at things. I will just say that up front.

Secondly, I was the senior health official as was

stated assigned to the National Incident Command working with Thad Allen and the Coast Guard, which was indeed a tremendous experience and a real honor to do so. And gave me a lot of insight, but primarily gave me insight in two major areas; one being the intergovernmental relationships and the second being in the community governmental relationships. And I would like to touch on both of those a little bit.

Unlike other presenters I don't have any data to share with you all about what we and HHS are doing because many of us or most of us up here -- many of us up here are HHS and my role in this has been more of a collaborative function to try to work with all of our agencies and the other departments of the Federal Government to make sure that we can move forward effectively in this effort.

I would like to thank everyone here for the great work that has been done so far today. I would like to give special thanks of course, to Dr. Collins and Dr. Fineberg for the great efforts as well. And I would like to thank Dr. Nikki Lurie, as well, for the opportunities and leadership that she has given us.

I guess if there is one thing that I bring to this group it is the enthusiasm and dedication to this particular study. I think this is a tremendous

opportunity. I have had the opportunity going around the Gulf Coast with Secretary Mabus, Secretary Sebelius, Teri Manolio, a number of other individuals as we have gone around and talked to individuals and had town hall meetings and really listening meetings at all various levels regardless of whether it is a local fisherman or whether it is academic folks or whether it is hospital folks. And have found that the perspectives obviously as you all would imagine are quite different at times but there still remains a significant skepticism of government, but a significant interest in the issues of health evaluation particularly for the population themselves.

I have a lot of enthusiasm actually for this study and the recruitment in the study. I think the retention in the study will be a major point as we move forward and one of trust that has already been discussed pretty significantly.

My experiences require me to underscore the importance and comments made by Drs. Parker and Kass earlier and that is really one of -- I won't go into great detail with this, but really underscores the critical importance of bringing our communities in as leaders, not just as advisory boards, but as leaders to assist us as we move forward by carefully listening to their concerns and

incorporating their concerns into our efforts.

I think the idea of a community liaison which was discussed by Dr. Kass I think is a tremendous idea. Taking a local individual to work within their community; somebody who is respected and has done great work and to really guide the efforts in that community.

I think that carefully planning out our discussions at appropriate educational levels with a focus on the interests of the individuals and the individuals within the community and thoughtfully discussing what we need and what they need are critically important.

And as I mentioned, my discussions throughout the region really strongly underscore the vital importance of hearing from the community the issues that they have related to health, which are sometimes significantly different than we hear both in academics where I have spent much of my life and in government where I have spent much of my life. I guess the power of the community is really the greatest potential for success we have.

Within the Federal Government I think that we have done a pretty good job over this experience and others in working together as collaboration. I have seen NIH, CDC, the Coast Guard, many others, OSHA, others, FDA work together in a way that to me was unprecedented. My hat is

off to those in the room who have really done this good work. There is still work that needs to be done and clearly within the Federal Government there are similarities to academics with jealousies between departments and so forth just like we find in every situation.

But what I have found is that if we are able to step up to the mission as we are here and as we have done so far that we will be able to get through that very well. I think we have a real and a fairly rare opportunity to further integrate the culture of community into the Federal Government and into academia by this experience particularly if it is broad and widely disseminated throughout the government with wide integration of effort.

I think our President, I think our secretaries and our cabinet certainly get the importance of community and I think this offers the opportunities to bring it into the halls of the majority of government as well. Thank you. That is all I have.

MS. JACKSON: Good afternoon and thank you for inviting me today. I am Princess Jackson, the Regional Administrator for the Health Resources and Services Administration Office of Regional Operation Dallas Regional Division. This is an area that is going to encompass

looking at five states and that is Arkansas, Louisiana, New Mexico, Oklahoma, and Texas.

I am here today to provide you an update to the agency's response to the recent Gulf of Mexico oil spill and our ongoing efforts to anticipate, monitor, and respond to the potential health threats to workers and the public. And these are prepared remarks.

HRSA is committed to ensuring access to medical and behavioral health care for workers and families impacted by the oil spill. The department is especially concerned about the health of clean-up workers who have been exposed to oil and chemical dispersants and have taken the lead in making sure that worker safety remains a top priority. Community health centers located throughout the Gulf Coast region continue to provide primary care for community members who need medical evaluations and treatment. Today 91 health centers are providing coordinated medical, mental health and other services to almost 300,000 patients across the New Orleans for parish area.

To date, HRSA has not received information indicating a significant increase in the number of patients requesting care from HRSA grantees for health effects from the oil spill. HRSA remains in contact with HRSA-funded

organizations in the Gulf area regarding their role in supporting efforts to help clean-up workers and others affected by the oil spill maintain their physical and mental health.

In addition, HRSA has maintained NHSC, National Health Service Corps clinicians who served its sites along the Gulf Coast and use HRSA poison control centers as part of the department's coordinated action plan to help residents.

HRSA supports continued operation of the five poison control centers currently taking calls from the public. We expect there will be a continuation to the high number of calls over the next six months to expand access to health care and attract primary care physicians and clinicians to the Gulf Coast regions. The National Health Service Corps loan repayment program already provides loan repayment to eligible clinicians to work in underserved areas like those along the coast.

In conclusion, the agency remains in contact with HRSA supported organizations located in the Gulf area regarding their role supporting efforts to provide health services to those impacted by the oil spill. Thank you.

MS. RUSIECKI: Good afternoon. I am Jennifer Rusiecki and I am with the US Coast Guard Reserve and

joined today with Commander Erica Schwartz with the US Coast Guard. And the first thing we would like to say is Admiral Tedesco who is our Chief of Health, Safety and Work-Life apologizes that he couldn't be here today, but he has expressed very strong support for this study and that is why we are here today to discuss what the Coast Guard could provide to support this study.

Probably one of the more valuable that we can provide is a sort of roster of Coast Guard Deepwater Horizon oil spill responders. This is something that was devised after Katrina to provide a tool whereby people could request assets in the Coast Guard. If you are in the Coast Guard, you can say we need this particular asset and then somebody who has the asset can respond and say okay, well, we have someone that can fill that. And this thing is called the Mobilization Readiness Tracking Tool.

And basically what it has that is of value to this effort is a start and end date of people who were deployed to the Gulf. It does not include very detailed information about job tasks that people are involved in. Probably the most detailed information it includes is the general office where people were working or under which people were working if they are working in the field.

