

SRP P42 APPLICATION GUIDELINES

Release Date: October 2010

Department of Health and Human Services

National Institutes of Health

National Institute of Environmental Health Sciences

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Definitions

Introduction

The National Institute of Environmental Health Sciences (NIEHS) is proposing the continuation of the Superfund Hazardous Substance Research and Training Program (P42) [referred to as the Superfund Research Program (SRP) Centers]. SRP Center grants will support coordinated, multi-project, interdisciplinary research Centers to address the mandates legislated under the Superfund Amendments and Reauthorization Act of 1986. The objective for the SRP is to develop a holistic research agenda for the protection of human health. This is accomplished by the establishment of interdisciplinary Centers that link and integrate biomedical research with related non-biomedical (e.g. engineering, geology, ecology) research within the context of unique scientific themes developed by the applicant.

These guidelines are to be used only in conjunction with the Request for Applications (RFA) ES-10-010, titled "Superfund Hazardous Substance Research and Training Program." The RFA details the scientific topics pertaining to this Program. A copy of the RFA is available from the NIH Guide for Grants and Contracts (<http://grants1.nih.gov/grants/guide/rfa-files/index.html>), the NIEHS website (<http://www.niehs.nih.gov/funding/grants/announcements/request.cfm>) or the SRP RFA Webpage, (<http://www.niehs.nih.gov/research/supported/srp/funding/rfa.cfm>).

Each funded grant is required to contain a minimum of:

- Two approved Biomedical Research Projects. These research projects address biomedical or human health-related implications of hazardous substances. This includes: mechanistic-based toxicology studies, human risk assessment, epidemiology, genetic susceptibility, computational toxicology, biomedical engineering, etc.

- Two approved Non-Biomedical Research Projects. These research projects should address environmental science or engineering implications of hazardous substances. This includes: engineering, geology, ecology, microbiology, fate and transport studies, hydrogeology, remediation and detection sciences, etc.

Note: A Community Engagement Project can count towards one of the two biomedical or non-biomedical research projects, depending on the theme of the research project. These projects should utilize community-based participatory processes of planning, implementing, and communicating pertinent scientific results from primary research.

- An approved Community Engagement Core. The Community Engagement Core (CEC) must include: (1) a timeline with milestones, measurable outcomes, and a process to guarantee effective bi-directional exchange for needs, recommendations, and results with the community; (2) plan for interaction with government agencies; (3) plan for communicating to other SRP Centers the lessons learned from Center Community Engagement Components; (4) plan for coordination with the Center's Research Translation Core.
- An approved Administrative Core. The Administrative Core must include an external advisory committee which should provide oversight and advice to the Principal Investigator (Center Director) in accomplishing the Center goals.
- One approved Research Support Core. Research Support Cores must be used by at least two of the research projects. The core(s) must provide a Quality Control and Quality Assurance plan for providing analytical and quantitative services.
- An approved Research Translation Core. The Research Translation Core must include plans for: (1) communicating with SRP, (2) partnerships with government agencies, (3) technology transfer, and (4) information dissemination to other end-users.

If the above minimum requirements are not met, the application will be considered non-responsive and returned to the applicant.

It is critical that the applicant recognize that the SRP is more than just a basic research program, and the applicant should make investments in other crucial areas of SRP. Therefore, in addition to the required elements, the SRP strongly encourages the inclusion of:

- A Training Core

The following restrictions apply to each application:

- A new applicant may request a budget for direct costs of up to \$1.8 million dollars for the first year. New applicants may request up to four years of funding.
- Applicants submitting renewal (competing continuation) applications may request up to a three percent increase above the awarded direct costs of the last year of their continuation project (non-competitive renewal). Renewal applicants may request up to five years of funding.
- For all applicants, the budgets for each subsequent year may not exceed an escalation of three percent on recurring direct costs. Facilities and Administrative (F & A) costs incurred by requesting third party consortia or subcontracts are not included in the direct cost limitations (see NOT-OD-05-004). Applications that exceed the stated allowable budget caps for the first year will be returned non-responsive to the RFA.
- The Community Engagement Core is limited to \$100,000 direct costs in the first year, with subsequent years subject to the standard three percent cost escalations allowed by NIH.
- The direct costs of the Training Core are not to exceed six percent of the total direct costs for the total Center budget.

LETTER OF INTENT

Prospective applicants are asked to submit a letter of intent that includes a descriptive title of the proposed application, the name, address, and telephone number of the Principal Investigator (Center Director), the number (i.e., RFA-ES 10-010), and title of the announcement (i.e., Superfund Hazardous Substance Research and Training Program) to which the application is being submitted.

NIEHS also requests that the letter include:

- a descriptive title for each project and core
- the name of the project or core leader, and
- an indication whether the project is biomedical or non-biomedical and/or a community engagement project
- other key personnel and participating or collaborating institutions

Although a letter of intent is not required, is not binding, and does not enter into the review of a subsequent application, the information that it contains allows the scientific review administrator to estimate the potential review workload, determine the scientific expertise needed for the review panel, and helps avoid conflicts of interest in the review.

The letter of intent should be sent to:

Janice B. Allen, Ph.D.
Scientific Review Officer
Scientific Review Branch
Division of Extramural Research and Training
National Institute of Environmental Health Sciences
P.O. Box 12233; Mail drop K3-03
Research Triangle Park, NC 27709
For Courier delivery:
530 Davis Drive, Room 3080
Research Triangle Park, NC 27709
email: Allen9@niehs.nih.gov
office: 919-541-7556
fax: 301-451-5715

Note: Submission of the letter of intent by email is preferred.

Application Procedures

A. PHS 398 INSTRUCTIONS

Applications must be prepared using the most current PHS 398 research grant application instructions (PHS 398 Revised 6/2009). The PHS 398 is available at <http://grants.nih.gov/grants/funding/phs398/phs398.html> in an interactive format. For further assistance contact GrantsInfo, Telephone (301) 435-0714, Email: grantsInfo@nih.gov.

