

Part I Overview Information

Department of Health and Human Services

Participating Organizations

National Institutes of Health (NIH) (<http://www.nih.gov>)

Components of Participating Organizations

National Heart, Lung, and Blood Institute (NHLBI) (<http://www.nhlbi.nih.gov>)

Title: Centers for Advanced Diagnostics and Experimental Therapeutics in Lung Diseases Stage I (CADET I) (P50)

Announcement Type

New

Request For Applications (RFA) Number: RFA-HL-11-015

Note: A new version of the paper PHS 398 application form and instructions is being developed. The new form and instructions must be used to apply for receipt dates January 25, 2010 and beyond. Please download the new application form and instructions when they become available (by December 2009) from <http://grants.nih.gov/grants/forms.htm>. For more information on how the application is being restructured, please visit http://enhancing-peer-review.nih.gov/restructured_applications.html.

Catalog of Federal Domestic Assistance Number(s)

93.838

Key Dates

Release Date: February 26, 2010

Letters of Intent Receipt Date: April 12, 2010

Application Receipt Date: May 12, 2010

Peer Review Date: October 2010

Council Review Date: January 2011

Earliest Anticipated Start Date: April 1, 2011

Additional Information To Be Available Date (Url Activation Date): Not applicable.

Expiration Date: May 13, 2010

Due Dates for E.O. 12372

Not Applicable

Additional Overview Content

Executive Summary

- **Purpose.** The purpose of this FOA issued by the NHLBI, National Institutes of Health, is to invite applications for clinical research centers for Centers for Advanced Diagnostics and Experimental Therapeutics in Lung Diseases Stage I (CADET I). The overall goal of the CADET program (Stages I and II) is to accelerate the development of novel agents for the diagnosis and treatment of lung diseases and sleep disordered breathing through the use of rational strategies based on fundamental pathobiologic processes. CADET I provides the opportunity to explore potential target(s) for validation to determine which are amenable for development of mechanism-based modalities for direct clinical application in the prevention, diagnosis, and treatment of pulmonary diseases and sleep disordered breathing. Companion FOAs for Clinical Research Centers (CRCs) and a Data Coordinating Center (DCC) for CADET Stage II (CADET II) will be released at a later date. Both the CRCs and DCC announcements will be open competitions. Centers that have been awarded in CADET I may apply for Clinical Research Centers in CADET II.
- **Mechanism of Support.** This FOA will utilize the P50 award mechanism.
- **Funds Available and Anticipated Number of Awards.** Contingent upon the availability of funding, the total amount to be awarded for CADET I will be a maximum of \$30 million for the total program. It is anticipated that up to 30 awards, under this FOA, will be awarded for CADET I.
- **Budget and Project Period.** The total project period for an application submitted in response to this FOA is 2 years. Budgets for direct costs of up to \$300,000 per year (exclusive of indirect costs associated with consortia) and a project duration of up to 2 years may be requested for a maximum of \$600,000 direct costs over a 2-year project period. Because the nature and scope of the proposed research will vary from application to application, it is anticipated that the size and duration of each award will also vary. The total amount awarded and the number of awards will depend upon the numbers, quality, duration, and costs of the applications received. Awards issued under this FOA are contingent upon the availability of funds and the submission of a sufficient number of meritorious applications.

- **Application Research Strategy Length:** The P50 Research Strategy section may not exceed 12 pages, including tables, graphs, figures, diagrams, and charts. See [Table of Page Limits](#).
 - **Eligible Institutions/Organizations.** Institutions/organizations listed in [Section III, 1.A.](#) are eligible to apply.
 - **Eligible Project Directors/Principal Investigators (PDs/PIs).** Individuals with the skills, knowledge, and resources necessary to carry out the proposed research are invited to work with their institution/organization to develop an application for support. Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply for NIH support.
 - **Number of PDs/PIs.** More than one PD/PI (i.e., multiple PDs/PIs), may be designated on the application.
 - **Number of Applications.** Applicants may submit more than one application, provided they are scientifically distinct.
 - **Resubmissions.** Resubmission applications are not permitted in response to this FOA.
 - **Renewals.** Renewal applications are not permitted in response to this FOA.
 - **Special Date(s).** This FOA uses non-standard due dates. See [Receipt, Review and Anticipated Start Dates](#)
 - **Application Materials.** See [Section IV.1](#) for application materials.
- Hearing Impaired.** Telecommunications for the hearing impaired are available at: TTY: (301) 451-5936

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Part II - Full Text of Announcement

Section I. Funding Opportunity Description

1. Research Objectives

Despite enormous advances in the understanding of the pathologies of pulmonary diseases and sleep disordered breathing, the success rate for development of new diagnostics and treatments remains low. Of necessity, treatments have focused on symptom control in late stage disease and cover a broad spectrum of phenotypes. Efficacy of available treatment options varies greatly among patient subgroups and is largely unable to address disease inception and progression. Testing of therapies for lung diseases is hampered by lack of surrogate outcome measures correlating therapy to clinical outcome and informative phenotyping. Furthermore, lung diseases severely lack useful diagnostics that can be used for early detection, stratification, and prognostication.

An integrated approach is needed that is based on fundamental biologic processes, validation, phenotyping, biomarkers, innovative clinical methodologies and study design. This multidisciplinary approach will increase confidence in drug and diagnostic candidates in the heterogeneous human background and accelerate translation to practical application. Centers for Advanced Diagnostics and Experimental Therapeutics in Lung Diseases is a two-stage program that will encourage robust development of suitable novel candidates for development of new therapeutic and diagnostic strategies. CADET Stage I will allow for wide exploration and validation of novel target(s) for therapeutic and/or diagnostic development. Multiple target (s) may be explored in which case a defined pathway or system must have been previously demonstrated to have relevance to human disease. At the end of Stage I, the most promising target(s) should be selected and be ready for transition into the development process. CADET Stage II will be a related, but new, program that will support the development of novel therapeutics and/or diagnostics based on previously identified target(s) that have been robustly validated either in CADET I or via other research efforts with the goal of advancement of novel agents(s)/tools to early clinical trials by the end of the program. The ultimate goal is to achieve effective medical care in precisely identified populations that will benefit from mechanism-based interventions for prevention, diagnosis and treatment.