Not all Coast Guard personnel who responded to

the oil spill are included in this tracking system, which we call the MRTT, the Mobilization Readiness Tracking Tool, and that includes people who may have been on cutters who were responding, aviators who were responding and aircraft. We have been trying to put together a list of all of the people who have responded. That would be comprised of this MRTT roster, the list of people who were assigned to cutters and we are getting pretty specific information from the cutters. We are getting exact crew lists of people who were on the cutter during the period of interest from April 20th to the present. That would potentially be available. That is with respect to the exposed population.

With regard to the non-exposed population we basically have information on all of the other people in the Coast Guard. This is something that would have to be determined later on. Because all personnel in the Coast Guard are supposed to be mobilization ready, they have gone through an annual physical -- not a physical exam, but it is called a personal health assessment, periodic health assessment and that is an annual thing. Everyone in the Coast Guard should be ready for deployment. Of course that is not the case for every single person, but in general it is. We could provide the entire Coast Guard who is not involved in a response as a non-exposed part of the cohort.

Now trying to get at some way to identify those who were ready to go and ended up not getting deployed may be a little bit more challenging, but we can certainly discuss how we can go about doing that.

We also are gathering data from a survey that we administered to all of the responders. This was filled out upon demobilization by all reservists and at check out by all active duty personnel and civilians who responded. This survey contains information on location. It is general information on location of the response efforts and the missions performed as well as self-reported exposure.

The weaknesses that the current data that exists does not distinguish between the place and mission. For example, someone can list multiple places and multiple missions. We wouldn't know what people were doing where exactly.

And then finally we also have -- since we are part of the armed forces, we are part of the Defense Medical Surveillance System. There are some linkable medical data that exists on Coast Guard personnel as well as was mentioned previously, the Serum Repository. And I just mention one thing about that. The rules of the Serum Repository of that you can only access .5 mils of serum per person per blood draw, and those serums having kept at

minus 30 degree Fahrenheit. One limitation is that we really don't know anything about their processing. They come from all over the world. They are whatever is left over from the HIV testing.

Is there anything you would like to add? Okay.
Thank you.

DR. SPAHR: I am Jim Spahr with NIOSH. I help lead our response in the Gulf in this particular event. My job was the primary emergency coordinator for our agency to get our experts and subject matter people into the field and I helped lead the surveillance work collecting all the information and gathering the rostering information from the various responders.

NIOSH recognizes that this is a complex event. There were complex exposures. There were mixed populations of workers whether they were response workers, remediation workers or just other occupational workers in the local community as well as the community residents and their extended families. It is a complex event and it deserves a better understanding of the potential longer term health effects. NIOSH is very supportive of having multiple public health research modes come forward and look at this issue. As was earlier stated there is just not much good research out there on the long-term health effects from

large oil spills.

NIOSH's primary role to be collaborating in this longer term research approach would be to make all of our information available and as transparent as we already have. We have shared our roster of 54,000 response workers. We have shared our access to the BP employee list with the study group. We continued to analyze and interpret and post our HHE information on the Internet and communicate that to our state partners in weekly telephone calls with the state health officials.

We have done a couple of unusual things that I think have set a precedent in this event that will most likely happen in future events. I think it is remarkable that NIOSH partnered with OSHA to jointly issue interim guidances and other information. That will continue into the future. We will continue that mode of co-branding guidance material for the public that will help decrease uncertainty in future responses.

Also another unique thing that we did was our collaboration with BP itself, the responsible party in this event. Never before in such a large-scale event has the Federal Government had access to injury and illness data as we did in this event. We will continue to post that information on the web and interpret it in a public health

way. Those were two very unique things in this event I just wanted to highlight.

And the last comment I would like to say is that as far as moving forward in providing additional information for the long-term study, NIOSH is still continuing to conduct toxicology studies. We are doing animal-based research in dermal exposures and respiratory exposures from dispersants, oil mixtures and certain combustible materials that were related to in situ burning.

All that information will soon be posted and made available in a very transparent manner. We will support the research in that way. That concludes my remarks.

DR. CONLON: I am Michele Conlon. I am the Assistant Lab Director at EPA's Office of Research and Development. And I serve as the liaison for the laboratories for exposure and also for health effects for ORD to the agency for the Gulf Coast oil spill response. It has been a fun summer.

First I want to emphasize EPA's commitment to this study particularly ORD, our Assistant Administrator Dr. Paul Anastas. We are very committed to this study. EPA's mission is to protect human health and the environment.

We have, you wouldn't know it from the press, but

a very limited role in the deep sea emergency response. I think our role is limited to keeping and processing the applicants to the National Contingency Plan Product Schedule and making sure they do their flask test correctly so we can put them on the list of dispersants to use. It doesn't go much beyond that out at sea, but we have been right there all along helping out and partnering with the other agencies.

As I said, our mission is to protect human health and the environment. We don't have delegated authority to look at workers and we are very excited to collaborate and partner in this study because we would consider worker health and exposure and effects data to be an invaluable sentinel to gain insight into the general population; the effects of the general population and the nearby communities will see from the Gulf oil spill.

In our role, we have analyzed over 2000 samples of water and sediment for the variety of toxicants and pollutants in the oil and dispersant as well as background in situ levels. And we have analyzed over 3000 air samples to date. We have a very good picture of what the contaminants are that are reaching the general population.

One thing that we bring as an asset here is not just our analytical capabilities and the library of

background data, but we also have some research tools that may be unique across the federal families. One of them that I want to highlight is our exposure reconstruction approach whereby we can -- it is a biomonitoring design where based on a current sample we can know certain amounts of information about potential exposure. We can help reconstruct the extent and the mode of action and what happened to the individual whether they were exposed and to what extent.

I think sadly but somewhat to the benefit of the study we would know of the exposure dates to these workers and I think that the exposure reconstruction process that we have been developing and have at hand could be very useful for this study. I look forward to that collaboration. Thank you.

DR. MANOLIO: I really just want to say how grateful we are to the various agencies, the federal families as Michele referred to them in terms of the opportunities that our study has to contribute to your work and that you have to contribute to ours. I think in many ways we can make the response to the next effort even better by doing that.

DR. GOLDMAN: Great. We do have a couple of minutes for questions and discussion before we go into the

next session.

I did have one question and what that has to do with is that certainly we heard and we saw in the protocols while some thought is being given to what kind of information to give back to study participants and that where there are clear guidelines such as the clinical guidelines around blood pressure that some of these things will be thought through well in advance that if you have blood pressures in very high ranges, what to do with that. And it did occur to me, by the way, Princess Jackson, that perhaps HRSA could help in some of the low access parts of the region with linking people to medical care. That could be a nice help.

