

SUPERFUND BASIC RESEARCH PROGRAM

2009 SBRP External Advisory Panel:

Positioning the Program for Future Success
September 2009

Acronyms

ATSDR: Agency for Toxic Substances and Disease Registry

BEST: Board on Environmental Studies and Toxicology

COC: Community Outreach Core

EAG: External Advisory Group (2003)

EAP: External Advisory Panel (2009)

IACUC/IRB: Institutional Animal Care and Use Committee/Institutional Review Boards

NAEHS: National Advisory Environmental Health Sciences

NGO: Non-governmental Organization

NIEHS: National Institute of Environmental Health Sciences

NIH: National Institutes of Health

NRC: National Research Council

ORD: Office of Research and Development

P20: Planning Grants

P42: Multi-project Grants

PCB: Polychlorinated biphenyl

PPCP: Pharmaceuticals and Personal Care Products

R01: Individual Research Project Grants

R41: Small Business Technology Transfer Research grant, Phase I

R42: Small Business Technology Transfer Research grant, Phase II

R43: Small Business Innovation Research grant, Phase I

R44: Small Business Innovation Research grant, Phase II

RFA: Request for Applications

RPM: Remedial Project Manager

RTC: Research Translation Core

SARA: Superfund Amendments and Reauthorization Act

SBIR: Small Business Innovation Research

SBRP: Superfund Basic Research Program*

STTR: Small Business Technology Research Transfer

US EPA: United States Environmental Protection Agency

*In June, 2009, The Superfund Basic Research Program (SBRP) was renamed the Superfund Research Program (SRP). The name and acronym have not been changed for purposes of this report.

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1. EXECUTIVE SUMMARY

BACKGROUND

This report presents analyses and recommendations of the External Advisory Panel (EAP). The EAP was established to provide guidance for the future direction of the Superfund Basic Research Program (SBRP). The EAP was charged with analyzing and providing recommendations on key scientific issues that should frame SBRP research, and identifying emerging issues for future research. The SBRP also asked the EAP for input on the basic structure of the program as well as mechanisms to accelerate the application of research outcomes.

The SBRP has a demonstrable history of assembling interdisciplinary academic teams to address pressing basic research problems relevant to contamination of the environment at Superfund sites. The SBRP is likely the largest source of extramural research dollars that address these issues. The scientific programs funded to date have had measurable success in advancing scientific knowledge through high-quality research, as determined by bibliometrics (i.e., publications in high-impact, peer-reviewed scientific journals) and fulfillment of training goals. SBRP-funded research has addressed fundamental knowledge gaps in hazardous waste hazard, exposure and risk and has promoted development of hazardous waste management and remediation technology. Noteworthy examples include SBRP-funded research on complex mixtures, bioavailability, metal contaminants, sensors for site characterization and monitoring, and risk assessment tools. Some of this research has affected approaches to site monitoring and remediation and chemical assessments developed by regulatory agencies. Still, as is the case with related research programs (e.g., the Environmental Protection Agency's STAR Grants program), it is difficult to judge the extent to which SBRP research output is used in decision-and policy-making processes.

From the outset, the SBRP has emphasized multidisciplinary research. This is appropriate and should be continued and enhanced. Basic research programs can advance "science for science's sake", or they can advance knowledge to fulfill identified needs of stakeholders and decision-makers. The latter programs are at the interface of basic and applied research. This so-called translational aspect of the research carried out by programs like the SBRP appears to be highly valued by stakeholders and Superfund partner agencies. The emphasis on translation of basic science to application has always been a goal of SBRP. However, these efforts were enhanced substantially in 2004. It has taken the form of information dissemination and technology transfer activities in Multi-project Program Grants. While this is appropriate, it should be further refined in the context of a basic research program which supports direct application and problem solving. From this perspective, research translation has multiple phases, which feed into activities like validation, proof of concept, demonstrated application, and commercialization (where appropriate). Additional interaction with the Environmental Protection Agency (EPA), the Agency for Toxic Substances and Disease Registry (ATSDR), and stakeholders in communities affected by Superfund sites will be needed to fully realize the translational nature of the SBRP.

SBRP-funded research has a variety of audiences and users within EPA and ATSDR. For example, basic research that produces model parameters (e.g., mass transfer coefficients, reaction rate constants, or bioavailability measures) were acknowledged and valued by EPA Regional staff and consultants. Additionally, EPA's Office of Research and Development is a main and natural consumer of basic science output which is useful in risk assessment or in

understanding the mechanisms of toxicity for Superfund-related chemicals. The primary likely end-users of SBRP-funded engineering research are developers of remediation technologies or those who evaluate technology options at individual Superfund sites.

SBRP's quality research has increased knowledge, reduced uncertainty in risk assessment, and has helped incorporate scientific evidence into environmental policy and decision-making at Superfund sites. SBRP also provides an opportunity to connect emerging issues in managing and/or preventing exposure from releases of hazardous waste to the environment. Overall, SBRP activities fill an important niche in the science needs for site assessment and remediation, have had a positive impact on public health, and are worthy of continuation. However, increased interactions among the Superfund Agencies and key stakeholders are likely to increase the impact of this Program. Future resources for SBRP are likely to be highly scrutinized and accountability will be emphasized. External pressures to apply these resources to the most critical questions of our day are likely to increase. Therefore, it is even more important that SBRP demonstrates wise and efficient use of its resources in the future. Most importantly, SBRP should significantly advance efforts to identify and prioritize new (or ongoing) areas of emphasis and investigation.

The recommendations of the EAP, presented here, are based on a review of extensive written briefing materials provided by SBRP staff and contractors; a series of telephone Panel conferences; responses to Panel-generated questionnaires from grantees, agency, business, and community representatives; and finally on presentations and interviews with invited participants from those groups during a two-and-a-half day workshop with the Panel.

As detailed in the main body of the report, the EAP generated the following recommendations to guide future SBRP activities toward success:

- 1. Conduct a high-level strategic planning exercise to identify and promote research on emerging scientific issues critical for site assessment and remediation.
- 2. Increase level of program integration and promote interactions among grantees; this includes interactions between individual grantees and between individual grantees and Multi-project Grant programs.
- 3. Increase emphasis on translation of research towards remediation activities.
- 4. Promote effective and sensitive community outreach, especially as it pertains to communities affected by Superfund sites. This includes recognition of and sensitivity towards specific cultural identities and characteristics (e.g., the Indian Nation, its language and beliefs; challenges discussing sickness and death with translation of science; using different approaches for different communities; non-English speaking stakeholders).
- 5. Ensure critical review of continuously-funded, multi-project grants.
- 6. Develop and/or improve tools for assessing progress and achievements at the level of the individual grantee or Multi-project Grantee, and for the SBRP as a whole.
- 7. Develop metrics to assess the impact of SBRP research on the efficacy of siteremediation, decision making, and public policy. These metrics should be used to guide the future of research mechanisms and topics funded by the Program.

