



2015 NIEHS Core Centers Evaluation

Evaluation Advisory Subcommittee Final Report

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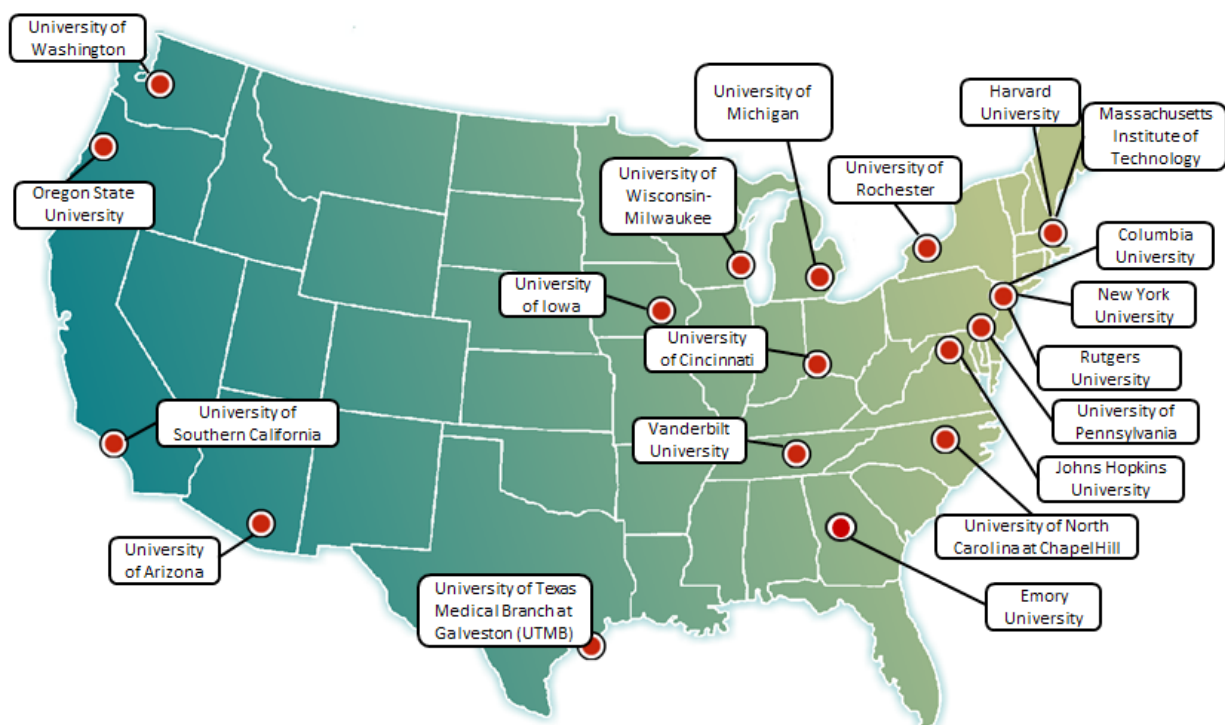
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Introduction

The Environmental Health Sciences Core Centers (Centers) program at the National Institute of Environmental Health Sciences (NIEHS) is a landmark program of the institute that has provided infrastructure support to universities across the country for more than 50 years. The aim of the Centers is to guide and support environmental health research at institutions throughout the United States, provide intellectual leadership in environmental health research, foster innovation, and support new ideas and collaborations among investigators. The Centers also provide career development for future leaders in environmental health science (EHS), by providing centralized scientific resources and facilities that are shared by investigators working on existing research projects funded by other research grant mechanisms. The Centers strive to translate research into public health outcomes and to foster community-academic partnerships through engaging communities in multidirectional communication with researchers (see Appendix A for an overview of the Centers program).

The following map shows the Centers that participated in the 2015 Centers evaluation. The Centers program undergoes a yearly competition, resulting in Center turnover and addition of new Centers ensuring that the environmental health remains cutting edge. The essential structure of each Center includes an administrative core, an overall strategic vision or theme, an Integrated Health Sciences Facility Core, a Community Outreach and Engagement Core (COEC), other optional facility cores, a pilot project program, and a career development core.



NIEHS conducts periodic evaluations to foster a culture of continuous learning and program improvement. In 2014, NIEHS formed an Evaluation Advisory Subcommittee (Subcommittee) to evaluate its Centers program (see Appendix B for a list of the Subcommittee members). This was the third programmatic evaluation of the Centers since their inception. The first evaluation focused on outcomes of the Centers program from 1993 to 2003, including key highlights, outcomes of pilot funding, and supplements to funding. The evaluation lasted more than 18 months and included substantial data collection, publication analysis, and examples of successful activities. The results of the evaluation resulted in changes to the funding opportunity announcement (FOA). Following the FOA changes, a second evaluation was conducted in 2010 that focused on the process that Centers used to fulfill their goals, and specifically to assess the effectiveness of the programmatic and structural changes that were made in the October 2005 FOA. The evaluation lasted approximately eight months and included grantee surveys from principal investigators and COEC leaders, publications, and analyses of facility cores (see Appendix C for a summary of previous Center evaluations).

The purpose of this evaluation is to assess the ability of the Centers program to produce complex, emerging, and translational environmental health research. Intended uses for the evaluation include characterizing what the Centers do, how they do it, and to what effect; identifying opportunities for program improvement and best practices; understanding how Centers can be used to implement the NIEHS strategic plan; and communicating the successes of the program.

The current evaluation goals included both process and outcomes of the Centers. Its main focus is the extent to which the Centers foster and produce complex, emerging, and translational environmental health research, including examples of the research they support, the strategies they use to facilitate the research, and the impacts of the research. The evaluation also addressed the strategies by which the Centers support career development and the NIEHS strategic plan. (See Appendices D and E for the evaluation overview and timeline.)

At the first meeting of the Subcommittee in September 2014, NIEHS reviewed the purpose and goals of the evaluation. A series of detailed evaluation questions, intended to drive discussion and evaluation of the Centers, and summative evaluation questions, intended to provide the outline for a final report, were presented by NIEHS staff.

Three webinars/conference calls were held in early 2015 to review data assembled from the Centers by NIEHS staff in support of the following detailed evaluation questions.

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|------------|---------------------------------------------------------------------------|
| Question 1 | What complex, emerging, and translational research are the Centers doing? |
| Question 2 | How do the Centers conduct complex, emerging, and translational research? |
| Question 3 | What are the achievements, successes, and impacts of the Centers? |
| Question 4 | What are the career development achievements of the Centers? |
| Question 5 | How can Centers help implement the NIEHS strategic plan? |

In June 2015, the Subcommittee met in person to begin answering the following summative evaluation questions and to plan the final products of the evaluation. The report was developed throughout the summer, and key findings were presented and discussed with the National Advisory Environmental Health Sciences Council on September 9, 2015.

1. How does the Centers program bring value, or lead the EHS field, in relation to complex, emerging, and translational research?
2. What can the Centers do, that can't be done with other research grant mechanisms?
3. What promising processes and strategies emerge from the Centers as critical for the program and the EHS field, defined broadly and including public health?
4. How can the Centers help inform NIEHS about emerging fields and scientific opportunities?
5. How should the Centers be involved with identifying and implementing the next set of strategic plan goals?

The evaluation was conducted at the program level. Individual Centers were not evaluated independently. Given the size and length of the program, the evaluation was not intended to be comprehensive. The examples and analyses provided to the Subcommittee by NIEHS staff, and the examples described in this report, are intended to be viewed as illustrative and not exhaustive.

Question 1. How does the Centers program bring value, or lead the EHS field, in relation to complex, emerging, and translational research?

Centers make sense in a broad federal science-funded enterprise. Collaborative or team science is playing an increasingly important role in research. While both individual science and teamwork remain important, Centers foster a culture of collaboration. Each Center has a special relationship with NIEHS in planning, advising, and executing the strategic plan of NIEHS, and Centers are an ideal place for NIEHS to carry out complex, emerging, and translational science.

Centers change scientific culture. Centers provide an environment in which basic expectations are shifted to teamwork and away from individual science. Centers have an important ability to shape funding agencies through information, ideas, and practices, and create a marketing tool for groups of university scientists engaging in collaborative work. Centers establish an entity that can create or employ an entire paradigm of translation, from basic to product or process, clinical endpoint, or outreach tool. Outreach efforts become institutionalized and transparent to user groups, including the public. All types of funding become more impactful, because consortium methods, tasking, and subtasking creates opportunity, including grants, philanthropy, foundation, contracts, and partnerships. Centers create an incentive to belong, leading to a sense of value among all team members. A key report by Howard and Laird in 2013 pointed that out.¹

... the most vibrant scientific communities on university and college campuses, and the ones that are most likely to thrive in the new reality of funding for the sciences, will be those that encourage the formation of research teams and are nimble with regard to funding sources, even as they leave room for traditional avenues of funding and research.

