

## Submission Materials

### How can we send color copies of figures?

The color copies should be on the CD that you submit on July 17 to Linda Bass. Figures labels should include the corresponding page numbers in the application.

### Can you please expand on what is acceptable material for the appendix?

Information that is required and/or essential to the review of your application should not be placed in the Appendix. The Appendix should not be used to circumvent page limits. Appendix material should be sent to Linda Bass on CD. The following materials may be included in the appendix:

- Up to 3 publications of the following types. In each case include the entire document:
  - Manuscripts and/or abstracts **accepted** for publication but not yet published.
  - Published manuscripts and/or abstracts where a free, online, publicly available journal link is not available.
  - Patents directly relevant to the project.

*Do not include unpublished theses or abstracts/manuscripts submitted, but not yet accepted, for publication.*

- Surveys, questionnaires, and other data collection instruments, clinical protocols, and informed consent documents.
- Color images of gels, micrographs, etc., provided that a photocopy (may be reduced in size) is also included within the page limit of the Research Strategy. **No images may be included in the appendix that are not also represented within the Research Strategy.**
- For materials that cannot be submitted on CD (e.g., medical devices, prototypes), applicants should contact the Scientific Review Officer for instructions following notification of assignment of the application to a SRG. Applicants are encouraged to be as concise as possible and submit only information essential for the review of the application.
- Publications that are publicly accessible must not be included in the appendix. For such publications, the URL or PMC submission identification numbers along with the full reference should be included as appropriate in the Bibliography and References Cited/Progress Report Publication List section of the Research Plan, and/or in the Biographical Sketch.

### Should electronic copies be submitted to Linda Bass in addition to the two additional paper copies?

No. Linda Bass will receive an electronic copy from CSR. A signed, typewritten original of the application, including the checklist, and three signed photocopies must be delivered to CSR on or before the application due date. At the same time send 2 additional copies to Linda Bass. All copies of the Appendix files must be sent to Linda Bass as directed in [RFA-ES-12-001](#).

### Can you give a little more information about the additional material we can submit prior to September 3?

Applicants are required to follow the instructions for post-submission materials, as described in [NOT-OD-10-115](#). Only 3 pages of supplemental information will be accepted. The font size must be the same as the font size in the application. No new information (not already discussed in the application) will be accepted.

### Can we send relevant papers that have been submitted or published in between July 17 and September 3 for the committee consideration?

No materials will be accepted after September 3. Citations for relevant papers may be submitted as part of the 3 page supplemental information. Applicants are required to follow the instructions for post-submission materials, as described in NOT-[OD-10-115](#).

**Please clarify the application page limit restrictions.**

There are strict page limits that must be followed. Each Research Project has a total of 15 pages (see designation below). You cannot take pages from one Research Project to devote to another Research Project. If a Research Project goes beyond the pages designated below for each category, it will be deemed non-responsive and returned. The same rule applies to the specific page limitations for the individual Cores.

**Each Research Project:**

Cover Page: 1 page

Summary: 1 page

Specific Aims: 1 page

Research Strategy: 12 pages

**Administrative, Facility, & Community Outreach/Translation Core-Each Core:**

Cover Page: 1 page

Summary: 1 page

Specific Aims: 1 page

Core Structure, Administration & Services: 6 pages

## **Data Sharing Plan**

**Are all data included in the data sharing plan?**

All data should be considered for data sharing. Data should be made as widely and freely available as possible while safeguarding the privacy of participants, and protecting confidential and proprietary data.

**Is a data sharing plan required?**

To facilitate data sharing, investigators submitting a research application requesting \$500,000 or more of direct costs in any single year to NIH on or after October 1, 2003 are expected to include a plan for sharing final research data for research purposes, or state why data sharing is not possible.