But it also occurred that there are a lot of measurements that are going to be done such as if there is really going to be evaluations of levels of chemicals say in house dust or in blood or urine that where it is very difficult a priori to lay out the same kind of framework that one might for blood pressure, but there could be the possibility of finding results that are unexpected for which there needs to be at least consideration of action that may not be action that would be taken by the NIH, but rather would fall into somebody else's jurisdiction whether it is EPA's or NOAA's or NIOSH or whomever, OSHA probably

more like would be responsible. And whether there has been any kind of consideration of having some kind of a monitoring committee that might monitor those data, engagement of the Federal Government, and again remembering because it is the Federal Government there may be an expectation that there is that kind of communication.

DR. MANOLIO: That is an excellent point. And I think we need to find ways to do that very effectively without taking the time of too many people to look over data that aren't critical and yet we may not know what are the data that are most critical. Our plan at present and I would love to hear what people would suggest the best way forward is really to convene the group that we convened on August 19th periodically and probably for some key individuals ask you to become partners in this study as was suggested earlier this afternoon and actually become investigators with us on that. But we would really love to hear your suggestions on how best to get this information back to you.

DR. GALLOWAY: Personally, I think that is a great plan. I think that the meeting that we had between the federal agencies was very effective and brought a sense of comradery that I think could be built upon and would allow us insight into the work that continues on. So any way,

that we can participate and support NIH in this role certainly very willing of course.

RADM DEITCHMAN: I would echo Jim's comments. I would also raise a question that I don't answer for and that is I agree that there are some functions that other agencies may be better equipped better to handle than NIH. For example, your example about how we need to establish a mechanism where health problems that are identified and of course the study can be referred to providers.

At some point looking at the numbers we are talking about we might be asking HRSA to undertake a sizable commitment maintaining having some people engaging in that as their full-time responsibility. When do we need to start expanding what we think of as the funded parts of the study? When does HRSA need to get some money to support that their provision of that adjunct as oppose to just saying okay HRSA, you got this part of it now? It is not just HRSA. I don't want to put Princess Jackson on the spot.

MS. JACKSON: No problem at all. I do want to say that we are in the preliminary discussions of this right now. We are still looking at ways that we would be able to provide the assistance that is needed. At this point it has been determined that most of our community health

centers are somewhat away from where this is actually happening and so making that connection to be able to get them there has been something that we have been discussing. We are still in those preliminary discussions at this point of making that determination as to how we would best be able to serve.

DR. GOLDMAN: Questions or points that members of the committee want to raise at this point with the federal panel?

DR. PARKER: Not to put anybody on the spot, but let's just say I am there and I am an interviewer and I have gone in and I have seen someone and their PFTs don't look too good and their FEV1 and their FVC are way out of line and they are wheezing and they are short of breath and they are a little hypertensive and I am there for two-and-a-half hours. I am going to pay \$25 for their time and the nearest health care provider that could see them is three hours away. What exactly do we say and do to that community because word will spread like fire that we are in there and we are talking to people? It may not happen a lot, but it doesn't take many. And what that does to enrollment and to the kind of responses that we get from others who hear about it. How do we figure this out before we get started?

DR. MANOLIO: You raise a good question and one that I think keeps many of us up at night. You are absolutely right that we may walk into a situation that we hadn't anticipated, and those are things that we have to lay out before we start as much as we can. But you never know. We can't have a protocol that says if they are wheezing at this level or if their PFT is that level, do X, Y, and Z. We have to hire interviewers and train them in a way that they know when they need to call for help and then we need to have that help system in place. And that is going to vary from community to community and from provider to provider and there may be community health centers and there may not and all of those things clearly need to be laid out. They are not laid out yet.

DR. PARKER: I just have one other thought. I love the way you turn to them and ask their input and their opinion about -- a few minutes ago when you turned to the panel. I am just wondering if there is a way to turn to the community and ask that and really get their input up front about the fact that the intention of the study is the following. We are going into it -- we know a few things, but there is a lot more where we don't know, which is the purpose of doing the study to start with. What we want to do is work with them to figure out how we all stay on the

same page about what we did.

DR. MANOLIO: You couldn't be more right. Aubrey Miller is coming up behind you to tell you the efforts we started in.

DR. MILLER: And that is what have been asking them is specifically those types of questions and actually what would make sense for referral basis, what kind of services they employ. And even talking to some of the local health care providers saying would this be satisfactory. Could we refer them? We have started to undertake that but it is going to be an extensive outreach effort.

DR. MANOLIO: Would you have any suggestions as to how we could better do that?

DR. PARKER: Yes. I would. It is a big study. It does present enormous opportunity and it is on a fast track and I get all that. But it always seems to me that very well thought out qualitative stuff up front before we go after the quantitative. I think a systematic qualitative look at some of this might really help with understanding some of the themes and some of the approaches and really what is on the mind of the people that we are really trying to link with could really be insightful more than just pilot testing of quantitative, but really sort of

stepping back and making sure that up front when we engage that we are all sort of on the same page about what the top three to five biggest issues are and making sure that from the base all the way across and across all the constituencies we are all speaking the same language about the same topics.

It just makes me kind of nervous. These unexpected we are going to respond on the other side versus we at least are on the same page at the beginning. I think something that takes advantage of the great qualitative methodologists and sort of social science approach to some things when you really don't know and you want to open up and cast a big net up front could really help inform some of the issues that I think keep resurfacing and making us -

DR. GOLDMAN: As a very pragmatic suggestion to make use of the local public health infrastructure and they know who is practicing and caring for people in their communities. And don't step on her toes certainly or don't assume there is no one there before you check because there may be people there who are ready to receive them.

DR. SANDLER: Can I have clarification -- your comments were more about what the participants expect. Is that --

PARTICIPANT: -- interviewing and staff on both sides --

DR. SANDLER: I think the idea of finding out -- if we go into the community and identify somebody that we think has a problem and we start making referrals and they want us to mind our own business, we ought to know that up front too before we start coming up with complex plans and follow up for people who don't want to do this.

PARTICIPANT: Echoing on Ruth's comment is that I think we should do a focus group, not just with community leaders, but actually community members because we have been talking about community leaders. But as we all know, community leaders have their own biases and their own opinions in terms of what they want for the community and sometimes it does not really represent the scope of what the community really wants. For example, if you do a study and then you get the wrong partners and there is conflict with the partnership, what happens? Maybe the community leader might recommend people to your study but those members might falsify the data. They might, okay, I will do it because my priest or my preacher or my monk tell me to do it, but I really don't have a vested interest in it and then it is easy to say yes to everything.

