

PART ONE: RESEARCH AND PROGRAMMATIC ISSUES - RECOMMENDATIONS

Comment	Response
SBRP Science	
<p>(1) New flexibility associated with annual competitions should be used not only to address unmet needs and emerging issues, but also to improve performance and quality in areas that have not yet been adequately addressed.</p>	<p>The SBRP plans to continue its interactions with EPA and ATSDR, not only to identify new research avenues, but also to ensure that efforts are continued to address scientific challenges that have not yet been fully met.</p>
<p>(2) A mechanism to identify emerging areas of need is not clearly defined. Stakeholder meetings may only highlight the application, rather than identify basic research questions. Such a mechanism should be established to receive stakeholder input on data needs on relevant, emerging issues.</p>	<p>Since the inception of the Program, the SBRP has invested significant resources into ensuring that the Program is aware of emerging areas of need. An on-going, robust strategy is in place that includes regular communication with stakeholders such as EPA, ATSDR, industry and environmental groups to identify long-term research needs. SBRP staff regularly participates in EPA and ATSDR meetings and scientific workshops and the Program sponsors an average of 12 scientific meetings, workshops and conferences each year with the specific intent of identifying data needs and gaps.</p>
<p>(3) SBRP staff should consider placing the summary information contained in the EAG review volumes on the SBRP website. Doing so would make a visible statement about the overall quality of the science being generated, and serve as a reminder to current and future grantees of the competitive standards sought and supported by the SBRP.</p>	<p>The three volumes of background materials, <i>Superfund Basic Research Program: A Legacy in Multidisciplinary Research</i>, and the final report of the External Advisory Group are available on the web at: http://www-apps.niehs.nih.gov/sbrp/eag/</p>

PART ONE: RESEARCH AND PROGRAMMATIC ISSUES - RECOMMENDATIONS

Comment	Response
<p>(4) The Program has grown through its continued partnership with the EPA, both in Washington, DC, and at the regional level. SBRP-funded program directors should become aware of the areas of ongoing EPA research that are relevant and could potentially overlap with SBRP research (i.e., within the office of Research and Development [ORD]) and the extension and application of science within the EPA Regions.</p>	<p>The SBRP believes that communication with EPA to establish partnerships and identification of areas of research relevant to EPA to be activities that are the responsibility of Program staff, not the grantees. The SBRP will continue to interact with EPA and ATSDR and will share relevant information with grantees. Program staff will include Program Directors in meetings with EPA Regional staff as appropriate. In addition, the Program will continue to include EPA representatives in the SBRP Annual Meetings.</p> <p>The SBRP believes that grantees should actively communicate important research outcomes to appropriate audiences, including EPA. The requirement for a Research Translation Core in RFA ES-04-001 clarifies this concept for grantees.</p>
<p>SBRP's Programmatic Contributions to Public Health</p>	
<p>(5) Each SBRP-funded program has an external advisory board; currently, three of the programs have representatives of state health departments on their external advisory boards. Ensuring that public health practitioners, especially non-academic state and local public health officials, have a strong role in the strategic planning activities of these boards is important and recommended. Such members can assist in providing a link between the community and the research strategy and priorities of the programs. They can also help in placing students and providing them experiences outside of the laboratory. It is important for programs, as they mature, to maintain flexibility to adjust their programs and their advisory structures to complement their research.</p>	<p>In the new RFA, the SBRP recommends that External Advisory Committees include scientific expertise appropriate for their research program and ensure representation of appropriate stakeholders. While the Program agrees that inclusion of public health representatives is of value, the SBRP encourages grantees to seek out experts that are appropriate for their research program.</p>

PART ONE: RESEARCH AND PROGRAMMATIC ISSUES - RECOMMENDATIONS

Comment	Response
<p>(6) NIEHS should develop a system to track how the education and training functions of SBRP-funded programs are building public health capacity; particularly, subsequent employment of the trainees should be monitored. Formal tracking of students for documentation and evaluation purposes is essential and should be implemented. Elements of such documentation should include contact data, field of employment, and post-SBRP training.</p>	<p>The Program is in the process of developing a plan to track the progress and contributions of SBRP-funded trainees. The challenge is to design a process that will maximize the quantity and quality of relevant data collected while minimizing the additional burden placed on grantees and Program staff.</p> <p>The SBRP will develop a plan and document the progress of this effort.</p>
SBRP Synergy	
<p>(7) Continue development of the SBRP publications database until it is complete and fully searchable. This could (and should) be used to explore synergy among multidisciplinary projects by searching for inter-project and inter-program publications. Citation indices could be examined for those deemed synergistic as compared to those deemed to be non-synergistic.</p>	<p>The SBRP is in the process of re-building its database and website. New database tools will allow for searches to identify inter-project and inter-program publications as well as publications by SBRP researchers from different disciplines (e.g., chemistry and biology).</p>
<p>(8) Continue the integrated science approach in SBRP research programs.</p>	<p>The new RFA contains language emphasizing the importance of interdisciplinary research. The SBRP will continue to encourage and support multidisciplinary and interdisciplinary research.</p>
<p>(9) Consider additional types of discipline synergy, e.g., sociology, economics, psychology (Refer to Part Two, Section 3I, Subsection c of this report for further EAG observations and recommendations on Encouraging the Integration of Additional Academic Disciplines).</p>	<p>The SBRP agrees that inclusion of additional disciplines could lead to a broader, more holistic approach to address environmental health issues. This next step in the on-going evolution of the Program will require extensive research and planning to design an appropriate strategy - this effort would include consultation with discipline experts and hosting workshops.</p> <p>The SBRP will develop a plan and document the progress of this effort.</p>