NIH guidance and policy information can be found at

[http://grants.nih.gov/grants/policy/data\\_sharing/data\\_sharing\\_guidance.htm](http://grants.nih.gov/grants/policy/data_sharing/data_sharing_guidance.htm)

## **Human Subjects**

**What are the human subjects requirements?**

**NIH Requirements**

As required by the NIH, for each Research Project that proposes to include Human Subjects and/or Vertebrate Animals in the research, detailed information regarding: the Protection of Human Subjects; the Inclusion of Women, Minorities, and Children; and the use of Vertebrate Animals MUST be included. For all research involving human subjects, the Review Committee will assess the adequacy of protections for research participants against research risks, and the appropriate inclusion of women, minorities, and children, based on the information provided in

the application. Please see the [PHS398 Application Guide](#) regarding information required for the inclusion of Human Subjects and Vertebrate Animals in the research. This document will provide you with all the information NIH needs for the use of human subjects and vertebrate animals in research. Applications submitted that do not include this information in each Research Project will be considered incomplete and returned without review.

### **EPA Requirements**

In addition, EPA requires a Human Subjects Research Statement (HSRS) (4 pages) for the Overall application. Please note the RFA regarding the requirements for this category. The EPA HSRS will not be factored in the evaluation of the application but should be provided in the Overall Program Project Section of the grant application. These pages do not count towards the 12 page limit for this section.

### **Targeted/Planned Enrollment Tables**

One table of Total Enrollment to identify gender and racial/ethnic enrollment must be submitted for each Research Project that will use Human Subjects in the research (please see the [PHS398 Application Guide](#)).

## **Program Project**

### **Please clarify what information should be included in the overview of the program project?**

This overview section must contain justification for the program project grant mechanism and describe those goals that are not readily attainable through individual research project grants. This section should include: the face page; an abstract; a description of the objectives of the program as a whole that describes the relationship of the individual research projects to the entire program project and the special benefits to be achieved by funding as a program project grant rather than as a series of individual research grants; a list of participating personnel; the consolidated budget for the program project grant (summarizing budgets for the component parts and core); a description of facilities available including major instruments and special program resources; administrative arrangements for overall scientific leadership, quality control, and management of the program project grant; and a separate overall listing of the proposed person months on the program project grant and actual and pending research support from all sources for each project leader (including percent effort devoted to each project). This section must also detail the relationship of existing support to the proposed program project and describe planned modifications to that support in the event of funding, for example, folding in support for related funded research.

### Program Introduction and Statement of Objectives

- Describe the major theme of the Center, its goals and objectives, background information and the overall importance of the research to the missions of NIEHS and EPA. This should include the children's disease(s) and primary environmental stressors of study and the overall hypotheses to be tested. The applicant must provide a compelling rationale for the environmental significance of the children's disease(s) of interest. The program should be viewed as a group of interrelated research projects, each of which is individually scientifically meritorious but is also complementary to the other projects, and related to the overall theme developed for the Center.
- Describe the rationale for the total proposed program. Explain the strategy for achieving the expected results and outcomes defined for the overall program and how each research project

and core relates to that strategy. Highlight how the findings of the research efforts will impact clinical and public health practice and how the CEHC will facilitate this translation.

- Indicate and describe any collaborative arrangements between investigators in the group and the anticipated unique advantages that would be gained by the interdisciplinary approach proposed for the research being conducted.
- Explain how different components of the organization, including key personnel, will interact, why they are essential to accomplishing the overall goal of the research, and how combined resources create capabilities that are more than the sum of the parts. Very clear evidence that the key personnel will collaborate effectively must be presented in the application.
- Describe briefly a summary of how the program will incorporate the essential elements of the Children's Environmental Health and Disease Prevention Centers program including the approach for Community Engagement, the Pediatric Health Specialist, and Career Development.