NIEHS has a unique opportunity to advance the scientific culture at institutions, based on the strategic interpersonal elements embraced by the Centers.

- **Recruitment of personnel.** Centers foster the recruitment of the finest faculty, using a model of continuous collaborative support, encouraging participation by faculty who are committed to research. Centers create this venue, even in lean times, leading to a powerful opportunity to attract the best students and staff.
- **Mentoring of talent.** Mentoring is required at all stages of a career. Training of research scientists takes place in research laboratories, not classrooms, and Centers provide a special environment for mentorship. The science community of Centers also creates and supports development of early or new investigators, through mentoring opportunities; for the midcareer scientist, as in team-building and leadership development; and to the senior researchers, as mentor, emerging, complex, or translational experts.
- **Assembly of teams.** The assembly of research teams within Centers creates a culture of collaboration, optimizes recognition of emerging elements more readily, and provides for a rich and lively research culture. Collaborative teams focus on complex problems more readily and efficiently. Such work raises the prestige of a university within the academic realm, as well as within the science environment and the broader community.
- **Leadership.** Centers do not exist without leadership, and each Center director is the chief executive officer of that particular venture. Centers innovate around EHS themes. Driven by the vision of the director, the themes are nurtured by the skills of the director in effectively communicating the collective evolving vision, as an essential element of all Centers. The social science skills of directors cement the strength of a Center's spirit. Center directors are stewards of the program, so succession planning is a very important consideration.

In short, each Center brings together many intelligent people, with NIEHS extramural funding, interested in the same problems. This is a strategic positioning element essential for Center growth. The formation of the Center itself fashions an environment of multidisciplinary or interdisciplinary research paradigms.

Centers practice innovation. Innovation is a strategic process that can be taught. In Centers, innovation is established as a core value and a Center provides the venue to recognize innovation when it occurs. The opportunity to combine a variety of viewpoints is an empowering component of Center membership. These include opportunities to capitalize on a discovery challenging an existing paradigm, provide a community-based approach to addressing emerging approaches or understanding, lend additional impact to development of complex approaches to complex problems, or initiate mechanisms to exploit translational science in a group setting. Innovation occurs when opportunity meets preparedness. Preparedness comes in many forms, from the educational preparation of participants to the mentoring of new investigators, from pilot projects to seminars, from facilities to core resources. The values inherent in the Centers and the scientific community that is created by the Centers provide an environment in which innovation emerges. The most successful Centers embrace the concepts of emerging, complex, and translational science components within an innovation environment.

Centers bring value to emerging science. Emerging science is the category that most scientists understand the best. It is the discovery aspect of our being, and is readily recognized as new information and data. When the information generated does not fit the paradigm expected, it is even more exciting, because the result is belief-altering or paradigm-shifting. Such aha moments may be common in science, but researchers do not always have the opportunity to lay the groundwork for more surprises and innovations. Centers provide a structure for this through pilot projects, which provide high-risk, high-payoff opportunities for trying out a new idea. Success, redesign, or failure is equally valid as endpoints. Translational science might be the final pinnacle for a high-risk idea that generated a product, process, therapy, treatment, data set, or policy decision.

Centers have an opportunity to provide the venue to take a high-risk question, funded by a pilot project grant, to discovery, innovation, product development, and translation. Processes should be established to encourage innovation in an emerging science concept, and to be able to describe the processes by which Centers recognize and invest in emerging science.

Emerging science can be at the interface of disciplines and the importance of cross-institutional and cross-discipline interaction should be emphasized. Currently, there are few incentives for a Center to bring in scientists from other fields, when the metric for membership is holding an NIEHS grant, or Centers are scored on only the number of NIEHS grants the institution holds. It creates a mixed message when NIEHS wants Centers to bring other people into the EHS realm, but funding from other institutes is not counted as part of the EHS sliding scale within a portfolio. Such an approach is not forward-thinking and may actually work against a focus on emerging science.

Centers bring value to complex science. Centers invigorate the interaction of people. The sharing of ideas, the value of different points of view, even differences in beliefs about how things work are all potentially important aspects of complexity. The inclusion of all facets of understanding can yield new levels or higher powers of knowledge generation, contributing to the complex nature of science. Complex science might serve as the fertile ground from which an emerging idea becomes evident, or from which it is born.

NIEHS must help Centers explore more difficult problems. The problem might include multiple mechanisms, such as molecular, metabolic, structure-activity relationship recognition, and omics, to answer a question about a toxicological phenomenon. NIEHS must continue to encourage pursuit of complex questions. What is complex today will not necessarily be complex tomorrow. NIEHS must encourage a willingness to set aside existing paradigms to look at things in new ways, such as endocrine disruptor, epigenetics, and exposome research. Centers should be encouraged to address tough scientific questions and areas.

Centers bring value to translational science. Centers, with their strong emphasis on community outreach and engagement, have a finger on the pulse of the health of the American society. The research generated in the Centers may identify unknown or unmet biomedical needs that may lead to paradigm shifts, new research agendas, data sets for the risk assessment community, or products or processes important to understanding or treating disease.

The Centers, with their broad community of collaborating scientists, can reach out to industries in pharmaceuticals, engineering, data analytics, and others. Just because the translational product may lie outside of the Centers, its value is no less important to the institute. Often the most important products or tools translate from one institute to another at NIH, the National Science Foundation, or other agencies, and may actually be repurposed for other uses and needs. The translational science potential developed by the Centers cannot be underestimated.

The scientific discoveries supported by the Centers also have the potential to be translated by a corporate partner or recipient. Centers should be encouraged to interface with the Small Business Innovation Research and Small Business Technology Transfer program communities. NIEHS informs regulatory processes, industries, and agencies. If more intentional partnering with engineering and physics were to be fostered, a greater or more comprehensive solution may evolve. A concerted move to focus more on problem solving in partnership with regulators, industries, and agencies could lead to a new level of enhanced scientific understanding and translational science.

The translational science potential developed by the Centers cannot be underestimated.

Finally, if the translational product does not reach the American people, its value is diminished. Centers have the capability to execute this complex emerging process of translating discovery to the betterment of the human condition. It is important to reiterate that the NIEHS research agenda encompasses all diseases with an environmental facet, and thus embraces and supports all of NIH. NIEHS is relevant to the work of other institutes, and the work of other institutes can be engaging and empowering to the work of NIEHS. Emerging science is compelling, complex science crosses disciplines, and translational science can be incorporated throughout the entire NIH research and development portfolio.

Question 2. What can the Centers do, that can't be done with other research funding mechanisms?

The Centers are consistently viewed as a vehicle for investigator and trainee interactions — an intellectual hub for EHS that serves as a magnet to draw investigators to the EHS field from a variety of disciplines, including those who are typically not involved in this area of research. These interactions often result in enhanced scholarship and creativity through exchange of ideas. The opportunity to have a Center that brings scientists and trainees together fosters collaborative research and forges new collaborations. Facility cores can also bring individuals together to discuss research. The COECs extend this intellectual hub to the community, creating opportunity for creativity, generation of new ideas, and exchange of different perspectives on environmental issues.

NIH-funded Centers are used to build a solid reputation for environmental health research at their home university, and enhance the ability of institutions to recruit outstanding faculty and trainees to both the Center and the department or institution. While some of the interaction and services that individuals receive from Centers may duplicate those that are available in a specific department or institution,

many of the interactions and services would not be available without the Center structure. For example, funding for pilot projects, leading to new funding opportunities; scientific collaborations crossing departments or colleges; and attracting individuals to the environmental health field are important results enabled by Centers, and not necessarily duplicating those available at institutions. While most universities have research facility cores, the Centers defray the cost and enhance access to equipment, technologies, and support staff for investigators and trainees, enabling more rapid advancement of science. In addition, the Centers serve as a mechanism of teaching new skills or introducing investigators to new equipment and methods, and ultimately encouraging investigators to focus on EHS. Likewise, the research facility cores and the interactions that occur among investigators can also facilitate the development of new techniques and methodologies, or unique applications of existing methods. Strong and successful Centers also enhance the stature of environmental health research within the larger research community of a university.

Research facility cores ... facilitate the development of new techniques and methodologies, or unique applications of existing methods.

The training outcome of Centers can be important to a university. While NIEHS does not provide specific requirements regarding training, there can be significant synergy between the Centers and training grants, both attracting trainees to the university, and demonstrating important resources and cores to support all aspects of research training. The administrative core of the Center plays a key part in defining expectations for optimizing training opportunities. Through seminar series and access to cores, trainees accompany and interact with faculty members. Similarly, Centers enhance existing mentorship opportunities within a university. While the impact on the training and mentoring environment of a university may be indirect, it is essential to the success of a Center.