PART ONE: RESEARCH AND PROGRAMMATIC ISSUES - RECOMMENDATIONS

Comment	Response
(10) Continue hosting the SBRP Annual Meeting, as it provides for valuable interaction among SBRP researchers.	The SBRP plans to continue to sponsor annual meetings of its grantees and encouraging optimal interaction among its grantees.
Technology and Information Transfer	
(11) The SBRP should develop a definition of the term “technology transfer” for the benefit of those who conduct and those who use SBRP research. The term has many meanings to different individuals and organizations.	In RFA ES-04-001, the SBRP defined technology transfer as moving research findings into application. In some instances, this may include formal technology transfer (i.e., application for patents), and for others, technology transfer may be conducted on a less formal basis (i.e., non-patented application of research advances – moving research from bench scale to demonstration).
(12) SBRP-funded programs should not rely solely on technology transfer offices in host institutions. Each program should designate an individual whose responsibility is optimizing technology transfer. Evaluation of technology transfer results should be formally included in annual reviews.	The SBRP agrees with this comment and in RFA ES-04-001 required that each proposal include a Research Translation Core designed to actively communicate important research outcomes to appropriate audiences to ensure the accurate and timely use of data. One specified function of this Core is to foster technology transfer. With respect to formal evaluation, grantee progress is reviewed annually. Milestones are examined, significant advances are noted and instances are identified where SBRP staff could provide assistance with technology transfer activities. The SBRP will explore options for requesting additional specific information in annual updates that would highlight technology transfer progress.
(13) Given the maturity of the SBRP, SBRP staff are encouraged to keep the technology transfer theme as an essential element of the SBRP Annual Meeting, and to continue to use the website to publicize the agendas and Annual Meeting summaries.	The theme of each annual meeting is determined by a Planning Committee formed by the Program Director at the host university. While Technology Transfer may not always be the dominant theme, it will continue to be an important element of each meeting. The SBRP plans to continue to use its website to publish meeting-relating information both before and following each annual meeting.

PART ONE: RESEARCH AND PROGRAMMATIC ISSUES - RECOMMENDATIONS

Comment	Response
(14) The existing publications database should be further developed to be fully searchable by author, keywords, research areas and project of origin as soon as possible.	<p>The SBRP is in the process of re-building its database and website. New database tools will allow for more rigorous searches of the publications data and will allow SBRP staff to identify interdisciplinary publications.</p> <p>At this time the SBRP publications database contains only citation information - it does not include publication-specific abstracts and keywords. Abstracts and keywords could be collected for new data entries. Back-filling the database for the over 6000 publications already included would be a resource-intensive undertaking, which would have to be done at the expense of other Program tasks or needs.</p>
(15) The list of peer-reviewed journals in which SBRP researchers publish should include a comparison of impact and citation indices.	<p>Information on impact factors and citation indices are important evaluation tools. Impact factor information will be available to SBRP staff in the new database system, but will not be available on the public website.</p>
Grant Program Outreach Activities	
(16) What is expected by the outreach efforts of SBRP-funded programs should be further refined and more effectively presented in future RFAs. To be clear about what is expected, SBRP staff need to identify overall outreach goals, priorities and audiences, perhaps through a more formalized coordination at the Program level.	<p>In response to this comment RFA ES-04-001, released in June 2003, clearly states the SBRP's priorities and goals for grantee outreach activities. The SBRP defined community outreach to be "extending support or guidance to communities, community advocates or community organizations living in proximity to or affected by hazardous waste sites." Outreach activities are to be done in full partnership with targeted communities, and in conjunction with the EPA, the ATSDR or other technical assistance programs. Each Community Outreach Core is to have systems in place to measure milestones or outcomes.</p>