The purpose of CADET I is to bring together multi-disciplinary teams that will explore, validate and select the best potential target(s) that are amenable for development of novel therapeutics and/or diagnostics. Applicants may pursue validation of either a novel therapeutic or diagnostic or both. Target candidate(s) should have already been identified with established correlation between target levels and/or activity and human disease, based on previously performed, hypothesis-driven research. Research should focus on selection and validation of the most promising, specific target(s) for future development. Milestones should also be proposed to monitor progress and feasibility as the project progresses. Applicants should establish

transdisciplinary teams with expertise necessary to meet the goals proposed in their program and may use the multiple principal investigators (PI) option (http://grants.nih.gov/grants/multi_pi?index) . Applicants must also include a statement that the PI's institution has an intellectual property policy that covers the proposed research, if appropriate.

Proposed research should focus on further robust validation of the identified target(s) with the goal of testing the therapeutic potential of the target(s) to increase the likelihood of successful clinical development. Depending on the body of knowledge that exists for a particular target(s), pathway or system, research is expected to focus on testing the mechanistic relationship between the target and disease pathology, on the assessment of target levels and activities and on the development of reagents necessary for the validation process. It is expected that robust validation strategies will include the use of human cells and/or tissues. Applicants must also state the long-term development goal for the identified target(s).

Research Activities

The following are examples of research activities responsive to this FOA. Activities should focus on selection of the most promising target(s) for therapeutic and/diagnostic development by the end of CADET I. These are **examples only**; applicants should not feel limited to the subjects mentioned and are encouraged to submit other activities/approaches pertinent to the objectives of this FOA.

- Screening assays that provide a comprehensive understanding of target function in human cells/tissues.
- Definition of patient populations most likely to respond to target inhibition.
- Development of reagents for use in testing target levels and/or activity (e.g., antibodies, RNAi)
- Assessment of target distribution and localization *in situ*.
- Development of *in vitro* systems to determine target activity, ideally with potential for conversion to high-throughput format.
- Use of animal models for demonstration of disease abrogation correlated with target activity and/or levels and showing potential importance of target modulation.
- Assessment of target activity in appropriate cellular system(s).
- Validation of pre-clinical and/or clinical markers for applications in early diagnosis and intervention in retrospective and/or prospective human population studies with the goal (s) of identifying individuals for early intervention, predicting treatment response, and optimizing treatment for individual patients.

Examples of research projects that are not responsive to this FOA include:

- Applications which do not include the use of human cells, tissues, and/or populations in the validation process.
- Applications which do not state a previously identified target(s), biological pathway, or system with relevance to human disease.
- Applications which do not state the expected long-term development goal.
- Applications which do not state appropriate milestones to monitor progress of the project.
- Applications proposing hypothesis based mechanistic research for initial discovery of potential target(s).

Organization of CADET I

CADET I will be a collaborative program of up to 30 awards and the NHLBI.

Clinical Research Centers (CRCs) are responsible for proposing a research project as detailed above and for participating as a full member of CADET I. This may include participation in meetings and teleconferences. Each CRC will be required to participate in a collaborative and interactive manner with all other awardees and the NHLBI in all aspects of the program. This may include sharing methods, tools, approaches, results, and contributing to and utilizing the synergy of the group. It may include development of common protocols and/or definitions, as appropriate.

The Principal Investigators will have the primary responsibility for: all aspects of the CADET I studies, including conducting the research, collaborative development of additional group activities, analyzing and interpreting data, preparing publications, and working with the NHLBI to disseminate research findings. PIs will also be responsible for developing common definitions and standardization across protocols, if appropriate.

It is anticipated that in person meetings and teleconferences will be necessary to facilitate progress, interaction and possible collaboration within the program. Teleconferences may be held up to once a month and in person meetings may be held up to two times a year in the greater Washington, D.C area. All sites will be expected to participate in calls and, at a minimum, the PI(s) must attend each meeting and must budget travel funds for this purpose.

It is possible that some CADET I studies will involve support or other involvement of industry or other third parties. However, except for licensing of patents or copyrights, support or involvement of any third party will occur only following notification of and concurrence by NHLBI. Awardees must follow NHLBI policy concerning third party agreements.

See [Section VIII, Other Information - Required Federal Citations](#), for policies related to this

announcement.

Section II. Award Information

1. Mechanism of Support

This funding opportunity will use the P50 award mechanism(s).

The Project Director/Principal Investigator (PD/PI) will be solely responsible for planning, directing, and executing the proposed project.

This FOA uses "Just-in-Time" information concepts. It also uses non-modular budget formats described in the PHS 398 application instructions (see

<http://grants.nih.gov/grants/funding/phs398/phs398.html>).

2. Funds Available

The total amount of funding that the NHLBI expects to award for CADET I is \$30 million for up to 30 awards and for a project period of up to 2 years in response to this FOA. Applicants may request direct costs of up to a maximum of \$300,000 per year (exclusive of indirect costs associated with consortia) and a project duration of up to 2 years for a maximum of \$600,000 direct costs over a 2-year project period. Designated funding levels are subject to change at any time prior to award, due to unforeseen budgetary, administrative or scientific developments.

Because the nature and scope of the proposed research will vary from application to application, it is anticipated that the size and duration of each award will also vary. Although the financial plans of the IC(s) provide support for this program, awards pursuant to this funding opportunity are contingent upon the availability of funds and the receipt of a sufficient number of meritorious applications.

Facilities and administrative costs requested by consortium participants are not included in the direct cost limitation, see [NOT-OD-05-004](#).

NIH grants policies as described in the [NIH Grants Policy Statement](#) will apply to the applications submitted and awards made in response to this FOA.