This Executive Summary and the following expanded report are organized into the following sections (in approximate order of priority): Strategic Planning, Priority Research Areas, Metrics, Portfolio Development, Communication and Collaboration, Data Dissemination, Translation, Community Outreach, and Training. Comments on the responsiveness of SBRP to the 2003 EAG report are also included.

A. Strategic Planning

There was consensus among EAP members that the time has come to initiate a high-level strategic planning effort. The extent and intensity of review and analysis and the resources required to achieve a strategic plan are beyond the scope of the current EAP review or that of the 2003 External Advisory Group.

Since the time the SBRP was created by the Superfund Amendments and Reauthorization Act (SARA) of 1986, science and technology have advanced substantially, and the landscape of relevant scientific research and expectations for community involvement has evolved. There is also a growing understanding of the importance of translational research - beginning with the basic research that leads to a key, important scientific understanding then stepping through the research needed to apply that understanding in the field or, in medicine, by the clinician. Therefore, the EAP strongly recommends that SBRP immediately initiate efforts to develop a strategic plan to provide for clear program goals and priorities in the context of an appropriately balanced portfolio. The goal should be the development of a strategic plan that identifies not only priority areas of investigation, but the process by which priorities are routinely reassessed and iteratively modified. This will provide strong interim guidance for the Program, transparency for the public, and a strong basis for future external evaluation and recommendations. An important consideration is how the SBRP fits into and leverages other related research efforts sponsored by the federal government and the private sector.

There are several well-established approaches to the strategic planning process (e.g., NRC/ BEST commissioned reports; outside contractor/facilitator) which should be considered by SBRP management, prior to choosing and implementing one approach. Regardless of the chosen approach, the strategic planning process should engage a broad range of participants beyond traditional stakeholders such as EPA, Remedial Project Managers and community representatives. By including a broad group of participants, it may be possible to envision and implement important new priorities in the fields of remediation and environmental management. The strategic planning process should also include "gap analysis" and should attempt to identify and address limitations in the SBRP portfolio. Another goal would be to identify and prioritize research goals, include specific environmental chemicals and agents of concern, some of which may already be present at existing Superfund sites or other contaminated areas and some that are of emerging concern. Areas ripe for collaboration or expansion within and between funded SBRP programs should be identified, as well as opportunities to interact with non-SBRP programs, such as risk assessment programs at EPA. The strategic planning process should provide the framework upon which programmatic elements such as requests for applications (RFAs) and other research initiatives are developed within SBRP, and guide development of milestones and timelines which can be used to measure the success of SBRP as a whole, as well as its individual component programs. Transparency should be maintained in all aspects of the strategic planning process. Ultimately, strategic planning will accelerate research progress and translational application of research findings, and will allow SBRP and its stakeholders evaluate the overall impact of SBRP on environmental and human health.

B. Priority Research Areas

SBRP should carefully consider its research goals and objectives in the context of its strategic planning process, as described above. However, the SBRP 2009 EAP identified a number of important and compelling research areas, which it considers to be immediately relevant to future progress in environmental management, remediation and environmental health. In brief, these areas are: 1) emerging toxicants and novel compounds, agents or activities; 2) efficient remediation, waste reduction and energy efficiency (e.g., green technologies); 3) cumulative toxicity and risk assessments, including those for complex toxicant mixtures; 4) exposure assessments and modeling; and 5) identification of susceptible populations (children, the elderly, the immuno-compromised, those with limited access to health care, the impoverished). Discussion and rationale for research in these areas is included in the main body of the EAP report.

C. Metrics

There is continued need for appropriate, state-of-the-art bibliographic and non-bibliographic metrics for evaluating progress towards SBRP goals at the individual program level. Use of appropriate metrics is a mechanism to ensure reasonable progress toward pre-determined milestones on an acceptable timetable. Appropriate metrics are especially needed for translation and outreach/communication efforts to demonstrate impacts of the Program on public health outcomes in communities affected by Superfund as well as other communities. Development of such metrics should be an activity included in the strategic planning process.

D. Portfolio Development

SBRP should continue to develop its portfolio using appropriate grant mechanisms, including R01, P42, SBIR and STTR grants. Additional areas for consideration would be: P20 planning grants to facilitate the entry of new research teams into the program; and other mechanisms that promote coordination between individual grantees and/or grantee programs. In addition, the Panel suggested the need to facilitate increased interactions between grantees or grantee programs and cooperating agencies and institutions (i.e., EPA, ATSDR, CDC etc.) or among a combination of grantees, agencies, and/or affected communities.

E. Collaboration and Communication

The EAP felt that SBRP could potentially gain "added value" by promoting more synergy among its grantees and grantee programs. SBRP could promote synergistic interactions by establishing one or more pilot programs to complement and extend ongoing research in an SBRP Multi-project Grant program. SBRP Program staff could also require that each Multi-project Grantee develop at least one collaborative project with another Multi-project Grantee. Collaborations with cooperating agencies and communities should also be promoted, as described above.

F. Data Access and Dissemination

It is the responsibility of SBRP staff to mandate appropriate data access and dissemination practices by its grantees. There does not appear to be oversight or some mechanism to ensure that this is a routine and complete practice by grantees. Therefore, SBRP should immediately establish a mechanism, such as a committee, to improve and monitor data access and dissemination and to provide ongoing oversight of this process. The goal would be to ensure that SBRP grantees deposit annotated and raw data into appropriate repositories according to current protocols and guidelines within an acceptable time frame. For cases where formats

have not been standardized, the SBRP would provide guidance to grantees, either by providing a format or expressing expectations. Agency and public access to appropriate levels of information, and appropriate consideration of intellectual property issues should be guaranteed. The ethical and social implications of the released data, as well as economic impacts should also be carefully considered in developing guidelines for data release. To improve and facilitate compliance and prevent misuse of the data, database interfaces should be "user-friendly" and include the mechanism for facilitating the interpretation of data through annotation and consultation with SBRP scientists and Program staff. Access and dissemination of readily interpretable SBRP-funded data and information would result in a valuable legacy of this long-term Program.

G. Translation

Translational research, that is, science that begins with the basic research findings then moves all the way to the application (e.g., in remediation, risk assessments, policies and decisions), should be the ultimate goal for SBRP-funded research. This is not a simple matter, and the strategic planning exercise should provide recommendations in this area. Meanwhile, proposals to the SBRP should, at a minimum, identify potential translational outcomes, discuss appropriate timelines (which may vary for different types of research), and identify multi-disciplinary partners who may be needed to effect translation. In addition, the EAP recommends to SBRP that translation efforts at all levels be more proactive, that a continued emphasis be placed on the improvement of public health as an outcome, and that milestones and a timetable are specified when translational outcomes are described. The EAP acknowledges that SBRP results are often applicable in non-Superfund communities and encourages continuation of this effort. Depending on the nature of the research, this may require researchers to work closely with site managers and contractors doing site remediation. In other situations this will not be appropriate and interaction with organizations such as the National Center for Environmental Assessment within the EPA or ATSDR may more effective in achieving the research translation goal. Finally, certain research translation will best be achieved by actively engaging communities at existing Superfund sites.