PART ONE: RESEARCH AND PROGRAMMATIC ISSUES - RECOMMENDATIONS

Comment	Response
<p>(17) Efforts to refine communication and collaboration should be explored within outreach programs or processes underway within other parts of the NIEHS and the EPA. SBRP should consider increasing the level of formal relationships/collaborations/coordination efforts between outreach efforts at the individual SBRP-funded program level and the NIEHS COEP Resource Center, the Community-Based Participatory Research and Environmental Justice projects, the EPA's Superfund Community Involvement and Outreach Center, or the outreach programs of the EPA's Hazardous Substance Research Center's Technical Outreach Services for Communities (TOSC) program and Technical Assistance for Brownfield communities (TAB).</p>	<p>The SBRP agrees that the Outreach Cores would benefit by being part of such a network. Concepts and strategies to initiate a network are being considered and include sponsoring joint conferences and integration of SBRP materials into the COEP Resource Center. However, it must be kept in mind that the SBRP has a specific Congressional mandate, unique from the COEPs.</p> <p>At the Program level, efforts have increased to build partnerships with EPA and ATSDR outreach activities.</p>
<p>(18) SBRP staff should also consider re-categorizing and re-defining the overlapping non-research goals of SBRP-funded programs, adding goals that are not currently specified (e.g. See Appendix 1, Outreach Goal IV, "Data Integration," and Outreach Goal III, "Collaboration Building") under a more inclusive umbrella Communications Core.</p>	<p>The SBRP has addressed this comment. RFA ES-04-001 requires that each proposal include a Research Translation Core designed to actively communicate important research outcomes to appropriate audiences to ensure the accurate and timely use of data.</p>
<p>SBRP Education and Training</p>	
<p>(19) NIEHS should develop a system to track how the education and training functions of individual SBRP-funded programs are building environmental protection and public health capacity; particularly, subsequent employment of the trainees and the impact they appear to be making relative to their colleagues from other training programs should be monitored. Formal tracking of students for documentation and evaluation purposes is essential and should be implemented. Elements of such documentation should include contact data, field of employment, evidence of impact in the field, and post-SBRP training.</p>	<p>The Program is in the process of developing a plan to track the progress and contributions of SBRP-funded trainees. The challenge is to design a process that will maximize the quantity and quality of relevant data collected while minimizing the additional burden placed on grantees and Program staff.</p> <p>The SBRP will develop a plan and document the progress of this effort.</p>

PART ONE: RESEARCH AND PROGRAMMATIC ISSUES - RECOMMENDATIONS

Comment	Response
(20) It is recommended that all trainees be required to have experience with the Outreach Core.	In response to this comment, RFA ES-04-001 identifies participation in the Community Outreach Core as an opportunity for trainees. The Program agrees that outreach experience for trainees is of value, but encourages grantees to design training programs that are appropriate to the research and trainee population.
(21) Provision of training for health care providers and environmental managers, as recommended in the 1998 ReNEW report, could be conducted as an educational activity of the Outreach Cores.	<p>RFA ES-04-001 clearly defines the goals and responsibilities of the Outreach Cores. The Research Translation Core is charged with the communication of research findings to broad audiences, which includes health care providers and environmental managers when appropriate.</p> <p>Through an interagency agreement, NIOSH provides both continuing education for hazardous substance professionals and graduate academic training to occupational safety and health professionals for practice, research and teaching with a specialization in hazardous substances.</p>
SBRP's Transition to Annual Competition and Flexibility in Funding Mechanisms	
(22) In order to ensure a smooth and orderly transition, it is important to communicate the re-competition plan to all potential applicants as soon as possible with specific information as to how the preparation of proposals will be affected.	SBRP must operate within the guidelines and policies of NIEHS with respect to announcing and releasing RFAs. The first announcement was made in the NIEHS Guide (September 16, 2003) and was followed shortly by and Applicant Information Meeting (a videocast of this meeting is available at http://www-apps.niehs.nih.gov/sbrp/rfa/).
(23) If flexibility will permit, RFAs should be published as soon as possible.	SBRP must operate within the guidelines and policies of NIEHS with respect to announcing and releasing RFAs. The first announcement was made in the NIEHS Guide (September 16, 2003) and was followed shortly by and Applicant Information Meeting (a videocast of this meeting is available at http://www-apps.niehs.nih.gov/sbrp/rfa/).

PART ONE: RESEARCH AND PROGRAMMATIC ISSUES - RECOMMENDATIONS

Comment	Response
(24) SBRP staff should investigate whether non-biomedical R01-type projects, not traditionally in the scope of NIH programs, might be funded by some innovative grant mechanism within the SBRP.	In 2003, the SBRP utilized the Exploratory/Developmental grants, the R-21 grant mechanism, to invest in non-biomedical R01-type projects. The Program will continue to explore options for additional funding strategies, within financial restraints, to build a consistent, sustainable small grant research effort.
(25) If other NIH grant mechanisms are used, it should be made clear to applicants and peer reviewers that, because of the special and specific needs of the Superfund Program, relevance must be addressed. The NIH peer-review mechanism may provide for these special needs.	All SBRP funds are distributed via the NIH RFA mechanism. Each SBRP RFA clearly states that applicants must address relevance. SBRP staff review Letters of Intent and make recommendations as appropriate to ensure that applicants address relevance.
SBRP Communication and Partnership Activities	
(26) Additional analyses of publication authorship, as available through the SBRP website, might be used to provide further tracking evidence of the effectiveness of intra-, inter- and external collaborations and technology transfer among SBRP researchers. Thus, multidisciplinary research should be evidenced in part by publication authorship and acknowledgements that reflect participation of multiple laboratories, and/or by evidence of SBRP publication citation of other SBRP-generated technology.	<p>Collection and analysis of data relevant to the evaluation of effectiveness of SBRP research collaborations are areas of great interest to the SBRP staff. Quantification of "effectiveness" is complex and difficult. Currently available methods are being examined and may be adopted or modified as appropriate to the needs of the Program.</p> <p>The SBRP is in the process of re-building its database and website. New database tools will allow for searches to identify inter-project and inter-program publications, as well as publications by SBRP researchers from different disciplines (e.g., toxicology and engineering). The SBRP will consider adding search tools to identify SBRP citation of other SBRP-generated technologies. Multidisciplinary collaborations with researchers outside of the SBRP will be more difficult to identify and document; the Program will consider available options.</p>