Especially I know the Asian American community

intimately. They are very respectful. They don't say no when it is coming from their leader particularly the preachers, the religious leaders. They won't say no, but in terms of your results it might be wrong results because they are just doing it because they were asked to do it. I think it would be really important to really have accurate data.

Following with that are interviewers, bilingual interviewers. Having information translated is not enough. The bilingual interviewers outreach worker really needs to know the information well. They need to be really intimate of the questions that are being asked so it won't be just where they are just reading the information or maybe the translation is done wrong. That is really important in terms of translation. It is not just the idea about translation, but it is about health literacy within the interviewer and outreach workers.

DR. GOLDMAN: We have several people who have had their hands up. One last comment, go ahead, from a committee member and then those of you who want to speak can you stand up at the mikes actually so I can see how many of you there are. We have about six minutes left in this session.

DR. COHEN: I will be brief and I don't want to

beat a dead horse, but we keep referring to terms like unanticipated experiences. I think with tens of thousands of visits I would be shocked if within the first two weeks you don't come across severe hypertension, out of control diabetes, status asthmaticus. And I think working with Miss Jackson and when you have someone in the community and you are in a zip code, we should know exactly who we could reach out to if someone doesn't have a primary care physician. If we do it by zip code or other means, the person there in their house will know exactly where they can refer someone to instead of trying to back into that later.

MR. EGGERT: Yes, Russ Eggert, again, with Florida Department of Health. In terms of the last comments I would just recommend at least in Florida to be sure to reach out to the local county health department. Many of the health departments in Florida provide primary care services. A number of them are also federally qualified health centers. I think that would be certainly a good resource and of course you would want to work with them up front to see what arrangements might be made to help in that regard.

DR. MASON: I am Tom Mason. I am formerly with the NIH and I know here at South Florida, Florida's first

college of public health. We used to be able to say we were the only college of public health. And the one thing just echoing on what my colleague here said from the state department of health is Admiral Deitchman knows. These states are networked. We are a sister state to Mississippi with regards to preparedness. You have a network of individuals who are already primed to go out, to reach out, and to provide these types of, if you will, interactions and referrals. I would encourage all of you to think along the lines in addition to all of you, many of whom I know, and all of the good work that you are doing to look to some of the other local resources. Our economy health officers are extremely well trained and we exercise them unmercifully with regards to disaster preparedness. Just ask us. We do that. That is why we are number one.

Also, we are number one. We are number one because we sit with the communities. We sit with the communities. It is truly community engagement. When we sprayed our population here with malathion, we all came together, you better believe, hello, as Florida's then only college of public health.

And I would encourage you when you think about community advisors, community partners that you don't lose site of the fact that in addition to the county health

officers, in addition to those particular groups, you have many of us former PHS officers who are scattered to the four winds who are out there. We are predeployed as Admiral Deitchman has heard me give this talk before. We are predeployed. We are ready and more than willing and more than able to facilitate.

You have select subpopulations. We have plenty right here in Tampa. There are plenty in the four states. Use those resources effectively. We have raised our hands more than once to serve and we are proud to serve again. Thank you.

DR. OSOFSKY: I will be extremely brief because we could make similar comments about the health departments and the clinics and the federally qualified health clinics that are available. In addition, one of the things that is going on paralleling our study is resource mapping in the most impacted areas. I would encourage if it is all possible with the other states that are involved if we have this resource mapping so that it is clear where resources are available also see where gaps are, but where resources are available so that in addition to emergency lines or hotlines one can look at what are the nearest resources of a quality-type nature, which I think could be very helpful in these visits and during these interviews.

DR. LICHTVELD: From a practical perspective it takes nine months to do a good community-based study. We don't have nine months. That is very practical. We will have to do what our next best is.

Secondly, when we say the community there are many communities and the parish health department are very much part of that community. In addition to the governmental resources one resource that is region wide and HRSA is too are the pediatric environmental health specialty units. Then you know those. They are in region six and that is a resource.

Also, we tend to gravitate very quickly when we talk about health care to physicians and nurses. There are pharmacists. There are other paraprofessionals that provide the kind of health care that we focus on.

And the last thing I want to say is I didn't get to it on my slides, but there will be people who are hypertensive and don't have medication because they can't afford to fill it or they didn't have time. There will be people who are in status asthmaticus almost who don't have medication. Just asking the question they will give you the right answer, but that is actually not their health status.

DR. GOLDMAN: Thank you all. That was a

wonderful panel and to all the audience for participating in this. Did you want to make one last comment? You can.

DR. MILLER: -- we have the agency groups too because there are other studies that are going on just like CASPER was just done by CDC out in Alabama I believe. And all these networks they used the referral ideas about what their strategies were when they went and did the CASPER about how they are going to refer people so that we could develop whatever is going on whether if it is BRFSS or other surveys to think about unifying this so there aren't just referral networks. They are all over the place that this becomes really a collective strategy of how we do this and to make sure that those assets are utilized in a thoughtful and coherent way otherwise it is just all over the place. I just wanted to throw that out there.

DR. GOLDMAN: Thank you very much for that and thank you all.

(Applause)

We are going to move on to our next panel.

Agenda Item: Summaries of Panel Discussions

DR. FINEBERG: Ladies and gentlemen, thank you very much. This has been a very rich and informative discussion and I am very pleased that we have an opportunity now to revisit -- we have an opportunity now to

revisit with the chairs of each of our panels for their reflections and points that they especially would highlight or like to augment from the earlier discussion. And I suggest that we take them in the order that we heard each of our panels and that means, Dr. Goldstein, we will begin with you on the discussion about study goals and design.

DR. GOLDSTEIN: I think we decided that more research is needed. And for that we have been here all day. We have heard recurring themes throughout the day and one of my problems in trying to write these out was trying to think of what we said specifically in the morning that was not repeated throughout the day. For instance, we just heard the concept that it is a complex study with complex population and that starts off the challenges and you heard in the research design approaches issues having to do with how does one set up a study of this magnitude while not being able to do the things that one would normally do over nine months, was it that you said? That would be for a community-based study but perhaps a year down. I don't know how much time you really like to set this study up.

PARTICIPANT: -- four years to design the last cohort.

