Disease Investigation through Specialized Clinically Oriented Ventures in Environmental Research (DISCOVER)

FAQs

Administrative Issues

Q. What is meant by 'Applicants may submit only one application'?

A. The NIEHS has removed this limitation; applicant Institutions may now submit more than one application for DISCOVER Centers provided they are scientifically distinct. However, given the limited resources available to this solicitation, it is unlikely that NIEHS would consider funding more than one application per Institution.

Q. What is the role of the Center Director?

A. The Center Director is responsible for overall Center administration including assurance of scientific coordination across projects and cores and preparation of reports to the NIEHS and external advisors. The Center Director is not required to be a physician nor does s/he need to direct one of the research projects.

Q. What is the role of the Lead Physician-scientist?

A.The Lead Physician-scientist is responsible for assuring the translation of research findings between the research projects, and to provide clinical insight, leadership, and direction to the research effort of the Center as a whole. The Lead Physician-scientist is not required to be the director of one of the research projects.

Q. Must the Lead Physician-scientist by actively involved in treating patients?

A. The Lead Physician-scientist must have an MD degree, or equivalent, in order for the application to be judged responsive. The Lead Physician-scientist is not required to have an active clinical practice; however, the qualifications and ability of this individual to provide a clinical perspective for ensuring the translation of mechanistic and patient-oriented research will be a significant review factor as indicated in the 'Review Criteria' section of the RFA.

Q. What are the required minimum level of effort commitments for the Center Director, Lead Physician-scientist, and Project Leaders?

A. The Center Director and Lead Physician-scientist are required to devote a minimum of 15% effort to the Center and Project Leaders should devote a minimum of 20% effort. These roles are distinct, therefore, the minimum percent effort commitments of these individuals do not offset each other. For example, an individual who acts as Center

Director, Lead Physician-scientist, and Project Leader would devote a minimum of 50% effort to the DISCOVER Center.

Q. What is the purpose of the Administrative Core?

A. The Administrative Core oversees the organizational, budgeting and reporting aspects and will coordinate the overall activities of the center such as symposia, meetings of the internal and external advisors, and center publications. The administrative core will also coordinate the product development and translation projects which NIEHS intends to support through competitive supplements in years 3-5.

Q. Will foreign applications be accepted?

A. Applications from foreign institutions will not be accepted to this program. Foreign collaborations including projects based at foreign sites may be appropriate if scientifically justified and adequate plans for integration into the DISCOVER Center are provided. These collaborations will be factored into the peer review of the Centers.

Scientific Issues

Q. What is meant by a 'Biological Toxicant' as a 'Primary Stressor'?

A. Studies on the effects of biologically-derived toxicants such as mycotoxins, aflatoxin, endotoxin, or cockroach allergen would be appropriate as the primary stressor focus of a DISCOVER Center. Studies of infectious pathogens are not appropriate as a primary focus. The influence of co-morbid infectious disease on the response to a primary stressor is appropriate for the DISCOVER program. Applicants are encouraged to contact the DISCOVER program team and discuss their focus to determine the appropriateness of their primary stressor(s).

Q. Will studies on the environmental transmission of infectious pathogens be responsive as the primary focus of a DISCOVER Center?

A. No, studies that focus on the environmental transmission of infectious pathogens will not be considered responsive. If, however, studies focus on a pathogenic factor produced by an infectious pathogen, the application may be responsive.

Q. What is the role of epidemiology in the DISCOVER Centers?

A. Population studies with a suitable patient-oriented disease/dysfunction focus and which can be completed within the 5 year time frame and the budgetary limitations of a DISCOVER Center are allowable under this solicitation. Applicants intending to include significant population based studies should contact the DISCOVER program team and discuss these efforts to determine their appropriateness.

Q. How will the required two mechanistically-oriented and the two patient-oriented projects be identified?

A. The applicant should identify which projects are to be considered mechanistic and patient-oriented in the Program Introduction and Statement of Objectives section of the application.