PART ONE: RESEARCH AND PROGRAMMATIC ISSUES - RECOMMENDATIONS

Comment	Response
<p>(27) For the purpose of encouraging effectiveness and ease of technology transfer, additional elements or restructuring to the SBRP website should be considered. Because the current website is constructed to visualize and focus on the activities of the individual SBRP-funded programs, it does not provide a particularly useful centralized resource to visualize and capture the overall science and technology output and value of the SBRP. Some additional options that should be considered for the website are best represented by how the materials were organized in the three-volume set of review materials provided by NIEHS for the EAG (Volumes 1-3, <i>Superfund Basic Research Program: A Legacy in Multidisciplinary Research</i>).</p>	<p>The SBRP is in the process of re-building its database and website. The new site will be centered on topic and technology categories, but will also allow users to access information organized by grantee.</p>
<p>(28) The current website does not readily allow for integrated analyses of program-wide information in that it is mostly focused on individual programs. For the purpose of encouraging and facilitating technology transfer, a website record of SBRP-funded program projects, publications and other science products could also be organized by patents issued or pending, non-patented applications, small business startups and SBIR grants (e.g., as outlined in Volume 1, Section 1b, Attachment C of <i>Superfund Basic Research Program: A Legacy in Multidisciplinary Research</i>).</p>	<p>The SBRP is in the process of re-building its database and website. The new site will be centered on topic and technology categories. The site will also contain pages (Bibliometrics and Success Stories) that will highlight technology transfer accomplishments to date.</p>
<p>(29) The current SBRP website is grantee-oriented. To further visualize both the breadth and focus of science of being produced by the SBRP, a re-organization of the site by major topic areas, as outlined in the information in Volume 2 of <i>Superfund Basic Research Program: A Legacy in Multidisciplinary Research</i>, could be extremely valuable.</p>	<p>The SBRP is in the process of re-building its database and website. The new site will be centered on topic and technology categories, but will also allow users to access information organized by grantee.</p>

PART ONE: RESEARCH AND PROGRAMMATIC ISSUES - RECOMMENDATIONS

Comment	Response
<p>(30) Because some industry sectors or businesses may have a large stake in the science used to address health and environmental issues associated with Superfund sites, efforts to increase the distribution of the Research Briefs to these audiences should be considered.</p>	<p>Since the inception of the Research Briefs, the Program has worked to expand distribution to stakeholders – and the Briefs now reach ~2,800 readers each month. The SBRP agrees that industry and business sectors are valuable target audiences and will continue on-going efforts to increase distribution of the Research Brief to these audiences.</p> <p>The SBRP will develop a plan and document the progress of this effort.</p>
<p>(31) NIEHS should consider using the Research Briefs to effectively illustrate science/technology transfers between investigators within, across or external to their funded institution.</p>	<p>When applicable to the research finding presented, the Research Briefs highlight the multidisciplinary aspects of research projects. The SBRP will continue this effort and increase its emphasis in the future.</p>
<p>(32) Consider making the Distinguished Lecturer series available more broadly through electronic communication technology.</p>	<p>The SBRP will explore making the Distinguished Lecturer series available more broadly through electronic communication technology. As a first step, the Program must identify appropriate audiences.</p> <p>The SBRP will develop a plan and document the progress of this effort.</p>
<p>(33) SBRP staff should continue to improve upon communication with EPA regions when the research involves investigations and applied technology at specific Superfund sites. A directory of research scientists and their areas of expertise, including those beyond the SBRP, will help the EPA and the NIEHS to improve the cross-cutting, interdisciplinary nature of this research Program.</p>	<p>Communication of research advances to EPA Headquarters and Regional offices is an on-going, high priority of the SBRP. The Program plans to continue these efforts.</p> <p>In consultation with the EPA, the SBRP is constructing a "Directory of Expertise" identifying areas of expertise, environmental media studied, and chemicals of interest for researchers in the multi-project programs.</p>

