

NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH SCIENCES
Division of Extramural Research and Training
Center for Risk and Integrated Sciences

NATIONAL ADVISORY ENVIRONMENTAL HEALTH SCIENCES COUNCIL
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Concept Clearance

Research Resources for the Environmental Health Sciences

Introduction

Recent decades have seen a rapid emergence of new technologies and approaches to advance biomedical research including a range of 'omics, imaging, and high throughput screening technologies, animal models as well as informatics and computational approaches. Many of these technologies have been rapidly adopted by the research community and have become 'standard' research techniques available at most research intensive institutions. Other technologies are less amenable to widespread adoption due to high infrastructure costs, need for a highly specialized workforce or, by nature, simply are not amenable to distributed adoption (databases).

While an SBIR, R21 or R01 application may be appropriate for the development of a technology or the application of an established, unique resource to a specific research project, these traditional research mechanisms do not adequately address the long term maintenance or access issues important to the broader scientific community. A program project or Center grant may enable broader access to a core facility for a local institution but rarely is that appropriate to broad access beyond that local community. The NIH has developed the R24 and P41 mechanisms for support of research resources for the broader community. The use of such mechanisms could speed the application of emerging technologies to the environmental health sciences and advance our understanding of the impact of environmental factors on human health.

Research Goals and Scope

This concept will establish a program solicited by an annual program announcement and is viewed as becoming a long-standing Institute program to provide support for the sharing of technological resources to the environmental health sciences community. The program is not intended to be used for the development of new technologies but rather to support access to existing unique technological resources to investigators funded by the NIEHS or conducting work appropriate to funding by the NIEHS for use by the Environmental Health Sciences community. Funds from the award(s) would be used to maintain the infrastructure including support for an experienced technical staff and support for required supplies.

A funded project will function much like a facilities core from a Center grant. For instance, in the case of an R24 providing access to an analytical technology such as a unique proteomics, metabolomics or epigenetics capability, it will receive samples (through a small 'application' process) and provide the investigators with data. The level of analysis of that data may depend on the particular project and will be factored into the prioritization of access to the resource.

Many different technologies could be appropriate to this mechanism including:

- High throughput screening systems and libraries of environmental chemicals
- Unique 'omics capabilities beyond those typically available at most Institutions, such as those enabling analysis at the single cell level or capturing dynamic changes at the 'omic level
- Advanced imaging capabilities for measuring in vivo or in vitro responses to environmental factors
- Large-scale capabilities in analytical chemistry and mass spec enabling comprehensive body burden assessment
- Unique and highly complex animal model systems such as primate models or large scale recombinant-inbred mouse models
- Broadly applicable databases for the environmental health sciences

Mechanism and Justification

It is envisioned that the NIEHS R24/P41 program will be solicited through a broadly focused PAR with a single annual receipt date for three consecutive years. Applicants will be required to submit a detailed letter of intent (which will be required due to a minimum budget of \$500k). This letter must include a justification detailing the existence of a unique research resource and a description of a pre-identified user base of NIEHS funded investigators as well as an overall budget and management plan. These letters will be evaluated by a committee of program scientists across DERT with preapproval of concepts by a program committee prior to application submission required. Applications of sufficient import or those deemed as requiring greater staff oversight may be converted to cooperative agreement mechanisms.

Projects will be funded for five years, with competitive renewal possible. Individual projects will have direct costs between \$500k and \$1M with appropriate justification. It is anticipated that 1-3 awards will be made annually. The project may include limited funds to support the continued development of technology or the resource as well as to market the resource to the broader environmental health community. However, the fundamental intent and bulk of the resources must be on maintenance and delivery of the resource to a user base.

Documentation of use of the resource by the broader EHS research community will be a vital aspect of the annual non-competitive renewal process. The solicitation will make clear that under-utilized resources will not receive non-competitive renewals; awardees

will be expected to document utilization beyond their institution and known collaborators in the non-competitive renewal.

Portfolio Analysis

NIEHS does not currently use either the R24 or U24 Resource-Related Research Projects or P41 Biotechnology Resource Grants mechanisms. We do support several technologies through our Core Centers that would potentially be appropriate to this mechanism including, for instance, Accelerator Mass Spec capabilities, multi-dimensional metabolomics, or advanced imaging capabilities. Some suitable technologies have been developed by investigator R01s or other special programs such as automated high-throughput screening and 'omics analysis, the comparative toxicogenomics database, or the Comparative Mouse Genomics Centers Consortium. Some other resources have been partially supported by NIEHS through trans-NIH efforts such as the Knock Out Mouse Project and the collaborative cross.

Other Institutes have made extensive use of the R24 mechanism with a total of 232 R24 projects receiving funds across NIH (from 17 ICs) in FY10; in addition a total of 83 U24 awards were made from 12 ICs. The funded R24s typically result from broadly based solicitations such as that proposed here although some ICs have released focused solicitations for translational or genetic work, for instance. U24's are typically solicited for a focused topic or can result from conversion of an R24 project.