Section III. Eligibility Information

1. Eligible Applicants

1.A. Eligible Institutions

The following organizations/institutions are eligible to apply:

- Public/State Controlled Institutions of Higher Education
- Private Institutions of Higher Education
- Hispanic-serving Institutions
- Historically Black Colleges and Universities (HBCUs)
- Tribally Controlled Colleges and Universities (TCCUs)
- Alaska Native and Native Hawaiian Serving Institutions
- Nonprofits with 501(c)(3) IRS Status (Other than Institutions of Higher Education)
- Nonprofits without 501(c)(3) IRS Status (Other than Institutions of Higher Education)
- Small Businesses
- For-Profit Organizations (Other than Small Businesses)
- State Governments
- Indian/Native American Tribal Governments (Federally Recognized)
- Indian/Native American Tribally Designated Organizations
- County Governments
- City or Township Governments
- Special District Governments
- Independent School Districts
- Public Housing Authorities/Indian Housing Authorities
- U.S. Territory or Possession
- Indian/Native American Tribal Governments (Other than Federally Recognized)
- Regional Organizations
- Other(s):
 - Eligible Agencies of the Federal Government
 - Faith-based or Community-based Organizations.

1.B. Eligible Individuals

Any individual with the skills, knowledge, and resources necessary to carry out the proposed research as the PD/PI is invited to work with his/her institution to develop an application for support. Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply for NIH program support.

More than one PD/PI, or multiple PDs/PIs, may be designated on the application for projects that require a "team science" approach and therefore clearly do not fit the single-PD/PI model. Additional information on the implementation plans, policies and procedures to formally allow more than one PD/PI on individual research projects is available at http://grants.nih.gov/grants/multi_pi. All PDs/PIs must be registered in the NIH eRA Commons prior to the submission of the application (see <http://era.nih.gov/ElectronicReceipt/preparing.htm> for instructions).

The decision of whether to apply for a grant with a single PD/PI or multiple PDs/PIs is the responsibility of the investigators and applicant organizations, and should be determined by the scientific goals of the project. Applications for grants with multiple PDs/PIs will require additional information, as outlined in the instructions below. When considering multiple PDs/PIs, please be aware that the structure and governance of the PD/PI leadership team as well as the knowledge, skills and experience of the individual PDs/PIs will be factored into the assessment of the overall scientific merit of the application. Multiple PDs/PIs on a project share the authority and responsibility for leading and directing the project, intellectually and logistically. Each PD/PI is responsible and accountable to the grantee organization, or, as appropriate, to a collaborating organization, for the proper conduct of the project or program, including the submission of required reports. For further information on multiple PDs/PIs, please see http://grants.nih.gov/grants/multi_pi.

2. Cost Sharing or Matching

This program does not require cost sharing as defined in the current [NIH Grants Policy Statement](#).

3. Other-Special Eligibility Criteria

Number of Applications. Applicants may submit more than one application, provided they are scientifically distinct.

Resubmissions. Resubmission applications are not permitted in response to this FOA.

Renewals. Renewal applications are not permitted in response to this FOA.

Examples of Research which is not responsive to this FOA include, but are not limited to:

- Applications which do not include the use of human cells, tissues and/or populations in the validation process are not responsive to this FOA.

- Applications which do not state a previously identified target(s), biological pathway or system with relevance to human disease not are responsive to this FOA.
- Applications which do not state the expected long-term development goal are not responsive to this FOA.
- Applications which do not state appropriate milestones to monitor progress of the project are not responsive to this FOA.
- Applications proposing hypothesis based mechanistic research for initial discovery of potential target(s) are not responsive to this FOA.

Section IV. Application and Submission Information

1. Address to Request Application Information

The current PHS 398 application instructions are available at <http://grants.nih.gov/grants/funding/phs398/phs398.html> in an interactive format. Applicants must use the currently approved version of the PHS 398. For further assistance contact GrantsInfo, Telephone (301) 435-0714, Email: GrantsInfo@nih.gov.

Telecommunications for the hearing impaired: TTY 301-451-5936.

2. Content and Form of Application Submission

Prepare all applications using the PHS 398 application forms and in accordance with the PHS 398 Application Guide (<http://grants.nih.gov/grants/funding/phs398/phs398.html>).

Applications must have a D&B Data Universal Numbering System (DUNS) number as the universal identifier when applying for Federal grants or cooperative agreements. The D&B number can be obtained by calling (866) 705-5711 or through the web site at <http://www.dnb.com/us/>. The D&B number should be entered on line 11 of the face page of the PHS 398 form.

The title and number of this funding opportunity must be typed in item (box) 2 only of the face page of the application form, and the YES box must be checked.

Applications with Multiple PDs/PIs

When multiple PD/PIs are proposed, use the Face Page-Continued page to provide items 3a – 3h for all PD/PIs. NIH requires one PD/PI be designated as the “contact PD/PI” for all

communications between the PD/PIs and the agency. The contact PD/PI must meet all eligibility requirements for PD/PI status in the same way as other PD/PIs, but has no special roles or responsibilities within the project team beyond those mentioned above. The contact PD/PI may be changed during the project period. The contact PD/PI should be listed in block 3 of Form Page 1 (the Face Page), with all additional PD/PIs listed on Form Page 1-Continued. When inserting the name of the PD/PI in the header of each application page, use the name of the "Contact PD/PI, et. al." The contact PD/PI must be from the applicant organization if PD/PIs are from more than one institution.

All individuals designated as PD/PI must be registered in the eRA Commons and must be assigned the PD/PI role in that system (other roles such as SO or IAR will not give the PD/PI the appropriate access to the application records). Each PD/PI must include their respective eRA Commons ID in the eRA Commons User Name field.

Multiple PD/PI Leadership Plan: For applications designating multiple PDs/PIs, the section of the Research Plan entitled "Multiple PD/PI Leadership Plan" must be included. A rationale for choosing a multiple PD/PI approach should be described. The governance and organizational structure of the leadership team and the research project should be described, and should include communication plans, process for making decisions on scientific direction, and procedures for resolving conflicts. The roles and administrative, technical, and scientific responsibilities for the project or program should be delineated for the PDs/PIs and other collaborators.