PART ONE: RESEARCH AND PROGRAMMATIC ISSUES - RECOMMENDATIONS

Comment	Response
SBRP's Use of Metrics	
<p>(34) Quality of SBRP-funded programs should be more clearly defined through additional benchmarking, using a variety of metrics. Numbers of publications should be used, but other criteria should also be considered (quality of publications, citation indices, technology transfer success, etc.). Although information about project success has been collected, a more integrated strategy and clear plan for metrics identification, collection and evaluation should be documented for future use.</p>	<p>Bibliometric analysis and program evaluation are developing fields. Universally accepted metrics to evaluate impact and quality do not yet exist. The SBRP is planning to conduct an analysis of available program evaluation tools, and to evaluate tools as they emerge, to identify data and metrics that can be reasonably collected and rigorously analyzed to serve as benchmarks of Program accomplishments.</p> <p>The SBRP will develop a plan and document the progress of this effort.</p>
<p>(35) One metric of impact on public health is the documentation of altered behavior. SBRP staff should examine ways to do this at the risk assessor, remediation manager, public health official and general public levels.</p>	<p>This is an exceptionally complex area, and accepted metrics to evaluate impact and quality do not yet exist. The Program will continue to collect anecdotal data that provides evidence of public health impact. The SBRP will examine potential strategies and determine if this evaluation is achievable with the Program's limited resources.</p>
<p>(36) Further metric(s) reflecting synergy, education and training, and outreach should be developed.</p>	<p>Bibliometric analysis and program evaluation are developing fields – quantifying synergy adds yet another layer of complexity. Universally accepted metrics to evaluate impact and quality do not yet exist. The SBRP is planning to conduct an analysis of available program evaluation tools, and to evaluate tools as they emerge, to identify data and metrics that can be reasonably collected and rigorously analyzed to serve as benchmarks of Program accomplishments.</p> <p>The SBRP will develop a plan and document the progress of this effort.</p>

PART TWO: FUTURE DIRECTIONS - OPPORTUNITIES FOR THE FUTURE

Comment	Response
Risk Analysis	
<p>(37) Since the study of Superfund sites and their remediation always requires both types of risk assessments (human and ecological), the trend toward integration must be encouraged. In the past, the SBRP has supported some crossover research in which human biomarkers are used to detect exposure in wildlife. This approach should be enhanced and built upon in the future. Accordingly, RFAs should be written to encourage the development of scientific approaches and methods that will advance the integration of human and ecological risk assessment.</p>	<p>In response to this comment, in RFA ES-04-001 the SBRP encourages "Scientific inquiry that develops a paradigm whereby knowledge gained through understanding ecological effects resulting from hazardous waste sites furthers our understanding of potential human health effects, provides a creative, holistic approach to integrate seemingly separate ecological and human health risk assessments into more comprehensive site models."</p>
Site Characterization	
<p>(38) It is appropriate for more SBRP-funded programs to utilize these advanced methods and for some to lead in their development. Sensor development and deployment within the SBRP could expand the capability for site characterization – broadly defined – and provide more information that relates to function and potential dysfunction of an organism or system, e.g. response to specific toxicants</p>	<p>In RFA ES-04-001, the SBRP encourages "Application of new and advanced technologies to develop biosensors, self-contained miniaturized toxicity-screening kits and miniaturized analytical probes and data analysis tools that allow for real-time, on site monitoring ... The resulting data can then be placed in context of how contaminants affect nearby populations -- human or wildlife."</p>
<p>(39) Site characterizations should be improved to obtain more detailed information on the total environment of a contaminated site, utilizing a dynamic systems approach. The purpose should be to understand as much as possible about the site in its present condition, and if possible before the effects of the contamination, and to be able to predict the status of the site in the future. While specific parts of the system – soils and groundwater, air emissions, biota, humans, etc. – must be dealt with individually, more emphasis needs to be directed toward the integration of this information and toward a better understanding of the total system at scales ranging from the molecular to that of the total site and its environs.</p>	<p>The Program's emphasis on the holistic nature of site characterization is reflected in the Exposure Assessment section of RFA ES-04-001. Applicants are encouraged to address the holistic, integrated nature of the systems they are evaluating.</p>

PART TWO: FUTURE DIRECTIONS - OPPORTUNITIES FOR THE FUTURE

Comment	Response
<p>(40) Particular attention needs to be given to characterization of the effects of the contamination on biological communities, including humans, focusing not only on the chemical contaminants that may have entered these systems but also on the changes in community structure that may have occurred as a result of contamination or habitat changes. For humans, this should include information on apparent exposure groups and improved quantitative estimates of exposures over time, effects on health broadly defined, as well as mental, social and behavioral patterns.</p>	<p>Such studies will require the integration of additional disciplines (e.g., sociology, economics) into the SBRP. This next step in the on-going evolution of the Program will require extensive research and planning to design an appropriate strategy - this effort might include consultation with discipline experts and hosting symposia.</p> <p>The SBRP will develop a plan and document the progress of this effort.</p>
Environmental Informatics	
<p>(41) The SBRP has historically supported the use of innovative approaches and advanced technologies. The Program should expand its support of research that proposes to utilize new analysis and visualization methods to interpret environmental information, and provide insight into the processes that influence the observed patterns. This can apply to molecular scale information obtained from gene microarrays to regional scale information obtained from consortia of sensors, including satellite and smaller-scale observation platforms. However, these tools will make communication with the public, increasingly important within the Superfund program, more difficult when databases are complex. This will require new approaches to abstract massive amounts of data into a form more understandable to the affected public.</p>	<p>In RFA ES-04-001, the SBRP states that "the Program's approach emphasizes basic and applied research, using state-of-the-art techniques, to improve the sensitivity and specificity for detecting adverse effects in humans or in ecosystems exposed to hazardous substances." Applicants are encouraged to integrate state-of-the-art technologies such as micro/nano-arrays, "omics" approaches and imaging technologies, with traditional methodological approaches.</p> <p>The inclusion of Research Translation Cores as required components of multi-project programs requires grantees to identify appropriate audiences and develop appropriate mechanisms to ensure that these groups have timely access to research findings.</p>

