

New RFA for Six Children's Environmental Health Centers

The National Institute of Environmental Health Sciences (NIEHS) and the U.S. Environmental Protection Agency (EPA) are requesting applications for \$9 million in awards for six Centers for Children's Environmental Health and Disease Prevention Research. Launched in 1998, the centers program was designed to promote multidisciplinary interactions among basic, clinical, and behavioral scientists and community based organizations with the goal of accelerating translation of research findings into the prevention and clinical decision making arenas and giving necessary information to communities and policy makers.

Currently, the network includes 12 centers, which were created to facilitate research related to children's environmental health problems that is national in scope. The coordinated programs seek to understand the mechanism of environmentally induced diseases in children, to incorporate exposure assessment and health effects research, and to develop and validate risk management and prevention strategies. NIEHS and EPA made awards for eight centers in 1998, and an additional four in 2000. Awards for the original eight centers run out this fiscal year. The six new awards will expand the focus of the continuing program. Research at the centers strives to probe the impact of environmental exposures on the etiology and prevention of health concerns in children and to explore their unique susceptibilities, be they genetic or environmental. The research is in keeping with the mission of all research at NIEHS, which broadly defines the environment to include everything from social issues to nutrition and pollution and more.

Respiratory diseases, childhood neurodevelopment and learning, and organ system development and pathobiology are topics of interest in the RFA. Research can focus on children of all ages from the earliest stages in the womb to late teenage. New research emphasis areas include childhood cancer and birth defects. The RFA opens up the possibility to focus on intermediary end points and not necessarily wait for disease outcomes, explains NIEHS's Gwen Collman, scientific program administrator. Not only diseases but functional deficits linked to exposures are also of interest.

Proposals should include a minimum of three scientific projects, including a lab-based project that focuses on mechanism, a community-based project that entails a partnership with a community-based organization, and a discipline-specific project chosen from epidemiology, exposure assessment and remediation, behavioral sciences, economics, or social policy research. The projects should be created within a theme that ties them together with core center activities, including community outreach and translation of research results, outlined in the RFA.

Research teams must have an established relationship with a community-based organization and disseminate information to the community at least once per year. The grant application must include an external advisory board, an expert center director, and support for a new investigator. The center director and research leaders must plan to attend an annual grantee meeting. If environmental specimens will be collected, the team must use a quality assurance plan.

NIEHS will conduct the peer review process. NIEHS should receive letters of intent by April 16, 2003, and the National Institutes of Health should receive applications by May 16, 2002. Awards will begin in November 2003. Letters of intent are not binding. Applications will be accepted without a letter of intent on record, but they helpful for assembling the special emphasis review panel.

Q: Will you expand upon what you mean as community based? What do you define as community? Is it the community where the research is being carried out or does it have to be a national organization? Do they have to be lay individuals?

A: Your choice of a community-based organization should be related to the choice of the scope of your science. Each of the centers should have a scientific theme in one of these areas that we've described in the RFA. And it should also reflect the kind of studies that you intend to do. So if you're going to study the neighborhood that surrounds the university where you are, then your community-based organization should be those people or those organizations that represent the community and work with them on the issues you're going to study right in that vicinity. If the research is more national in scope or statewide or represents a different kind of catchment area, then your input from the community-based organizations should be commensurate with that. So it very much depends on the scope. Rather than one specific answer, there are a wide variety of groups out there that could be considered to be community-based organizations. The key is that the investigators need to work with those organizations from the get-go. These people should have a very active role in the planning the work of the centers and in the dialog that goes on with the center research. They should work with you to do community outreach to get the findings back out to the community or information out to whatever you feel is the appropriate audience for the work that you're going to do at the center.

Q: Can you expand upon what you mean by an established relationship with a community-based organization?

A: Established means different things to different groups. So there's no set definition for the amount of time you need to be working with them or the intensity with which you need to be working with them. The most successful projects in our program are groups where there's clear indication that you've worked together to put the proposal together and that your previous history with them indicates a successful working relationship in the future. It really varies on a case-by-case basis what that means.

Q: Is it appropriate to have a multi-site study?

A: It's up to the investigative group to come up with what's defined as an appropriate methodology to answer the questions that you think are important in your center. And there's no prohibition to do studies involving more than one site.

Q: What about partnering with researchers at different universities across the country to create a center?