If budget allocation is planned, the distribution of resources to specific components of the project or the individual PDs/PIs should be delineated in the Leadership Plan. In the event of an award, the requested allocations may be reflected in a footnote on the Notice of Award.

Additional information is available in the [PHS 398 grant application instructions](#).

3. Submission Dates and Times

Applications must be received on or before the receipt date described below ([Section IV.3.A](#)). Submission times N/A.

3.A. Receipt, Review and Anticipated Start Dates

Letters of Intent Receipt Date: April 12, 2010
Application Receipt Date: May 12, 2010
Peer Review Date: October 2010
Council Review Date: January 2011

Earliest Anticipated Start Date: April 1, 2011

3.A.1. Letter of Intent

Prospective applicants are asked to submit a letter of intent that includes the following information:

- Descriptive title of proposed research
- Name, address, and telephone number of the Principal Investigator
- Names of other key personnel
- Participating institutions
- Number and title of this funding opportunity

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 IC staff to estimate the potential review workload and plan the review.

The letter of intent is to be sent by the date listed in [Section IV.3.A.](#)

The letter of intent should be sent to:

Director, Office of Scientific Review
Division of Extramural Research Activities
National Heart, Lung, and Blood Institute
6701 Rockledge Drive
Room 7214, MSC7924
Bethesda, MD 20892-7924 (Express mail zip: 20817)
Telephone: (301) 435-0270
FAX: 301-480-0730
Email: nhlbchiefreviewbranch@nhlbi.nih.gov

3.B. Sending an Application to the NIH

Applications must be prepared using the forms found in the PHS 398 instructions for preparing a research grant application. Submit a signed, typewritten original of the application, including the checklist, and three signed photocopies in one package to:

Center for Scientific Review
National Institutes of Health
6701 Rockledge Drive, Room 1040, MSC 7710

Bethesda, MD 20892-7710 (U.S. Postal Service Express or regular mail)
Bethesda, MD 20817 (for express/courier service; non-USPS service)

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, two additional copies of the application and all copies of the appendix material must be sent to:

Director, Office of Scientific Review
Division of Extramural Research Activities
National Heart, Lung, and Blood Institute
6701 Rockledge Drive
Room 7214, MSC7924
Bethesda, MD 20892-7924 (Express mail zip: 20817)
Telephone: (301) 435-0270
FAX: 301-480-0730
Email: nhlbchiefreviewbranch@nhbi.nih.gov

3.C. Application Processing

Applications must be **received on or before the application receipt date** described above ([Section IV.3.A.](#)). If an application is received after that date, the application may be delayed in the review process or not reviewed. Upon receipt, applications will be evaluated for completeness by the CSR and for responsiveness by the reviewing Institute. Incomplete and/or non-responsive applications will not be reviewed.

The NIH will not accept any application in response to this funding opportunity that is essentially the same as one currently pending initial review, unless the applicant withdraws the pending application. However, when a previously unfunded application, originally submitted as an investigator-initiated application, is to be submitted in response to a funding opportunity, it is to be prepared as a NEW application. That is, the application for the funding opportunity must not include an Introduction describing the changes and improvements made, and the text must not be marked to indicate the changes from the previous unfunded version of the application.

Information on the status of an application should be checked by the Principal Investigator in the eRA Commons at: <https://commons.era.nih.gov/commons/>.

4. Intergovernmental Review

This initiative is not subject to [intergovernmental review](#).

5. Funding Restrictions

All NIH awards are subject to the terms and conditions, cost principles, and other considerations described in the NIH Grants Policy Statement. The Grants Policy Statement can be found at [NIH Grants Policy Statement](#).

Pre-award costs are allowable. A grantee may, at its own risk and without NIH prior approval, incur obligations and expenditures to cover costs up to 90 days before the beginning date of the initial budget period of a new award if such costs: (1) are necessary to conduct the project, and (2) would be allowable under the grant, if awarded, without NIH prior approval. If specific expenditures would otherwise require prior approval, the grantee must obtain NIH approval before incurring the cost. NIH prior approval is required for any costs to be incurred more than 90 days before the beginning date of the initial budget period of a new award.

The incurrence of pre-award costs in anticipation of a competing or non-competing award imposes no obligation on NIH either to make the award or to increase the amount of the approved budget if an award is made for less than the amount anticipated and is inadequate to cover the pre-award costs incurred. NIH expects the grantee to be fully aware that pre-award costs result in borrowing against future support and that such borrowing must not impair the grantee's ability to accomplish the project objectives in the approved time frame or in any way adversely affect the conduct of the project (see NIH Grants Policy Statement http://grants.nih.gov/grants/policy/nihgps_2003/NIHGPS_Part6.htm.)

6. Other Submission Requirements

Qualifications and Experience. Applicants should describe qualifications and experience in the appropriate narrative sections of the application and in biosketches. Applicants for CADET I must have the necessary experience and expertise in both the relevant biology and target validation. Applicants should have an established research program and demonstrated leadership. An appropriate time commitment is expected from the principal investigators and any co-investigators. If the multiple PI option is used, a Leadership Plan must be included in the research plan section of the application (see below).

Collaboration. Applicants should state their general support of collaborative research and their willingness to participate in a collaborative and interactive manner with other CADET I awardees and the NHLBI in all aspects of CADET I. Applicants should indicate willingness to participate in sharing with other awardees and include resource plans for data and/or model organisms, as appropriate.

Applicants should indicate their willingness to attend all Steering Committee (SC) meetings in the greater Washington D.C. area, which may include conference calls up to two times a month and in-person meetings up to 2 times a year. Applicants must budget travel funds for the PI, at a minimum, to attend all SC meetings.

PHS398 Research Plan Component Sections

All application instructions outlined in the PHS 398 Application Guide are to be followed, with the following additional requirements:

- Introduction (required for a resubmission or revision application) is limited to 1 page.
- Specific Aims is limited to 1 page.
- Research Strategy, including tables, graphs, figures, diagrams, and charts is limited to 12 pages. See [Table of Page Limits](#).

