Regional Translational Research Center Planning Grants

RFA Number: RFA-RM-05-008

Part I. Overview Information

Department of Health and Human Services

Participating Organizations:
National Institutes of Health (NIH), (http://www.nih.gov)

This RFA is developed as an NIH Roadmap Initiative. All Institutes and Centers participate in Roadmap Initiatives. The RFA will be administered by NCCAM on behalf of the NIH.

Announcement Type:
New

Catalog of Federal Domestic Assistance Number(s): 93.389

Key Dates
Release Date: October 1, 2004
Letters Of Intent Receipt Date(s): December 1, 2004
Application Receipt Dates(s): January 19, 2005
Peer Review Date(s): March 2005
Council Review Date(s) : May 2005
Earliest Anticipated Start Date: May 2005
Additional Information To Be Available Date (URL Activation Date): Not applicable
Expiration Date: January 20, 2005

Executive Summary

- **Purpose:** This RFA invites applications for planning grants submitted by self-assembled groups of institutions to conceptualize and design Regional Translational Research Centers (RTRCs) to foster more efficient and robust translational research. Once operational, RTRCs will provide a broad menu of clinical research expertise, services, and core technologies to multiple institutions within a region. The goal: to enhance the bi-directional—bench to bedside and bedside to bench—communication that characterizes translational research. Planning grants to organize the content, administration, and governance of three center models may be submitted: (1) a regional center (RTRC) to provide clinical research services that may include data/statistical/bioinformatics support, assistance with regulatory issues and communication with IRBs, recruitment cores, pilot project support, and specialized staff as appropriate ; (2) a core technology center (C-RTRC) to offer *only* core technologies on a regional or national scale to aid the study of disease pathogenesis or early-phase clinical interventional studies; and (3) an expanded center (E-RTRC), a hybrid of the first two models, to provide regional clinical research services *plus* core technologies on a regional or national scale. Future RFAs will request applications for the actual RTRCs.
- **Funds available** : The NIH Roadmap is providing $3 million for this initiative.
- **Size and duration of awards:** Individual planning grant awards may be up to $150,000 in total costs for 1 year.
- **Number of individual awards:** Subject to the number of meritorious applications it receives, NIH anticipates awarding planning grants as follows:10-15 RTRCs, 2-4 C-RTRCs, and 3-6 E-RTRCs; a minimum of 20 grants will be awarded.
- **Mechanism of support:** The P20 (Exploratory Center) mechanism will be used.
- **Eligible organizations:** Eligible to apply are for-profit or non-profit institutions; public or private institutions, such as universities, colleges, hospitals, and laboratories; units of State and local governments; eligible agencies of the Federal government; domestic institutions/organizations; and faith-based or community-based organizations. Foreign institutions are not eligible to apply.
- **Eligible principal investigators:** Individuals with the skills, knowledge, and resources necessary to plan, organize, and administer an RTRC, C-RTRC, or E-RTRC are eligible principal investigators. An individual may be a principal investigator on *only one* planning grant application.

- **Number of applications each applicant may submit:** An institution may be party to multiple applications for any of the three center types, although it may be the applicant institution on *only one* application. Again, note that an individual may be listed as the principal investigator on *only one* application.
- **Application materials are available from:** Application materials will be posted at http://grants.nih.gov/grants/funding/phs398/phs398.html. For background information, please visit http://nccam.nih.gov/rtrc.
- Telecommunications for the hearing impaired: TTY 301-451-0088

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Part II. Full Text of Announcement

Section I. Funding Opportunity Description

1. Research Objectives

PURPOSE OF THIS RFA

As *Phase One* in a two-phase process, this RFA invites applications for planning grants to form self-assembled groups of institutions to conceptualize and design Regional Translational Research Centers (RTRCs). The goal of *Phase Two* is to create infrastructure that will enhance investigators' ability to perform cost-effective and robust translational research. Once operational, RTRCs will provide regional or national clinical research services and expertise and, depending on the model proposed, a state-of-the-art core technology.

A planning grant application may propose one of three models (described more fully in the BACKGROUND section, below):

- A regional center that provides clinical research services (RTRC).
- A center that offers *only* core technologies on a regional or national scale (C-RTRC).
- An expanded center that provides regional clinical research services *plus* core technologies on a regional or national scale (E-RTRC)

Recognizing that no single model will meet all research needs, this RFA encourages applicants to be innovative in proposing new ways of providing these resources on a regional or, as appropriate, national scale. It welcomes applications from collaborating institutions that seek to develop a robust planning process to conceptualize the content, administration, and governance of the proposed RTRC model.