Centers offer the potential for individuals to become members of a community of environmental health scientists and trainees. While investigators and reviewers often note the strengths associated with Center membership, there are different models and levels of membership across funded universities. There are few common expectations of the size of Center membership and the expectation of members. There may be significant overlap between Center membership and departmental membership. There are also some differences in the requirements for membership across Centers. However, in most cases, vigorous independent research programs supported by extramural funding, preferably through NIH, and particularly NIEHS, is a common quality among Center members. Reasons for structuring membership in different ways, optimal membership size, and benefits of different membership structures are not clear. The Subcommittee recommends that common language be developed regarding Center membership, and that standard metrics regarding membership be established, such as senior versus junior members, student members, and established EHS investigators versus scientists new to the field.

Centers enhance research collaboration. Research collaboration will always occur among scientists, but the Centers further encourage all investigators to expand their circle of collaborators and help to facilitate and coordinate collaborations. Bringing individuals together to discuss advancement in the field of environmental

health fosters collaboration. Faculty can see overlap between programs of research and opportunities to frame new questions. The extent to which collaborations develop that might not otherwise happen without the Center, can be difficult to quantify. Regular member meetings and retreats offer a mechanism to share research interests and foster collaboration. The support provided by the Center's administrative core can enable this to happen.

Centers create opportunities for trainees and faculty to learn the importance of community

engagement. A distinguishing characteristic of the Centers is the opportunity for investigators and trainees to interact and communicate with the public. Centers provide a mechanism, via the COEC, to enhance and build better interactions between scientists and communities. The degree and nature of community engagement differs across the Centers, as would be expected for all aspects of Center activities. Importantly, the Centers focus not only on communicating with the public, but on engaging them, making the public a part of the research. Community needs also lead to new research questions and techniques. This engagement promotes mutual respect, improved interactions, and a sustained investment in community.

Centers provide a mechanism, via the COEC, to enhance and build better interactions between scientists and communities.

Centers offer the opportunity to engage in human environmental health population studies. Several examples were given of how the Centers have expanded access to cohort and population studies. The requirement of having an Integrated Health Sciences Facility Core is the newest component of the Centers program, and many examples of its positive impact are emerging. However, some confusion still exists about the core function, including how it is defined, and the importance of studying clinical versus population-based samples. It is not yet clear to what extent the cores will bring value to the overall Center structure and what impact they will bring to the field.

Centers increase a university's commitment to environmental health research. The presence of a funded environmental health center within a university increases the stature and visibility of environmental health in the larger university community, but also requires increased investment from the university in the field. Institutional support for the Center from the host university cannot be required by NIEHS, but Centers highlight this support as an important factor of their success. Examples are needed to help characterize and demonstrate how, and to what extent, institutional support enhances the outcomes of a Center. Future evaluations should consider how to assess the role of institutional support in Center success.

Discussion. The Centers provided multiple examples of how they enhance the capability of universities and communities to reach outcomes that would not have occurred otherwise. Measuring impact and the difference that Centers make is multifactorial. It is not clear that we have the metrics or data to measure impact in each of the areas outlined above. The variability across Centers is also their strength, and it is probably not desirable to quantify the importance, or score each Center, in each of these areas. The challenges in measuring impact in each of these areas, as well as examples of positive outcomes, were discussed extensively. The life cycle of a Center appears to be an important component for consideration. Metrics for success may differ for new

Centers compared to long-standing Centers. The balance between initiation and enhancement of opportunities in new Centers needs to be compared to the long-term outcomes and sustainability of older Centers. Just as NIEHS needs to be very discerning in the review of new Center proposals, older Center grants should also show advancement and adaptation as science evolves.

Question 3. What promising processes and strategies emerge from the Centers as critical for the program and EHS field, defined broadly and including public health?

The variety of excellent work done by the Centers is impressive. Particularly striking is the many ways that Centers are innovative in each of their components, creating novel approaches to carrying out their mission and goals. While evaluation of the Centers took into account the historical metrics that have been used to assess their progress, the focus on these promising processes and strategies went beyond the routine boundaries of the assessment, as a plethora of valuable activities was revealed. These promising processes and strategies should be widely shared and disseminated with other Centers, NIEHS programs, and the environmental health community overall.

Two major benefit sectors. Two major benefit sectors were addressed in the evaluation.

- *The Centers program.* Because this evaluation is of the Centers, the report was tailored to the structure of the Centers. This enables individual Centers, the Centers program, and NIEHS to gauge their success, by seeing their best work coming out of each required component.
- *The EHS field overall.* Because NIEHS is interested in advancing the field of environmental health overall, promising processes and strategies were included that could extend beyond the Centers program.

The benefits described for these two sectors are linked. For example, career development could be used to recruit faculty with expertise needed by a Center, or those who can bring in more grants. This helps the individual Center and the overall Centers program. At the same time, such career development initiatives can train non-environmental scientists to take up environmental health. Since Centers need to show growth in expanding the cadre of environmental health scientists, such efforts are valuable. Similarly, recruiting other scientists into the EHS field can enhance the ability to address emerging and complex areas, such as neuroscientists who can help advance the growing area of neurological health effects from environmental toxicants.

Ways to look at promising processes and strategies. As reports from the Centers were reviewed, and analysis of their efforts was carried out, two major prisms for examining promising processes and strategies were employed.

- *Examples from each Center component.* A Center's growth and success at renewal depends on each component functioning smoothly and creatively, and hence promising work for each component might be highlighted.
- *Examples from creative and innovative subject areas and approaches.* Centers have a whole nature, more than just the sum of their components. These areas and approaches are detailed below.

- Multiple Center collaborations and engagement with other NIEHS Center programs.
- Benefits to global environmental public health.
- Facilitating research of important cohorts outside of the Centers.
- Translational research training for Centers.
- Translational science for policy, public health interventions, and community benefit.

Both of these prisms — Center components and broader arenas — allow review at the Center level, as well as at the EHS level as a whole. There is some overlap here, which is inevitable and beneficial. The examples in the following section illustrate some of the activities that were viewed to be very promising and not always part of the required activity of a Center.

Through the prism of required cores and components

Administrative core

- Creative retreat activities. One of the ways that an administrative core holds together the complex Center is to hold retreats. Several examples of creative approaches to retreats were found.
 - University of Rochester included pilot project presentations and guest speakers from outside the Center, and the retreat was coupled with an external advisory subcommittee review.
 - At Emory University's retreat, members gave one-minute reports, since not everyone knows what other researchers are doing. One year this led to a common interest in the microbiome and also prompted the formation of a journal club.
 - University of Iowa used its retreat as a matchmaking session, to help members find expertise in other members.
 - As a way to encourage interaction, Harvard University's retreat had assigned seating, and members interviewed their neighbor and then introduced them to the group.
 - Harvard University also hosted a flash funding competition, where investigators had five minutes to present a research proposal. The group then voted for the best project and the winner received \$10,000 to fund the project. About 10 people proposed projects, and there was a tie for the winner.
- Creative research coordinating activities. Not all Center members may be aware of the range of facilities and research support in the university, both in and out of the Center. Two Centers developed creative solutions to this.
 - University of Washington's Center paid part of one researcher's salary to be a guide to campus-wide facilities and research.
 - University of North Carolina at Chapel Hill appointed a Director of Translational Research to help members carry out translational research activities.

Facility cores

- Facility cores range widely in their nature.
 - Seven Centers provided training for members to use tools in various facility cores, in order to teach marketable skills to members and trainees.
 - Oregon State University worked with a community group, Beyond Toxics, that had received a U.S. Environmental Protection Agency environmental justice grant. This was as an excellent example

of coordination between a facility core and COEC. They developed a mobile exposure device consisting of a passive sampling wristband, spirometer, and app-loaded smartphone.

Integrated Health Sciences Facility Core

- Links between institutional Clinical and Translational Science Award programs were surprisingly important, with 15 Centers engaged in these connections. Another benefit of the Integrated Health Sciences Facility Core was to introduce researchers to human studies. For example, New York University scheduled a meeting for each newly recruited scientist with the leaders of the core, to help them identify appropriate study populations they might not be aware of. This is an example of a broader strategy that could be used to introduce new Center members to each of the Center cores. This could also be used for recruitment purposes.
- University of Wisconsin-Milwaukee created a Translational Research Subcommittee, which interacts with the entire Center research community as part of the Integrated Health Sciences Facility Core. It provides a formal mechanism to engage all new members, with the aim to encourage their involvement in translational research and to stimulate connections with other members who share common interests and might become future collaborators.