Budget Component

This FOA uses non-modular budget formats described in the PHS 398 application instructions (see <http://grants.nih.gov/grants/funding/phs398/phs398.htm>).

Appendix Materials

All paper PHS 398 applications submitted **must** provide appendix material on CDs only. Include five identical CDs in the same package with the application. See <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-08-031.html>.

Do not use the Appendix to circumvent the page limitations. An application that does not observe the required page limitations may be delayed in the review process or not reviewed.

Resource Sharing Plan(s)

NIH considers the sharing of unique research resources developed through NIH-sponsored research an important means to enhance the value of, and advance research. When resources have been developed with NIH funds and the associated research findings published or provided to NIH, it is important that they be made readily available for research purposes to qualified individuals within the scientific community. If the final data/resources are not amenable to sharing, this must be explained in Resource Sharing section of the application. See http://grants.nih.gov/grants/policy/data_sharing/data_sharing_faqs.htm.

(a) *Data Sharing Plan*: Regardless of the amount requested, investigators are expected to include a brief 1-paragraph description of how final research data will be shared, or explain why data-sharing is not possible. Applicants are encouraged to discuss data-sharing plans with their NIH program contact. See [Data-Sharing Policy](#) or <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-032.html>.

(b) *Sharing Model Organisms*: Regardless of the amount requested, all applications where the development of model organisms is anticipated are expected to include a description of a specific plan for sharing and distributing unique model organisms and related resources, or state appropriate reasons why such sharing is restricted or not possible. See [Sharing Model Organisms Policy](#), and [NIH Guide NOT-OD-04-042](#).

(c) *Genome-Wide Association Studies (GWAS)*: Regardless of the amount requested, applicants seeking funding for a genome-wide association study are expected to provide a plan for submission of GWAS data to the NIH-designated GWAS data repository, or provide an appropriate explanation why submission to the repository is not possible. A genome-wide association study is defined as any study of genetic variation across the entire genome that is designed to identify genetic associations with observable traits (such as blood pressure or weight) or the presence or absence of a disease or condition. For further information see Policy for Sharing of Data Obtained in NIH Supported or Conducted Genome-Wide Association Studies, [NIH Guide NOT-OD-07-088](#), and <http://grants.nih.gov/grants/gwas/>.

All applicants are expected to describe their plan to share data and tools generated, as appropriate, through the support of this FOA with the broad scientific community.

Section V. Application Review Information

1. Criteria

Only the review criteria described below will be considered in the review process.

2. Review and Selection Process

Review Process

Applications that are complete and responsive to the FOA will be evaluated for scientific and technical merit by an appropriate peer review group convened by NHLBI and in accordance with NIH peer review procedures (<http://grants1.nih.gov/grants/peer/>), using the review criteria

stated below.

As part of the scientific peer review, all applications will:

- Undergo a selection process in which only those applications deemed to have the highest scientific and technical merit, generally the top half of applications under review, will be discussed and assigned an impact/priority score.
- Receive a written critique.
- Receive a second level of review by National Heart, Lung, and Blood Advisory Council.

The mission of the NIH is to support science in pursuit of knowledge about the biology and behavior of living systems and to apply that knowledge to extend healthy life and reduce the burdens of illness and disability. As part of this mission, applications submitted to the NIH for grants or cooperative agreements to support biomedical and behavioral research are evaluated for scientific and technical merit through the NIH peer review system.

Overall Impact

Reviewers will provide an overall impact/priority score to reflect their assessment of the likelihood for the project to exert a sustained, powerful influence on the research field(s) involved, in consideration of the following five scored review criteria, and additional review criteria (as applicable for the project proposed).

Scored Review Criteria

Reviewers will consider each of the five review criteria below in the determination of scientific and technical merit, and give a separate score for each. An application does not need to be strong in all categories to be judged likely to have major scientific impact. For example, a project that by its nature is not innovative may be essential to advance a field.

Significance. Does the project address an important problem or a critical barrier to progress in the field? If the aims of the project are achieved, how will scientific knowledge, technical capability, and/or clinical practice be improved? How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?

Investigator(s). Are the PD/PIs, collaborators, and other researchers well suited to the project? If Early Stage Investigators or New Investigators, or in the early stages of independent careers, do they have appropriate experience and training? If established, have they

demonstrated an ongoing record of accomplishments that have advanced their field(s)? If the project is collaborative or multi-PD/PI, do the investigators have complementary and integrated expertise; are their leadership approach, governance and organizational structure appropriate for the project? Do the PD/PIs have a prior record of successful collaboration?

Innovation. Does the application challenge and seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions? Are the concepts, approaches or methodologies, instrumentation, or interventions novel to one field of research or novel in a broad sense? Is a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions proposed?

Approach. Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project? Are potential problems, alternative strategies, and benchmarks for success presented? If the project is in the early stages of development, will the strategy establish feasibility and will particularly risky aspects be managed?

If the project involves clinical research, are the plans for (1) protection of human subjects from research risks, and (2) inclusion of minorities and members of both sexes/genders, as well as the inclusion of children, justified in terms of the scientific goals and research strategy proposed? What is the likely feasibility of the proposed therapeutic and/or diagnostic approach? What are the merits and the feasibility of the expected evolution of the project, including specific, appropriate milestones and timelines?

Environment. Will the scientific environment in which the work will be done contribute to the probability of success? Are the institutional support, equipment and other physical resources available to the investigators adequate for the project proposed? Will the project benefit from unique features of the scientific environment, subject populations, or collaborative arrangements?

Additional Review Criteria

As applicable for the project proposed, reviewers will consider **the following additional items in the determination of scientific and technical merit, but will not give separate scores for these items.**

Protections for Human Subjects. For research that involves human subjects but does not involve one of the six categories of research that are exempt under 45 CFR Part 46, the committee will evaluate the justification for involvement of human subjects and the proposed

protections from research risk relating to their participation according to the following five review criteria: (1) risk to subjects, (2) adequacy of protection against risks, (3) potential benefits to the subjects and others, (4) importance of the knowledge to be gained, and (5) data and safety monitoring for clinical trials.