A: It can work in a variety of different ways. If you have several partners at different universities who bring strength to your group and you can show that you've worked together successfully in collaboration then that's OK to do this through a contractual method. So one group becomes the prime grantee and then you work with your collaborators through subcontracts. The caution with that is that those programs are much more expensive so you have to be very careful about how you portion your funds because there are indirect costs and such that are associated with subcontractors.

Q: Do you attempt to balance the awards for centers geographically or regionally? For example, if there is an existing center in a given metropolitan area or state will that work against new applicants?

A: We've never taken the approach where we set a target to have X number of programs in one area versus the other. We allow the peer review process to help us decide where the best science and the best centers are. We do look at balance, we look at program priority, and take these things into consideration, but we don't have a preconceived formula of what we want to see. We don't have a formula that says we need to have a certain number of centers in each region of the country. When there are several applicants within the same geographic area, we look at the questions that they are going to ask. We look at things like are they covering issues that are appropriate in their region or is there the opportunity for them to work together. If there's going to be more than one center in a region, then we look for an added value to the overall network of the program. So it's not like some of the other agencies that are looking to have one center in each geographic region across the country.

Q: How specific are the research topics of interest for study at the centers? Are you interested in multiple disease endpoints?

A: The disease areas that are described in the RFA are guidelines for the kinds of research we're interested in. It's actually not totally inclusive. If there's another problem that has an environmental etiology that's worth studying and that fits broadly in those categories, we'd be interested. Something like organ systems development and pathobiology, for instance, is a pretty broad topic. If you can imagine, we're just giving you some examples. But if your program can make a good case for studying something that maybe we haven't thought about, we'd be open to that. It's possible to study multiple disease endpoints as long as the approach fits together well in your theme. So it depends how you phrase your theme whether multiple endpoints are appropriate, whether multiple exposures are appropriate or perhaps you just want to focus in on one disease-exposure relationship. The design is up to the investigative group.

Q: Will you be making new awards?

A: All of the awards will be new. As of November 1, there will be brand new awards. There will be eight centers that are finishing. We are assuming that many of those will recompute.

We have no preset formula for deciding which centers will be recompetes and which will be new ones. Again we'll use our peer review process to identify the best programs and look at balance and other issues outlined in the RFA.

Q: Can the grantees be based outside the United States?

A: The primary grantee needs to be a U.S. organization. But there is an opportunity for international collaboration through subcontracting.

Q: Is the outreach component for outreach's sake or should there be a mechanism for evaluating its efficacy?

A: All good outreach efforts should have some evaluative component to them. You should build that into your strategies. Certainly, with working your community groups they'd want to see some evaluation of the effort and efficacy of their efforts and that kind of thing.

Q: How is the core defined in terms of outreach?

A: There can be opportunities for things like focus groups, the development of materials, programs with the schools or the legislature or whatever you feel your appropriate targets are depending on your theme and the way you set up your center. It's pretty broad. It gives you the opportunity to develop all these strategies that we need to make sure the information we're getting from the scientific research gets to the right people.

Q: Will a preference be given to existing centers?

A: This is an open competition for all investigators across the country. And we think there are other centers, other university groups, other researchers out there who are doing just this stuff without being a part of our centers program. I can't tell you that they're going to come in at a disadvantage if what they've been doing is very much related to the centers program. And there may be groups that have been at this business for longer or they've been in a related business but maybe they haven't added some environmental issues that they're ready to do right now. So we're looking to broaden that as well and have these groups be considered in the next round of applications. It all just depends on how all the applications are written and what the peer review panel thinks of them.

Q: Would NIEHS be interested in exposures to therapeutic agents, which have been well studied in other programs?

A: Exposures are often very broadly based. There might be some therapeutic agents that can be used as models. It reflects the portfolio that the institute has to date. If the justification is there for including such an agent and you can make a case for it, then obviously it would be accepted.

Q: Does the research have to specifically target the cellular level, for example? The RFA lists a broad spectrum of scientific approaches, do they all have to be included?

A: It's broad. It's meant to bring in all the different disciplines and have them represented in the center. We're not going to limit you to only focusing your questions in one way. You can use the breadth of tools that are available in the laboratory. It can be animal research or human research. It can be clinical or non-clinical, but we want to make sure that all those disciplines are represented. We feel that conversations that include all these different investigators make for a richer scientific endeavor.

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