As the PHS 398 is used primarily for the traditional research grant applications, several sections of the PHS 398 must be modified and expanded to provide the additional information needed for the reviewers to evaluate SRP Center grant applications. Detailed guidelines are presented below to assist the applicant in making the necessary modifications. It is important to note that these guidelines are intended as a supplement to the instructions in the PHS 398 and; therefore, the latter instructions will not be repeated extensively in this document. The structure provided in these instructions is not intended to preclude the consideration of deviations made on a case-by-case basis after discussions with and concurrence by appropriate institute staff.

B. SUBMISSION INSTRUCTIONS

The signed original and three copies of the completed application, including the checklist, should be mailed to the Center for Scientific Review (CSR). **Do not include appendix material in copies sent to the CSR.**

Center for Scientific Review
National Institutes of Health
6701 Rockledge Drive
Room 1040-MSC 7710
Bethesda, MD 20892-7710
(Courier and express services use zip code 20817)
Personal deliveries of applications are no longer permitted (see <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-040.html>).

At the time of submission to CSR, two additional copies of the signed application and **five identical CDs** of the Appendix material (in PDF format, clearly identified by project and core) must be sent to:

Janice B. Allen, Ph.D.
Scientific Review Officer
Scientific Review Branch
Division of Extramural Research and Training
National Institute of Environmental Health Sciences
P.O. Box 12233; Mail drop K3-03
Research Triangle Park, NC 27709
For Courier delivery:
530 Davis Drive, Room 3080
Research Triangle Park, NC 27709
email: Allen9@niehs.nih.gov
office: 919-541-7556
fax: 301-451-5715

Note: Appendix material is to be submitted on CDs in PDF format, and will no longer be accepted on paper.

Applications must be received at CSR and NIEHS by April 15, 2011.

It is essential to note that the application submitted is the document of record. No substitutions of pages will be allowed. However, if the Principal Investigator wishes, he/she may submit errata documents to the NIEHS SRO.

There is a period of several months between the time of submission of the application and the initial review. In the event of substantial new findings during this interval, the applicant is encouraged to contact the SRO to seek permission to submit supplementary materials. These materials will generally not be accepted within 30 days prior to the initial scientific review. The SRO will make the final determination as to what additional information will be provided to the reviewers.

C. PRE-APPLICATION CONSULTATION WITH NIEHS SUPERFUND RESEARCH PROGRAM STAFF

Because of the complexity of the SRP Center grant applications, the Principal Investigator (Center Director) is strongly encouraged to contact SRP program administrators early in the grant preparation process. SRP program administrators can advise the applicant on (1) the relevancy of the proposal to the programs supported by NIEHS; (2) the scope of the SRP, P42 guidelines, and review guidelines; and (3) the preparation of a complete and well-developed application (e.g., integration of all projects into the theme of the overall Center).

Due to a new requirement for each Center to include an approved Community Engagement component, the Center Director and Community Engagement Core/Project leader are strongly encouraged to communicate with SRP program administrators prior to submission of the application.

Although the applicant is encouraged to seek guidance from SRP program administrators before the receipt of applications, such guidance does not presume or guarantee an award. The initial contact with program administrators is the responsibility of the potential applicant. This interaction may take the form of correspondence, such as e-mail, telephone conversations, etc. However, program administrators will not provide a scientific critique of a draft application.

D. GENERAL INSTRUCTIONS

This section supplements the information and instructions found in the PHS 398 instructions (see <http://grants.nih.gov/grants/funding/phs398/phs398.html>). Except as modified in the following sections, the official instructions for the PHS 398 must be followed for all new, resubmission, and competitive renewal applications.

Restructured Application Forms and Instructions. Please note that a new, restructured version of the paper PHS 398 application and instructions was released 11/23/2009 ([NOT-OD-10-016](#)). Applications submitted for this RFA must use these new forms (PHS 398 Revised 6/2009). Using incorrect application forms (including applications that have an incorrect mix of old and new forms) will be delayed and may not be reviewed. For details of application changes please see http://enhancing-peer-review.nih.gov/docs/application_changes.pdf.

Typeset Requirements. The typeset limitations described for PHS 398 must be adhered to for all applications.

Page Limitations. The page limitations specified for PHS 398 apply to the individual projects and cores of the application. As indicated in [NOT-OD-09-149](#), applicants responding to this RFA will be required to adhere to the current page limits for specific sections of the application: 12-page Research Strategy; 4-page Biographical Sketch; 1-page for Specific Aims and Introduction to Application (for resubmission).

Page Numbering. All pages should be numbered consecutively throughout the application beginning with the Face Page as page 1. Number the PHS 398 form pages as necessary. Individual Research Projects and Cores should become part of the overall numbering, and must not be numbered separately.

Organization of the Application. The components of the application should be in order as suggested in Illustration 1 at the end of this document. Following this format will facilitate the review of the application.

Appendix. NIH has issued a notice on the change in policy limiting Appendix materials that may be submitted with grant applications to NIH/AHRQ/NIOSH. Please see **NOT-OD-07-018** (<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-07-018.html>) for information on what materials are allowed in the appendix.

Resubmission (amended) Applications. All resubmission applications must include an "Introduction to Resubmission Application", for each project, core, and for the overall Center. **This introduction is limited to 1 page.**

E. SPECIFIC INSTRUCTIONS

SECTION I

The Face Page. PHS 398 Form Page 1 (Face Page). The title for the application (# 1) should be chosen to correspond to the major theme of the Center. Under #2, check "YES" in response to a specific Request for Application, use ES-10-010 for the Number and include "Superfund Hazardous Substance Research and Training Program" for the Title. This information is essential for the expeditious assignment of the application.