The application should describe a planning process to address current gaps in and roadblocks to translational research in the applicant's region. The expertise, resources, services, and technologies that could overcome those challenges should be identified, together with agreements to integrate new resources with existing ones and a method to ensure that resources would be effectively and equitably distributed across a proposed region.

In *Phase Two* of this process, NIH will disseminate a new RFA for applications to launch actual RTRCs, C-RTRCs, and E-RTRCs. That RFA, not yet developed, will be released in 2006. NIH intends to commit approximately $27 million in FY 2006 to support 8-10 RTRCs of various models. You do not need to have applied for or have received a planning grant to be eligible for this second phase.

Interested parties seeking clarification on this RFA are invited to submit queries to nihrtrccomments@mail.nih.gov and to participate in a live videoconference at which a panel will answer questions from the attendees. All prospective applicants are invited. Applicants should submit written questions prior to the meeting by e-mail to the Agency Contacts listed below.

The meeting is scheduled for November 10, 1:00-2:30 EST in Suite 401, 6707 Democracy Blvd., Bethesda, Maryland. Those who wish to participate using videoconference or teleconference facilities may contact the videodesk, (telephone 301-594-8433 or e-mail: videodesk@list.nih.gov). Contact should be made by November 2, 2004, to assure appropriate link-up. Those unable to join the live event can view a video recording at http://nccam.nih.gov/rtrc.

BACKGROUND

Consultants to several NIH Roadmap working groups have observed that a lack of comprehensive resources is impeding collaboration between laboratory and clinical investigators. Although certain investigator communities, such as the NIH Clinical Center or the extramural communities supported by cancer centers or industry, can access a menu of research resources, such resources must be more widely available to the broader research community to facilitate translational research.

For purposes of this RFA and planning efforts leading to its development, translational research is defined as studies at the interface of the bench and bedside. Information flow at this interface is bi-directional, requiring close interaction between clinical and bench scientists. In translational research, clinical and bench scientists advance the diagnosis of diseases and use their knowledge of natural history and pathogenesis to investigate the effects of novel interventions in early-phase clinical studies (I-

IIA). Complementing these clinical studies are laboratory investigations of clinical specimens that contribute to a fuller understanding of the diseases, their etiology, pathophysiology, pathogenesis, diagnosis, and treatment.

To evaluate resource needs, Roadmap planners established the RTRC Working Group, whose members represent 12 NIH Institutes and Centers (ICs). Beginning in January 2004, the RTRC Working Group consulted with relevant stakeholders representing academic health centers, industry, and the not-for-profit sector.

Discussions among Working Group members and interviews with investigators at multiple academic health centers revealed that substantive resources for translational research are already being provided by NIH ICs through individual grants; training and career awards; and mission-specific centers. Examples of the latter include the Diabetes Research and Training Centers (National Institute of Diabetes and Digestive and Kidney Diseases), the Conte Centers (National Institute of Mental Health), the Collaborative Network for Clinical Research on Immune Tolerance (National Institute of Allergy and Infectious Diseases), the Alzheimer's Disease Centers (National Institute on Aging), and the Cancer Centers (National Cancer Institute).

In addition, the National Center for Research Resources funds 80 General Clinical Research Centers (GCRCs) at a total cost approaching $300 million a year. Each GCRC serves investigator needs within its own institution, providing inpatient and outpatient beds, research coordinators, statistical consultations, training, regulatory oversight of protocols, and core laboratory support, such as biochemistry and immunoassays. Through consultation with academic investigators, however, the RTRC Working Group learned that investigators' needs outpace the resources of GCRCs at their institutions. Collaborations that could build on clinical research resources currently funded by NIH were seen as a cost-effective stimulus to translational research that would expand the patient base for individual studies and create economies of scale.

To foster such collaboration, the RTRC Working Group agreed that this effort should proceed in two phases. *Phase One* would be solicitation of planning grant applications to provide institutions with support to collaboratively develop comprehensive plans for an RTRC. *Phase Two* would be a subsequent solicitation for applications to develop the RTRCs themselves.