#### Organizational and Administrative Structure

- Describe in detail and by diagram the organizational structure of the program including an administrative and management plan that achieve an integrated, coordinated interdisciplinary research program.
- In broad terms describe how the administrative core supports the goals and organization of the program. Include a discussion of the function of advisory groups (both internal and external) used in the capacity of advisors and overseers of quality control. Identify the expertise needed but do not identify by name the external consultants serving on advisory groups. Be aware that the external advisory committee must meet at least once a year and must present a written report to the NIEHS program staff two months prior to the end of the fiscal year in order to ascertain progress to secure the next year's funding.
- Describe the role of the Director and the investigators responsible for the direction of the research projects and core units. The Director of the overall CEHC is called the Principal Investigator; the leaders of the individual projects are referred to as Project Leaders. Indicate where, in the chain of responsibility, advisory groups (internal and external consultants) would be used.
- Describe how the CEHC will be used to advance cross-disciplinary training in environmental health sciences and children's research. Include a description of the existing training resources and activities available through the applicant institution and the potential pool of trainees, with clear delineation of how the Center will enrich/augment these existing resources.
- Indicate how the Center's progress towards expected scientific and training outcomes will be monitored and adjusted as needed.
- Describe the relationships between the proposed Center and other existing research, academic, and administrative units of the applicant institution such as schools, centers, institutions, departments, and central administration.

## **Fourth Research Project**

### **Is the fourth research project optional?**

Yes. Applicants may propose an *optional* fourth research project in children's environmental health designed to provide an opportunity to expand the research capabilities of institutions that are traditionally not highly funded for research and development capacity and for institutions that have unique missions and have historically provided services to health disparity populations including minority, low income and tribal communities.

**Does the fourth project need to be in a low income, or minority or tribal population or do they just need to meet the criteria?**

To be eligible for this optional project, applicants are strongly encouraged to partner with institutions receiving less than \$35 million/year in federal funding for research and development as listed in the National Science Foundation's publication "[Federal Science and Engineering Support to Universities, Colleges, and Nonprofit Institutions: FY 2007](#)," Table 12, column 2. More information on potentially eligible institutions can be found on [EPA's web site](#). Ideally this project would enhance the research capabilities of those colleges and universities receiving less than \$35 million/year in federal research and development funding as listed in the NSF 2007 publication; train new investigators in emerging issues in children's environmental health with state of the art tools and methodologies; and provide career development opportunities. A successful application will demonstrate meaningful and active participation, as well as a collaborative research process involving both institutions. Applicants should demonstrate how the proposed research in this project will be integrated with the other three research projects and identify how the project will significantly advance the field in protecting children's environmental health.

**Will the score of the optional fourth project factor in to the overall score of the center? Will it be reviewed separately?**

The score of optional project 4 will factor into the overall score of the Center; however, the optional project will be reviewed separately.

**For the fourth project, is there any requirement for distribution of funding between minority institution and parent?**

No.

**Will it be possible to get funding for a fourth project later (i.e., after a center is funded)?**

No. The fourth project must be included in the overall application due July 17, 2012 to be considered for funding

## **Key Personnel**

**Does the program director have to be the PI for one of the projects or Cores?**

Yes. The Program Director must be the PI for the Administrative Core. The Administrative Core will provide oversight, coordination and integration of all Center activities.

**Is there a minimum percent effort required for the Director of the Center?**

Individuals in senior leadership positions should provide intellectual, administrative, and scientific leadership for the Center and are critical to its overall effectiveness and evolution. These individuals should be in place and committed to a defined percent effort. Each PD/PI must have measurable effort (greater than zero), and the level of effort must be adequate to achieve the proposed goals.

**Is there a minimum amount of effort required for each of the research projects in the P01?**

Each PD/PI must have measurable effort (greater than zero), and the level of effort must be adequate to achieve the proposed goals.

### **Faculty Development Investigator**

**Do the entire 3 person months of the new Faculty Development Investigator (FDI) also have to be budgeted in the Administration Core? Or can the 3 person months be split between admin core and research project budgets?**

The 3 person-months can be split between the admin core and the research project budgets. Effort attributed to the research project budget should be allocable to that specific project, while effort attributed to the administrative core should reflect the planned level of effort for any other career development related activities, as described in the development plan.