Center Summary, Performance Sites, and Key Personnel. PHS 398 Form Page 2. Provide an abstract of the overall theme of the proposed multi-project Center, the research strategy including the integration of a multidisciplinary research approach, the relevance to the National Superfund Program and the benefits to be achieved.

For Performance sites, indicate where the work described in the Research Plans will be conducted. If there is more than one performance site, list all the sites, including Veteran's Administration facilities and foreign sites, and provide an explanation on the Resources Format page of the application.

The Key Personnel should include the Principal Investigator (Center Director) and each of the Project and Core leaders and consultants (if considered Key Personnel). List the Principal Investigator's last name first. All other key personnel should be listed in alphabetical order, last name first. For each individual provide: name, organization (their institutional affiliation), and role on the project. Under role on the project, indicate how the individual will function with regard to the proposed project (e.g., Project Leader, Core Leader, etc.). Use additional pages as necessary.

Complete Research Grants Table of Contents. One complete Table of Contents, similar in format to the PHS 398 Form Page 3, must be provided and should follow the overall page numbering indicated above. Bearing in mind that the application will be reviewed project by project, prepare a detailed Table of Contents that will enable reviewers to find specific information readily. Projects/cores should be identified by number or letter, title, and name of the project/core leader.

Detailed Composite Budget for First 12-month Period. PHS 398 Form Page 4. Summarize the budget for the entire Center. (Follow the PHS 398: "Detailed Budget for Initial Budget Period.") Continuation pages may be used if needed to list all personnel.

Composite Budget for All Years, All Projects. PHS 398 Form Page 5 (Budget for Entire Proposed Period of Support). Summarize the budget for the entire Center for the requested additional years of support. Applicants may request a project period of up to five years.

Individual Budgets (Identify for each project/core individually). Using duplicate copies of PHS 398 Form Pages 4 and 5, prepare a separate budget for each individual project, sub-contract and core unit. In the upper left hand corner, identify the project number or core. All proposed costs must be fully justified for both the initial 12-month and future year budgets as indicated in the PHS 398 instructions.

It is the intent of the NIEHS and SRP to hold annual meetings of grantees. Funds for travel by appropriate staff (i.e., Principal Investigator, Business Manager, and four students) to attend a three-day meeting should be included in the Administrative Core's budget for each year. The Community Engagement, Research Translation, and Training Core Leaders should also plan on attending the annual meeting. Expenses for this travel should be included in individual core budgets. The location of the meeting site will rotate among the different grantees and Research Triangle Park, NC.

Other budget considerations: the direct costs for the Training Core are not to exceed 6% of the total direct costs for the entire Center budget; the Community Engagement Core is not to exceed \$100,000 direct costs in the first year with subsequent years subject to the standard cost escalation of three percent.

Table of Research Support Core Utilization. In order to assist the reviewers in determining the relationship between the Research Support Cores and the Research Projects, a table should be provided that indicates the percentage use of each core relative to the individual projects. See Illustration 2.

Table of All Professional and Non-Professional Personnel. In order to aid in the review of the application, a tabular listing of all participating personnel should be prepared. List the Principal Investigator (Center Director) first, followed by everyone else, in alphabetical order. This is to include everyone listed in the application. Information to be included in this table: name, role in Center and associated project (i.e., Project Leader, senior investigator, post doctoral student, graduate student, technician, consultants, etc.) and affiliation (department or collaborating institution as appropriate). To be in compliance with NIH Conflict of Interest policy (http://grants2.nih.gov/grants/peer/COI_Information.pdf), external advisory members should be included **only** if they provided input in the design and preparation of the application. See Illustration 3.

Table of New, Continuing, Substantially Modified, Completed, or Discontinued Projects and Cores. To assist review of renewal/resubmission applications, include a table listing projects and core components (by project title and Project/Core Leader) that denotes which projects are new, continuing, substantially modified, completed, or discontinued in the latest funding cycle. This table should coincide in order and number with the projects and cores in the current application. Also indicate which projects are considered to be biomedical research and which are considered non-biomedical research. See Illustration 4.

All Biographical Sketches. Provide biographical sketches for all key personnel and Other Significant Contributors, including consultants. The Principal Investigator (Center Director) biographical sketch should precede all others; others should follow in alphabetical order. Use duplicate copies of the PHS 398 Biographical Sketch Format page for each Project/Core Leader. Include only one copy of each biosketch in the application. Item A is the Personal Statement. Items B and C ("Positions and Honors," and "Selected Peer-review Publications"). Item D provides information on research support. List both selected ongoing and completed (during the last three years) research projects (federal or non-federal support). **List biographical sketches according to relevance, beginning with the projects that are most relevant to the research proposed in this application.** Briefly indicate the overall goals of the projects and responsibilities of the key person identified on the Biographical Sketch. Note: Do not include person months or direct costs. Each biographical sketch is **limited to 15 publications and 4 pages each.** See <http://grants.nih.gov/grants/funding/phs398/biosketchsample.pdf> for an example biographical sketch.

Table of Use of Human Subjects or Vertebrate Animals. In order to facilitate the identification of projects and cores using human subjects and/or vertebrate animals, a table should be included. List all Research Projects and Cores indicating the information requested on the PHS 398 Face Page #4 and #5. See Illustration 5.

Resources. Using the PHS 398 Resources Format page, investigators must describe how the scientific environment will contribute to the probability of success of the project, unique features of the environment. The institutional investment should be demonstrated for the success of Early Stage Investigators (e.g. resources, classes, etc.). If more than one campus or location will be involved, briefly describe each setting. If unique resources are available, briefly describe these and their relevance to the proposed Center.

SECTION II: OVERALL CENTER PLAN

This section is unique to a Multi-Project Center application. The information requested in this section, for the most part, is not covered in the PHS 398.