COEC

- Some Centers made a major effort to include community partners in funding opportunities.
 - Columbia University has Center co-leadership with WE ACT, one of the nation's leading environmental justice organizations. Sixty percent of the COEC's total funding goes to WE ACT.
 - Emory University had a mini-grant model that was awarded to promising community-initiated research activities, and set aside one mini-grant each year for students who partner with a community group.
 - Rutgers University has a creative approach to its pilot project review process that screens proposals for their potential for community collaboration.
- Many Centers provided examples of COECs responding to community needs.
 - New York University worked with residents of Garfield, New Jersey on community concerns and sampling of a hexavalent chromium spill.
 - Johns Hopkins University responded to community requests around demolition safety protocols, trash dumping, and neighborhood cleanups.
 - University of Texas Medical Branch at Galveston supported residents who asked for sediment sampling from Hurricane Ike.
 - Columbia University was very involved with WE ACT and the New York City government on number 6 heating oil phaseout.
 - University of Pennsylvania uses a targeted communities model that embraces long-term relationships with a community and promotes a holistic view to building trust to improve public health.
 - University of Southern California regularly sponsors community connections and conferences to provide communities with an opportunity to voice their concerns and contribute to the Center's research agenda.

- The University of Wisconsin-Milwaukee COEC helped the Cleaner Valley Coalition get a local coal-fired power plant converted to a natural gas plant.
- There were some valuable examples of COECs providing education and training, and improving environmental health literacy.
 - University of Arizona offered professional development courses for teachers, made presentations to students and parents, and conducted training for environmental quality professionals.
 - Oregon State University produced resources and curricula for teachers, and engaged in social media and other Web-based education, in tandem with government, tribal communities, and advocates.
 - Johns Hopkins University ran a course to teach environmental health community outreach skills to students.
 - Vanderbilt University administers several training programs in environmental health, and works closely with the NIEHS T32 training award program to support eight predoctoral students and six postdoctoral fellows.

Pilot projects

- Six Centers used pilot projects to stimulate and support community engagement.
 - University of Cincinnati earmarked pilot project funds specifically for community outreach and engagement activities, a practice that NIEHS might consider a requirement for all Centers or providing NIEHS supplemental funding for such pilot projects.
 - Emory University invited representatives from community groups to serve as reviewers for the pilot project applications.
- Some Centers have used a focused theme for pilot project awards, as when Rutgers University dedicated all of their 2011 pilot program funds to transdisciplinary projects on the World Trade Center effects.
- The University of Cincinnati Affinity Group Award encouraged scientists from different fields to apply together for innovative, transdisciplinary projects.
- Pilot projects are a very good mechanism for bringing scientists from other fields into environmental health. For these individuals, a pilot award serves as an environmental health funding ice breaker, as it might otherwise be hard for them to seek support from NIEHS in the absence of any previous environmental health experience.
- Pilot projects also provide an opportunity for Centers to encourage investigators to explore new areas of research.
 - University of Iowa uses pilot projects to support researchers who are exploring a new area of research or initiating a new collaboration.
- Nine Centers used pilot projects to promote translational, complex, and emerging research.
 - University of Arizona used pilot project funding to encourage applications from junior investigators with little experience doing translational research.
 - University of Michigan uses pilot projects to fund translational research with the goal of promoting the development of novel solutions that will ultimately improve patient and community health outcomes.

Through the prism of subject areas and other approaches

This category of promising processes and strategies falls outside of the usual evaluation criteria for Centers. In locating these other aspects of Center activities, the Subcommittee found many valuable activities that might not ordinarily be noticed or captured.

Multiple Center collaborations and engagement with other NIEHS Center programs

There are a number of strong examples of how Centers go beyond the usual sole center focus and contribute to a larger environmental health presence. Additionally, NIEHS puts much effort into linking its various programs, especially through the Partnerships for Environmental Public Health program. It is significant that Centers have chosen to join with these other NIEHS efforts. Some of these collaborations have resulted in successful proposals for other types of NIEHS center programs.

- University of Texas Medical Branch at Galveston and University of Pennsylvania set up a consortium, through a U19 research program cooperative agreement, that is focused on polycyclic aromatic hydrocarbon (PAH) exposure due to the Deepwater Horizon oil spill.
- University of Southern California's work on air pollution and obesity led to the formation of a Children's Environmental Health Center, and more recently a Health Disparities Center.
- Massachusetts Institute of Technology, Johns Hopkins University, and Vanderbilt University collaborated on aflatoxin exposure as a paradigm in molecular toxicology.
- Six COECS received additional NIH funding to explore hydraulic fracturing, leading to an often-cited article in *Environmental Health Perspectives*.
- University of Cincinnati has been working with a Breast Cancer and the Environment Research Program grantee on perfluorocarbon (PFC) testing and providing results to study participants, decision-makers and stakeholders.
- Oregon State University has been working with the Louisiana State University Superfund Research Program on response, recovery, and resilience in disasters.

Benefits to global environmental public health

While it might be expected that Centers are focused on issues in the U.S., they are also using their expertise to contribute to major environmental challenges in Asia, Africa, and Latin America. It is not clear how much this translational research fits within the scope of a funded Center, so that concern needs to be addressed.

- University of North Carolina at Chapel Hill has worked in Vietnam on lead smelters.
- Rutgers University has worked in Mexico on air pollution and lung function.
- Columbia University has worked on a cookstove project in Ghana.

Facilitate research on important cohorts

The Centers also provide access to cohorts, typically through the Integrated Health Sciences Facility Cores. These cohorts provide opportunities for researchers to test hypotheses about environmental exposures and human health with large populations, and more importantly to follow them over time.

- Emory University added a new subset of participants to a current cohort of workers who had occupational exposure to polybrominated biphenyl (PBB).

Translational Research Training

Translational research is central to the evaluation process being done for the Centers and a major NIEHS thrust. However, many Centers are recognizing that scientists, particularly those from basic science research backgrounds, do not know how to do translational research, or how to translate their work to others. Examples of training opportunities that are being provided at Centers are as follows.

- New York University promoted cross-core collaboration focused on increasing clinician-scientist interaction.
- Harvard University created cross-cutting translational working groups in areas including metals, organics, and particulate matter.
- Oregon State University offered a dissemination roadmap for its Center members, to help them learn the multiple ways to do translational science.
- Massachusetts Institute of Technology, University of Michigan, University of North Carolina at Chapel Hill, University of Washington, and University of Cincinnati have all used translational coaches to work with Center members to identify opportunities to move research to another area in the translational research spectrum.

Translational science for policy, public health interventions, and community benefit

Core centers also play a vital role in translating science findings into policy and public health interventions that create benefits for the broader community.

- University of Rochester conducted lead exposure science that led to a national law on lead in housing and prevention programs, regulation, and enforcement.
- Columbia University has worked on biofuel burning.
- University of Wisconsin-Milwaukee has a strong urban gardening focus that led to a university initiative on urban agriculture.
- New York University set up mobile labs to study diesel exhaust and asthma, working with four community groups.

Discussion and recommendations

The Subcommittee found that important processes and strategies are emerging from Centers that do not always align with the NIEHS quantifiable metrics. NIEHS should develop additional ways to capture the important work emerging out of Centers, and determine the most useful reporting method. Program officer visits to a select number of Centers can help build the framework for a new data tool that would result in a new, more holistic, and more narration-oriented evaluation. Many of the examples described above illustrate valuable forms of innovation. The Subcommittee believes that innovation in process and strategies should be expected and that NIEHS should add examples of innovations to the FOA as a way to encourage novel approaches and infrastructure. The collaborations across Centers were viewed as highly positive. Mechanisms to support these activities could be provided both in the FOA and by providing supplemental funding. However, as illustrated by some of the Centers, collaboration does not always require additional funding. Also viewed as positive is the synergy that can be built between the Centers and other center programs within a university. This synergy boosts the strength of each Center, as well as increases the overall environmental health

infrastructure. Finally, Centers have discovered innovative ways to build community involvement beyond their COEC. This is an admirable development and should be encouraged. Involvement of Centers in the NIEHS Partnerships for Environmental Public Health meetings and webinars should be encouraged, to further their understanding of the importance of community involvement in all dimensions.

Question 4. How can the Centers inform NIEHS about emerging fields and scientific opportunities?

The Centers support research that represents the full spectrum of complex, emerging, and translational EHS. The Centers are incubators for the next generation of environmental health researchers, and their members serve as leaders in the EHS field. The Centers provide a forum for leaders to exchange ideas and perspectives that have the potential to lead to transformative research. The Centers provide a physical and virtual space for collaboration with other disciplines on environmental health questions. And finally, the Centers support of high risk, high reward pilot projects, interdisciplinary projects, and early, unconventional ideas help foster complex, emerging, and translational EHS research. Thus, the Centers in their position of facilitating a broad range of environmental health research, have a unique view into the contributions and emerging opportunities of EHS research to the larger scientific landscape. This knowledge is not currently shared in any systematic manner with NIEHS staff.

The Centers provide a forum for leaders to exchange ideas and perspectives that have the potential to lead to transformative research.

Reporting by the Centers is annual and focused on the specific research that is conducted at each individual Center. Placing the research within a Center, in the context of the larger landscape and emerging scientific opportunities in EHS, has not, to date, been a focus. This knowledge resource has been unexploited by NIEHS.