The RTRC Working Group's effort culminated with a 90-person RTRC Planning Meeting in July 2004 to address topics considered of greatest significance in establishing RTRCs. Experts internal and external to NIH echoed previously heard stakeholder views and identified potential benefits that could come from extramural collaborations with the NIH Clinical Center (for meeting outcomes, see http://nccam.nih.gov/rtrc/). They concurred that the needs of investigators exceed current resources—a consensus that provides the framework for this RFA. To meet these needs, participants envisioned three possible models to facilitate robust translational research:

- *RTRCs* —Regional centers that offer clinical research services, including data/statistical/bioinformatics support, assistance with regulatory issues and communication with IRBs, recruitment cores, pilot project support, and specialized staff as appropriate.
- *C-RTRCs*— Centers that provide only research cores to provide robust core laboratory technologies that could be applied to specimens on a regional or national scale (e.g., an animal toxicology, primate, or bioimaging center). Support for good laboratory and clinical practices could also be proposed.
- *E-RTRCs* —Regional/national centers that combine the resources of an RTRC and C-RTRC.

PLANNING GRANT OUTCOMES: KNOWLEDGE GAINED

Planning for a center should engender thoughtful assessment of available resources, unmet needs, and innovative solutions built on logic and financial practicality. As applicants move through this process, they can expect to increase their knowledge of critical roles that RTRCs could play.

RTRCs and E-RTRCs: Possible Services

Applicants could propose planning for an RTRC or E-RTRC that draws from the following broad menu of services to support multiple institutions within a region.

• *Support for new pilot research projects employing the resources of the collaborating institutions that feature bench and clinical scientists as co-principal investigators. Such projects would be analogous to the NIH Bench-to-Bedside Awards Program, details of which are available at http://www.cc.nih.gov/researchers/resources/btb.shtml.*

New resources are generally required to determine whether the clinical potential of a promising laboratory finding can be realized. Such funds must be available promptly and be accompanied by an organizational structure that allows full compliance with regulatory requirements. Central review of translational research projects through NIH is likely to be too slow to match investigators' needs, while experience with a pilot project program at GCRCs has shown that institutional committees can provide the necessary critical levels of review. The consortium of investigators on which the RTRCs will draw will be large and diverse enough to review pilot projects speedily and with the requisite depth of expertise.

- *Development of mechanisms for interactions with the NIH Clinical Research Center.*

The NIH Clinical Center (http://www.cc.nih.gov/index.cgi) offers opportunities and infrastructure support for clinical research that can be very difficult to duplicate in academic medical centers. This includes advanced imaging facilities, research protocol design tools, translational research training programs, and unique opportunities for bench-to-bedside interactions in the intensive study of the natural history and targeted therapy of human disease. Applicants may wish to consider innovative ways that the envisioned RTRC could interact with the Clinical Center. Such collaborative projects should be enacted at the most senior leadership levels, involving, for example, coordination between the Dean of Research and the Clinical Center Director.

- *Support for core services to assist with patient recruitment.*

Subject recruitment is time-consuming, costly, and requires special expertise. Core services to facilitate patient recruitment include access to expertise in outreach activities, assistance in development of recruitment material, and access to specialized recruiters with particular ethnic, cultural, and language characteristics important for minority recruitment.

- *Assistance with implementation of the FDA Good Clinical Practice Regulations and the ICH Good Clinical Practice Consolidated Guideline in the development of human study protocols, their consent forms, and requisite Investigational New Drug (IND) applications.*

Because investigators consistently voice their need for help in meeting regulatory requirements, each RTRC should offer assistance in all aspects of regulatory compliance. Assistance could include creating and maintaining an office with staff to prepare and submit documents to regulatory agencies on behalf of the investigatory team.

- *Provision of expertise in study design and biostatistical analysis.*

Critical in the effective implementation of translational research is optimum study design and analysis. Investigator groups require early consultation with statisticians able to provide advice on all aspects of the investigative approach and the analytic plan. The biostatistical support available through GCRCs, for example, is designed primarily to support protocol development but does not in general support the flexibility and speed of response that an RTRC will require.

- *Support of data accrual, database management, and data warehousing, as well as provision of clinical informatics platforms and services, including protocol tracking and development of case report forms.*

Translational researchers will need access to good informatics practices, including full electronic support for online protocol authoring, review, and approval followed by data tracking, warehousing, and auditing. Standard informatics technology—databases, XML and DHHS-supported ontology, and clinical information communication standards increasingly used throughout industry and government—should be fully utilized.