Resubmission Application Introduction. This introduction should discuss in general terms the overall concerns raised from the previous application and provide an overview of changes made. **This introduction is limited to 1 page.** More detailed information (e.g. specific responses to project summary statements) should be provided in each project/core introduction in Sections III-VIII of this document.

Overall Center Theme. This section should introduce the major theme of the Center (**limited to 1 page**).

Overall Center Plan. The Overall Center Plan section contains the Center's Aims and Introduction sections. The Center's Aims section should describe the Center's goals and objectives and is **limited to 1 page**. The Center Introduction provides an overall description of the Center and its strategy and is **limited to 12 pages**. More instructions on the Center Introduction are provided below.

- **Center Introduction.** The Center Introduction, **limited to 12 pages**, should give a broad overview of the Center using greater detail than that presented in the "Project Summary" in Section I. Include background information, relevance to SRP's primary stakeholders, and how the research Center is developed around mechanistic research that will contribute to solving a particular problem (or set of problems) related to health effects, risk, detection and/or remediation of hazardous substances. The Introduction should include a description of the multidisciplinary and interdisciplinary nature of the Center, how each project and core contributes to the theme, and how the Center will achieve the integration and interaction among biomedical and non-biomedical research. **Applicants must clearly indicate which projects are biomedical and non-biomedical. The Center's Community Engagement component (project or core) should be clearly indicated.**

The organizational structure of the Center should be described in the Center Introduction. Include a diagram to demonstrate the interactions between the different Center units. Also, briefly describe how the Administrative Core will support the overall goals and organization of the Center. More detailed information on the management of these items should be included in the Administrative Core Research Strategy Section.

Renewal Applications. Competing renewal applications must include a general progress report that describes achievements under the grant since the last competitive review. The Principal Investigator (Center Director) should carefully prepare this section, and it should not be a copy of the material included for the individual projects. (The individual research projects will also provide a "Progress Report" under the "Approach" section of the Research Strategy.) This is the section where the benefits of the Center can be expressed/demonstrated. Items to be included are:

- Brief summary of major accomplishments that can be attributed to the SRP Center Grant,

- o Brief explanation of how the accomplishments of the Center have contributed to the National Superfund Program (i.e. National Priorities List sites and/or related sites contaminated by hazardous substances),
- o Brief report on projects and cores that are not being continued, and the reason for deleting them from the Center. Be certain to reference relevant tables in Section I of the application.

Bibliography and References Cited/Progress Report Publication. This list of publications should follow the same format as Research Plan item 5 (see PHS 398 Instructions). For renewal applications, include a list of all publications and completed manuscripts that are a direct result of the support provided by the SRP Center Grant. **With an asterisk, denote each publication that is a result of formal collaborations among different projects within the Center.**

Applicant may also wish to refer to the review criteria for the Overall Center in Section V.1. of the RFA.

SECTION III

All Projects and Cores.

- For all PHS 398 form pages, the name of the Principal Investigator (Center Director) of the P42 grant application should be placed in the upper right corner of each page, not the name of the project/core leader.
- *Title Page.* For the title page of individual projects/cores, the PHS 398 "Continuation Format" Page should be used and the project/core number, the title of the project/core, and the project/core leader should be denoted.
 - o Research Projects should be designated as Project 1, Project 2, etc.
 - o Research Support Cores should be designated by A, B, C, etc. All other cores should be designated by its function: e.g. Administrative Core, Research Translation Core, etc.
- *Project Summary.* The "Project Summary" of the project/core should be prepared on a duplicate copy of PHS 398 Form Page 2. All performance sites and key personnel on the project/core should be identified.
- *Relation to Overall Center.* Each individual project should clearly state its relevance to the overall Center and its primary theme, its contribution to and its interactions with the other projects and cores. Interactions with the Research Translation Core should be included.
- *Community Engagement Component Statement.* A one-page "Community Engagement Component Statement" must be included for all Community Engagement Cores and/or Community Engagement Projects. The applicant should use this statement to describe the community-based participatory processes being utilized, as was described in the RFA. This statement should:
 - o Clearly define the community of interest or community partner, community's and researchers' roles, and topics that are of interest/priority to the community.
 - o Indicate how the activity/research will lead to improved public understanding of research and long-term, bidirectional relationships between the academic institution and the community for the benefit of both.
 - o Demonstrate the community's acceptance of the role as a partner in the project/core and that the community's engagement is an integral part of the research (e.g., involvement in planning, organization, and design of research; letters of support from the community).
 - o Include a management plan for maintaining transparent communications between the community and the academic partners

- throughout the entire research process. The plan should address methods of building and sustaining community partnerships and community participation.
- Provide previous experience/evidence for conducting community engagement activities/projects.
 - Identify the research environment and how it will enhance the likelihood of successful completion of the activity/project.
- *Research Plan.* All sections of the Research Plan should use Continuation Pages and follow PHS 398 Instructions. If collaborative or consortium arrangements are included in the application, PHS 398 Instructions should be followed. Discussion should be included as to how the collaborative arrangements will be of value in achieving the specific objectives of the project.
 - *Resubmission/Renewal Application Introductions* are included for each project and core. For these sections, list each area of concern noted in the Summary Statement for the previous project or core, and provide a clear response to each concern. Summarize the changes that have been made in the resubmitted (revised) project/core. Do not include an extensive description of each change in the introduction. In the body of the project /core, highlight paragraphs with significant changes by bracketing, indenting, or changing the typography. If the changes are so extensive as to include most of the text, this exception should be explained in the Introduction to the Resubmission Application. Do not underline or shade changes. **This section is limited to 1 page.**
 - *Specific Aims* are limited to one page.
 - *Research Strategy.* The page limit for the Research Strategy section will be sub-divided into three parts: Significance, Innovation, and Approach. The Approach sub-section will include both Preliminary Studies for New Applications and Progress Report for Renewal/Resubmission Applications. See [NOT-OD-09-149](#).
 - Applicants should carefully read and adhere to the PHS 398 instructions concerning children, gender, and minority inclusion in human study populations.
 - Include "Letters of Support" and collaborative arrangements/consultants (Research Plan item "14") that are identified in the application.
 - Include "Resources Format Page" within the individual Research Projects and Core sections. Include at the end of the Research Strategy.
 - Appendix material is not a part of Section II. All appendix material for each project/core should be included in Section XI (see below for details).
 - **Note:** The following information should **not** be included in the individual projects or cores. They should be included only in Section I of the application.
 - "Face Page"(Form Page 1)
 - "Research Grants Table of Contents" (Form Page 3)
 - "Detailed Budget for Initial Cost Period" (Form Page 4)
 - "Budget for Entire Proposed Period of Support" (Form Page 5)
 - "Biographical Sketch Format Page"