DR. GOLDSTEIN: We have heard over and over again about the issues of the exposure side of it is going to be

difficult because we are starting late. There are lots of databases that are out there that will be helpful, but we have just heard how they are not really very well linked together so linkage of some of those databases.

We have heard about the need on the exposure side to have some opportunity to validate what the exposure was using a couple of different approaches on the same population so that you have some subset of your populations on which your exposure is reasonably acceptable that that is really what the exposure was.

We heard from our speakers about the importance of being sure that we have outcome data that are going to be meaningful in relationship to the exposure data. Dale put it very well at the beginning to say that we can't really be fully predictive of what the outcome is going to be. This is not a fully direct study. Did the agriculture health study which also had lots of potential end points and you are coming out with all sorts of interesting potential associations, hypothesis generation, but there was a very strict hypothesis which guided that study which was the fact that there is a lot of Non-Hodgkin's lymphoma among agricultural workers. There are other cancers among agricultural workers. That was a very specific hypothesis.

This is much more of an open ended. What are we

going to find given the exposures? And even more of a problem because we are not sure what the exposures are in many ways so that it is not -- it would be almost simple if it was the volatile hydrocarbons that we knew people were being exposed to because we have a pretty good idea of what benzene does and toluene and et cetera. In fact, we are not quite sure about the toxicological endpoints that are of concern for moose or tarballs or however we are going to describe what may be the major exposures to people.

It was -- in fact, Lynn, I think brought it up about the issue of the NIEHS at the same time doing more toxicological studies. We heard from NIOSH that they are doing toxicological studies of some of the exposure. Things just sort of helped guide the endpoints in the study.

There were a number of suggestions that I won't bother repeating because again they keep on getting repeating having to do with the specifics of being able to determine what are you going to do with exposure data that is missing, what are you going to do with -- again, I am repeating myself now with the validation of the studies.

You have a design which includes a large group and a smaller group. You made an estimate of 70 percent of what you are going to be able to do from a large group to a

small group. You have heard lots of different -- during the day you have heard lots of different folks saying well you are never going to do it or oh you will do it easily because these people are really cooperative. You are going to need to pretty soon get into the field and find out what that kind of response rate is going to be if you are going to be able to really mount this study in any organized way. I very much hope it is the latter that you will get lots of cooperation very quickly, but obviously that is an important thing as part of your experimental design.

Those are just some of the issues that came up throughout not only the morning, but throughout the day.

DR. FINEBERG: Thank you very much, Bernie. Next we will move on to Francesca and discussion of the data collection and cohort surveillance and maintenance.

DR. DOMINICI: I will provide -- try to do it in a high level summary what I have heard today making some main points. First, I think I heard the importance of try to set the bar very high and that was a point that Harvard Fineberg made or how we will make sure that these studies will be part breaking and of course it will not be probably will be hard to be part breaking in any dimension but what will be the dimension where I think that this could be really something that could be considered as a new

framework for conducting epidemiologic studies of disasters.

And the panel was a lot of discussion about the devil is in the details and the importance of documenting since the beginning how the study will be run and so in terms of defining the administrative core. Who is going to do what?

There was a lot of discussion and that is how I defined it and the general umbrella of the data core, which would be really documenting and deciding ahead several very important internal issues on data quality, data linkage, which is coming up all the time, data sharing, data management, how data query will be addressed. That was in the detail.

David Tollerud brought up the importance of also trying to develop a sustainability plan as basically as what would be needed so then all of these efforts would be sustained.

There was a discussion about how to prioritize the specific question that will be addressed by the NIEHS investigator as a part of this study. What will be further studies? There is a part of a RFA.

There was a discussion, I think, and it called for the importance of adding interdisciplinary expertise as

well as a data collection expertise of the study team and I think that was a team also which was very prevalent in the last section that we have.

We can learn on some success stories on well-planned data collection for research instead of being reactive and I think David Tollerud brought important I think was a meaningful and important example of the Army and how actually they were able to make significant progress from starting from being in a position where they didn't even know who was exposed to the Agent Orange and then ending up now with actually having a well-planned monitoring sampling.

I am just going to conclude that with some of the ethical issue discussion, there was posed a question. Is it that -- if we can come up with disease, is this guideline or how to protect personal information when we are in the long-term studies of environmental disaster?

Also, there was a lot of discussion and an important point is that how to formalize and crystallize of how the information would be collected. What type of information will be disclosed? And then I think very importantly was to plan ahead and what type of information we will need to ask and whether some of them are sensitive information would be very needed.

DR. FINEBERG: Thank you very much Francesca. Next we will turn to Susan Santos for relating to the community.

DR. SANTOS: Great. I will try to put this in a couple of categories that I heard and then some themes in those categories. Clearly the first we have heard a lot today about engaging the community and what that really means. We heard that it was important for study design, enrollment, retention, and ultimately the credibility of results.

One of the key themes that came out is that engagement starts with listening and listening is not a static process. We moved on to who should you be listening to and there has already been efforts with the webinars and some sessions and focus on NGOs and community leaders, but a number of times today the recommendation came out about going out and doing focus groups, which I would again support and endorse and that we need to think about that with the general public, the different states, the Asian community, the African American community, the Latino community, the Korean community, all the different communities that will make up and comprise people who are normally employed full time, people who are not employed full time.

I think if you start to look at the same matrix you are going to have for who gets into the study will give you clues also as to who you want to talk to and listen to in terms of focus groups.

Focus groups can also provide an opportunity for pretesting of materials; the consent form being one. At least some of the general language that might be tricky. We see this again and again that people simply don't understand terms that kind of roll off of us as being clear. That is an important thing to do.

There was discussion about moving beyond looking at community to inform towards a more collaborative model, and again thinking about what does that really mean in the context of this study. Is it building community infrastructure so that the community has an ongoing way in network for looking at environmental issues or health issues? Is it looking at health resources? Is it providing resources to deal with individual health issues? I think we have to really think about what collaborative means in the context of this study and what you can and cannot do, but that clearly needs to be thought about.

Discussion today focused on the importance of not just the CAB. I think everyone endorsed the idea of a CAB. There has been research going on from day 101 in public

participation about community advisory boards, but really again in terms of thinking through how to establish this one, multi-state, number of different populations again. What does that need to look like? Who should be a member? And clearly one of the lessons learned from CABs has been setting up the expectations of what the CAB is for, what is its purpose, what are the expectations on members. Is this something that is going to be yearly? Every two years you rotate. There is so much richness to thinking about the CAB that it deserves I think an in-depth discussion about that. It is a critical component of it.