Questions and Answers from the Application Information Meeting

Q. When you talk about a clinical trial, for those of us in reproductive technologies, would this pay for procedures such as fertility treatments?

A. What is generally intended is the discovery and validation of biomarkers and the development of clinical interventions. However, the goals of this program are broad and additional topics will be considered. Applicants are strongly encouraged to get in touch with a member of the IMIC group, as listed on the DISCOVER website and in the RFA, to discuss specific circumstances.

Q. Optional Core facilities—where are those costs accounted for in the budget?

A. Any Core costs must be within the 1.5 million direct cost caps; this is why applicants are encouraged to make use of existing Cores so that DISCOVER budgets can be directed at the research projects rather than Cores.

Q. Could you please provide clarification of the MD requirements. In introductory remarks, Dr. Sassaman made the point that the NIEHS considers clinical researchers to include non-MDs as well. Does the lead Physician-scientist have to be an MD?

A. Yes. Lead Physician-scientist must have an MD, but a non-MD may be appropriate for leading a specific clinical project in a DISCOVER application.

The fundamental role of the Lead Physician-scientist is to ensure integration of the mechanistic and clinical effort across the program, an effort which will require the unique physician-scientist perspective. It is also important to note that the 15% required commitment is associated with the overall program, in essence a 4-5% commitment for each research project. The same is also true for the Center Director, who is responsible for administrative coordination across the projects.

Q. The RFA indicates the need for a Center Director and Physician Scientist. Can one person serve both roles?

A. Yes, they can be the same person, but the percent efforts must add as if they were different persons. For example, if the Center Director and Physican scientist are the same

individual, the effort of this one individual must be 15% + 15% =30%. If this person also is a project leader, the effort must be 15% + 15% +20 % =50.

Q. About the review panel, perhaps I misunderstood something you said. If I put in a Center proposal with 4 independent projects, will there be 3 reviewers for the whole application, or 3 for each project?

A. I am sorry for the confusion; I did not mean to imply that each application would have only 3 reviewers. The number of reviewers will depend on the number of projects and cores and needed expertise; with four projects, you could have as many as 12 for each application.

Because the reviewers for individual components will focus on their assigned projects more than the rest of the Center proposal, they may not read every section in the application in great detail. It is imperative that you, the applicant, include information, in EACH project, about how the projects are integrating with each other and with the cores. Do not assume that each reviewer will make the connections across all parts of the application of you.

Q. Why are we asked not to give names for the External Advisory Committee? For most Centers, these EABs have already been established, and we want the reviewers to know we have the biggest names on the EAB. Your comments indicate that any individuals who have agreed to be on an EAB cannot be reviewers of the DISCOVER applications. Is this true?

A. Yes. We know this is an awkward issue. Naming EABs prior to review is a big problem for NIEHS because we are trying to put together the very best review panel. If you have assembled your EAB, you are limiting the pool of reviewers that we can call on. Bottom line is that if you have already made contact with potential EAB members you should include their names in the application because those individuals will be in conflict whether or not they are listed. If no contact has been made, do not include names, but do indicate the kinds of expertise that will be sought for the EAB.

Q. I need more information about the Lead Physician-scientist. Can it be an MD who does epidemiology?

The essence of the Lead Physician-scientist is a person who understands both mechanistic and clinical research and can draw connections between them. Provided that the epidemiologist is qualified to fill that role, that would be appropriate. The review committee will look at the ability of this person to enable integration. This is the critical point for review more so than the initials after the name. A pure epidemiologist or clinician with no experience in mechanistic research would likely not be considered favorably by the review panels evaluation of the Lead Physician-scientist.

Q. Can the Center Director and Lead Physician-scientist be the same individual? Could the roles be reversed such that the Lead Physician-scientist directs the overall program as PI and an Associate Director oversee the administrative coordination?

A. Yes, an individual can have dual roles but the percent efforts must add.

It is acceptable, with adequate justification, to have the Lead Physician-scientist be the designated center PI with a separate Center Director who oversees the administrative coordination of the DISCOVER Center.