- *Mechanisms to facilitate coordinated IRB review or establish a central IRB for protocols conducted by multiple institutions served by an RTRC.*

Planning grant applicants are invited to develop a process to optimize patient protection utilizing, for example, the integration or centralization of IRB functions. Numerous examples exist of “common” IRBs that serve multiple institutions, ranging from the large commercial Western IRB to smaller cooperatives at academic institutions and the NCI pilot project. Investigators could be materially assisted if the institutions that were part of an RTRC were able to create and operate a shared “common” IRB for translational research.

- *Support for translational research fellows who cross disciplinary and institutional lines.*

Patient-oriented researchers capable of substantively participating in multidisciplinary teams are needed. Training across institutional lines would be desirable.

C-RTRCs and E-RTRCs: Possible Laboratory Services

Applicants also could plan for C-RTRCs and E-RTRCs that offer core laboratory technologies not easily, efficiently, or widely available and that could be applied to specimens sent by other institutions in the United States. These technologies are needed for state-of-the-art studies of disease pathogenesis and early-phase clinical interventions. Below are examples of such technologies.

- *Real-time PCR.* Quantitative endpoints extend the usefulness of PCR but are best performed under rigorously controlled conditions in a core lab.

- *Informatics and expert statistical support to adequately interpret the genetic and microarray results.*

- *Pharmacokinetic and pharmacological services, including specialized animal/primate cores and LC-MS.*

- *Bioimaging and advanced molecular imaging support, including computerized image analysis and synthesis of MRI PET probes.*

For additional examples of core services, please review the Core Services Breakout Session PowerPoint Report at http://nccam.nih.gov/rtrc.

PLANNING GRANT OBJECTIVES

Planning grant applications should identify a region—the communities of investigators to be served—and describe a robust planning process to develop the content, administration, and governance of an RTRC. This might include, for example, a process to identify (1) current gaps in and roadblocks to translational research within a geographic region; (2) needed expertise, resources, services, and technologies to overcome these gaps and obstacles; (3) a method of integrating new and existing resources; and (4) a strategy for administering and governing a center to ensure effective, equitable distribution of resources among collaborating institutions. In addition, applications should justify why the proposed planning approach will be effective and propose a timeline for achieving all planning steps.

The envisioned RTRC, C-RTRC, or E-RTRC must serve investigators at more than one institution. Although the definition of a "region" will be left to applicants, comprehensive and inclusive formulations will be favored. Centers, however, must be broad and encompass the research interests of multiple NIH ICs. For example, applications that merely duplicate efforts now underway or sponsored by NIH ICs will not be accepted. In regions where some of the proposed services are now available, applications must describe how planned RTRC or E-RTRC activities will be integrated with these services.

Applications in response to this RFA should broadly discuss the planning process for developing an RTRC that incorporates many of the elements described below:

1. Translational Focus. Note a b road translational research focus, as documented by the structure and objectives of the proposed center, research support, and the publications of center members.

2. Region Served. Identify institutions being served. The application might describe a plan for judicious and justifiable selection of center members. The application should include a letter from a high-level administrator (for example, the Dean of Research or the NIH Clinical Center Director) at each collaborating site to indicate the institution's agreement to be involved in the proposed RTRC.

3. Resources and Services. Describe or propose a needs analysis; propose a process to determine expertise, resources, or technologies that the RTRC will offer. Justification for the proposed resources and services are their ability to support excellent translational science. The planning process may consider, for example, how to provide services to multiple investigators; the strategic scientific importance of the resource; the quality of the science the resource supports; and the quality, cost, and cost-efficiency of the service relative to that of equivalent services from other sources.

4 . Organization, Administration, and Governance. Develop plans to develop, organize, administer, and govern a regional or national center that takes full advantage of partners' capabilities in advancing translational research and fostering scientific interactions. Plans might include shared administration and governance; appropriate access to shared resources, even if partnering institutions are widely dispersed; means of resolving differences among partnering institutions; plans for continued evaluation and flexibility of provided services; and processes for billing costs to investigator grants (chargebacks).

5 . **Senior Leadership.** Explain how senior leadership will be selected. Criteria might include scientific and administrative qualifica tions; experience and effectiveness; a ppropriateness of the director's position within the institution; and representation on decision-making committees relevant to the center's objectives.

6. Facilities. Describe how plans will be developed to ensure adequate space and facilities in each partnering institution and at RTRC headquarters.