For research that involves human subjects and meets the criteria for one or more of the six categories of research that are exempt under 45 CFR Part 46, the committee will evaluate: (1) the justification for the exemption, (2) human subjects involvement and characteristics, and (3) sources of materials.

Inclusion of Women, Minorities, and Children. When the proposed project involves clinical research, the committee will evaluate the proposed plans for inclusion of minorities and members of both genders, as well as the inclusion of children.

Vertebrate Animals. The committee will evaluate the involvement of live vertebrate animals as part of the scientific assessment according to the following five points: (1) proposed use of the animals, and species, strains, ages, sex, and numbers to be used; (2) justifications for the use of animals and for the appropriateness of the species and numbers proposed; (3) adequacy of veterinary care; (4) procedures for limiting discomfort, distress, pain and injury to that which is unavoidable in the conduct of scientifically sound research including the use of analgesic, anesthetic, and tranquilizing drugs and/or comfortable restraining devices; and (5) methods of euthanasia and reason for selection if not consistent with the AVMA Guidelines on Euthanasia. For additional information, see <http://grants.nih.gov/grants/olaw/VASchecklist.pdf>.

Biohazards. Reviewers will assess whether materials or procedures proposed are potentially hazardous to research personnel and/or the environment, and if needed, determine whether adequate protection is proposed.

Resubmission Applications Resubmission applications are not permitted in response to FOA.

Renewal Applications. Renewal applications are not permitted in response to this FOA.

Revision Applications. Not applicable to this FOA.

Additional Review Considerations

As applicable for the project proposed, reviewers will address each of the following items, but will not give scores for these items and should not consider them in providing an overall

impact/priority score.

Applications from Foreign Organizations. Not applicable to this FOA.

Select Agents Research. Reviewers will assess the information provided in this section of the application, including (1) the Select Agent(s) to be used in the proposed research, (2) the registration status of all entities where Select Agent(s) will be used, (3) the procedures that will be used to monitor possession use and transfer of Select Agent(s), and (4) plans for appropriate biosafety, biocontainment, and security of the Select Agent(s).

Resource Sharing Plans. Reviewers will comment on whether the following Resource Sharing Plans, or the rationale for not sharing the following types of resources, are reasonable: (1) Data Sharing Plan (http://grants.nih.gov/grants/policy/data_sharing/data_sharing_guidance.htm); (2) Sharing Model Organisms (<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-04-042.html>); and (3) Genome Wide Association Studies (GWAS) (<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-07-088.html>).

Budget and Period Support. Reviewers will consider whether the budget and the requested period of support are fully justified and reasonable in relation to the proposed research.

Selection Process

The following will be considered in making funding decisions:

- Scientific and technical merit of the proposed project as determined by peer review.
- Availability of funds.
- Relevance of the proposed project to program priorities.
- Maintenance of programmatic balance within CADET I. The majority focus of CADET I will not be on the sole validation of new diagnostics.

NIH considers the following in evaluating Center grant applications:

- The scientific and technical merit of the proposed program.
- The qualifications and experience of the center director and other key personnel.
- The statutory and program purposes to be accomplished.
- The extent to which the various components of the proposed program would be coordinated into one multi-disciplinary effort within the center.
- The extent to which the center's activities would be coordinated with similar efforts by

- other organizations.
- The administrative and managerial capability of the applicant.
- Other factors which the awarding IC considers appropriate in light of its particular statutory mission.

3. Anticipated Announcement and Award Dates

Not Applicable

Section VI. Award Administration Information

1. Award Notices

After the peer review of the application is completed, the PD/PI will be able to access his or her Summary Statement (written critique) via the [eRA Commons](#).

If the application is under consideration for funding, NIH will request "just-in-time" information from the applicant. For details, applicants may refer to the [NIH Grants Policy Statement Part II: Terms and Conditions of NIH Grant Awards, Subpart A: General](#).

A formal notification in the form of a Notice of Award (NoA) will be provided to the applicant organization. The NoA signed by the grants management officer is the authorizing document. Once all administrative and programmatic issues have been resolved, the Notice of Award will be generated via email notification from the awarding component to the grantee business official.

Selection of an application for award is not an authorization to begin performance. Any costs incurred before receipt of the NoA are at the recipient's risk. These costs may be reimbursed only to the extent considered allowable pre-award costs. See Also [Section IV.5. Funding Restrictions](#).

2. Administrative and National Policy Requirements

All NIH grant and cooperative agreement awards include the NIH Grants Policy Statement as part of the Notice of Award. For these terms of award, see the NIH Grants Policy Statement Part II: Terms and Conditions of NIH Grant Awards, Subpart A: General (http://grants.nih.gov/grants/policy/nihgps_2003/NIHGPS_Part4.htm) and Part II Terms and Conditions of NIH Grant Awards, Subpart B: Terms and Conditions for Specific Types of

Grants, Grantees, and Activities

(http://grants.nih.gov/grants/policy/nihgps_2003/NIHGPS_part9.htm).

3. Reporting

Awardees will be required to submit the [Non-Competing Continuation Grant Progress Report \(PHS 2590\)](#) annually and financial statements as required in the [NIH Grants Policy Statement](#).

A final progress report, invention statement, and Financial Status Report are required when an award is relinquished when a recipient changes institutions or when an award is terminated.