Again, bringing in community members as leaders, not just in an advisory capacity was talked about, and recognizing that the CAB is not synonymous with community involvement. There was also a recommendation for community liaisons, which I think was a wonderful recommendation and something to be considered.

Move away from that broad category of engaging the community and there is some overlap here, but thinking specifically about consent, enrollment, and retention. There were discussions about privacy issues. A lot of discussion about how do you in frame the value and the benefit for individuals participating. And there was language in the consent form. I might have some specific

thoughts about some of that specific language.

And then how do you set expectations about the study will do and won't do. In research that has been done looking at how people perceive and remember community health studies, kind of epi-studies versus risk assessments versus what they think it is going to give them. It is very clear that there is not a great understanding even when people say they have been given informed consent about there is still this expectation that it will answer individual health questions and not just the population. And I think that will be one of the richest areas where impact can be made here about how do we bridge that, thinking broadly about that, and creatively about that. But clearly setting expectations for people in terms of that.

The issue of incentives has been discussed. I think there were comments that you have obviously already taken strides in terms of -- gift cards are great. And don't wait three weeks. Give it to people now. But I think one of the things that still hasn't been fully perhaps discussed is the notion of how much and is it the same amount to everybody and again thinking about this population clearly something. When you are looking at the length at time for both getting people -- it says something

about how much people are valued. That is a big part. If we are telling people your participation is important then sometimes how we remunerate people is a sign of that value. I think we have to think about the message that says.

The issue of training consenters and interviewers I think was important. Training them and what we call RTQs, answering tough questions, the ones that may be about fish levels or water quality. The ones that aren't just about the purview of the study, but a broader set of Q and A and resources that can be provided to people because they are the frontline. If you can't score there, the ability for people to want to stay in the study is going to be greatly diminished.

Given the constraints in consent language that you might have from a legality. There are ways of doing supplemental materials that are really high level and easy that don't undercut the legality of making sure someone understands, but really get at that dialogue that was talked about before which is what did people understand this study to be involved and what will it do and what will it not do. There are some creative ways I think that that can be built into the consent process.

The last thing and I don't like saying the last thing because it always is the last thing is the notion of

communicating clear results. I think everyone agrees how critical it is: clear messages, concise messages. Reality often is that is usually the last thing to get done in part because we are waiting. We are busy doing the work of enrolling and updating and we don't have the results. But I think there are a number of things that can be thought about up front in terms of communication. We know issues of uncertainty. We know issues about how you explain associations versus cause and effect. There are a number of things that could be looked at, again, relative to the study of design that will give us the lead to what are those key communication challenges that are going to be faced and can we start working through those now. Again, that is something I think there has to be focus on.

Making referrals was talked about; the need to have that referral. If you find the high blood pressure, if you find somebody who has glucose levels. Think about the use of social workers who are experts in being able to triage resources within the community and what role they might be able to play as part of that.

I can't stress enough about the issue of communicating household sample results. There has been some interesting work done by Silent Spring Institute and others were looking at environmental household samples

where there are no standards. You can't compare and say it is below the threshold or it is above this. And again referrals might be what people do if they find they have high levels of PAH or high levels of pesticides in their home. Having to think again what are the resources that we give people for those things and not just for blood pressure. Some of those things there.

In pointing out that -- people have pointed out that health literacy is more than a matter of language and so cultural sensitivities and a number of things into health literacy. Will that be a part of the design in terms of thinking again about the health literacy aspects of this?

Communications plan. That was mentioned. There was note of a communications plan. Probably looking for some more depth on that again. Channels is clear when we talk about newsletter or web 2.0 or just websites, but really the heart and soul of segmenting it. What are the issues? Thinking through more thoroughly a communications plan. And then again last but not least what is the plan for sustaining community engagement involvement throughout the long period of time?

DR. FINEBERG: Thank you very much, Susan. And Lynn, your reflections for the interagency participation.

DR. GOLDMAN: Well, it seemed to me that given the unusual nature of this study and that is that it is basically a disaster epidemiology study. It is a very different kind of piece of research than what the NIH is usually involved with. And also that there is therefore great urgency in trying to move things forward that there seems to be an opportunity that a number of the other agencies have the ability to help contribute to moving things forward in a way that is much more collaborative among the agencies and we would usually see for research.

We had heard that there is a lot of monitoring data both on the environment and on human health, a lot of the human health data collected from the states that there is effort underway to quality assure some of that. It all hasn't been assured. And there is effort underway to bring the data together into some kind of a single tool and that would seem to be potentially very useful thing for the people involved in designing the study if that can happen sooner rather than later obviously.

That there seemed to some unique skills that are available in some of the agencies that might be helpful, such as one example that was given this exposure reconstruction capability that might be useful.

That other agencies or others within the NIH, us,

could help us with the toxicology and perhaps helping to a priori come up with alert levels or ways to interpret data.

And more of a personal reflection on my part but post the Katrina episode and all of the issues that occurred with the formaldehyde and the trailers. I think that one thing that we saw is in the context of having gone through a disaster that people have a view that data should be provided to them immediately and the interpretation immediately. And that is going to be very challenging. It is not the usual way that epidemiology is done. But I think that is a case worth looking at carefully in terms of a process.

Obviously that the timing of such collaborations is going to be important if those resources are to be brought to bear that they need to be brought to bear in a timeframe that makes sense in terms of progress moving forward for the study. Although it actually occurred to me again in editorial comment that the passive phase may be doesn't need to be as informed by some of this information as the active phase when actual measurements are being taken on people and even more input is needed for the biomedical studies and so that maybe there is a way of timing all of this so that it could be reasonably brought together.

We heard about the potential for making a mapping of clinical resources that could be very useful not only for the study but perhaps for other purposes.

And not last but not least certainly that the federal agencies seem to have a multitude of various partners and relationships and people that they are working with in these communities already and everything from the public health agencies. It is the CDC seems to connect with. HRSA connecting with the federally funded clinics and I am sure that you could tick off a number of others where there are these preexisting relationships that perhaps could be utilized to kind of amplify the ability to reach people in the community.

There seemed to be a very complex web actually of federal agencies involved with this and it looks very challenging to me. I noticed on the slides the way that the agencies not only wear different uniforms, which were kind of obvious, but also speak different languages. I saw words on some of the slides that I have never seen before and I consider myself to be pretty literate. But I think from the standpoint of the public, it is one face and that is part of the challenge here with the vets(?).