NIEHS is interested in capturing, in a timely manner, information from the Centers on the scientific impact of research in the broader scientific landscape, and the scientific opportunities emerging from that research.

The Subcommittee identified the following characteristics of research supported by Centers that is expected to lead to broad scientific opportunities.

- Research that challenges conventional wisdom.
- Insights leading to new methods and technologies.
- Concepts combined in new and unexpected ways.
- New fundamental questions or new directions for research.
- Major change in understanding of existing scientific concepts.
- Translational research.
- Interdisciplinary collaborations extending the scientific impact of environmental health research.

It is clear from the information that NIEHS gathered from Centers and for this report that the Centers are facilitating this type of research through multiple mechanisms, including pilot projects, core support, collaboration support, translation guides, and recruitment of staff with diverse expertise. Additionally, Centers provide opportunities, through Center meetings and retreats, for investigators to share their ongoing research with those working in different areas. Center administrative cores, Integrated Health Sciences Facility Cores, and COECs also provide assistance in connecting investigators with others in the Center and elsewhere who have a particular needed expertise.

The Center annual progress reports do provide a variety of data from which some information on the impact of their research on emerging fields and scientific opportunities can be gleaned, including publications, descriptions of administrative functions, pilot projects, meeting agendas, COEC activities, and lists of faculty and new recruits and their expertise. While analysis of the data provided by the Centers allowed the Subcommittee to see many examples of emerging science and scientific opportunities for EHS broadly, the Subcommittee concluded that the reporting mechanisms for conveying the impact and context of Center research could be improved. As mentioned previously, adding narrative to the reports may be useful. However, inclusion of explicit descriptions of the impact of their research on the larger scientific landscape should be conveyed. In order to provide timely information to NIEHS, reporting between annual reports should be encouraged in a manner that is not burdensome to Center directors.

Reporting mechanisms for conveying the impact and context of Center research could be improved.

The Subcommittee recommends that NIEHS establish a timely reporting framework for placing published and ongoing Center research in the context of the larger scientific landscape. To develop this framework, NIEHS might invite the Center directors to contribute to a draft working framework. This drafting process could prove to be a useful exercise for Center directors in managing their Center, and for NIEHS in planning future initiatives. The framework should evolve over time as experience is gained, and should showcase the breadth of science across the EHS landscape. A cautionary note is that the value of the framework should outweigh the burden of creating it for both the Center directors, as well as NIEHS staff. In summary, the Subcommittee recommends the following actions to enhance the communication between Centers and NIEHS on emerging fields and scientific opportunities.

- Reporting by Centers on the impact of their research, including outcomes, on the EHS and broader scientific landscape.
- Expanding the information that Centers provide in their annual reports about collaborations with other NIEHS funded centers and programs, and with non-NIEHS funded programs, such as Clinical and Translational Science Award programs, Superfund Research Program centers, and National Science Foundation programs.
- Reporting on the challenges and contributions of Center support for collaborative, complex, emerging, and translational research, including specific examples.

- Engaging Center directors in development of a framework for timely reporting of outcomes and impact of Center-supported research.
- Hosting a scientific-focused annual retreat for Centers, with a specific emerging field and scientific opportunity themed competition each year, and requiring publication of abstracts.
- Categorizing Center research projects and focused topics, on an ongoing basis, in an annual scientific program report.

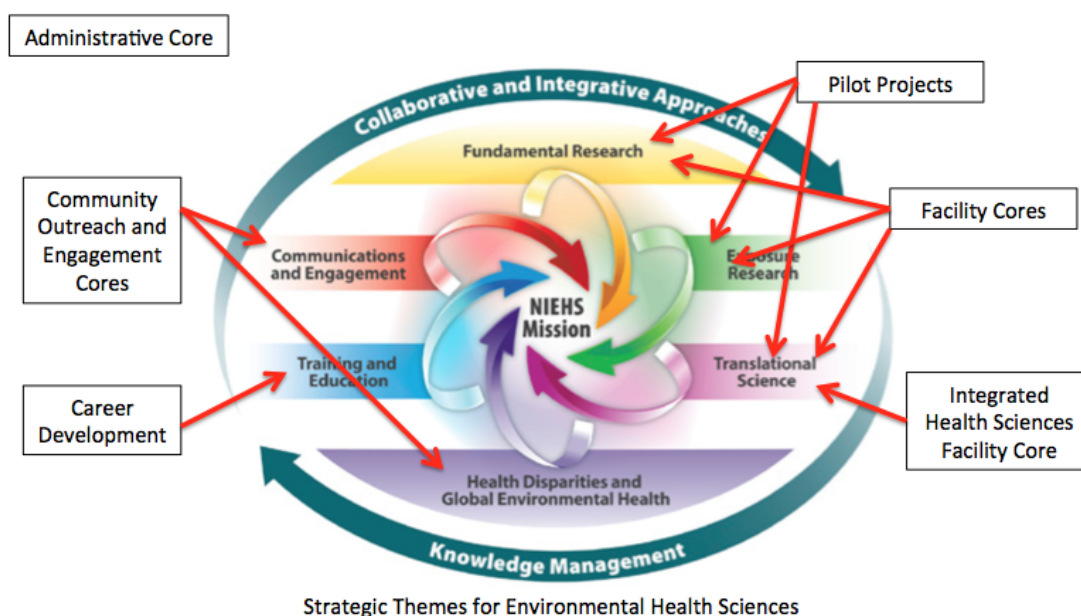
Question 5. How should the Centers be involved with identifying and implementing the next set of strategic plan goals?

The Subcommittee explored the following questions in regard to the role Centers play in the implementation and updating of the NIEHS 2012-2017 strategic plan (see www.niehs.nih.gov/about/strategicplan).

- How can the Centers help implement the NIEHS strategic plan?
 - What are the Centers doing to address the strategic plan goals?
 - What strategic plan goals are addressed in research supported by the Centers?
- How should the Centers be involved with identifying and implementing the next set of strategic plan goals?
 - How can the Centers be used to identify gaps?
 - How should future strategic plan goals be framed?

How can the Centers help implement the NIEHS strategic plan?

The current NIEHS strategic plan describes a number of goals and themes. The diagram below indicates how each of the mandated components of the Centers relate to the themes of the strategic plan.



The Subcommittee compared the research within the Centers to the strategic plan themes and goals and concluded that the following bolded areas were addressed in many pilot projects and Center-supported grants, mostly R01 research project grants. There were fewer examples of the nonbolded themes and goals.

GOALS

- Fundamental mechanisms
- Individual susceptibility
- Exposure science
- Combined environmental exposures
- Emerging health threats
- Health disparities
- Knowledge management
- Teaching, education, and training
- Training new researchers
- Economic impacts
- Bidirectional communication

THEMES

- Fundamental research
- Exposure research
- Translational science
- Health disparities and global environmental health
- Training and education
- Communications and engagement
- Knowledge management
- Integrative approaches

It was not surprising to the Subcommittee that most Center-supported projects are associated with the more basic research themes and goals. If the EHS community wants to encourage a higher proportion of translational and applied activities in association with the Centers, NIEHS may need more targeted funding activities to encourage a rebalancing of efforts. The Subcommittee emphasized that it did not expect the Centers to implement all strategic themes and goals equally, but did conclude that some aspects of the strategic plan appear to currently be underrepresented within the Centers. Each Center does not have to be involved in all aspects of the NIEHS strategic plan, but collectively their activities should span most or all of the themes over time. The current metrics that the Centers use to report their activities may also lead to an inability to quantify or describe work within some areas of the strategic plan. That is, Centers are likely to be involved in more activities and more types of activities relevant to the strategic plan than are currently being reported.

Areas meriting close attention include the following.

- **Health disparities.** Center directors should be given opportunity to report examples of the work in their Center that contribute to the overarching research agenda, to understand the disproportionate risks of disease, and to define and support public health and prevention solutions in affected populations. This important area should be specifically listed in the Centers' routine reporting.
- **Teaching of EHS at all levels of education and training.** Teaching of EHS should be encouraged from kindergarten through professional, to increase scientific literacy and generate awareness of the health consequences of environmental exposures. This is not addressed in the evaluation. While professional and scientific seminars for trainees and faculty are described, there should be opportunity, particularly in the translational and community engagement work of the Centers, to describe education of the public and preprofessional groups.

- **Evaluating economic impact.** The evaluation of the Centers did not address this subject, and there was no evidence that any Center is engaged in work in this area. Evaluating economic impact should be expanded to a larger social science agenda, which is something NIEHS is focused on in other NIEHS programs, such as the Superfund Research Program and the Partnerships for Environmental Public Health program.
- **Bidirectional communication.** This topic is barely mentioned in the reporting from the Centers. The lack of bidirectional communication seems unlikely, given the mission of COECs, so it points to a possible problem in reporting or coding.