Section VII. Agency Contacts

We encourage your inquiries concerning this funding opportunity and welcome the opportunity to answer questions from potential applicants. Inquiries may fall into three areas: scientific/research, peer review, and financial or grants management issues:

1. Scientific/Research Contacts:

Gail Weinmann, M.D.
Division of Lung Diseases
National Heart, Lung and Blood Institute
Two Rockledge Center, Suite 10164
6701 Rockledge Dr. MSC 7952
Bethesda, Maryland 20892-7952
Telephone: (301) 435-0233
FAX: (301) 480-5577
Email: weinmang@nhlbi.nih.gov

Patricia Noel, Ph.D.
Division of Lung Diseases
National Heart, Lung and Blood Institute
Two Rockledge Center, Suite 10164
6701 Rockledge Dr. MSC 7952
Bethesda, Maryland 20892-7952
Telephone: (301) 435-0202
FAX: (301) 480-3557
Email: noelp@nhlbi.nih.gov

2. Peer Review Contacts:

Director, Office of Scientific Review
Division of Extramural Research Activities
National Heart, Lung, and Blood Institute
6701 Rockledge Drive
Room 7214, MSC7924
Bethesda, MD 20892-7924 (Express mail zip: 20817)
Telephone: (301) 435-0270
FAX: 301-480-0730
Email: nhlbchiefreviewbranch@nhlbi.nih.gov

3. Financial or Grants Management Contacts:

John Diggs
Office of Grants Management
Division of Extramural Research Activities
National Heart, Lung, and Blood Institute
6701 Rockledge Drive
Room 7128, MSC 7926
Bethesda, MD 20816-7926
Telephone: 301-435-0166
FAX: 301-451-5462
Email: diggsjw@nhlbi.nih.gov

Section VIII. Other Information

Required Federal Citations

Use of Animals in Research:

Recipients of PHS support for activities involving live, vertebrate animals must comply with PHS Policy on Humane Care and Use of Laboratory Animals (<http://grants.nih.gov/grants/olaw/references/PHSPolicyLabAnimals.pdf>) as mandated by the Health Research Extension Act of 1985 (<http://grants.nih.gov/grants/olaw/references/hrea1985.htm>), and the USDA Animal Welfare Regulations (<http://www.nal.usda.gov/awic/legislat/usdaleg1.htm>) as applicable.

Human Subjects Protection:

Federal regulations (45CFR46) require that applications and proposals involving human subjects must be evaluated with reference to the risks to the subjects, the adequacy of protection against these risks, the potential benefits of the research to the subjects and others, and the importance of the knowledge gained or to be gained (<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm>).

Data and Safety Monitoring Plan:

Data and safety monitoring is required for all types of clinical trials, including physiologic toxicity and dose-finding studies (Phase I); efficacy studies (Phase II); efficacy, effectiveness and comparative trials (Phase III). Monitoring should be commensurate with risk. The establishment of data and safety monitoring boards (DSMBs) is required for multi-site clinical trials involving interventions that entail potential risks to the participants (NIH Policy for Data and Safety Monitoring, NIH Guide for Grants and Contracts, <http://grants.nih.gov/grants/guide/notice-files/not98-084.html>).

Sharing Research Data:

Investigators submitting an NIH application seeking \$500,000 or more in direct costs in any single year are expected to include a plan for data sharing or state why this is not possible (http://grants.nih.gov/grants/policy/data_sharing).

Investigators should seek guidance from their institutions, on issues related to institutional policies and local IRB rules, as well as local, state and federal laws and regulations, including the Privacy Rule.

Policy for Genome-Wide Association Studies (GWAS):

NIH is interested in advancing genome-wide association studies (GWAS) to identify common genetic factors that influence health and disease through a centralized GWAS data repository. For the purposes of this policy, a genome-wide association study is defined as any study of genetic variation across the entire human genome that is designed to identify genetic associations with observable traits (such as blood pressure or weight), or the presence or absence of a disease or condition. All applications, regardless of the amount requested, proposing a genome-wide association study are expected to provide a plan for submission of GWAS data to the NIH-designated GWAS data repository, or provide an appropriate explanation why submission to the repository is not possible. Data repository management (submission and access) is governed by the Policy for Sharing of Data Obtained in NIH Supported or Conducted Genome-Wide Association Studies, [NIH Guide NOT-OD-07-088](http://grants.nih.gov/grants/gwas/). For additional information, see <http://grants.nih.gov/grants/gwas/>.

Access to Research Data through the Freedom of Information Act:

The Office of Management and Budget (OMB) Circular A-110 has been revised to provide access to research data through the Freedom of Information Act (FOIA) under some circumstances. Data that are (1) first produced in a project that is supported in whole or in part with Federal funds and (2) cited publicly and officially by a Federal agency in support of an action that has the force and effect of law (i.e., a regulation) may be accessed through FOIA. It is important for applicants to understand the basic scope of this amendment. NIH has provided guidance at http://grants.nih.gov/grants/policy/a110/a110_guidance_dec1999.htm. Applicants may wish to place data collected under this funding opportunity in a public archive, which can provide protections for the data and manage the distribution for an indefinite period of time. If so, the application should include a description of the archiving plan in the study design and include information about this in the budget justification section of the application. In addition, applicants should think about how to structure informed consent statements and other human subjects procedures given the potential for wider use of data collected under this award.

Sharing of Model Organisms:

NIH is committed to support efforts that encourage sharing of important research resources including the sharing of model organisms for biomedical research (see http://grants.nih.gov/grants/policy/model_organism/index.htm). At the same time the NIH recognizes the rights of grantees and contractors to elect and retain title to subject inventions developed with Federal funding pursuant to the Bayh Dole Act (see the NIH Grants Policy Statement http://grants.nih.gov/grants/policy/nihgps_2003/index.htm). All investigators submitting an NIH application or contract proposal, beginning with the October 1, 2004, receipt date, are expected to include in the application/proposal a description of a specific plan for sharing and distributing unique model organism research resources generated using NIH funding or state why such sharing is restricted or not possible. This will permit other researchers to benefit from the resources developed with public funding. The inclusion of a model organism sharing plan is not subject to a cost threshold in any year and is expected to be included in all applications where the development of model organisms is anticipated.