SECTION IV

Administrative Core. Follow instructions in the PHS 398 for the Research Plan, as appropriate, for describing the Administrative Core. This section should detail information introduced in the Center's Introduction regarding the Principal Investigator (Center Director) and the Organizational Structure of the Center. This section should include an administrative and management plan that will achieve an integrated,

coordinated multi-disciplinary research Center. A narrative description should be provided that includes the planning and coordination of research activities and research translation activities; the integration of cross-disciplinary research; and the oversight of fiscal and resource management. Indicate who will be responsible for each of these activities. Describe the role(s) of advisory groups and consultants. Relevant experience of the Core Leader may also be cited. If this is a competing renewal, summarize activities carried out during the preceding performance period. Applicant may also wish to refer to the Administrative Core review criteria in Section V.1. of the RFA.

SECTION V

Research Translation Core. Follow instructions in the PHS 398 for the Research Plan, as appropriate, for describing the Research Translation Core. A narrative description should be provided that includes plans for (1) communication within SRP; (2) partnering with government agencies; (3) technology transfer; and (4) information dissemination to other end-users. Discuss how the Research Translation Core will interact with the other research projects and cores in fulfilling the goals of this core. Indicate who will be responsible for each of these activities. Applicant may also wish to refer to the Research Translation Core review criteria in Section V.1. of the RFA.

SECTION VI

Research Support Cores. Follow the instructions in PHS 398 Research Plan, as appropriate, for describing the Research Support Core. Information that should be included is as follows:

- Describe the function of the core as a resource to the Center. This section must clearly present the facilities, techniques, and professional skills that the core will provide. As justification for the core, briefly indicate the specific Research Projects that will use the resources of the core. A Research Support Core is principally designed as a service or resource component; it would be highly unusual to include research in a core (a possible exception would be methodology development). Please contact the Institute staff if you require guidance on this issue.
- Describe the role of the core as a resource to the Center as a whole. Discuss ways in which these centralized services will produce an economy of effort and/or savings in overall costs compared to their inclusion as part of each project in the Center.
- Include a Quality Assurance Statement ONLY for Research Support Cores that provide analytical, quantitative services to the Center. If required, the Quality Assurance Statement should be included after the Research Strategy. Refer to "Section IV.6 – Other Submission Requirements and Information" of the RFA for additional information.
- If this is a competing renewal, summarize activities carried out during the preceding performance period. Include core utilization by the individual Research Projects. This should be part of the "Progress Report for Renewal/Resubmission Applications" section of the Research Strategy.
- Applicant may also wish to refer to the Research Support Core review criteria in Section V.1. of the RFA.

SECTION VII

Community Engagement Core: Follow the instructions in PHS 398 Research Plan, as appropriate, for describing the Community Engagement Core. A one (1) page narrative description named "Community Engagement Component Statement" should be provided that describes how the goals of the Community Engagement Core will relate to the Center's theme, and how the Core Leader will interact with the Project Leaders and community. Indicate how this Core will coordinate with established community groups. Note that this is a distinct core that is separate from the information transfer requirements of the Research Translation Core. Select a title that uniquely describes the activities of the Core. For competitive renewals, summarize the accomplishments and milestones met during the preceding performance period. Applicant may also wish to refer to the Community Engagement Core review criteria Section V.1. of the RFA.

- *Community Engagement Component Statement.* A one-page “Community Engagement Component Statement” must be included for all Community Engagement Cores and/or Community Engagement Projects. The applicant should use this statement to describe the community-based participatory processes being utilized, as was described in the RFA. This statement should:
 - Clearly define the community of interest or community partner, community's and researchers' roles, and topics that are of interest/priority to the community.
 - Indicate how the activity/research will lead to improved public understanding of research and long-term, bidirectional relationships between the academic institution and the community for the benefit of both.
 - Demonstrate the community's acceptance of the role as a partner in the project/core and that the community's engagement is an integral part of the research (e.g., involvement in planning, organization, and design of research; letters of support from the community).
 - Include a management plan for maintaining transparent communications between the community and the academic partners throughout the entire research process. The plan should address methods of building and sustaining community partnerships and community participation.
 - Provide previous experience/evidence for conducting community engagement activities/projects.
 - Identify the research environment and how it will enhance the likelihood of successful completion of the activity/project.

SECTION VIII

Training Core. Follow instructions in the PHS 398 Research Plan, as appropriate, for describing the Training Core. A narrative description should be provided that reflects interdisciplinary approaches to training. For competitive renewals, it is important that the application identify the students who participated in the Training Core during the previous funding cycle. Applicant may also wish to refer to the Training Core review criteria Section V.1. of the RFA.