The Subcommittee was impressed with how NIEHS relates all of its internal activities to the current strategic plan.

Announcements of funding opportunities and presentations to the National Advisory Environmental Health Sciences Council are all described in the context of the goals and themes of the NIEHS strategic plan. The Subcommittee

concluded that NIEHS should encourage the Centers to embrace the strategic plan framework in their work.

NIEHS should encourage the Centers to embrace the strategic plan framework in their work.

The Centers' administrative cores should be reporting about their activities in the context of the strategic plan, in the same way that NIEHS staff has embraced the plan when reporting on new and existing initiatives. The Subcommittee noted that, to date, only two Centers have reported activities in the context of the strategic plan. To facilitate this expanded reporting, the Subcommittee recommends that NIEHS staff provide templates, tools, and examples to assist the reporting process in the context of the strategic plan.

It would also be helpful for the Centers to share their results and success stories related to the strategic plan goals and themes. These successes should be shared with the larger EHS community, funders, and the lay public, through publications, presentations, conferences, and other means. NIEHS should also look to promote opportunities for the Centers to have increased communication with one another, including sharing information about the risks taken with pilot projects, whether they worked out or didn't, so that other Centers can learn from these experiences.

The Subcommittee also concluded that the Centers could play a stronger role in communicating the strategic plan and guiding its implementation in the broader EHS community. They also made the following suggestions.

- **Advancing community engagement**

This is something that NIEHS leadership talks about a lot, in many different venues. Community engagement is bidirectional. Engaged communities inform scientists of the environmental concerns of their members and their perceived research needs. Likewise, scientists prioritize their research to address community needs and concerns, and translate the findings from their research to the community. There is a need for more focused analysis of how to train scientists and students for community engagement, and how to train scientists to effectively communicate scientific concepts and findings to lay audiences and the community. This model is currently seen in the Superfund Research Program where the Research Translation Cores help investigators translate the work of each of their research projects.

- **Internal education**

Centers should have dedicated meetings at which they discuss the strategic plan, and promote ideas for furthering its goals and themes in the Center and its constituent research community.

- **Exchange learning**

Center members should travel to other Centers to exchange learning. Ideally, a trainee could accompany an investigator or core leader. This could be a pilot approach.

- **Implement P30 FOA more strongly**

The P30 FOA needs to make clear that proposals should take seriously the NIEHS strategic plan, and the review panel and program officers need to highlight it in the application and review process.

- **Provide metrics for reporting**

Centers need a good set of metrics for reporting their activities related to the strategic plan.

- **Alternative sources for metrics.** Instead of reviewing the translational research literature, which may be very broadly defined, and instead of Clinical and Translational Science Award program metrics, which are noted as problematic, articles written by NIEHS awardees that tackle these kinds of questions should be looked at, such as Brown², Haynes³, Pennell⁴, and Wing⁵. Consider using Baron et al.⁶ report on the translational work on environmental justice and community-based participatory research programs as a source for metrics.
- **Attendance at meetings.** Center members should attend the Partnerships for Environmental Public Health and National Institute on Minority Health and Health Disparities annual meetings, since they often have themes that are part of the strategic plan, such as health disparities and environmental health literacy.
- **Use of narratives.** The Subcommittee recognized that while coding of narrative reports can present challenges, they were a rich source of information about the work in the Centers. Historical knowledge of ways that Centers are addressing these important strategic goals should be used, based on notes by program staff. Data may currently be insufficient to adequately describe activities across all or most Centers. A pilot project could be done with several Centers, including onsite visits, to help develop methodology and criteria.

How should the Centers be involved with identifying and implementing the next set of strategic plan goals?

Most of the Centers are overseen by scientists who are recognized EHS national and international leaders. So, it should not be surprising that they were heavily involved in shaping the current NIEHS strategic plan. Many Center directors and members from across the nation participated in the multi-stage strategic planning process that NIEHS employed to develop the current plan. Opportunities for involvement included an open call for ideas and feedback through a Web-based interface, participation in the 150+ person open space format in-person meeting, and the ability to provide feedback on initial drafts of the strategic plan. The Subcommittee commends NIEHS on the quality of the process that generated the current strategic plan and its inclusiveness, and agrees that the Centers and their leadership should play a significant role in any interim activities to assess and refresh the plan before the next major planning exercise in 2016-2017.

In relation to the Subcommittee's recommendation regarding how Centers can inform NIEHS about emerging fields and scientific opportunities, we recognize the recommendation has a direct connection to the NIEHS strategic planning process. The scientific awareness activities the Subcommittee recommends will contribute to a strategic plan gap analysis. That is, Centers will help define emerging fields, scientific opportunities, missing areas, and things that should receive greater emphasis in the future.

NIEHS may also wish to conduct focused workshops with Center leadership around the strategic plan. These could include a brief review of its content and the alignment of the each Center's current activities with the goals and themes. But the bulk of the discussion should be around how Centers could assist NIEHS to enhance strategic activities in areas where there is less effort currently. These meetings would also provide opportunities to promote communities of interest across the Centers, and could highlight success stories of projects that involved multiple Center collaborations, collaborations across institutes within NIH, and collaboration across other agencies.

Key messages from the Subcommittee

The Subcommittee identified several key messages during its deliberations.

P30 Centers serve as critical hubs for environmental health research

Numerous examples were provided by the Center directors of ways in which the Centers foster interactions, collaborations, training, mentoring, innovation, and application of leading edge, interdisciplinary approaches. The intellectual interactions may not have occurred in the absence of the environment created by the Center. The resources that are provided within the Centers to both junior and more accomplished investigators are significant and provide valuable assistance to investigators pursuing new areas of scientific inquiry. An important aspect of the Centers is that they introduce many individuals to the area of EHS and offer opportunities for individuals to interact with NIEHS who might not if the Center did not exist. Many of the current Centers are long-standing, which highlights the importance of leadership succession and sustainability planning.

Centers are a source of collaboration and sharing for EHS

Examples provided by the Centers point to the ability of the Centers to connect across the university with other research centers that may or may not be funded by NIH, or specifically NIEHS. This collaboration among centers was viewed by the Subcommittee to be highly positive. The potential for Centers to connect both with other centers in their own institutions or across institutions has not been fully realized. The Subcommittee recommends that NIEHS do more to enhance cross-collaboration. These collaborations could occur at the investigator level, as well as with core facilities and other institutions or agencies.

COECs are a critical and integral component of the Centers

With their strong emphasis on community outreach and engagement, Centers have a finger on the pulse of the public. Thus, the COECs are viewed as critical to the Centers. The definition of community is broadly defined as anything beyond academia, and includes a variety of entities, including neighborhoods, populations, and other stakeholders. The COECs are viewed as a critical component for the translation of Center work and

environmental health to the public. If the work of the Centers does not reach the American people, its value is not fully realized. The COECs should not only be viewed as the mechanism for translating the work of the scientific community, but also the body that ensures that Center members can engage in translation. The COECs also play a critical role in ensuring that the scientific community hears and responds to the priorities and research needs of the community. Community engagement should be an expectation of all Center members, and should be explicitly and thoughtfully considered for all aspects of the Center, including pilot projects, cores, and research project users of facilities.

Importance of the Centers embracing the strategic plan

One of the most challenging areas of the evaluation was the determination of the extent to which the Centers embrace the NIEHS strategic plan. To date, the Centers have not been asked to address or provide examples of how they align with the strategic plan, but ample examples arose regarding the potential for the Centers to play a more important role in this area. Specifically, the COECs within the Centers could provide a platform for helping to educate the public about the overall goals of the strategic plan. Pilot project programs and other initiatives, especially in translational work, could provide a resource for NIEHS for growing underrepresented areas of the strategic plan. Cross-collaboration among the Centers could allow for the development of communities of interest around special topics that align with the strategic plan, such as the current inter-Center workgroup on fracking.

Reporting

The review Subcommittee appreciated the large volume of data that the Centers produce and that was distilled by NIEHS staff. Yet there was the overarching sense that a lot of the data have been collected historically and may not adequately reflect the parameters currently of most interest. Specifically, new metrics are needed to capture translational research, innovative science, community engagement, and collaboration and sharing across and within Centers. Measures are needed to accurately determine the extent to which the Centers enhance the institutional infrastructure for EHS research. Core use is routinely measured, but the data suggest that most research projects were found to use only one core. Broad use of cores by investigative teams is encouraged. It wasn't clear that the current system captures all that the information about core use, given their critical role in the Center infrastructure. Methods are needed to measure the extent to which Center cores are derived from infrastructure already present in the university, and what specific additive value that Center funding brings. It is important to track the outcomes of core usage, the extent to which trainees are able to use core facilities, and how these costs are recovered. In general, the Subcommittee found that the formal metrics did not capture much of the exciting work of the Centers. Rather, narrative accounts of Center activities provided a more thorough and in-depth database that the Subcommittee drew upon.