PART TWO: FUTURE DIRECTIONS - OPPORTUNITIES FOR THE FUTURE

Comment	Response
<p>(42) All of these approaches [to abstract massive amounts of data] are appropriate for SBRP-funded programs and offer the opportunity for some program proposals to include mathematicians and modelers to a great advantage. These approaches are justified because of the new information and tools that are now emerging and becoming available to environmental health investigators, brought on by dramatic advances in the biosciences and informatics, to name only two of the rapidly changing fields of science.</p>	<p>In RFA ES-04-001, the SBRP states that "Research is encouraged to develop new approaches to bring together existing data from experimental approaches (e.g., genetics, genomics, proteomics, metabonomics) and to integrate the data with hypotheses using mathematical and computational approaches."</p> <p>In addition, the Program acknowledges the challenges posed by the quantities of data produced by new technologies. The SBRP intends to consider the potential impacts on and opportunities for the Program. This effort might include consultation with discipline experts and hosting symposia. The SBRP will document the plan and the progress of this effort.</p>
<p>(43) In addition, there is growing consensus that it is time for environmental research to deal with the complexity of biological systems, rather than taking a more reductionist approach.</p>	<p>In RFA ES-04-001, the SBRP seeks to support research with an "integrative" or systems level approach [that] seeks to understand the structure and dynamics of regulatory networks within biological systems to better understand the mechanistic underpinnings of disease risk."</p>
<p>Environmental Processes</p>	
<p>(44) SBRP-funded research should focus on mechanistically-based science in its support of environmental studies to the same extent as it has in human health studies.</p>	<p>Understanding the mechanisms whereby toxicants induce adverse human and environmental health effects is at the heart of the SBRP. In RFA ES-04-001, the Program seeks to support "mechanistic research that includes laboratory-based studies unraveling disease pathways at the molecular and cellular level to the organ and whole animal level, as well as human-based and ecosystem-based mechanistic studies."</p>

PART TWO: FUTURE DIRECTIONS - OPPORTUNITIES FOR THE FUTURE

Comment	Response
<p>(45) Mechanistic studies of environmental processes in the past have too often focused only on either biological systems to the exclusion of chemical-physical processes, or vice versa. SBRP-funded programs should lead in the integration of these studies, especially in the study of complex systems where human health issues are linked to occurrence, transport, and transformations of chemical substances.</p> <p>These studies must increasingly deal with variations and interconnectivities within the system, and to issues such as the complex mixtures of substances in heterogeneous environments and how their physical-chemical properties determine human exposures. Thus, multi-dimensional models are needed that describe these substances from source to receptors, and within receptors through complex pathways to the incipience of dysfunction or disease.</p>	<p>The SBRP strongly encourages its grantees to apply creative, state-of-the-art technologies as appropriate. The RFA released in September, 2003 strongly advocates for the integration across disciplines in order to address the complex scientific issues that arise from the complexity of environmental systems.</p>
<p>(46) Additional, integrated studies imply more detailed data sets and more sophisticated methods for their interpretation, and more elegant mathematical methods for their modeling. Indeed, the entire area of computational biology and computational toxicology are important potential growth areas for the SBRP. A common interest in relational databases as a result of such sophisticated treatment should foster future symposia, workshops, and study groups across programs within SBRP, across NIEHS, and, in fact, across the sciences.</p>	<p>The SBRP acknowledges the challenges posed by the quantities of data produced by new technologies. The SBRP intends to consider the potential impacts on and opportunities for the Program. This effort might include consultation with discipline experts and hosting symposia. The SBRP will document the plan and the progress of this effort.</p>

PART TWO: FUTURE DIRECTIONS - OPPORTUNITIES FOR THE FUTURE

Comment	Response
Human Health Effects	
<p>(47) More studies are needed that use the <i>omics</i> to inform the mode of action, pharmacokinetic models for tissue dosimetry, and pharmacodynamic dose-response models of chemicals that are important at Superfund sites.</p> <p>Perhaps one criterion for funding of these studies should be the promise of new information that is likely to provide a breakthrough in the assessment of the effects of a particular compound.</p> <p>In particular, the advent of <i>omics</i> technologies allows such assessments to be explored at exposure-dose levels representative of real-world conditions found at Superfund sites.</p>	<p>The SBRP strongly encourages its grantees to apply state-of-the-art technologies, including the "omics", as appropriate.</p> <p>The SBRP always has and continues to allow for chemical-specific research.</p> <p>In RFA ES-04-001, the SBRP makes multiple references to the importance of studying environmentally relevant concentrations (which may be very low doses) of hazardous substances.</p>