DR. FINEBERG: Thank you very much, Lynn. Let me thank all of the panelists for your concise and informative

summaries. We really appreciate it very, very much. Thank you all very much.

(Applause)

I would just like to make a couple of observations from my vantage point observing through the day. I think it is notable that the only reason we are able to have such a rich discussion is because of the incredibly intense work that has already been accomplished mainly at the NIEHS, but surely with the support and engagement of all of the agencies, the partners, the participants from every side who have contributed to the development of the protocol that we had with us and it was a remarkable, remarkable start and I want to give tribute to Dale, all your colleagues at the NIEHS and elsewhere for doing such an incredible job getting it up to this point.

I can only imagine knowing Francis as I do that he gave the usual instruction which is do it fast, do it right, and do it economically to which the only logical reply is which two do you want. We can do it fast and economically, but it won't necessarily be right, or we can do it right and economically, but it won't be fast, or we can do it fast and right, but it is going to cost a lot.

The truth is we are asking you to do all three. And we are asking you to do it in a way that is path

breaking because this is a type of study which has never been assembled in the timeframe that you are being asked to assemble it and is being conducted under circumstances, which unlike the unusual Washington political imperative of time. This is actually scientifically driven by time urgency because the availability, the recall, and the consequences of this bill will deteriorate over time and therefore every week's delay before you can actually get started means a more difficult time of discovery.

I was reminded as we went through this day and particularly, Lynn, your last comment about language of a meeting I recently attended hosted by the Federal Reserve Board and the purpose of this meeting was bringing together for the first time they believe urban planning and public health to talk about cities of the future that would not only function well, but be healthy. And both sides were talking about the importance of the CDC and it was wonderful to hear both sides talk about that until we realized that one side was talking about the Centers for Disease Control and Prevention and the other side was talking about community development corporations.

(Laughter)

And I was thinking about that when we talked about the importance of the CAB, what is the A and you are

going to have to think about this A. Is it advisory which is the standard name? Is it assistance? Is it advocacy? Is it ambassador? What exactly are we asking the community to become in joining with us in partnership? And this brings me really to one of the key points. It may be very uncertain. Truly it is uncertain whether this study even if ideally launched will ultimately discover disease and health consequences. It is uncertain whether that will be an outcome.

But what can be certain is that from methodology, the processes, and the manner in which you conduct this study, you have the opportunity to set new standards. You have an opportunity to engage with a community in a way that has never quite been accomplished at every level in pre-planning, in conduct, and in analysis in the past. You have an opportunity to bring the various agencies more than eager to participate into new engagement on research and discovery for public health. You have an opportunity to put in place a new model that combines the protection of data privacy and access to data, which Francis started us off with this morning, in a way that has never quite been accomplished jointly in the past.

You have an opportunity, I would submit, to engage in a kind of active, pretesting that will inform the

study and not just give guess work about whether an incentive of this size matters or a letter framed in that manner would make a difference. Test it out. Get those informants to have those reaction groups in the area and actually see how many people and which group would sign up if we did it this way or that way. How many would like it that way versus this way? Know before you launch.

You have the opportunity here, in other words, with the parent study and the offspring studies which are already in process of hosting a sponsorship and funding to have a family approach to research which is very seldom carried out in a coherent way.

However the study is successful in the core science to understand the health outcomes, you have simultaneously the opportunity virtually to guarantee that this will be a very worthwhile initiative methodologically and in terms of both science and relation to community-based research.

I think this has been a very rich and a very worthwhile discussion and I want to thank especially all of the commentators and advisors who gave of their time today to participate in our panels and to give the benefit of their best thinking. And I want to thank again especially the committee and the staff who have made this possible and

offer my congratulations especially, Lynn, as chair to you for work going forward. And I am going to turn the program back over to you for final discussion and public engagement. Thank you all to the chairs very, very much and thank you all for your participation.

Agenda Item: Public Comment

DR. GOLDMAN: My understanding is that there is no list of people signed up for public comments, but that we are open at this point in time for public comment. There has been a lot of comment that has already been made, but I think this is an opportunity before we close this workshop if there are things that haven't been said that you think should be said. If you think that there are points that were made that were lost in the summaries that were just given or just ideas that you want to make sure are highlighted to come forward and do so. And so we have the mikes and please come forward. State your name. Thank you.

DR. TRAPIDO: Hi. I am Ed Trapido from LSU Health Sciences Center. We all know that of all the studies that have been done there have been no more than eight that have looked at health effects and a smaller number that have done long-term effects. The longest one was four years of mental health effects.

I have heard today is how to get this going. We all know that if we are going to look for the long-term effects of the exposures particularly for cancer and for other diseases of long latency, how can it be built and I know the federal budget goes year by year, but how can it be built so there is a structure that will allow and a sample size large enough that will allow long-term follow up for diseases which are generally rare but that this one won't be the ninth study that had a short-term follow up and that after five or seven years ends because there weren't enough people followed or because the infrastructure wasn't being built.

DR. GOLDMAN: Dr. Collins, can I ask you to -- and that has come up in an earlier comment as well, the issue of I guess the budgetary horizon and why does it appear so short.

DR. COLLINS: Well, it is a problem of course that the federal budget for biomedical research gets picked every year and you never quite know the trajectory and at the moment the trajectory doesn't look very encouraging given the concerns about deficits growing and the economy struggling and so on.

I think that was the reason, therefore, why this was scoped out as a five-year study but with the intention

of being able to extend it beyond that and I think Dale in the presentation made that clear. The extension beyond five years, however, would be of uncertain character in terms of whether this was record linkages assessing possibilities that by regular contact there were experiences of morbidity and mortality that you didn't expect or whether you would actually continue the process of coming to a more personal interaction with the participants.

Some of that, I guess, will depend upon what happens in the first five years. Do we begin to see hints of signals or not? There are certainly a lot of people out there who think this is way overkill and there is not going to be any medical consequences of what has happened here and this will be a tough decision to decide because probably in five years for a long latency condition like cancer we really won't have very much information to know whether we should keep going or not and that is going to be a tough decision that will have lots of inputs. I can promise you that if I am around in any kind of role here it will be done in a very public way trying to figure out the balance between the costs and the benefits of continuing this study. But I think right now it would be very hard to map beyond the five-year period exactly what we will want

to do.

DR. GOLDMAN: I would agree with that and it occurs to me that if I were trying to propose a study such as this one as an R grant that I would have a very hard time getting it funded for even a much shorter period of time because of the fact that it is in some ways exploratory and there are not that the hypotheses are broad and the system isn't really well set up for funding this kind of research. But to go beyond five years it is very difficult to predict whether the initial findings are going to be of a nature that people will feel that there is valuable information to be gained. And I think that that is fair enough.