A translational framework in EHS research is needed

The October 2005 FOA was modified to stipulate that Centers were required to include an Integrated Health Sciences Facility Core to facilitate translational and clinical research, either patient-oriented or population-based, that enhance translation of basic research findings into practical applications for patients and communities. This addition was in direct alignment with the NIEHS strategic plan that aims to understand

individual susceptibility across the life span to chronic, complex diseases resulting from environmental factors, in basic and population-based studies, to facilitate prevention and decrease public health burden.

All 20 Centers indicated in their applications that they used the Integrated Health Sciences Facility Core to help promote translational research. However, the way in which this was accomplished varied. Examples include support for global population research studies, assistance with studies involving human participants, and encouraging investigators to include environmental measures in their funded cohort studies. There was much flexibility in the design of the Integrated Health Sciences Facility Cores, with some cores providing opportunities for Center members to obtain clinical samples and patient data needed for their research and other cores supporting studies of the etiology, pathogenesis, and course of disease in patient populations. NIH supports bench-to-bedside translational research within the Clinical and Translational Science Award program or other translational programs from various NIH institutes and centers. NIEHS Centers provided examples of partnerships with Clinical and Translational Science Award programs that take advantage of the resources offered by the programs, such as pilot program funding, training for students and junior investigators, access to biorepositories and other data, access to clinical and community populations, and biostatistics training and services.

The wide array of examples of translational research was so great that the evaluation Subcommittee spent considerable time exploring models that capture the translational process within the EHS domain. Historically EHS has focused on the health of broad populations and not necessarily the health of groups of patients. While the Subcommittee believes that the link between environmental exposures and diseases seen in clinical practice is critically important, requiring Centers to conduct studies of clinical populations may not be desirable.

The major components that appear to be offered by the Integrated Health Sciences Facility Cores include the following.

1. Helping educate investigators on the meaning of translational research and ways to increase its presence in the research portfolio.
2. Service provision including assistance in recruitment, independent review board assistance, transport of biological samples, and translation of discovery into innovation and practice.
3. Collaboration with existing Clinical and Translational Science Award programs to broaden and expand research beyond the patient population and the traditional clinical trial model.

The Subcommittee concluded that generating a common definition of translational research is also something NIEHS should consider and communicate. It may be difficult for some Centers to self-categorize or present their own research as translational, if a shared understanding is not developed on what this term means. The Subcommittee discussed translational science as a research process, product, data set, or technology that contributes to the health of the American people.

Information dissemination is communication or science translation, but not translational research. The importance of educating environmental health researchers on translational research compelled the Subcommittee to propose a model that could

Generating a common definition of translational research is something NIEHS should consider and communicate.

encompass the science within the Centers and educate others for how the EHS community can contribute to the body of knowledge on translational research. The importance of describing translational research in environmental health led the Subcommittee to draft a separate document that is being submitted to NIEHS as a starting point for the important discussion that needs to be held in the EHS community.

Recommendations

In summary, the key recommendations described in the report included the following.

1. NIEHS should develop additional ways to capture the important work emerging out of Centers, particularly in regard to emerging and translational research, and to determine the most useful reporting method. Metrics are needed to capture collaborations within an institution and across the other Centers.
2. Templates and standard reporting tools need to be developed to capture and quantify Center activities that align with the NIEHS strategic plan. Also, mechanisms are recommended to increase the engagement of the directors in evaluating progress on goals of the strategic plan and future strategic planning activities.
3. The role of the Center director is critically important to the outcomes of a Center. Strategies are needed to assure sustainability of strong Center leadership. Development of impactful EHS leaders of the future should be a goal of the program.
4. The COECs are critical to the Center structure and function, but their scope and function vary across Centers. Opportunities exist to optimize the role of the COEC, particularly in increasing the capacity of all environmental health scientists to understand and engage in translational work.
5. A common definition of translational research in EHS is needed. The Subcommittee is developing a separate document proposing a first step in beginning the dialogue on a common framework that could be used across all Centers, and which would improve our ability to measure engagement in translational research.

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Appendix A

NIEHS Centers Program Overview

Program Description

The Centers program provides funding for institutional infrastructure to support scientific equipment, facilities, and other resources shared among researchers tackling related environmental health questions. The Centers foster interactions among researchers to allow them to take advantage of innovations and approaches beyond what individual scientists would be likely to attain by working independently.

The Centers program is intended to provide the intellectual leadership and foster innovation to accelerate and deepen the insights gained from environmental health research conducted along the spectrum from basic science to population and public health and dissemination. The NIEHS approach is for this mechanism to foster integration, coordination, and translational cooperation among investigators conducting high-quality research clearly related to the effects of environmental factors on human health; integrate and build upon existing programs in order to answer complex questions leading to improved strategies towards preventing environmentally-induced disorders; and interact bidirectionally with affected communities. While the program clearly sets the expectation that Centers will address issues of complex, translational, and emerging research, it leaves the interpretation of these concepts open and offers some flexibility for the Centers to identify their specific research areas.

In fiscal year 2014, there were 21 active Center grants. Many of the grants have a long history of support through the Centers program. Nine programs have been in existence for more than 35 years, and five programs have been in existence for more than 10 years.

In order to provide increased flexibility in organization and structure, the Centers can create dynamic features which meet the ongoing intellectual needs of their members. These features can change as the intellectual needs change, in order to accommodate new opportunities for research and collaboration, but the Centers are required to have six specific components as part their programs.

- Administrative core
- Integrated Health Sciences Facility Core
- Facility cores
- COECs
- Pilot projects
- Career development

Administrative Core

The administrative core oversees organizational, budgeting, and reporting aspects of the Center, and provides the leadership for scientific and programmatic activities. The core is expected to do the following.

- Coordinate and integrate Center components and activities.

- Assess productivity, effectiveness, and appropriateness of Center activities, and identify scientific opportunities and areas for collaboration among Center members.
- Organize Center activities, such as retreats, invitation of consultants, meetings, and focus groups.
- Organize the internal and external advisory groups.
- Keep track of meeting minutes and measures of success, including use of Center facilities, publications, pilot project awards, and new grant applications resulting from preliminary data enabled by the Center.
- Interact with other Centers, NIEHS, and other appropriate individuals, groups, or organizations.

Integrated Health Sciences Facility Core

The Integrated Health Sciences Facility Core supports collaborative efforts among basic scientists, clinical researchers, community engagement experts, and public health practitioners by doing the following.

- Providing services and access to instrumentation and technologies that foster integration of basic science, public health research, including epidemiology and intervention studies, and patient-oriented clinical research.
- Supporting research to improve early detection, prevention, and therapeutic strategies for environmentally-related disorders.
- Enhancing partnerships between researchers and community-based organizations that impact on conduct of clinical and public health research.

Among its functions, the core provides services that capitalize on access to well-characterized patient groups and control subjects for research projects, including study subject recruitment and retention activities, and follow-up by mail, phone, or in-person to gather needed data for research projects. Clinical services include clinical laboratory or other assessments, pathology services, collection, processing and long-term storage of human tissue samples, blood, urine, or other biospecimens, and preparation of questionnaires or other assessment tools. The core also facilitates and supports partnerships between study investigators and human populations, communities, or health care providers.

Facility Cores

Facility cores draw on Center research needs, including, but not limited to, animal use and transgenic animal models, imaging, tissue culture, pathology support, biostatistics and statistical support, oligonucleotide synthesis, analytical chemistry, proteomics, bioinformatics, exposure assessment, and handling of human tissue specimens. Although facility cores provide services for Center members, they also play an important role in developing new methodologies, adapting instrumentation for Center needs, and educating Center members of the value and utility of services and methods.

COEC

COECs are responsible for translating and disseminating Center research results into environmental public health knowledge for identified audiences. COECs develop and implement appropriate outreach and engagement programs, to increase awareness and understanding of environmental health research being conducted at the Center. COECs also serve to advance the field of community engagement, by evaluating

outreach models, disseminating results at local and national levels, and promoting models for national implementation. COECs are encouraged to collaborate with each other.

COECs are not expected to conduct community-based participatory research, as it is not their intended goal. In addition, COECs are not allowed to develop K–12 curricula.

Pilot projects

A pilot project program is an integral part of the Center and should be designed to support pilot studies for basic or clinical biomedical, epidemiological, educational, or behavioral research. The pilot project program should support short-term projects to explore the feasibility of new areas of study which leads to collection of sufficient data to pursue support through other funding mechanisms. Pilot projects are intended to do the following.

- Provide initial support for new investigators to establish new lines of research.
- Allow exploration of possible innovative new directions representing a significant departure from ongoing funded research for established investigators in EHS.
- Stimulate investigators from other areas of endeavor to apply their expertise to environmental health research and environmental medicine.
- Foster opportunities that meet goals set out in the Center plan. Pilot projects should strive to fill in gaps in research areas relevant to the scientific focus of the Center.