H. Community Outreach

Community outreach programs should be designed around the collection of information on problems of importance to stakeholders at Superfund sites around the country. This should include community members and should guarantee effective dissemination of relevant research results to affected communities. This information collection activity can also provide a venue for expert input into communities regarding the state-of-the-science on emerging issues. However, these activities should be carefully coordinated with ATSDR, US EPA, and CDC Regional staff so that conflict and mis-communication are avoided. If implemented correctly, SBRP researchers in communities can provide both a source of information to the Program that will be valuable for Program planning purposes and can serve as scientific advisors to aid the communities who are grappling with difficult local and national Superfund scientific issues.

I. Training

Superfund science and engineering problems will continue to be priority environmental and public health issues for years to come. SBRP should make a concerted effort to expand the training of graduate students and post-docs in relevant disciplines. In addition, there is a need to train transdisciplinary researchers who understand, for example, both basic science and environmental / civil engineering, or both bioinformatics and toxicology. This could be

accomplished through a number of mechanisms including expansion of existing Multi-project Grants or establishment of research service awards and training grants for graduate students and post-docs requiring post-educational work in the Superfund and/or public health fields. Research service awards served a valuable role in the past and are coming back into favor. This form of training should be actively explored by the SBRP.

2. EXPANDED REPORT

Background

SBRP was created by the National Institute of Environmental Health Sciences (NIEHS) / National Institutes of Health (NIH) under the Superfund Amendments and Reauthorization Act (SARA) of 1986. The mandate of the SBRP is to develop techniques to detect, assess, evaluate, mitigate and minimize adverse effects of environmental contaminants on human health. SBRP research activities support and complement Superfund activities at EPA and ATSDR. Until 2001, the NIEHS and the ATSDR received their funding for SARA-related activities as pass through funds from the EPA. Since that time, the Program has continued to evolve with funding in the \$40 to \$50 M range annually, provided through an appropriation to the Department of Health and Human Services.

SBRP conducts basic research in many Superfund-related areas, including biomedicine, ecology, epidemiology, toxicology, molecular biology, hydrogeology, engineering and soil science. The Program was founded on the premise that basic research was needed to provide a sound science underpinning to understanding, prioritizing, and addressing environmental and health issues at Superfund sites. NIEHS has recognized the interdisciplinary nature of these Superfund-related problems and the need to go beyond academic pursuit of knowledge toward their solutions.

Currently, the large majority (94%) of the SBRP annual budget is used to directly support SBRP research, which is implemented through four grant mechanisms: P42 - Multi-project grants, R01 -Individual Research Project grants, SBIR - Small Business Innovation Research, and STTR - Small Business Technology Transfer Research grants. All grant applications are subject to the competitive NIH peer-review process. The balance of the budget supports Program administration.

P42 grants, which form the core and majority of the SBRP portfolio, are grants composed of multiple research projects and cores assembled by researchers with complementary skills, experience and resources. This mechanism is critical for SBRP, because of the complex nature of hazardous waste management and remediation, and because of the need to integrate both biomedical and non-biomedical research components to address these issues. SBRP P42 grantees are required to include translational components in their research program. They are highly recommended to also include outreach and training components, as well. In its initial round of funding, SBRP funded four P42 grants for five years each, at a total annual budget of \$3M. In the period 1995-2000, SBRP funded 19 P42 grants. SBRP currently supports 14 P42 grants at an annual budget of approximately \$41M. In the period 1990-2000, approximately one-third of the grants turned over. The funding success rate for SBRP applications was 48%, 19% and 12.5% in 2005, 2006 and 2008, respectively.

The R01 mechanism is used by SBRP to meet high-priority research needs such as in situ remediation of contaminated sediment or the development of novel nanotechnology-based

remediation technology. SBRP began funding through the R01 mechanism in 2006 in response to recommendations from the 2003 EAG. Two Requests for Applications (RFAs) for R01 funding have been released since 2006. It is anticipated that eleven R01 grants will be funded in 2009 with an annual budget of approximately \$2.5 M.

The SBIR and STTR (R43, R44, R41, R42) grant mechanisms are used to promote application and commercialization of innovative monitoring and remediation technologies. Grant opportunities are announced via the NIH Omnibus solicitation annually. SBRP provides Phase I and Phase II funding to small biotechnology and bioengineering companies that are developing novel strategies to monitor, manage and/or remediate hazardous environmental waste. These grants were initiated in 2001 at the federally mandated level of 2.8% of the budget (approximately \$1.3M). SBRP currently funds two Phase I and three Phase II SBIR/STTRs. SBRP Development and Oversight Procedures

Over the years, the SBRP has relied on solicitation of input and review on various levels to assure that the output of the Program represents quality, relevant science. It has sought input on critical and emerging science issues through sponsorship of workshops and conferences and through the development of liaisons with its Federal partners. This input has been factored into requests for applications (RFAs) which have also been subjected to review by the scientific community, EPA and ATSDR. However, there has been no concerted effort at strategic planning to reevaluate the mission and goals of the program since its inception.

Peer review of submitted grant applications is one of the primary oversight mechanisms used by SBRP to assure the quality of the science that it produces. This is the first level of review, which is designed to ensure that awards are made according to objective quality standards. Each funded P42 program assembles internal and external advisory boards, who routinely evaluate research progress; P42 grantees submit annual progress reports to SBRP management; and SBRP management conducts on-site project reviews as needed. External reviews are conducted on a regular basis at the level of the individual project and at the level of the entire program. SBRP convened an External Advisory Group (EAG) in 2003, which conducted an independent review of the activities and accomplishments of SBRP as a whole. (The Executive Summary from the 2003 EAG report is available at the following URL: http://www.niehs.nih.gov/research/supported/sbrp/1/eag/docs/eag_execsummary.pdf). The charge to the current External Advisory Panel (EAP) is described in the following section.

Role, Charge and Process for the 2009 SBRP EAP

The 2009 EAP was convened by SBRP to provide guidance in shaping its future activities. The EAP was specifically asked to identify current and emerging scientific issues that are fundamental to the SBRP research mandate and to recommend activities and or approaches that would enhance the overall effectiveness of SBRP in reducing adverse effects of environmental hazardous waste on human health. The panel was also asked to comment on how to attract researchers conducting the best, cutting-edge research to address SBRP needs and to assist in training the next generation of investigators with relevant skills. The panel also focused on approaches to facilitate and accelerate the use of the scientific advances emanating from the Program.