7. Institutional Commitment. Explain the level of resources that participating institutions plan to provide to ensure that the RTRC reaches its full potential, as measured by the adequacy of space, positions, and discretionary funds controlled by the center director; oversight of faculty and staff critical to the RTRC; and plans for managing any change in center directorship. Applications also should note the underlying scientific expertise of the proposed RTRC.

8. Scientific Quality. Cite overall quality of translational science, representation of relevant scientific disciplines that maximize productivity, and value added by the proposed center to the research efforts of its members in promoting multidisciplinary translational research.

Section II. Award Information

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1. Mechanism(s) of Support

This funding opportunity will use the NIH P20 (Exploratory Center) award mechanism. As an applicant, you will be solely responsible for planning, directing, and executing the proposed project.

This funding opportunity uses the just-in-time budget concepts. It also uses the non-modular budget format described in the PHS 398 application instructions. Specifically, a detailed categorical budget for the "Initial Budget Period" and the "Entire Proposed Period of Support" is to be submitted with the application that reflects the scope of the proposed planning activity.

2. Funds Available

The NIH Roadmap intends to commit approximately $3 million in FY 2005 to fund a minimum of 20 planning grants in response to this RFA. An applicant must request a project period of 1 year and a budget for direct costs of up to $100,000. http://grants.nih.gov/grants/guide/notice-files/NOT-OD-04-040.html Because the nature and scope of proposed centers will vary by application, it is anticipated that the size of each award also will vary. Although the NIH Roadmap budget includes support for the RTRC Initiative, awards pursuant to this RFA are contingent on the availability of funds and the receipt of a sufficient number of meritorious applications.

This RFA is a one-time solicitation with an anticipated award date of May 2005. However, this RFA may be re-issued once more in 2005. Awards will remain active for 1 year, but no-cost extensions of 1 year may be granted.

Section III. Eligibility Information

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1. Eligible Applicants

1.A. Eligible Institutions

You may be party to and submit (an) application(s) if your organization has any of the following characteristics:

- For-profit or non-profit institution.
- Public or private institution, such as university, college, hospital, and laboratory.
- Unit s of State government.
- Units of local government.
- Eligible agency of the Federal government.
- Domestic institution/organization.
- Faith-based or community-based organization.

An eligible institution may be party to multiple applications. However, it may be the applicant institution on *only one* application . Please note that foreign institutions are not eligible to apply.

1.B. Eligible Individuals

Individuals with the skills, knowledge, and resources necessary to plan, organize, and administer an RTRC, C-RTRC, or E-RTRC are invited to work with their institution and individuals from partnering institutions to develop an application for support. Individuals from underrepresented racial and ethnic groups and those with disabilities are always encouraged to apply for NIH programs or to partner with principal investigators from other institutions to develop a responsive application. Please note that an individual can be listed as the principal investigator on *only one* application.

2. Cost Sharing

This program does not require cost sharing as defined in the current NIH Grants Policy Statement at http://grants.nih.gov/grants/policy/nihgps_2003/nihgps_Part2.htm#matching_or_cost_sharing.

3. Other—Special Eligibility Criteria

As noted above, an institution may be party to multiple applications for any of the three center types, although it may be the applicant institution on *only one* application. In addition, an individual may be listed as the principal investigator on *only one* application.

Section IV. Application Submission Instructions

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1. Address to Request Application Information

The PHS 398 application instructions are available at http://grants.nih.gov/grants/funding/phs398/phs398.html in an interactive format. For further assistance contact GrantsInfo, Telephone (301) 435-0714, E-mail: GrantsInfo@nih.gov.

Telecommunications for the hearing impaired: TTY 301-451-0088.

2. Content and Form of Application Submission

Applications must be prepared using the PHS 398 research grant application instructions and forms (rev. 5/2001). 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/. The D&B number should be entered on line 11 of the face page of the PHS 398 form.

See also Subsection VI.2. for additional information.

The title and number of this funding opportunity must be typed on line 2 of the face page of the application form and the YES box must be checked.