Career development

The Center program encourages clinical and basic scientists with a broad range of skills to work together on a unified theme, presenting a rich environment for young investigators to be exposed to and develop skills. By creating mentor/mentee teams that pair Center investigators having strong mentorship credentials with junior investigators, this component of the Centers program is intended to do the following.

- Support new investigators in progressing to more senior status and eventual NIEHS funding, by enhancing their research skills and knowledge in translational and clinical research.
- Assist new investigators in attaining independent status, or established investigators in developing new promising areas of expertise.

A career development plan is required by the Center that outlines the investigators who will participate; a description of cross-training, mentoring, or other opportunities and activities; and approaches to measure progress and attention to underrepresented minorities. Centers typically provide salary support for junior investigators or new Center members.

Appendix B

NIEHS Centers Program Subcommittee Member List

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Appendix C

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Appendix D

Summary of Previous NIEHS Centers Program Evaluations

	2004	2010
Timeframe	1993–2003	2007–2010
Focus	Outcomes	Process
Data	Key highlights Pilot projects Supplements	Programmatic and structural changes that were made in the 2005 FOA
Methods	Substantial data collection, site visits, publication analysis, “snapshots” of successful activities	Surveys from several cohorts (PI and COECs), publications, translational analysis of facility cores
Duration	>18 months	<8 months
Outcome	Major changes to FOA	No structural changes to FOA
Advisory Panel	Yes	No

2004 Evaluation

Twenty-six Center directors were asked to provide NIEHS with up to five key highlights, information on supplement outcomes, and data on pilot programs. The evaluation also included analyses of data from the NIH IMPAC II database. The data focused on the 1993-2003 time frame.

Key Evaluation Questions and Findings

1. How does the NIEHS P30 program compare to P30 programs at other NIH ICs [institutes and centers]?

NIEHS, like other ICs, uses a variety of mechanisms to support Center research, although from 1993 to 2003, NIEHS used the P30 mechanism exclusively. Because scoring across ICs is so varied, it was not feasible to compare scores among P30 grantees.

2. How has the scientific content of the NIEHS P30 program shifted from 1993 to 2003?

Centers demonstrated a trend toward less use of analytical and exposure assessment cores, and more use of toxicogenomic and proteomic cores. Also, less molecular biology and more microarray and novelomics technologies, and increased use of imaging. Still large numbers of animal model cores and biostatistical and bioinformatics cores. Gaps in research include risk and economic analysis of environmental questions.

3. How has the NIEHS P30 program helped to build research capacity in environmental sciences?

Center investigators tend to have slightly higher success rates (36.7% versus 31.5%) from 1999 to 2004. Available data do not indicate that the Centers program has helped build institutional research capacity. Centers tend to have an increase in the number of applications and awards submitted in the three years after a Center is established, but success rates do not change. Many pilot projects were able to secure

mainstream sources of funding. The supplements were used effectively, but evaluations focused on process and outputs, rather than impacts, for example, number of school systems adopting a curriculum, number of residents whose behavior regarding drinking water changed, number of teachers who applied their new skill in the classroom, and community actions that occurred as a result of the project.

4. How has the P30 program contributed significantly to the achievements of the field of EHS? And given the level of funding for this program, are the products commensurate with the NIEHS investment?

Research is generally exposure specific or discipline specific. The quality of the research, as judged by the snapshots, was variable. Publications were not in high profile or general interest journals, but rather in toxicological or cancer-focused journals. Collaboration among COECs was widely varied. Some COECs took on meaningful interaction with their partners and communities. Others did presentations, lectures, consulting, etc., that seemed to be unlikely to result in either capacity building or positive environmental impacts.

2010 Assessment

Focus on assessment of programmatic and structural changes that were made in the 2005 FOA.

Data collection included questionnaires completed by seven principal investigators and five COEC leaders, and analysis of publications and applications. Only able to look at the first two to three cohorts, depending on the question, because not enough time had gone by to fully assess the others. Key program elements assessed included the Integrated Health Sciences Facility Core, pilot projects, director's fund, COEC, scientific review criteria, and career development.

Key Evaluation Questions and Findings:

1. What changes resulted from the new Integrated Health Sciences Facility Core?

The Integrated Health Sciences Facility Cores funded new grants, facilitated new faculty and collaborations, and developed clinical expertise among researchers.

2. Are the Centers more translational?

The facility cores expanded their clinical and epidemiological studies, provided independent review board expertise to researchers, and provided access to biospecimen storage and processing, biomarker development, and data management and analysis services.

3. What is the benefit of the pilot projects?

Pilot projects address a wide range of topics and approaches and contribute strongly to the translation and career development aims of the program. Pilot projects also result in subsequent funding from multiple sources.

4. What is the benefit of COECs?

COECs are generating meaningful community partnerships and Centers had no objections to the community advisory board requirements.

5. What career development activities are supported and what were the results?

Career development activities included salary and grant support, workshops, and mentoring and training. These activities lead to new grants, collaborations, promotions, and new positions.

Appendix E

NIEHS Centers Program Evaluation Overview

Evaluation Purpose

To assess the ability of the Centers program to produce complex, emerging, and translational environmental health research.

Intended Evaluation Use

1. Characterize what the Centers do, how they do it, and to what effect. The evaluation is not intended to be an inventory of all Center activities and accomplishments.
2. Identify opportunities for program improvement.
3. Identify and promote best practices that we can leverage among the Centers and EHS researchers.
4. Understand how Centers can be used to implement the NIEHS strategic plan.
5. Inform understanding of the state of the program and communicate the successes of the program.

Evaluation Goals

1. Assess what kind of complex and emerging translational problems the Centers are addressing (Question 1).
2. Assess how the structural changes made in 2006 to the FOA contribute to the evolution of the Centers and their ability to do translational research (Question 2).
3. Assess how scientific collaborations, community partnerships, pilot projects, and facility cores contribute to the success of Centers (Question 3).
4. Assess career development outcomes within the Centers (Question 4).
5. Assess how the Centers can help implement the NIEHS strategic plan (Question 5).

Evaluation Questions

The goals above were translated into the following evaluation questions, organized into three broad areas — supporting complex, emerging, and translational research; providing opportunities for career development; and supporting the NIEHS strategic plan.

1. What complex, emerging, and translational research are the Centers doing?
2. How do the Centers conduct complex, emerging, and translational research?
3. What are the complex, emerging, and translational achievements, successes, and impacts of the Centers?
4. What are the career development achievements of the Centers? Not limited to complex, emerging, and translational research.
5. How can Centers help implement the NIEHS strategic plan? Not limited to complex, emerging and translational research.

Data Sources

We will develop a plan to compile and analyze data to answer the evaluation questions above, and present it to the Subcommittee. The evaluation will include both primary and secondary data sources, including documents and data that have previously been submitted by grantees. Prior to asking grantees for any information directly, we will review secondary data sources to ensure that we have obtained as much information as possible from these sources, in an effort to minimize the response burden on the grantees. Data we plan to review or collect include the following.

- Progress reports, including appendix tables
- QVR/IMPACII
- Data submitted or discussed during previous grantee meetings (COEC history wall/2013; CTE discussion/2014)
- Publication list
- Data submitted to program staff, including biographical information on newly recruited investigators
- NIEHS/DERT Portfolio Coding Database
- Interviews with principal investigators and other Center staff
- Group interviews with Center staff

Summative Questions for the Subcommittee

Taking the findings into consideration, the Subcommittee will be asked to answer the following summative evaluation questions.

1. How does the Centers program bring value, (i.e., lead the EHS field) in relation to complex, emerging and translational research?
2. What can the Centers do that can't be done with other research mechanisms?
3. What best practices emerge from the Centers as critical for the program and the EHS field (defined broadly and including public health)?
4. How can the Centers help inform NIEHS about emerging fields and scientific opportunities?
5. How should the Centers be involved with identifying and implementing the next set of strategic plan goals?

Appendix F

NIEHS Centers Program Evaluation Timeline

2014	
September 15	Provide Subcommittee with materials for kickoff meeting
September 30	Subcommittee Web kickoff meeting
October – December	Data collection and analysis, including progress reports, appendix tables, and interviews
December 15	Provide Subcommittee with data for Questions 1, 4, and 5
2015	
January 7	EAS Web meeting – Questions 1, 4, and 5
January – February	Coding and data analysis of interview data; incorporation of all data analysis
February – March	Internal NIEHS discussions of findings; additional data collection if needed
February 20	Provide Subcommittee with data for Questions 2 and 3
March 19	Subcommittee Web meeting – Questions 2 and 3
April	Grantee meeting – final data collection opportunity
April	Planning meeting for in-person meeting
May 15	Provide Subcommittee with data for June in-person meeting
June	Subcommittee meeting in conjunction with Council meeting
June – August	Prep for Council presentation
September	Council presentation