In carrying out its charge, the 2009 EAP considered a large amount of information prepared by SBRP program staff and its supporting contractor, MDB, Inc. The Briefing Document (prepared

by MDB, Inc.) is available at the following URL: http://www.niehs.nih.gov/research/supported/srp/about/about8_s1.cfm. The following written materials were provided to the EAP as appendices to the Briefing Documents:

Appendix A: Grant Funding History

Appendix B: Current Grantees

Appendix C: Examples of Notable Research Advances

Appendix D: SBRP-funded Activities at Hazardous Waste Sites

Appendix E: Research Translation Core Activities

Appendix F: Executive Summary: 2003 External Advisory Group Review

Appendix G: Risk e Learning Web Seminars

Appendix H: SBRP-funded Conferences

MDB, Inc. also solicited input from SBRP grantees, cooperating agencies and community representatives in the form of a voluntary questionnaire. Responses were collated and provided to the EAP for review (http://www.niehs.nih.gov/research/supported/srp/about/about8_s2.cfm).

The EAP convened for a 2.5-day meeting on January 19-21, 2009, in Durham, NC. All EAP members participated in the meeting either in person or via teleconference. The meeting included presentations by SBRP staff, SBRP grantees, and representatives from community interest groups, environmental consulting firms and co-operating federal agencies.

Presenters included the following individuals:

NIEHS

Claudia Thompson, PhD, Acting Director, SBRP Gwen Collman, PhD, Interim Director, Division of Extramural Research and Training, NIEHS Beth Anderson, MA, Program Analyst SBRP, NIEHS

SBRP Grantees

David Ozonoff, MD, Program Director, SBRP, Boston University Raina Maier, PhD, Co-Program Director, SBRP, University of Arizona Larry Robertson, PhD, Program Director, University of Iowa

Consultants

Cris Williams, PhD, Managing Health Scientist, ChemRisk Stephen Koenigsberg, PhD, Principal, Environ Paul Kostecki, PhD, Vice Provost for Research, University of Massachusetts, Amherst

Community Representatives

Lillie Lane, Public Information Officer, Navajo Nation Cynthia Babich, Co-Founder and Director, Del Amo Action Committee

Federal Partners

Randall Wentsel, PhD, Land Research National Program Director, EPA ORD Dave Drake, Remedial Project Manager, EPA Region 7 Tom Sinks, PhD, Deputy Director, NCEH/ATSDR

The agenda of the January 19-21, 2009 meeting and relevant Powerpoint presentations from the meeting are available at the following URL: http://www.niehs.nih.gov/research/supported/srp/about/about8_s2.cfm.

Staff from the SBRP provided valuable perspective on the history and vision for the Program. The Program has evolved and grown both in budget and number of grants provided. Most recently, efforts have been made to emphasize translation of the work of the Program to real world solutions to problems encountered at Superfund sites. In addition, the Program has redefined its community outreach efforts and initiated annual funding opportunities for individual researcher-initiated grants (RO1's). The Program continues to have a broad focus both in chemical contaminants studied as well as toxic sequelae investigated. The Program has also moved into non-biomedical research including ecotoxicology, fate and transport, monitoring, bioavailability, and various forms of remediation and site assessment technologies. SBRP management is committed to a strategy of enhancing partnerships with other agencies, states, tribes and other organizations; facilitating inter-laboratory projects; promoting technology transfer; and communicating research findings through multiple means including support for scientific conferences. There appears to be a concerted effort to build on successes of the past Program, supporting a full-spectrum of research, while at the same time preparing to address emerging issues as NIEHS moves the Program toward the future.

The Panel heard from Program investigators and representatives who were generally supportive of the directions of the Program. They expressed concern for the inherent tension between basic and applied aspects of the research but applauded the "structured flexibility" which seems to exemplify the Program. The Panel saw examples of the multi-disciplinary nature of the work of SBRP investigators which were directed toward informing clean-up goals and strategies based on fundamental knowledge, innovation and application. Investigators saw their role as also communicating their results to relevant federal agencies and stakeholders. Concerns expressed about the Program included limited resources, funding models, and incentives for collaboration, among others.

The Panel also received input from the Superfund consulting community. Representatives from this constituency saw themselves as recipients of the advances made in the SBRP. They expressed the need for the program to address a variety of difficult problems encountered when Superfund sites were evaluated for environmental and public health risks. Beyond these individual problems, they saw an evolution of the clean-up paradigms from relatively crude, energy-intensive engineering solutions, through in situ treatment approaches, to application of enhanced, energy-efficient technologies (sustainable approaches to remediation). They also expressed the need for enhanced communication of Program results. Particular concerns were expressed that Program development be better coordinated with federal and state regulators' needs. Accessibility of Program data and results was also raised as an issue.

Community stakeholders also provided valuable input to the Panel. It was apparent that community stakeholders viewed the SBRP as valuable and credible. There seemed to be an interest in having the SBRP and its investigators serve the "honest broker" role for communities dealing with federal and state regulators. While useful in some instances, this can result in conflicts with those agencies as expressed by comments provided below. All-in-all, however, the community outreach aspects of the SBRP were viewed positively by stakeholders and suggestions were provided for enhancing these activities as the Program develops.

Representatives from key federal partners also provided valuable input to the Panel. Generally speaking they saw the SBRP as providing basic research to assist the more applied activities at EPA and ATSDR. They saw opportunities for additional support through the SBRP for addressing science issues, supporting public health, risk assessment and remediation efforts and assisting in community outreach and education. The underlying theme of the input from these other federal agencies was that more communication and collaboration in Program development and application was needed. Examples of valuable input from the SBRP was cited (vapor intrusion; arsenic toxicity and treatment). However, more work is needed to assure that the valuable resources of the SBRP are well coordinated with Programs underway at EPA, ATSDR and state agencies. The consequence of a lack of coordination was perceived as the pitting of one Program or agency against another and confusion among the public regarding important scientific issues associated with Superfund sites and clean-up requirements. Suggestions were provided to the Panel regarding approaches to enhanced coordination and collaboration.

Issues and Recommendations for the Future Based on a Review of SBRP Current Activities

The EAP noted that SBRP, since its last review in 2003, has been productive and has promoted research that facilitated significant improvements in Superfund or Superfund-related activities, as well as in hazardous waste management technology. Thus, in general, the EAP found that SBRP activities have been appropriate, useful and significant. There was a consensus among the 2009 EAP that the SBRP had been responsive to several recommendations of the 2003 EAG report. Continued support for interdisciplinary research, use of multiple funding mechanisms, enhanced information dissemination and explicit community involvement represent several noteworthy enhancements to the Program in response to the 2003 EAG report. Implications of these Program changes and suggestions for continued enhancement are detailed below.

In reviewing input from SBRP and its stakeholders, the EAP identified several areas where there is room for improvement, as discussed below. Based on this input and the Panel's analysis of the SBRP, the EAP generated the following recommendations:

- 1. Make a concerted effort at high-level strategic planning to identify and promote research on selected emerging scientific issues.
- 2. Increase level of program integration and promote interactions among grantees; this includes interactions between individual grantees and between individual grantees and Multi-project Grant programs.
- 3. Increase emphasis on translation of research towards remediation and assessment activities.
- 4. Promote effective and sensitive community outreach, especially as it pertains to communities affected by Superfund sites; this includes recognition of and sensitivity towards specific cultural identities and characteristics (i.e., the Indian Nation, its language and beliefs; challenges discussing sickness and death with translation of science; using different approaches for different communities; non-English speaking stakeholders).
- 5. Ensure critical review of continuously-funded, multi-project grants.
- 6. Develop and/or improve tools for assessing progress and achievements at the level of the individual or Multi-project grantee, and for the SBRP as a whole.
- 7. Develop metrics to assess to impact of SBRP research on the efficacy of site remediation, decision making, and public policy.