SECTION IX

Plan for Sharing Data. A data-sharing plan should be developed for the overall Center, if appropriate. For those including a data-sharing plan, the precise content will vary depending on the data being collected and how the investigator(s) is planning to share the data. For example, applicants may briefly describe the expected schedule for data sharing, the format of the final dataset, the documentation to be provided, whether or not any analytic tools also will be provided, whether or not a data-sharing agreement will be required and, if so, a brief description of such an agreement (including the criteria for deciding who can receive the data and whether or not any conditions will be placed on their use), and the mode of data sharing (e.g., under their own auspices by mailing a disk or posting data on their institutional or personal website, through a data archive or enclave). Investigators choosing to share under their own auspices may wish to enter into a data-sharing agreement. For NIH instructions and policy see http://grants.nih.gov/grants/policy/data_sharing/index.htm.

SECTION X

Checklist. Fill out the PHS 398 Checklist Form Page; refer to the PHS 398 for further instructions.

SECTION XI

Appendix. See the PHS 398 instructions for information on submitting appendix materials and refer to "B. Submission Instructions" of this document for number of copies, format, and mailing instructions. **Applicants should refer to NOT-OD-07-018 for new limits on appendix materials:**
<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-07-018.html>.

Note: The application appendix should not be used to circumvent the page limitations of the "Research Strategy". Please submit five CD copies of Appendix material (in PDF form) to Dr. Janice Allen, SRO, as listed in "B. Submission Instructions" of these guidelines. If an appendix will be added, it is encouraged, but not required, that a summary listing of the Appendix materials be provided. This list should clearly identify Research Project and Cores in the same order as they appear in the application.

Review Procedures and Factors

For a description of the review procedures and review factors, refer to RFA ES-10-010 "Superfund Basic Research and Training Program". When RFA ES-10-010 is issued, the applicant can obtain a copy from the NIH Guide for Grants and Contracts (<http://grants1.nih.gov/grants/guide/rfa-files/index.html>), the NIEHS website (<http://www.niehs.nih.gov/funding/grants/announcements/request.cfm>) or the SRP RFA Webpage (<http://www.niehs.nih.gov/research/supported/srp/funding/rfa.cfm>).

Detailed review criteria can be found in Section V.1. of the RFA pertaining to the assessment of the overall merit of the multi-project Center grant proposal, the scientific merit of the individual research projects and cores, the multidisciplinary and integrated nature of the Center, and the qualifications of the Principal Investigator (Center Director).

Policies and Assurances

The award and administration of SRP Center Grants are subject to the same policies and procedures as other research grants. These policies and cost principles are set forth in the current PHS Grants Policy Statement, other NIH and NIEHS issuances, and Federal legislation and regulations.

Staff Consultation

Prior to application submission and especially while the application is being developed, inquiries about the SRP Center grant application process may be addressed to any of the scientific program officials listed below:

William Suk, Ph.D.
Director, Center for Risk and Integrated Sciences
Division of Extramural Research and Training
National Institute of Environmental Health Sciences
P.O. Box 12233 K3-04
Research Triangle Park, NC 27709
Telephone: 919-541-0797
Email: suk@niehs.nih.gov

Claudia Thompson, Ph.D.
Center for Risk and Integrated Sciences
Division of Extramural Research and Training
National Institute of Environmental Health Sciences
P.O. Box 12233 K3-04
Research Triangle Park, NC 27709
Phone: (919) 541-4638
Fax: (919) 541-4937
Email: thomps14@niehs.nih.gov

Heather Henry, Ph.D.
Center for Risk and Integrated Sciences
Division of Extramural Research and Training
National Institute of Environmental Health Sciences

P.O. Box 12233 K3-04
Research Triangle Park, NC 27709
Phone: (919) 541-5330
Fax: (919) 541-4937
Email: henryh@niehs.nih.gov

Questions of an administrative or fiscal nature not directly related to the scientific aspects of the application should be directed to the Grants Management Branch officials listed below:

Lisa Archer Edwards, M.B.A.
Grants Management Branch
Division of Extramural Research and Training
National Institute of Environmental Health Sciences
111 T.W. Alexander Drive
P.O. Box 12233, K3-11
Research Triangle Park, North Carolina 27709
Telephone: 919-541-0751
Fax: 301-451-5334
E-mail: archer@niehs.nih.gov

Michelle Victalino
Grants Management Branch
Division of Extramural Research and Training
National Institute of Environmental Health Sciences
P.O. Box 12233, K3-11
Research Triangle Park, North Carolina 27709
530 Davis Dr. Keystone Bldg. Rm 3047
Morrisville, NC 27560
Telephone: 919-316-4666
Fax: 301-451-5334
E-mail: victalinom@niehs.nih.gov

Once the application has been submitted to the NIH/NIEHS, the primary point of contact should be through the Scientific Review Branch officials listed below:

Janice B. Allen, Ph.D.
Scientific Review Officer
Scientific Review Branch
Division of Extramural Research and Training
National Institute of Environmental Health Sciences
P.O. Box 12233; Mail drop K3-03
Research Triangle Park, NC 27709
For Courier delivery:
530 Davis Drive, Room 3080
Research Triangle Park, NC 27709
email: Allen9@niehs.nih.gov
office: 919-541-7556
fax: 301-451-5715

ILLUSTRATIONS

Illustration 1: Outline for the Organization of the Application

For ease of review it is strongly suggested that applications be organized according to the following outline:

SECTION I

- Face Page
- Center Summary, Performance Sites and Key Personnel
- Complete Research Grants Table of Contents
- Detailed Composite Budget for First 12-month Period
- Composite Budget for All Years, All Projects

- Individual Budgets (Identify for each project/core individually)
- Table of Research Support Core Utilization (See Illustration 2)
- Table of All Professional and Non-Professional Personnel (See Illustration 3)
- Table of New, Continuing, Substantially Modified, Completed, or Discontinued Projects and Cores.
- All Biographical Sketches (limited to 15 peer-reviewed publications and 4 pages per biographical sketch)
- Table of Use of Human Subjects and Vertebrate Animals
- Resources