Questions relating to the DISCOVER Grantsmanship presentation

Q. The idea of being overly ambitious, this can differ a lot. What is overly ambitious for one person may be doable for another. This speaks to the review criteria that will be used. I encourage NIEHS to ensure that, if a project is indicated to be overly ambitious, the reviewers make clear what this means.

A. We understand this issue and will instruct reviewers to be specific in their criticisms, specifically as relates to 'overly ambitious' projects.

Q. This idea of product; I assume that all of the projects should be going toward one product. But what about projects that are in the discovery phase. We may not have a product in five years, but we could have a good plan for a product. Can you give an example?

A. A 'Product' doesn't have to mean something physical, but can be 'Knowledge' that will lead to a translatable discovery. The translation has to have a focus on eventual impact on human/public health within the scope of the DISCOVER Center. It can be physical (chip for in vitro diagnostic, set of biomarkers to distinguish phenotypes), but also the effort of moving the mechanistic knowledge to the translational impact. Identifying novel risk factors would be a product. Within the initial five year funding of the Center you may only have some preliminary findings and may not be able to know whether the intervention will work. You will, however, have to convince reviewers that this effort will lead directly to these outcomes. Our intention is to facilitate this by providing additional funds through supplementary awards starting in year 3 of funding.

Questions from the Q&A Session

Q. A budget question; if a group is using a shared animal model, with different basic projects using one animal model, where does this go in? Would it be in the individual projects or is there some other place this would go in?

A. This could go into a facility core or in a number of individual projects, depending on the economy of scale that may make a Core appropriate.

Q. Disease process is essential, but what about the environmental factor? Should it be one or multifactorial?

A. As stated, we are not being overly prescriptive and this is somewhat open to what would be appropriate for the project you propose. It is certainly conceivable that a project could focus on several toxicants which lead to a single disease end point, a single toxicant which leads to several distinct diseases or a traditional one-toxin-one-disease focus. The ultimate requirement of the program is that you focus on relevant primary stressors (as defined in the RFA) and human disease, within that broad scope, we are very flexible.

Q. Related to clinical project, if you have resources from existing cohorts, is that usable, or do you need to be collecting this prospectively? For example, if you have banked samples from another clinical project, is that acceptable?

A. Yes, you can build on these resources, but you would have to use these resources in a different way than was envisioned initially in the study. That is, the initial project that generated the samples could not itself be considered the clinical project for meeting the DISCOVER criteria, but a logical extension of that project could be included.

Q. Where would the annual meeting be held? Locally or not?

A. Our intent is that this will rotate among the centers.

Please comment more on Center Director and Physician-scientist roles? It sounds like this needs to be two different individuals.

A. Our personal preference would be that these should be two different individuals so that you can have two different perspectives. The Director would be able to focus on the administrative aspects and will not have to be focused also on the integration of the clinical and mechanistic and visa-versa for the Lead Physician-scientist. You can have one person, however, and be considered responsive provided the minimum level of commitment is met (15% for each role).

Q. Please clarify the wording about collaborative agreements outside of the Center, which are allowed, but the RFA indicates that the DISCOVER has to have a home.

A. The 'Home Institution' must have at least 50% most of the projects. These could be in different departments, or even colleges/schools within the University. There is no requirement to create a new independent organization for this Center.

Q. What are you looking for in institutional support?

A. We do not require cost sharing, and not having will not count against you. This is Institutional Support will be one of the review criteria, however. You should understand

that the support can be in many forms; the institution can pay for a piece of equipment, can subsidize Core resources or give space or protected time to mention a few.

Q. For those of us who are local and are collaborating with intramural, how can this work?

A. Active collaborations are great. We (DERT) will not pay for intramural research, however. This means that you cannot include a project that will be conducted intramurally. You can provide supplies for an intramural researcher to conduct research in your extramural laboratory. Grant monies cannot be used for intramural salaries, however. It is also acceptable to provide, for instance, postdoc salary support for someone on your grant who is working at NIEHS.