A. Strategic Planning

Initiate an intensive and extensive strategic planning process based on a comprehensive review of the SBRP program and its stated short- and long-term goals

There was consensus among the EAP that a high-level strategic planning effort should be initiated. Vision is not defined as seeing things in their current state, but the ability to imagine how they could be in the near and distant future. The Program has undergone regular review and assessment of progress using standard metrics applied in the basic sciences. By all accounts, the SBRP has been a success in the basic sciences of environmental toxicants, their fate and transport, and in the development of novel approaches to remediation. However, what is not clear is the extent that the program has significant impacts on decision making, regarding site remediation, policy and legislation. Moreover, the involvement and impact of the funded research on affected communities has been variable, and its effectiveness and sensitivity to cultural diversity and needs of the community is also not clear.

Since the time the SBRP was created by the Superfund Amendments and Reauthorization Act (SARA) of 1986, science and technology have substantially advanced, and the landscape of relevant scientific research and expectations for community involvement has evolved. There is also a growing understanding of the importance of translational research - that is, maintaining the thread of research, from basic research that leads to fundamental scientific understanding, through to the research needed to achieve its use in the field or, in medicine, by the clinician. The extent and intensity of review and analysis and the resources required to achieve a strategic plan are beyond the scope of the current EAP review or that of the 2003 External Advisory Group. The EAP therefore, strongly recommends that SBRP immediately initiate efforts to develop a strategic plan to provide for clear program goals and priorities in the context of an appropriately balanced portfolio and a clear vision of the program's future directions. Some of the questions that the strategic planning effort should address, but not be limited to, the following:

- 1. Is the original mission developed for the SBRP in response to SARA still relevant given advances in science and technology over the past twenty years?
- 2. How might the Program's mission be altered to increase the impact on site remediation, decision making, public policy and regulation?
- 3. Are the current administrative and leadership structure and resources optimal for operating the Program? For example, is current program staffing sufficient to conduct the collaboration with the scientific community and other federal agencies which will be needed for future success?
- 4. What are the appropriate levels of involvement and roles of affected communities in the SBRP?
- 5. What are appropriate levels of interaction between the SBRP and other government agencies and NGOs?
- 6. What is the best way for the SBRP to achieve the goal of translational research? Is the recent enactment of a mandatory Translational Core an effective approach to disseminating research findings to stakeholders, and toward this overarching goal? How should efficacy be assessed?
- 7. What are the mission critical areas of research for the SBRP? How should the SBRP interact with other research programs within the NIEHS, NTP, EPA, NIH and ATSDR

to ensure its research is optimal? Does the current balance of basic biomedical and applied research ensure the greatest impact of the SBRP? What is the appropriate balance moving forward?

- 8. Is the current peer review process adequate to ensure that science with the highest impact is supported by the program? How can it be enhanced?
- 9. Are the present allocation and funding mechanisms the most appropriate to achieve the goals of the Program?
- 10. How are decisions regarding new directions and emerging issues made? Is the current decision making process optimal?
- 11. Should the SBRP take a more proactive role in anticipating future contaminants or focus on existing problems?
- 12. What level of visibility of the program within the government and the public is optimal given program resources and competing demands? How can this best be achieved?

While the EAP made an attempt to address many of these issues within the present report, the panel was not charged with or configured to conduct strategic planning. It is therefore strongly suggested that the SBRP initiate an immediate, intensive, and extensive strategic planning process based on a comprehensive review of the SBRP and accounting for its future vision. There are several well-established approaches to obtaining the input needed and facilitating the strategic planning process (i.e., NRC/BEST; outside contractor/facilitator) which should be considered by SBRP management prior to choosing and implementing one approach.

B. Priority Research Areas

SBRP should carefully consider its research goals and objectives in the context of an intensive and extensive strategic planning process, as described above. However, the SBRP 2009 EAP recommends that the following research areas be considered during this process. The EAP does not intend this list to be obligatory or inclusive: It is merely a list of areas that EAP members find important, compelling and relevant for future progress in environmental management, remediation and environmental health. However, it is important that the decision making process for how future or emerging compounds are selected for inclusion in the SBRP be evaluated in the strategic planning process.

Potential effects of emerging toxicants and novel compounds, agents or activities

Several novel toxicants and toxicant-related issues that have emerged recently may have potential impact at Superfund sites. These include issues such as global climate change, production and use of nanotechnology-based tools and materials, as well as agents associated with alternative/green energy production and infrastructure development. It is important for SBRP to recognize and anticipate the environmental impact and potential environmental and health consequences of these novel materials and technologies, and to proactively develop tools for managing potential problems associated with their development and wider implementation to prevent development of future Superfund-level problems. In contrast, SBRP-funded grantees have to date tended to focus on well-characterized contaminants, such as chlorinated solvents, PCBs, dioxins, PAHs, arsenic and lead. In future, SBRP should also assess impacts due to additional compound classes, such as PPCPs, engineered nanomaterials, perfluorinated compounds, endocrine disruptors, or indoor air pollutants, as well as combinations of toxicants associated with alternative fuels and mining operations. It is however

important that the Program develop a process for selecting these emerging compounds, so as not to overly dilute its efforts or duplicate efforts funded by other agencies and programs.

A recent example of the adverse impact of a novel compound is perfluorooctanoic acid (PFOA) and other perfluorinated chemicals. Because the toxicity of PFOA was not appreciated until recently, numerous manufacturing sites became heavily contaminated with PFOA, leading to serious threats to human health. Through strategic planning, as discussed above, a process could be developed by which emerging areas are identified and targeted for additional review and/or new research activity. These would include high volume or high impact agents (or processes), with demonstrated potential for adverse environmental impact. Research on the potential toxicological hazards associated with these emerging toxicants could help avert large-scale contamination and formation of future Superfund-level sites.

Global climate change is another emerging issue that could ultimately have an effect on policy decisions. It is anticipated that climate change will alter susceptibility, patterns of chemical degradation, and toxicant mobility. Any of these issues might affect future remediation decisions, and have an impact on previously-remediated Superfund sites. Thus, it is relevant for SBRP to model short-term effects of predicted climate change on Superfund sites and vulnerable populations living in those communities. It would be worthwhile for SBRP to model the effect of multiple external variables (including climate, water table, hydrology, chemical interactions) on chemical transport and fate and spontaneous formation of new chemicals in existing Superfund sites over time. These studies should also attempt to anticipate the potential health and environmental effects of novel toxicants, if they are predicted to form at any significant level in existing Superfund sites. Finally, it has been predicted that climate change could increase toxicant-induced burden and stress on sensitive populations, making some Superfund research more relevant to these individuals. For example, increased fugitive dust burdens, already evident in areas of prolonged drought, could increase the mobility of adhered toxicants, leading to increased respiratory stress in sensitive populations. Therefore, identification of emerging issues associated with climate change and their implications for current and future policy could help pre-empt future Superfund-level problems. However, caution must be used to ensure that the predicted effects of climate change on Superfund related issues be based on the best and most up-to-date science and free of undue public and political pressures.