Inclusion of Women And Minorities in Clinical Research:

It is the policy of the NIH that women and members of minority groups and their sub-populations must be included in all NIH-supported clinical research projects unless a clear and compelling justification is provided indicating that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. This policy results from the NIH Revitalization Act of 1993 (Section 492B of Public Law 103-43). All investigators proposing clinical research should read the "NIH Guidelines for Inclusion of Women and Minorities as Subjects in Clinical Research" (<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-001.html>); a complete copy of the updated Guidelines is available at http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm. The amended policy incorporates: the use of an NIH definition of clinical research; updated racial

and ethnic categories in compliance with the new OMB standards; clarification of language governing NIH-defined Phase III clinical trials consistent with the new PHS Form 398; and updated roles and responsibilities of NIH staff and the extramural community. The policy continues to require for all NIH-defined Phase III clinical trials that: (a) all applications or proposals and/or protocols must provide a description of plans to conduct analyses, as appropriate, to address differences by sex/gender and/or racial/ethnic groups, including subgroups if applicable; and (b) investigators must report annual accrual and progress in conducting analyses, as appropriate, by sex/gender and/or racial/ethnic group differences.

Inclusion of Children as Participants in Clinical Research:

The NIH maintains a policy that children (i.e., individuals under the age of 21) must be included in all clinical research, conducted or supported by the NIH, unless there are scientific and ethical reasons not to include them.

All investigators proposing research involving human subjects should read the "NIH Policy and Guidelines" on the inclusion of children as participants in research involving human subjects (<http://grants.nih.gov/grants/funding/children/children.htm>).

Required Education on the Protection of Human Subject Participants:

NIH policy requires education on the protection of human subject participants for all investigators submitting NIH applications for research involving human subjects and individuals designated as key personnel. The policy is available at <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html>.

Human Embryonic Stem Cells (hESC):

Criteria for federal funding of research on hESCs can be found at <http://stemcells.nih.gov/index.asp> and at <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-09-116.html>. Only research using hESC lines that are registered in the NIH Human Embryonic Stem Cell Registry will be eligible for Federal funding (<http://escr.nih.gov>). It is the responsibility of the applicant to provide in the project description and elsewhere in the application as appropriate, the official NIH identifier(s) for the hESC line(s) to be used in the proposed research.

NIH Public Access Policy Requirement:

In accordance with the NIH Public Access Policy (<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-08-033.html>) investigators must submit or have submitted for them their final, peer-reviewed manuscripts that arise from NIH funds and are accepted for publication as of April 7, 2008 to PubMed Central (<http://www.pubmedcentral.nih.gov>), to be made publicly available no later than 12 months after publication. As of May 27, 2008, investigators must include the PubMed Central reference number when citing an article in NIH applications,

proposals, and progress reports that fall under the policy, and was authored or co-authored by the investigator or arose from the investigator's NIH award. For more information, see the Public Access webpage at <http://publicaccess.nih.gov/>.

Standards for Privacy of Individually Identifiable Health Information:

The Department of Health and Human Services (DHHS) issued final modification to the "Standards for Privacy of Individually Identifiable Health Information," the "Privacy Rule," on August 14, 2002. The Privacy Rule is a federal regulation under the Health Insurance Portability and Accountability Act (HIPAA) of 1996 that governs the protection of individually identifiable health information, and is administered and enforced by the DHHS Office for Civil Rights (OCR).

Decisions about applicability and implementation of the Privacy Rule reside with the researcher and his/her institution. The OCR website (<http://www.hhs.gov/ocr/>) provides information on the Privacy Rule, including a complete Regulation Text and a set of decision tools on "Am I a covered entity?" Information on the impact of the HIPAA Privacy Rule on NIH processes involving the review, funding, and progress monitoring of grants, cooperative agreements, and research contracts can be found at <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-025.html>.

URLs in NIH Grant Applications or Appendices:

All applications and proposals for NIH funding must be self-contained within specified page limitations. For publications listed in the appendix and/or Progress report, internet addresses (URLs) **must** be used for **publicly** accessible online journal articles. Unless otherwise specified in **this** solicitation, Internet addresses (URLs) should **not** be used to provide any **other** information necessary for the review because reviewers are under no obligation to view the Internet sites. Furthermore, we caution reviewers that their anonymity may be compromised when they directly access an Internet site.

Healthy People 2010:

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2010," a PHS-led national activity for setting priority areas. This FOA is related to one or more of the priority areas. Potential applicants may obtain a copy of "Healthy People 2010" at <http://www.health.gov/healthypeople>.

Authority and Regulations:

This program is described in the Catalog of Federal Domestic Assistance at <http://www.cfda.gov/> and is not subject to the intergovernmental review requirements of Executive Order 12372. Awards are made under the authorization of Sections 301 and 405 of the Public Health Service Act as amended (42 USC 241 and 284) and under Federal

Regulations 42 CFR 52 and 45 CFR Parts 74 and 92. All awards are subject to the terms and conditions, cost principles, and other considerations described in the NIH Grants Policy Statement. The NIH Grants Policy Statement can be found at <http://grants.nih.gov/grants/policy/policy.htm>.

The PHS strongly encourages all grant recipients to provide a smoke-free workplace and discourage the use of all tobacco products. In addition, Public Law 103-227, the Pro-Children Act of 1994, prohibits smoking in certain facilities (or in some cases, any portion of a facility) in which regular or routine education, library, day care, health care, or early childhood development services are provided to children. This is consistent with the PHS mission to protect and advance the physical and mental health of the American people.

Loan Repayment Programs:

NIH encourages applications for educational loan repayment from qualified health professionals who have made a commitment to pursue a research career involving clinical, pediatric, contraception, infertility, and health disparities related areas. The LRP is an important component of NIH's efforts to recruit and retain the next generation of researchers by providing the means for developing a research career unfettered by the burden of student loan debt. Note that an NIH grant is not required for eligibility and concurrent career award and LRP applications are encouraged. The periods of career award and LRP award may overlap providing the LRP recipient with the required commitment of time and effort, as LRP awardees must commit at least 50% of their time (at least 20 hours per week based on a 40-hour week) for two years to the research. For further information, please see: <http://www.lrp.nih.gov>.

[Weekly TOC for this Announcement](#)
[NIH Funding Opportunities and Notices](#)



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