SECTION II: OVERALL CENTER PLAN

- Resubmission Application Introduction (1 page limit)
- Overall Center Theme (1 page limit)
- Overall Center Plan: contains Center Aims and Overall Goals and Objectives (1 page limit)
 - Center Introduction (12 page limit)
 - Background Information
 - Relevance to SRP Primary Stakeholders
 - Significance of the Research
 - Multidisciplinary and Interdisciplinary Approach
 - Principal Investigator (Center Director)
 - Organizational Structure
 - Additional Information for Renewal Applicants
 - Major accomplishments
 - Contribution to National Superfund Program (and related sites)
 - Reports on discontinued projects
 - Bibliography and References Cited/Progress Report Publication List

SECTION III: RESEARCH PROJECTS

- Title Page: Include Title, Research Project Leader and Research Project number (1,2,3, etc.)
- Project Summary, performance sites and key personnel (PHS 398 Form Page 2).
- Relation of Project to Overall Center (1 page limit)
- Community Engagement Component Statement (only for Community Engagement Projects, 1 page limit)
- Research Plan
 1. Introduction to Application (Resubmission only, 1 page limit)
 2. Specific Aims (1 page limit)
 3. Research Strategy (12 page limit)
 - a. Significance
 - b. Innovation
 - c. Approach
 - Preliminary Studies/Progress Report
 4. Inclusion Enrollment Report (Renewal or Resubmission Applications only)
 5. Bibliography and References Cited/Progress Report Publication List
 6. Protection of Human Subjects
 7. Inclusion of Women and Minorities
 8. Targeted/Planned Enrollment Table
 9. Inclusion of Children
 10. Vertebrate Animals
 11. Select Agent Research
 13. Consortium/Contractual Arrangements (if applicable)
 14. Letters of Support (e.g., Consultants) (if applicable)
 15. Resource Sharing Plan(s)
- Resources (PHS 398 Resources Format Page)

REPEAT THE ABOVE FOR EACH RESEARCH PROJECT

SECTION IV: ADMINISTRATIVE CORE (REQUIRED)

- Title Page: Include 'Administrative Core' and Core Leader
- Project Summary, performance sites and key personnel (PHS 398 Form Page 2)
- Relation of Core to Overall Center (1 page limit)
- Administrative Core Plan
 1. Introduction to Application (Resubmission only, 1 page limit)
 2. Specific Aims (1 page limit)
 3. Research Strategy (12 page limit)
 - a. Significance
 - b. Innovation
 - c. Approach
- Preliminary Work/Progress Report
- 5. Bibliography and References Cited/Progress Report Publication List
- 13. Consortium/Contractual Arrangements (if applicable)
- 14. Letters of Support (e.g., consultants) (if applicable)
- Resources (PHS 398 Resources Format Page)

SECTION V: RESEARCH TRANSLATION CORE (REQUIRED)

- Title Page: Include 'Research Translation Core' and Core Leader
- Project Description, performance sites and key personnel (PHS 398 Form Page 2)
- Relation of Core to Overall Center (1 page limit)
- Research Translation Core Plan
 1. Introduction to Application (Resubmission only, 1 page limit)
 2. Specific Aims (1 page limit)
 3. Research Strategy (12 page limit)
 - a. Significance
 - b. Innovation
 - c. Approach
 - Preliminary Work/Progress Report
 5. Bibliography and References Cited/Progress Report Publication List
 13. Consortium/Contractual Arrangements (if applicable)
 14. Letters of Support (e.g., Consultants) (if applicable)
- Resources (PHS 398 Resources Format Page) (if applicable)

SECTION VI: RESEARCH SUPPORT CORES (REQUIRED)

- Title Page: Include 'Research Support Core', Title of Core, Core Leader, and letter of Core (A, B, C, etc.)
- Core Description, performance sites and key personnel (PHS 398 Form Page 2)
- Relation of Core to Overall Center (1 page limit)
- Research Support Core Plan
 1. Introduction to Application (Resubmission only, 1 page limit)
 2. Specific Aims (1 page limit)
 3. Research Strategy (12 page limit)
 - a. Significance
 - b. Innovation
 - c. Approach
 - Preliminary Studies/Progress Report
 4. Inclusion Enrollment Report (Renewal or Resubmission Applications only)
 5. Bibliography and References Cited/Progress Report Publication List
 6. Protection of Human Subjects (if applicable)
 7. Inclusion of Women and Minorities (if applicable)
 8. Targeted/Planned Enrollment Table (if applicable)
 9. Inclusion of Children (if applicable)
 10. Vertebrate Animals (if applicable)
 11. Select Agent Research (if applicable)
 13. Consortium/Contractual Arrangements (if applicable)
 14. Letters of Support (e.g., Consultants) (if applicable)
 15. Resource Sharing Plan(s) (if applicable)
- Quality Assurance Statement (required for analytical/quantitative activities)

- Resources (PHS 398 Resources Format Page)

REPEAT THE ABOVE FOR EACH RESEARCH SUPPORT CORE

SECTION VII: COMMUNITY ENGAGEMENT CORE (REQUIRED)

- Title Page: Include 'Community Engagement Core' and Core Leader
- Core Description, performance sites and key personnel (PHS 398 Page 2)
- Relation of Core to Overall Center (1 page limit)
- Community Engagement Component Statement (1 page limit)
- Community Engagement Core Plan
 1. Introduction to Application (Resubmission only, 1 page limit)
 2. Specific Aims (1 page limit)
 3. Core Strategy (12 page limit)
 - a. Significance
 - b. Innovation
 - c. Approach
 - Preliminary Work/Progress Report
 5. Bibliography and References Cited/Progress Report Publication List
 13. Consortium/Contractual Arrangements (if applicable)
 14. Letters of Support (e.g., Consultants; community members) (if applicable)
- Resources (PHS 398 Resources Format Page) (if applicable)

SECTION VIII: TRAINING CORE - (OPTIONAL)