Efficient remediation, waste reduction and energy efficiency

Some contaminants at Superfund sites are poorly accessible or cannot be managed effectively using existing remediation technology. Therefore, it is important to promote research on more efficient or novel remediation technology that can improve the bioavailability or accessibility of persistent contaminants. Approaches are needed to improve the level of mixing in the subsurface, to increase the rates of mass transfer, and to improve the efficacy of chemical and microorganism delivery. Furthermore, if the contaminants are sequestered through environmental transfer and transformation, research is needed to determine whether these processes will prevent future releases and exposures on a transient or permanent basis.

Research on remedial technologies should promote increased energy-efficiency and greater waste reduction (i.e., green technologies). For example, the remediation research should focus on reduced use of chemicals, increased use of recycled materials, energy conservation, and greater reliance on renewable energy sources. From this perspective, in-situ methods offer an advantage over ex-situ processes. Because novel remediation approaches, such as

those based on nanotechnology, could have unintended adverse environmental impacts, SBRP Multi-project grantees should be required to fully characterize novel approaches as to both their benefits and risks.

Cumulative toxicity and risk assessment (includes complex toxicant mixtures)

Communities near Superfund sites can be exposed to a wide range of chemicals originating from the site, and also various other environmental chemicals from nearby manufacturing, transportation, and other sources. Moreover, as emphasized in a recent report by the National Research Council (2008; Science and Decisions: Advancing Risk Assessment), background exposure (both endogenous and exogenous) and underlying disease processes contribute to population background risk and affect the dose response relationships of environmental chemicals. There is growing recognition that, in order to understand risk, the characteristics of the host population, the environmental chemical or chemical mixture, and the exposure milieu should be taken into account. The shape and low dose characteristics of dose response relationships for environmental toxicants may be substantially misrepresented if these factors are not adequately addressed. As noted in an earlier but recent NRC report (2007: Toxicity Testing in the 21st Century), toxicity results from biologic perturbations when they are sufficiently large or when the host cannot adapt. Thus the degree of toxicity is host specific and underlying health and disease status affect an individual's ability to adapt.

Though recognized as important scientifically, site assessments give little if any consideration to nonchemical stressors, population vulnerability and various background exposure and other risk factors. Affected stakeholder communities often question risk assessments as inadequate and point to their narrow focus and lack of comprehensiveness. Long-term basic research is needed to generate the underlying scientific understanding to support assessments that would more realistically characterize low-dose risk. Any strategic planning exercise should consider promising lines of research to advance our ability to better predict risk from interactions of sensitive population groups and life stages and chemical and non-chemical stressors.

In the near term, some advances can be made in the study of complex mixtures with high throughput toxicogenomic studies. Complex mixtures of toxicants are a significant problem in Superfund sites, as well as other areas of toxicology and environmental health. These mixtures of toxicants are known to interact in unexpected or poorly understood ways. Unfortunately, most toxicological studies use purified compounds and/or reconstructed mixtures, and data from these studies are the basis for regulation of individual compounds. However, the study of reconstructed mixtures becomes more and more difficult and less and less valuable as the number of components in the mixture increases.

In two separate studies, the National Research Council recently emphasized use of toxicogenomics to link biological response indicators (biomarkers) to mechanisms of toxicity, an approach which can readily be applied to chemical mixtures (NRC 2007; Applications of Toxicogenomic Technologies to Predictive Toxicology and Risk Assessment and NRC 2008 Toxicity Testing). In this approach, the mixture is treated as a single toxicant, which is then studied using standard toxicological methods. This approach could enhance the SBRP's efforts to evaluate and remediate Superfund sites, and to reduce their effects on human health.

Improved approaches to support exposure assessment and modeling

One of the goals of SBRP is to assess human exposure and conduct risk assessment with regard to Superfund sites and their remediation. Thus, SBRP should enhance exposure assessment on a continuous basis during site investigation and remediation activities. Ultimately, ambient levels of contaminants in air, water, and soil would be monitored "in realtime" and correlated with biological response indicators in potentially exposed as well as control populations over the time period that the site activities took place. These data would be used to model exposure in populations near a Superfund site, and could potentially yield better estimates of intake rates (e.g. soil and dust ingestion rates), bioavailability, and uptake rates. A range of simple-to-complex exposure models will be needed to interpret environmental and biological data. Chemicals with short or long biological half-lives present unique challenges, including, for example, the need to understand historical and background exposures for compounds with a long half-life. Optimally, modeling would be conducted for the entire exposed population as well as for any known genetically-susceptible subpopulations. There is also a need for new biomonitoring technology to reflect known genetic diversity, concurrent exposures and conditions, and so that health effects can be linked to well defined, real-time exposure data.

C. Metrics

There is continued need for appropriate bibliographic and non-bibliographic metrics for evaluating progress towards SBRP goals at the individual program level. Appropriate metrics are especially needed for translation and outreach/communication. Use of appropriate metrics is a mechanism to ensure reasonable progress toward pre-determined milestones on an acceptable timetable.

Require grantees to define and measure progress towards milestones on defined timetable

The mission of the SBRP is to develop and apply novel approaches to manage environmental contamination, reduce health and ecological risks, and conduct site remediation. Therefore, most SBRP-funded research is expected to have defined outcomes, and it is reasonable to expect SBRP grantees to provide unbiased and tangible measures of their success. SBRP should require potential grantees to include milestones and a projected timetable as a condition of funding. Progress towards meeting milestones in the expected timeframe would then be evaluated on a regular basis and used as a measure of success. Grantees should be required to provide metrics that not only reflect research progress, but also milestones in translation, communication, and outreach activities with the specific focus of reducing public health impacts at sites. Once again, strategic planning will be required to define the types of metrics that should be collected to assess the reevaluated mission of the Program.

Assess research impact through enhanced bibliometrics and novel approaches

Bibliometrics can be performed using the SPIRES database as a measure of citation frequency and research impact. However, this approach can underestimate the impact of SBRP-funded science on practical aspects of remediation as well as policy and regulatory processes and decisions. Recently, EPA National Center for Environmental Research has developed additional bibliometric approaches for assessing the overall impact of research projects. It is recommended that SBRP expand efforts to measure impact of SBRP-funded research, possibly through a collaborative effort with EPA.