I guess in terms of how we discuss it in the workshop report it is not that you are saying that it won't go passed. It is just that it is very difficult to predict the direction where the research is likely to go including whether it will continue to be a large study.

DR. COLLINS: I can make one more other comment since I am standing at the microphone here. The other aspect that is really sort of stepping even outside of this study and causing us to think as a nation going forward should we be better prepared the next time there is a disaster of some sort because there will be whether natural

or manmade. Natural disasters we have experienced recently with hurricanes and earthquakes and so on. And manmade ones there is a long list of scary things including awful experiences like dirty bombs that perhaps are lurking out there at least in our nightmares and maybe could happen in reality.

Shouldn't we be better prepared to think about a rapid response not just a response that is immediate trying to protect people against what are the health consequences are as soon as it happens but the research response and how do we have a program in place to be able in a very quick turn around with IRB approval and all of the other aspects of this to go forward. And does that mean we even need a fund if it is kind of sitting there to be tapped into for such disasters.

Nikki Lurie has been bringing this issue up and I don't know if she wants to say anything about it as we are sort of closing here. Nikki and I have talked about it. Teri Manolio has been part of that. Tony Fauci has as well. I don't think we would say at the present time we quite have an answer to this, but it does seem like a learning experience that we shouldn't miss the chance to reflect on.

DR. LURIE: Thank you, Francis. First, let me

just say thanks to all of you for being here today and for the really rich and informative and provocative conversation. I think it has been incredibly helpful.

With regard to this issue, I do think it is really important and I have been struck over the course of the last year as I have been in this position that we have had some pretty unusual events that we have responded to. Each hurricane is obviously a challenge, but we have had an H1N1 pandemic. We have had a massive earthquake in Haiti with untold kinds of injuries. And now we have had this oil spill. All of these things were clearly unanticipated and left us with a lot of scientific ambiguity. I think we had done some science planning with regard to planning for a pandemic and NIH did a fabulous job in particular getting up and figuring out what is the right dose of vaccine. Do we need one dose or two? Are there early signals that it is going to be safe, et cetera? And that was terrific.

But I think it is also fair to say that we were enough wrapped up in the day-to-day dealing with all of the challenges that it was harder to have the long view and say what science should we be doing. Fortunately there was a huge long history in influenza that really guided us in day-to-day decisions and a tremendous amount of science there.

With this event I think and many others that we worry about the science really isn't there and I am pretty convinced at this point that one of the things that I think we owe to future generations of people who deal with disasters is to do as good a job on the science as we can so that the next people don't have to confront the same situations that we do. There will be others for sure. But part of that may mean in fact thinking about as Francis was saying science as part of response. That we actually have a little bit of concept of operations.

And when something happens we say do we have the science -- what does the science tell us and then we say do we have the science we need to manage through this acute event and then are there scientific opportunities that we need to take advantage of so that we will never here again. How we organize that, how we fund it, how we do all those things I think should be the topic of further conversation and some really good thinking. But I am personally am convinced at this point that it is something that we need to get moving on.

DR. GOLDMAN: Before you came earlier, somebody mentioned an idea of actually preparing protocols ahead of time, pre-clearing them with IRBs, pre-clearing them with the OMB so that they are pre-positioned for immediate use

because those things take time to do developing, but the clearance processes as well. And we did not have OMB on our panel and that takes time too. Is that something that you guys are thinking about? I realize it is daunting because you are not sure exactly what you are going to have to do.

DR. LURIE: I will make a few comments in that regard and I think some of this about how we get the system organized going forward. As we plan for a pandemic over the last -- since 2005, there were in the national pandemic plan all kinds of things about protocols that were supposed to be designed ready to pull off a shelf in case X, Y, or Z happened. Those things didn't happen. Other things happened. Or that since people thought it was a really long way offer was sort of unthinkable or unimaginable. They didn't develop those protocols.

And so I think that the ideas are a really sound one, but I think probably as important is to have an IRB mechanism that can get moving very quickly. We missed some big opportunities even with H1N1 because it took IRBs and universities six months to turn around protocols. We need some kind of a national maybe IRB mechanism that can get moving pretty quickly. We need some way that we have a system with OMB that if you have to collect data in the

context of a public health or health emergency that you don't -- you can have a different way to deal with a very cumbersome clearance process and talk to more than nine people, et cetera. But those are system issues.

What I feel like our first order of business is to identify which pieces of the infrastructure do we need to be in place that will support the science around any kind of event one that imagine or one that we don't. I certainly think we ought to have our finger on who are the experts in the areas of the things that we are most worried about and know on a dime how to contact them. And then know on a dime that we would pull together a group and say while we are responding acutely and operationally, we need you to help us think about the science. But to get that infrastructure in place I think would be a really important thing for us to do and I welcome any and all suggestions and ideas about components of that infrastructure or how to make it happen.

RADM DEITCHMAN: Just to follow up on Admiral Lurie's comments, with this event when we talk about scientific research, we are talking about basic clinical science here. What are the health effects of this? I hope we would include -- expand that discussion to a sort of health care operational research. When these disasters

come along, we want to know -- just to take two examples from Haiti. When you have an airhead that has limited access, are we prioritizing the right kinds of aid to get in there as quickly as possible to save lives?

DR. GOLDMAN: I was going to say I know people like that too, but I think you are talking about something else. What is an airhead?

RADM: I am sorry. In this case it is an airport.

And the other is when we are sending down -- when we are bringing in all kinds of aid to provide orthopedic for the earthquake victims, is external fixation the right kind of -- the best type of clinical modality for low resource health care environment? It would have been great if we had been prepared to do case follow up to find out how those patients did. This is a raging debate in the emergency response community that we could have answered. There are several types of things that are covered by this idea of doing research in health care during disasters.

DR. GOLDMAN: Other comments? I see no one at the mike. There is one comment that I have which is that I want to very much extend appreciation to one of the staff of the IOM who put a tremendous amount of effort into making this day happen and that is Morgan Ford. And I have

something for you.

(Applause)

A little Florida souvenir, but thank you so much. You have no idea how little time -- we talk about doing it fast, doing it right, doing it with a low budget. Those are the people who do that. Thank you so much. And thanks to all of you.

(Applause)

(Whereupon, at 5:13 pm, the meeting was adjourned.)