- Title Page: List Title and Core Leader
- Project Description, performance sites and key personnel (PHS 398 Form Page 2)
- Relation of Project to Overall Center (1 page limit)
 - Training Core Plan
 1. Introduction to Application (Resubmission only, 1 page limit)
 2. Specific Aims (1 page limit)
 3. Research Strategy (12 page limit)
 - a. Significance
 - b. Innovation
 - c. Design and Approaches
 - Preliminary Studies/Progress Report
 5. Bibliography and References Cited/Progress Report Publication List
 13. Consortium/Contractual Arrangements (if applicable)
 14. Letters of Support (e.g., Consultants) (if applicable)
- Resources (PHS 398 Resources Format Page)

SECTION IX: PLAN FOR SHARING DATA

SECTION X: CHECKLIST

SECTION XI: APPENDIX

Illustration 2: Table of Research Support Core Utilization

Research Projects	Research Support Core A	Research Support Core B	Research Support Core C
Research Project 1	50%	0	80%
Research Project 2	0	0	0
Research Project 3	50%	30%	20%
Research Project 4	0	70%	0

Illustration 3: Table of All Professional and Non-Professional Personnel

Name	Role in Center	Affiliations
Dr. Georgia Matisse	Principal Investigator (Center Director) and Project Leader, Project 1	Dept. of Genetics, Univ of Moma
Ms. Helen Cassatt	Senior Technician, Project 1	Dept. of Genetics, Univ of Moma
Dr. Peter Catlett	Consultant	Dow Chemical Co.
Dr. Alfred Degas	Investigator, Project 3	Internat'l Institute of Genetics
Mr. Edgar Frankenthaler	Graduate Student, Project 4	Dept. of Engineering, Univ of Moma
Dr. Mary O'Keefe	Post Doc Fellow, Project 1	Dept. of Genetics, Univ of Moma
Dr. Henri Stieglitz	Core Leader, Core C and Investigator, Project 4	Dept. of Mol Bio, Univ of Moma

Illustration 4: Table of New, Continuing, Substantially Modified, Completed, or Discontinued Projects and Cores

Project Number/Core Name	Project/Core Status*	Project Core Leader	Title of Project/Core	Biomedical or non-Biomedical**	Current Project Number/Core Name
Project 1	CN	Georgia Matisse	Markers of Exposures to Mixtures	Biomed (CEP)***	Project 1
Project 2	N	Pablo Braque	Individual Susceptibility to Disease Risk	Biomed	Project 2
Project 3	S	Claude Pollock	Molecular Effects of Low Level Exposures	Biomed	Project 3
Project 4	CD	Ansel Modigliani	Redistribution of PAHs in Sediments	Non-Biomed	-
Project 5	D	Juan Monet	Remediation of PAHs	Non-Biomed	-
Administrative Core	CN	Georgia Matisse	Admin Core	-	Administrative Core
Core B	N	Juan Monet	Tech Trans Core	-	Core B
Core D	CN	Kathe Pollack	Biomarker Core	-	Core D

Community Engagement Core	N	Claude Kolliwitz	Supporting Community Involvement	-	Community Engagement Core
Training Core	S	Georges Picasso	Training Core	-	Training Core

* Continuing (CN), New (N), Substantially modified (S), Completed (CD), or Discontinued (D).

** For research projects only

*** Community Engagement Project (CEC)

Illustration 5: Table of Use of Human Subjects or Vertebrate Animals

Project Number or Core Letter	Human Subjects	Vertebrate Animals
Project 1	No	No
Project 2	Yes	No
Project 3	No	Yes
Project 4	Yes	Yes
Core C	Yes	No

DEFINITIONS

Division of Extramural Research and Training (DERT) – This is the component of the National Institute of Environmental Health Sciences that is responsible for the organization, funding, and management of the extramural research and training grants programs.

Grants Management Specialist –The NIEHS official that serves as the focal point for all business-related activities associated with the negotiation, award, and administration of grants.

National Advisory Environmental Health Sciences (NAEHS) Council – A chartered advisory committee, composed of both scientists and lay members, which performs the final advisory review of grant applications and advises on matters of significance to the policies, missions and goals of the NIEHS. The members include outstanding authorities knowledgeable in relevant programmatic areas that are especially concerned with the health needs of the American people.

Primary Stakeholders - SRP's primary stakeholders are its sister Superfund programs at the U.S. Environmental Protection Agency (EPA, <http://www.epa.gov/superfund/index.htm>) and Agency for Toxic Substances and Disease Registry (ATSDR, <http://www.atsdr.cdc.gov>). Additional stakeholders include other Federal agencies, State, local, and Tribal entities responsible for sites impacted by hazardous substances, as well as the individuals and communities living these sites.

Principal Investigator (PI) – The one person designated by, and responsible to, the applicant/awardee institution for the scientific and administrative direction and proper conduct of all aspects of a SRP Center grant. This term is used by NIH and will be used interchangeably with "Center Director."

Program Administrator – The NIEHS science administrator that is responsible for the development of initiatives and for the scientific management of the SRP. This person serves as the focal point for all science-related activities associated with the negotiation, award and administration of grants.

Project/Core Leader – The investigator who is responsible for the scientific direction and conduct of an individual Research Project or Core component of a SRP Center grant.

Scientific Review Officer (SRO) – The NIEHS science administrator that is responsible for the organization, management and documentation of the initial review process for applications.

Special Emphasis Panel (SEP) – An ad hoc advisory group composed of primarily non-Federal scientific experts who conduct the scientific and technical merit review (initial review) of grant applications and assign priority scores to applications recommended for further consideration. The SEP

is one type of Initial Review Group (IRG) referred to in many NIH publications. SEPs will be convened to review the SRP Center grant applications.

Summary Statement – The official record of the evaluation and recommendations of the SEP.