Because translation and outreach efforts do not always result in peer-reviewed publications, grantees should be encouraged to develop appropriate metrics within their programs to evaluate and document these efforts. Some potential metrics are: press coverage, letters documenting changes in organizational policies, the number of Superfund site communities contacted, letters of support from target audiences, effectiveness of communication. Research impact can be measured by: the number of screenings for exposure in local clinics; successful implementation of remedial actions informed by research and supported by communities based on outreach efforts; or reduced frequency of children trespassing on contaminated sites due to outreach efforts in schools. Evidence of these outcomes justify the utility of the program. While appropriate metrics will likely be unique to each grantee and to some extent determined on a case-by-case basis, the strategic planning process should be used to define the expected public impact of the SBRP. Public health outcomes could for example include the identification of highly exposed and genetically at risk individuals within the catchment area of the Superfund site, identification of at-risk remediation workers, development of intervention and prevention strategies for exposed populations, changes in land development policies to prevent future exposures, and changes in regulatory standards and statutes regarding environmental exposures. Metrics for impact on outreach and communication could include the development of culturally sensitive solutions to exposure reduction site remediation and prevention, involvement of communities in informed decision making and drafting of legislation.

D. Portfolio Development

SBRP should continue to develop its portfolio using appropriate grant mechanisms, including R01, P20, P42, K awards and training grants, SBIR, and STTR. Additional mechanisms should also be considered that promote coordination between individual grantees and/or grantee programs or interactions between grantees or grantee programs and cooperating agencies and institutions (i.e., EPA, ATSDR, CDC etc.)

Evaluate use of the R01 funding mechanism within SBRP

SBRP began using the R01 funding mechanism in 2006, primarily to target emerging areas of research that are felt to be insufficiently mature and therefore inappropriate for a program project grant. R01 grants currently constitute ~14% of the total number of SBRP awards, and ~2% the total funds dispersed by SRBP. Unlike research performed in SBRP Multi-project Grants, R01-funded studies are investigator-initiated studies that are not integrated into a larger research program. As a relatively new part of the SBRP portfolio, which uses resources that could be used to support other SBRP research, the existence of the R01 program should be evaluated and justified, as appropriate, over the next few years. However, because the SBRP R01 portfolio has only existed for two years, it is premature to evaluate its success at the present time. For example, some of the R01 grants may ultimately be integrated into existing programs, while others could form the nucleus for a new area of program emphasis, but these outcomes are not yet known. It is therefore recommended that the SBRP maintain the R01 grant program as a relatively small fraction of its total portfolio, and continue to monitor its success. The percent of total budget allocated via the R01 mechanism should remain low, so as not to negatively impact existing programs unless additional funds are made available to the SBRP.

Evaluate use of the P20 funding mechanism to increase funding of new investigators

It is a significant challenge to prepare and submit a competitive application for SBRP funding as a Multi-project grantee. This is in part because a large team of interdisciplinary researchers must be assembled and the proposal must propose and justify its research goals as well as

submit plans to develop a supporting research infrastructure, including a translational core and a community outreach component. The lead time for preparing a new (i.e., first-time) P42 application can be as long as two years, requiring significant commitment of time and resources. Because of this, proposals from previously-funded investigators or investigator teams are typically more competitive than proposals from new investigators. Furthermore, in some cases, the "cost" of preparing such a P42 proposal may be prohibitive for young or less-experienced investigators. This is unfortunate and could be detrimental to SBRP goals, because it could decrease the number of applications from investigators and investigator teams not previously funded by SBRP. These applications could be more likely to propose novel research on the critical issues surrounding new toxins and global change.

Therefore, it is recommended that the SBRP consider using a P20 funding mechanism to establish "planning grants" for up to two years with an annual budget that is 25-50% of an SBRP grant. Such a mechanism is currently used for Cancer Center grants, NIEHS Center grants, CTSA grants, etc. Although it could be argued that because the P20 mechanism was not used by SBRP in the past, it is not necessary now or in the future. However, addition of the P20 funding mechanism may lead to more novel SBRP programs and more rapid advancement of the SBRP mission.

The need for a unique cadre of individuals trained in both emerging basic sciences (i.e. omics) and environmental engineering will only increase as the need for site remediation increases and emerging issues and compounds are identified. Training this new pool of transdisciplinary scientists/engineers will require novel training programs and training grants. Development of this type of training infrastructure within SBRP funded institutions should be encouraged. This goal could be accomplished by direct support from the program, or redirection of existing of K award and training grant mechanisms to support this type of initiative that will bear fruit in the long term.

E. Collaboration/Communication

The EAP felt that SBRP could potentially gain "added value" by promoting more synergism among its grantees and grantee programs. SBRP could promote synergistic interactions by establishing one or more pilot programs which synergize with ongoing research or by requiring that each Multi-project Grantee develop at least one collaborative project with another Multi-project Grantee. Collaborations with cooperating agencies and affected communities should also be promoted, as described above.

Enhance research interactions among SBRP Grantees

In the past, SBRP-funded research has focused on a limited number of agents and sites, with significant overlap from one SBRP to another. Although this could reflect research needs (i.e., the number of sites with a specific contaminant; available or needed remediation technologies) and/or be guided by programmatic goals, it could also indicate redundancy in the Program, less than optimal use of resources, and failure to promote synergistic and/or complimentary research interests among SBRP grantees and SBRP Multi-project grantees. In contrast, the NIEHS-sponsored Toxicogenomic Research Consortium, and other similar research programs, has mandated cross-center research and sharing of resources. While this approach is not without difficulties, it often "adds value," in the sense that collaborations and resource sharing promote synergistic interactions, which accelerate research progress. Even in the absence of overlapping research interests, cross-grantee interactions should be encouraged. These

synergistic interactions might be fostered by a mandate that each grantee develop at least one collaborative project with another grantee.

Evaluate inter-agency collaborations on RFAs, strategic planning, grantee advisory boards

Various government agencies focus on different aspects of environmental contamination and exposure and risk associated with such contamination and exposure. EPA and the NTP assess the potential health impacts of toxicants, while the CDC annually quantifies exposure in a geographically representative cohort (NHANES). The SBRP should explore interagency collaborations based on synergistic opportunities to promote rapid research progress. Agency representatives should also be included on External Advisory Boards for SBRP Multi-project Grants. This will increase awareness of SBRP research in the agencies (especially at a regional level), and facilitate translation of research results. Reciprocally, input from the agency representatives to SBRP will facilitate identification of data gaps and research agendas relevant to Superfund remedial decisions and protection of public health.

F. Data Dissemination

As a matter of scientific leadership, data developed as part of the SBRP should be available in digital repositories that are referenced by the NIEHS as available for meta-analysis. The development of such repositories should incorporate considerations of intellectual property, copyright, IACUC/IRB, confidentiality and other mitigating circumstances. Investigators should also be provided adequate time for publication and should have perpetual access to the data collected in their laboratories/ programs. All data should be annotated and wherever possible, raw data should be made available to the broader scientific and lay communities five (5) to seven (7) years after the completion of studies. SBRP should, therefore, constitute a data sharing committee at its earliest convenience.