**Are the 3 person months expected to be for Career Development activities alone, or are they for research activities with the center (or both)?**

The 3 person-months may be a composite of both career development activities and activities tied to a specific research project with the center.

**If the entire 3 person months must go into the Admin Core, can we use the admin core budget justification to also address the research that the FDI will also be doing in the research project?**

The 3 person-months do not need to be attributed to the administrative core.

## **Clinical Health Specialist**

**Is it acceptable to have the clinical specialist conduct research on animals rather than humans if that what the science warrants?**

Yes. While the clinical specialist is not limited to conducting research on humans, this individual must be an active researcher who is qualified to assist with coordination and integration of the scientific projects and who will help ensure that the science under investigation will translate to clinical practice and/or have a positive impact on public health.

**Regarding the Health Specialist, the RFA states "...This function can be supported as part of the Admin Core at no less than 10% effort." Can this include 2 people at 5% effort?**

Although you may have multiple people who could fit the description of the Health Specialist, at least one must have a minimum of 10% effort on the administrative core for the purpose of assisting with the coordination and integration of the projects and ensuring that the science under investigation will translate to clinical practice and/or have a positive impact on public health. Two individuals at 5% effort each would be considered non-responsive.

## **Budget**

**Do subcontracts count toward the \$1M direct cost cap?**

The indirect costs for the subcontracts do not count toward the \$1M direct cost cap.

## **General**

**Are there a maximum number of projects allowable for the P01?**

While there is no maximum number allowable, applicants should send in their most meritorious projects. All projects received will be reviewed and scored.

**Page 11 of the RFA, under COTC, a NIEHS database management system is mentioned. Is this the same thing as the PEPH Resource center? If not how do we access this data management system?**

The RFA is referring to the NIEHS PEPH resource center.

**How important is having pilot data for an R01 if the project is very novel?**

Pilot data is essential in a Center project.

**Can you say something about foreign institutes? Can we include foreign counterparts as collaborators?**

Foreign components, as [defined](#) in the [NIH Grants Policy Statement](#), are allowed; however, the lead institution must be a domestic entity or organization.

**How many new Centers do you intend to fund?**

NIEHS and EPA intend to fund an estimate of 7 awards, corresponding to a total of approximately \$12 million per year combined from both agencies, including direct and Facilities and Administrative (F&A) costs, annually for 5 years beginning in fiscal year 2013. Future year amounts will depend on annual appropriations.

**Is it appropriate to simultaneously submit some projects as part of the Center and as independent R01s?**

Yes; however, the NIH will not fund a project that is already or will be funded through a different mechanism.

**Where should Centers coming up for renewal put their progress reports? Is that a separate section of the application or should this material be included in the Center overview?**

Centers up for renewal (NIEHS P01 grant eligible for renewal) should discuss their progress to date in the overview of the Center. It does not need to be discussed in the overview of the individual research projects.

**Can you clarify the text in the RFA about not accepting applications that are essentially the same as ones already or previously submitted?**

NIH will not accept any application in response to this FOA that is essentially the same (another NIH P01) as one currently pending initial peer review unless the applicant withdraws the pending application. NIH will not accept any application that is essentially the same as one already reviewed. Resubmission applications will not be accepted.

**What is the target age for this program?**

There is no targeted age; however, we are interested in protecting the health of children, and we use the biological term to describe a human between stages of birth and puberty and can include a fetus, as an unborn child.

**Does environmental health encompass only agents within the environment or would obesity be considered an environmental issue?**

Obesity is an appropriate outcome of interest but the effects on obesity must be linked to an environmental exposure.

**Are there any disease areas that are a priority?**

Diseases or disorders where an environmental exposure is suspected but less well established such as autoimmune disorders, childhood cancers, adverse birth outcomes, neuropsychiatric and neurological disorders are research topics of interest.