3. Submission Dates and Time

3.A. Receipt, Review, and Anticipated Start Dates

Letter of Intent Receipt Date: December 1, 2004
Application Receipt Date(s): January 19, 2005
Peer Review Date: March 2004
Council Review Date: May 2005
Earliest Anticipated Start Date: May 2005

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

The letter of intent is to e-mailed by the date listed above to:

Anthony Hayward, M.D., Ph.D.
Director, Division for Clinical Research Resources
National Center for Research Resources
6701 Democracy Blvd, Room 906
Bethesda, MD 20892
Telephone: (301) 435-0791
Fax: (301) 480-3661
E-mail: haywarda@mail.nih.gov

3.B. Sending an Application to the NIH

Applications must be prepared using the PHS 398 research grant application instructions and forms as described above. 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)

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

Martin Goldrosen
Director, Office of Scientific Review
National Center for Complementary and Alternative Medicine
6701 Democracy Boulevard
Democracy II , Room 401
Bethesda, MD 20892
(Bethesda, MD 20817 for express/courier service)
Telephone: (301) 451-6331
Fax: (301) 480-2419
E-mail:goldrosm@mail.nih.gov

Using the RFA Label: The RFA label available in the PHS 398 application instructions must be affixed to the bottom of the face page of the application. Type the RFA number on the label. Failure to use this label could result in delayed processing of the application such that it may not reach the review committee in time for review. In addition, the RFA title and number must be typed on line 2 of the face page of the application form and the YES box must be marked. The RFA label is also available at: http://grants.nih.gov/grants/funding/phs398/label-bk.pdf.

3.C. Application Processing

Applications must be received **on or before the application receipt date** listed in the heading of this funding opportunity. If an application is received after that date, it will be returned to the applicant without review.

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.

Although there is no immediate acknowledgement of the receipt of an application, applicants are generally notified of the review and funding assignment within eight (8) weeks.

4. Intergovernmental Review

This initiative is not subject to intergovernmental review.

5. Funding Restrictions

All 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 http://grants.nih.gov/grants/policy/policy.htm (see also Section VI.3.

Award Criteria). The maximum funding level per award is $150,000.

6. Other Submission Requirements

Required information, in addition to that requested in the PHS 398 form instructions, is listed below. All elements must be included in the 25-page limit.

Timeline

Include a specific section labeled Timeline after the Research Design and Methods section, which depicts planned actions over the 1-year award period.

Management Plan

In a separate section following the Research Design and Methods section, present a concise plan describing how team members will collaborate and how efforts of investigators from participating institutions will be coordinated.

Plan for Sharing Research Data

Not applicable at this time; however, *Phase Two* grants will require applicants to plan for sharing research data and resources.

Sharing Research Resources

Not applicable at this time, as noted above.

Section V. Application Review Information

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1. Criteria

OVERVIEW

RTRCs will serve several missions. The role of peer review is to assess the extent to which the planning process is likely to enable the applicants to submit a competitive RTRC application.

2. Review and Selection Process

Upon receipt, applications will be reviewed for completeness by the Center for Scientific Review and for responsiveness by the RTRC Working Group. Incomplete and/or unresponsive applications will not be reviewed.

Applications that are complete and responsive to the RFA will be evaluated for scientific and technical merit by an appropriate peer review group convened by NCCAM in accordance with the review criteria stated below.

As part of the initial merit review, all applications will:

- Undergo a selection process in which only those applications deemed to have the highest scientific merit, generally the top half of applications under review, will be discussed and assigned a priority score.
- Receive a written critique
- Receive a second level of review by the National Advisory Council for Complementary and Alternative Medicine on behalf of NIH.

3. Merit Review Criteria

Applications submitted in response to a funding opportunity will compete for available funds with all other recommended applications.

The goals of NIH-supported research are to advance our understanding of biological systems, improve the control of disease, and enhance health. In the written comments, reviewers will be asked to discuss the following aspects of the application in order to judge the likelihood that the proposed plan will have a substantial impact on the pursuit of these goals. The scientific review group will address and consider each of these criteria in assigning the application's overall score, weighting them as appropriate for each application.

- Significance
- Approach
- Innovation
- Investigator
- Environment
- Additional Review Criteria

The application does not need to be strong in all categories to be judged likely to have major scientific impact and thus deserve a high priority score. For example, an investigator may propose to carry out important work that by its nature is not innovative but is essential to move a field forward.

Significance: What is the vision for the RTRC for which the planning process will be undertaken? Are plans presented that would identify the roadblocks that an RTRC would overcome in advancing translational research? If the aims of the planning grant are achieved, will this enable the applicant to submit a competitive RTRC application?