PART TWO: FUTURE DIRECTIONS - OPPORTUNITIES FOR THE FUTURE

Comment	Response
<p>(48) It is very important that the SBRP be focused on the prime objectives of the Program and that encouragement be given to studies of Superfund chemicals rather than “model” compounds and to studies of humans rather than experimental animals when such studies are equivalent and ethical. As a complement to human research, animal studies should be designed to emphasize the types and levels of exposures representative of Superfund sites.</p>	<p>In RFA ES-04-001, the SBRP clearly defines the chemicals considered appropriate for the Program:</p> <ul style="list-style-type: none"> • Hazardous substances found with some frequency at Superfund sites. • Hazardous breakdown products of such substances formed in environmental media by physical, chemical or biological (e.g., plants, microorganisms, etc.) processes. • Hazardous metabolites of the above substances or their breakdown products formed in humans or experimental animals. • Chemicals with structural similarity to hazardous substances found at Superfund sites. <p>The SBRP does support epidemiology studies when they are the appropriate research approach. Animal studies are funded when it is not possible to study humans, and such studies are conducted at environmentally relevant exposure levels.</p>
<p>(49) The assessment of the implications of genomic variability on susceptibility of individuals and populations to potential environmental toxicants can and should be linked to laboratory-based whole animal and in vitro approaches. For example, the advent of transgenic and other genetically altered animal and cell models affords opportunities to explore the toxicological sensitivity to low-dose exposures in genetically-modified test systems created to parallel known human susceptibility elements.</p>	<p>As stated in RFA ES-04-001, "The Program recognizes the importance of identifying susceptible populations in order to reduce their burden of environmentally induced diseases." As with all areas of study funded by the Program, grantees are strongly encouraged to apply state-of-the-art technologies, including transgenic models, as appropriate.</p>

PART TWO: FUTURE DIRECTIONS - OPPORTUNITIES FOR THE FUTURE

Comment	Response
Ecological Effects	
<p>(50) Creative approaches that will integrate these new methods with traditional ecological assessment methods should be encouraged in future SBRP solicitations, particularly to demonstrate the combined human and ecological effects of chemicals. Ideally, these studies should yield a better understanding of the effects of these stressors as they actually occur in the environment and specifically at Superfund sites, not just as isolated compounds in cell cultures with individual organisms, although such studies are important. Again, creative approaches are needed that use new methods to obtain multidimensional models of these systems that approach reality.</p>	<p>The SBRP strongly encourages its grantees to apply creative, state-of-the-art technologies as appropriate. Ecological assessment strategies incorporating advances made in human studies are encouraged in RFA ES-04-001.</p>
<p>(51) Given the broad public health and environmental mandate of the SBRP, it seems particularly appropriate for some SBRP-funded programs to address the connectivity between human health and ecological condition. At both the theoretical and empirical levels, these studies could provide a more informed understanding of this relationship, and in the process provide practical guidelines for Superfund managers who must often attempt to balance human health and ecological risks.</p>	<p>The SBRP agrees that this is an important area of research. The Program plans to explore this concept further, with the goal of identifying relevant, do-able research avenues that could be included in future RFAs.</p>
Remediation and Risk Management	
<p>(52) Future SBRP-sponsored studies should continue to investigate innovative remediation approaches, but the requirements for the sophistication of the science need to be increased. Thus, areas such as microbiological remediation should be advanced through cooperative efforts with basic scientists in molecular and cell biology and others in the fields of transport, bioavailability and multidimensional modeling.</p>	<p>In RFA ES-04-001, the SBRP "encourages the development of innovative physical, chemical and biological technologies for remediating hazardous substances found at waste sites." In addition, the RFA states that "The use of modern molecular biology tools as well as biochemical, cellular or engineering approaches to enhance our understanding of the basic structural and functional properties of microbial and other populations involved in the bioremediation of hazardous substances is encouraged."</p>

PART TWO: FUTURE DIRECTIONS - OPPORTUNITIES FOR THE FUTURE

Comment	Response
<p>(53) Studies within SBRP-funded programs that would use new approaches to examine remediation and risk management would be welcomed; for example, through creative theoretical approaches based on computational and statistically-based biological models.</p>	<p>RFA ES-04-001 emphasizes the critical nature of the development of new bioinformatic approaches to bridge data from different disciplines in risk assessment and remediation evaluation studies:</p> <p>" . . . multi-dimensional models are needed to describe risk from the source of contamination, through the movement of contaminants within environmental media, to its uptake by biological receptors (i.e., human or wildlife) and the effect within biological receptors on complex cellular and molecular pathways to the incipience of dysfunction or disease. This will require more detailed datasets and more sophisticated methods for their interpretation and mathematical algorithms for their modeling."</p>
<p>Community-Based Participatory Research</p>	
<p>(54) Exposure studies – including their spatial and time variability – should be related to specific community groups who may be especially affected, such as the aged, children, and minorities or low-income populations</p>	<p>RFA ES-04-001 addresses the importance of including host factors (e.g., nutrition, health, lifestyle habits), and timing of exposure as critical to altering susceptibility and predisposition to disease.</p> <p>"The knowledge gained from understanding the interrelationships of factors in affecting host susceptibility and resistance will be key to reducing uncertainties in risk assessments and protecting health for the most vulnerable populations."</p>
<p>(55) Research is needed to show how this information is best transmitted to and interpreted for the community, and how it affects their attitudes and actions. Research can also inform how the community might be restructured after remediation is complete, i.e. how it can be made more healthy and sustainable through community empowerment or land use adjustments.</p> <p>Additional links with the EPA’s HSRC Technical Services to Communities (TOSC) program may be useful for SBRP-funded programs and affected communities.</p>	<p>In RFA ES-04-001, the SBRP states that it is "appropriate that community outreach activities be done in conjunction with the EPA, the ATSDR, or other technical assistance programs."</p> <p>The SBRP is currently exploring the development of a research agenda to study societal and behavioral issues.</p>