Considerations of intellectual property (a major coin of the realm in academe) mitigate the development of major repositories that contain both 'positive' and 'negative' data. With the advent of inexpensive electronic storage, there are a number of data repositories that vary in content and worth. New and future informatics tools will enable the curation of a large amount of data that meets minimum industry standards. Such repositories have the potential to "add value" to past research efforts and to enhance the cost efficiency of future research efforts.

Data repositories should incorporate multiple levels of access, and diverse tools for synthesizing data and generating reports. These features should be designed to maximize database utility and to accommodate the needs of multiple users/stakeholders. To ensure this outcome, diverse potential users should be given the opportunity for input early in the process of designing and building the database infrastructure.

G. Translation

Translation is the application of research findings so as to have a positive impact on human society. In the context of SBRP, research findings are expected to have an impact on environmental and/or human health. Effective translation should be the ultimate goal for SBRP-funded research. Therefore, proposals to the SBRP should, at a minimum, identify potential translational outcomes, discuss appropriate timelines (which may vary for different types of research), and identify partners who may be needed to effect translation. If the researchers envision that their best role is communicating the research results to the appropriate partners

who are better qualified to implement translational goals, then this should be identified in the proposal. An inability of the research community to effect translation should not in itself be a barrier to funding, as long as there is a vision and plan for possible translational outcomes.

There exists an opportunity for translation of SBRP basic science into practice. However, there currently exists a gap between the generation of data from cutting edge, basic science studies and the application of science to the management and/or remediation of Superfund sites or other hazardous waste remediation efforts. This gap can lead to latent or overt mistrust or distrust of the process. In some cases, this may simply be a question of time. That is, it can take a significant amount of time to acquire and validate sufficient, robust data and to process the findings into comprehensive risk assessment and/or remediation strategies.

The EAP recognizes, and encourages SBRP to recognize that the time frame for research translation may vary. For example, it may take substantially more time to develop translational applications for biomedical research and less time for non-biomedical research such as testing new site remediation technology. Different partners (i.e., engineering and/or product development firms) may need to be identified for different types of translational efforts, and in many cases, the appropriate regulatory agency may need to be engaged in the translational effort. It may also be necessary to develop and nurture relationships with individuals in affected communities. In some cases, the research community may play a minimal (or primarily informational) role in research translation.

Nevertheless, the EAP recommends that SBRP should proactively encourage translational efforts at all levels, that greater emphasis be placed on improvement of public health as an outcome, and that milestones and a timetable are specified, when translational outcomes are implemented.

H. Community Outreach

Many SBRP grantees have focused their outreach efforts on non-Superfund communities facing related exposures within their region. Interactions with Superfund-affected communities appear to be less common. The EAP recognizes the relevance of communication and translation of results to non-Superfund communities, but also recognizes importance of the SBRP in building, maintaining and improving relationships with communities who are directly impacted by Superfund sites and the expectations within those communities. Community representatives who interacted with the EAP at the January 2009 session emphasized the importance and value to them of "relationship-building," and repeated several times the phrase "relationship building is key." Relationships are built on open (i.e., two-way) communication with community stakeholders throughout all stages. Furthermore, community representatives emphasized that SBRP needs to become more sensitive to cultural issues that might influence the approach to community outreach, including the selection of tools/methods for effectively communicating information (i.e., visual vs. written media; English vs. Spanish vs. Navajo; etc.). Research agendas should also be responsive to data gaps identified by community members.

Effective outreach and development of respectful partnerships should be broadly targeted, to include community members, medical providers, advocacy organizations, and decision-makers/community leaders. While the goals of a specific SBRP Multi-project Grant should guide the choices, involvement of lay members of affected communities should receive high priority given the unique mandate of the SBRP. These relationships can serve an important role in

establishing the relevance of the SBRP through identifying data gaps and barriers to translation, thereby informing the research agenda. Researchers play an important role in communicating the science, identifying concerns, and answering questions, and they are likely to have a more independent perspective than SBRP administrative individuals. For example, community members often are concerned about land use as it impacts exposure assumptions, unique sensitivities of children or racial/ethnic subpopulations, or rare co-exposures. These concerns have implications for both the design of research and for effective translation.

Culturally appropriate outreach efforts lead to relationships based on trust, a key first step in effective multi-directional communication with affected communities. These relationships facilitate effective communication, and lead to better-informed communities and researchers. Ultimately, trust and communication are also essential to achieve the translational goals of SBRP. The community itself should be engaged in the design and implementation of translational programs. Engagement of the community in defining translational goals enhances the relevance of those goals and the likelihood of success. Ultimately, these efforts help protect and improve public health in communities impacted by Superfund sites (or other exposures to hazardous waste).

Specific ways for SBRP to improve community outreach might include:

- 1. improved physician and community leader training focused on culturally-sensitive approaches;
- 2. incorporation of community research studies into reports;
- 3. increased use of native language communication;
- 4. greater use of interactive community meetings in which community stakeholders can converse openly with appropriate knowledgeable SBRP representatives;
- 5. establishment of a liaison with National Children's Study in communities impacted by Superfund sites or other sites involving hazardous waste exposure; and
- 6. connection with regional Pediatric Environmental Health Specialty Units (PEHSU).

Finally, demonstration of inclusion of community partners through demonstrated outreach roles and allocation of budget to support community partners can be additional indicators of commitment and respect. All efforts, however, need to demonstrate some level of relationship with the target community and be supported through letters from non-governmental organizations or representative numbers of citizens within the community of choice.

While many paths will lead to effective outreach, the EAP feels increasing the emphasis on outreach and translation to affected Superfund communities will substantially strengthen the relevance of the SBRP in meeting its unique mandate. It is suggested that evaluation of the outreach proposals incorporate the concepts discussed here, that applicants be asked to demonstrate the appropriateness of their target audiences with respect to Superfund relevance as well as relevance to the research agenda; that some level of partnership with representative stakeholders be demonstrated, and the relevance of the community representative group be determined. Several models of effective outreach exist within NIEHS Centers and Partnerships for Environmental Health Programs, and it is suggested that RFAs incorporate those guidelines for both instruction of applicants and evaluation of proposals. Finally, as in other components of the SBRP, identification of metrics to determine success remains a necessary component of the plan.

The EAP also recognizes that EPA has active outreach within affected Superfund communities, and encourages the building of respectful relationships with those programs while stressing the difference in outreach goals. It should be clear to the community the different roles the academic and agency representatives play, again working to create open communication based on mutual respect and trust.

I. Training

Superfund science and engineering problems will continue to be priority environment and public health issue for years to come. SBRP should make a concerted effort to expand the training of graduate students and post-docs in relevant disciplines. This could be accomplished through a number of mechanisms including expansion of existing Multi-project Program grants or establishment of research service awards for graduate students and post-docs requiring post-educational work in the Superfund and/or public health fields. Research service awards served a valuable role in the past and are coming back into favor. This form of training should be actively explored by the SBRP.



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