Approach: Have the applicants described a robust planning process to develop the content, administration, and governance of an RTRC? Have the applicants indicated how they will plan to address the characteristics of an RTRC organization that will encompass translational focus, scientific quality, senior leadership, RTRC administration, and organizational capability? Does the applicant acknowledge potential problem areas in the planning process and consider alternative tactics?

Innovation: Have the applicants described any innovative approaches that will contribute to the planning process?

Investigator: Is the investigator appropriately trained and well suited to carry out this planning process? Is the work proposed appropriate to the experience level of the principal investigator and other researchers?

Environment: Are plans developed to evaluate the scientific or resource contributions that collaborating institutions will make to an RTRC? These plans could encompass criteria for partnerships, facilities, and institutional commitment. Is there evidence of institutional support for the development of an RTRC?

3.A. Additional Review Criteria

Not applicable.

3.B. Additional Review Considerations

Budget: The reasonableness of the proposed budget and the requested period of support in relation to the proposed research.

3.C. Sharing Research Data

Not applicable; however, as noted in Section IV, Subsection 6, *Phase Two* grants will require applicants to plan for sharing research data and resources.

3.D. Sharing Research Resources

Not applicable at this time, as noted above.

Section VI. Award Administration Information

1. Award Notices

After peer review of the application is complete, the Principal Investigator will also receive a written critique called a summary statement.

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 http://grants.nih.gov/grants/policy/nihgps_2003/NIHGPS_part4.htm

A formal notification in the form of a Notice of Grant Award (NGA) will be provided to the applicant organization. The notice of award signed by the grants management officer is the authorizing document.

Selection of an application for award is not an authorization to begin performance. Any costs incurred before receipt of the NGA are at the recipient's risk. These costs may be reimbursed only to the extent considered allowable pre-award costs.

Award notices will be sent by e-mail to the principal investigator and the grantee applicant institution.

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 grant 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.

The following Terms and Conditions will be incorporated into the award statement and will be provided to the Principal Investigator as well as to the appropriate institutional official, at the time of award.

2.A. Cooperative Agreement Terms and Conditions of Award

Not applicable.

3. Award Criteria

The following will be considered in making funding decisions:

- Scientific merit of the proposed project as determined by peer review .
- Availability of funds
- Programmatic priorities, to include inclusiveness of the specified region and breadth of scientific scope and relevance to the missions of multiple NIH ICs.

4. Reporting

Not applicable.

Section VII. Agency Contact(s)

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 Contact(s)

Anthony Hayward, M.D., Ph.D.
Director, Division for Clinical Research Resources
National Center for Research Resources
6701 Democracy Blvd, Room 906
Bethesda, MD 20892
Telephone: (301) 435-0791
Fax: (301) 480-3661
E-mail: haywarda@mail.nih.gov

2. Peer Review Contact(s)

Martin Goldrosen, Ph.D.
Director, Office of Scientific Review
National Center for Complementary and Alternative Medicine
6701 Democracy Blvd, Rm 401
Bethesda MD 20892
Bethesda, MD 20817 for express/courier service)
Telephone: (301) 451-6331
Fax: (301) 480-2419
E-mail: goldrosm@mail.nih.gov

3. Financial or Grants Management Contact(s)

George Tucker, M.B.A.
Grants Management Officer, Office of Grants Management
National Center for Complementary and Alternative Medicine
6701 Democracy Blvd, Rm 401
Bethesda, MD 20892
Telephone: (301) 594-9102
Fax: (301) 480-3621
E-mail: gt35v@nih.gov

Section VIII. Other Information

Required Federal Citations

Use of Animals in Research:
Recipients of PHS support for activated 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, June 12, 1998: 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, local IRB rules, as well as local, State and Federal laws and regulations, including the Privacy Rule. Reviewers will consider the data sharing plan but will not factor the plan into the determination of the scientific merit or the priority score.

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://grants1.nih.gov/grants/guide/notice-files/NOT-OD-04-042.html). 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 that is available at 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-02-005.html . Only research using hESC lines that are registered in the NIH Human Embryonic Stem Cell Registry will be eligible for Federal funding (see 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. Applications that do not provide this information will be returned without review.

Public 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 public 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 PA 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.

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. Unless otherwise specified in an NIH solicitation, Internet addresses (URLs) should not be used to provide information necessary to 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 PA 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 or Health Systems Agency review. 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.

Weekly TOC for this Announcement
NIH Funding Opportunities and Notices

Department of Health and Human Services

National Institutes of Health (NIH)
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Bethesda, Maryland 20892