PART TWO: FUTURE DIRECTIONS - OPPORTUNITIES FOR THE FUTURE

Comment	Response
Approaches to Achieve Synergy	
<p>(56) One suggested mechanism to further the synergistic goals of the SBRP could be to more fully develop interdisciplinary approaches to the study of Superfund events, sites, and chemicals. This concept, as compared to multidisciplinary approaches to the same studies, requires a closer relationship between the parties, including joint research discussions, training exercises, and enrichment experiences.</p>	<p>In RFA ES-04-001, the SBRP states "the goals and objectives of this RFA are to encourage the use of technological advances, as appropriate, to support multi-project, interdisciplinary research programs. ... It is expected that each interdisciplinary research program will develop an overall conceptual theme that fosters collaborative interactions, whereby projects are integrated, and specific emphasis is placed on interactions between the biomedical and non-biomedical research projects."</p>
<p>(57) Incorporating an evaluation framework within the multidisciplinary approach of the SBRP will:</p> <ul style="list-style-type: none"> • contribute tools for management and policy decisions • help to identify the research questions and data that are important to intended outcomes • build a body of knowledge that can be applied to other Superfund sites and communities. 	<p>Bibliometric analysis and program evaluation are developing fields. Acceptable metrics to evaluate impact and quality are still under discussion. The SBRP is planning to conduct an analysis of available program evaluation tools, and to evaluate tools as they emerge, to identify data and metrics that can be reasonably collected and rigorously analyzed to serve as benchmarks of Program accomplishments.</p> <p>The SBRP will develop a plan and document the progress of this effort.</p>
<p>(58) Mechanisms should be developed to foster the [inter-program] sharing of resources, expertise, and training and research programs.</p>	<p>Supplemental funding has been made available for collaborative research efforts among SBRP programs (e.g., UK & UC-D; Dartmouth & UAZ). The SBRP will continue to support these and similar types of collaboration.</p>
<p>(59) One useful alternative [to changes in F&A policy] that benefits all parties is to establish an "inter-program" project line, administered by the Administrative Core of each SBRP-funded program. A fixed amount - the EAG suggests \$50,000 plus the associated F&A - would be allocated annually for inter-program studies, along with a described mechanism for allocation and administration.</p>	<p>The SBRP is limited by NIH policy constraints, but will support inter-program collaborations to the fullest extent possible and will continue to look for innovative mechanism to support such collaborative research.</p>

PART TWO: FUTURE DIRECTIONS - OPPORTUNITIES FOR THE FUTURE

Comment	Response
<p>(60) At the SBRP level, a scientific and logistical interchange amongst directors would foster approaches that are inter-SBRP programmatic. Some mechanism outside of the SBRP Annual Meeting needs to be developed whereby brainstorming amongst program directors can take place, agendas can be developed which provide the intellectual future of the Program, and where the directors can seek ways to optimize limited resources.</p>	<p>SBRP will consider proposing the offer of logistical support for additional conference calls or web conferences to the Program Directors. However, the Program can not insist that the Program Directors assume this additional burden.</p>
<p>(61) Mechanisms for funding special initiatives or collaborations outside of the traditional SBRP must be developed.</p> <p>As an example, one could use the SBRP-funded program directors as a group to review and advise on funding special requests for inter-SBRP initiatives using monies held by SBRP staff. This would require an altruistic attitude on the part of the program directors, but with time could build a consensus of operation, themes, mechanism, and community.</p>	<p>Supplemental funding has been made available for collaborative efforts among SBRP programs, such as the "Quad Universities" meeting with EPA Region 6 and the SBRP will continue to be supportive of collaborative activities. The SBRP will consider options for cross-talk among the Program Directors for potential future initiatives.</p>
<p>(62) The special initiatives approach could also be used to begin to develop synergistic relationships between current SBRP-funded investigators/programs and, to date, non-traditional participants such as sociology, economics, ethnology, anthropology, psychology/behavioral medicine, and bioethics and philosophy.</p>	<p>The SBRP agrees that inclusion of additional disciplines could lead to a broader, more holistic approach to address environmental health issues. This next step in the on-going evolution of the Program will require extensive research and planning to design an appropriate strategy - this effort might include consultation with discipline experts and hosting workshops.</p>