

Recovery Act Limited Competition: Administrative Supplements for Re-engineering Protocol Implementation and Development (RaPID) of Phase 1 to 3 Cancer Protocols Conducted by Eligible NCI U10-Supported Cooperative Groups and NCI U01-Supported Cancer Radiology Networks

Key Dates

Release Date: December 30, 2009

Receipt Date: Friday, January 22, 2010

Purpose

The Division of Cancer Treatment and Diagnosis (DCTD) of the National Cancer Institute (NCI) announces the availability of administrative supplements to NCI-funded grants for Re-engineering Protocol Implementation and Development of Phase 1 to 3 Cancer Protocols in accordance with the recommendations of the NCI Operational Efficiency Working Group (go to <http://deainfo.nci.nih.gov/ADVISORY/ctac/1109/presentations> for more information and see "Operational Efficiency Work Group Update").

Background

Recent independent analyses of NCI-supported clinical trials systems have indicated an urgent need to re-evaluate engrained processes for developing and implementing phase 1-3 treatment protocols. For investigators to take full advantage of scientific opportunities available today for clinical research, novel solutions must be developed to speed up the excessive time that it currently takes to activate an NCI-sponsored clinical trial. NCI DCTD, primarily through its Cancer Therapy Evaluation Program (CTEP) and Cancer Imaging Program (CIP), sponsors multi-institution clinical trial organizations (i.e., NCI Cooperative Groups) that conduct both early phase and late phase multi-institutional trials that evaluate anticancer therapies and diagnostic tests designed to improve multiple outcomes including quality of life, delay in cancer progression, and overall survival. The focus of this initiative will be on improving processes and thus shortening the timelines for activating NCI-sponsored Cooperative Group phase 1- 3 treatment trials.

Eligibility

Parent grants that can be supplemented under this opportunity must involve the conduct of phase 1, phase 2, and/or phase 3 cancer clinical trials that are supported by the NCI Division of Cancer Treatment through use of cooperative group (U10) and/or radiology network (U01) cooperative agreements.

Activities to be Supported

Activities that can be supported through this administrative supplement funding opportunity include the following items.

1. Recruitment and hiring of one or more of the following:
 - Non-physician trial development managers, whose primary responsibility is tracking and managing clinical protocols in development to assure timely completion of all required activities;
 - Specialist medical writers to support protocol preparation and revision;
 - Physician senior protocol officers, with primary responsibility for assembling protocol scientific and clinical content and for coordinating resolution of outstanding scientific and clinical issues in protocol revision; and/or
 - Other staff roles that will facilitate timely preparation and revision of clinical concepts and protocols.

Research Plan Requirement: Application must state rationale for the specific role(s) for which support is being requested, relating the request to current processes and performance and placing it in the context of the overall Group action plan for meeting the OEWG agreed timelines for trial activation.

2. Acquisition or development and deployment of project management/protocol tracking systems to:
 - Track responsibility for and status of individual trial development steps;
 - Monitor timeline performance of individual trial development steps and the complete concept-to-activation process, both for individual trials and across the Group's trial portfolio; and/or
 - Facilitate the identification of reasons for any observed delays and suggest corrective actions.

Research Plan Requirement: The supplemental funding request must state how software will be selected and/or developed (including how it would be integrated with existing systems), and what the strategy will be for assuring that selected approach will be able to accommodate a variety of reporting requirements and data interchange standards. Commercial off-the-shelf (COTS) products will be given priority in view of the need to begin this initiative immediately.
3. Retention of specialist consultants to assist in analysis and re-engineering of protocol preparation and revision processes within the Group.

Research Plan Requirement: Application must state the rationale for requesting resources for process analysis as well as identity of consultant to be used and rationale for selection, or approach to be used to select consultant. No more than 10% (total costs) of the available funds may be requested for support of process analysis consultant support.
4. Travel and meeting resources to facilitate developing a Group action plan for achieving agreed OEWG timelines.

Research Plan Requirement: Application must state the rationale for requesting travel and meeting resources for action plan development. No more than 5% (total costs) of the available funds may be requested for support of action plan development.
5. Other activities.

Research Plan Requirement: Application must state rationale for supporting an activity not listed above, relating the request to current processes and performance and placing it in the context of the overall Group action plan for meeting the OEWG agreed timelines for trial activation.

Note: It is not required to request funds for each of the five categories listed above. The entire request can be limited to one category or several categories.

Budget and Funding Information

Four million (\$4.0M) in supplement funding is available. Funding of up to a maximum of \$500,000 total costs may be included in a administrative supplement request; note that funds are insufficient to enable every eligible cooperative agreement awardee to receive that maximum amount.

Submitting a Request

Applications must be received by 5:00 p.m. EST January 22, 2009. It is strongly preferred that applications be submitted via e-mail to the following two addresses:

- 1) ncictepanalyst@mail.nih.gov; and
- 2) kresse@mail.nih.gov.

Applications submitted via e-mail must include imaged signatures. If (and only if) e-mail submission is not possible, a hard copy may be sent instead per the instructions below.

For applications sent by U.S. mail:

Attn: Ms. Elise Kreiss

NCI Division of Cancer Treatment and Diagnosis

6130 Executive Boulevard, EPN Room 7009, MSC 7432

Bethesda, MD 20892-7432

(For applications sent by another express or courier delivery service, use Rockville, MD 20852.)

Requests should use the PHS 398 form available at

<http://grants1.nih.gov/grants/funding/phs398/phs398.html> and include the following elements in the request packet. Font size restrictions apply as designated within the PHS398 instructions. Please number the pages.

1) **Cover Letter** - Citing the number and title ("RaPID" is sufficient) of this Notice, specify a request for a Recovery Act Administrative Supplement, including the following information:

- Project Director/Principal Investigator (PD/PI) name;
- Parent grant number and title;
- Amount of the requested supplement (Include total cost);
- Name and title of the authorized institutional official; and
- Phone, email, and address information for both the PD/PI and the institutional official.

The cover letter must be signed by the authorized institutional official.

2) **PHS 398 Form Page 1** (Face page) [MS Word](#) [PDF](#)

- The title of the project (Box 1) should be the title of the parent award.
- This Notice should be cited in Box 2, and the title may be shortened to "RaPID." The "yes" box should be checked.
- The Project Director/Principal Investigator (PD/PI) must be the same as the PD/PI on the parent award. For Multiple PD/PI parent awards, the Contact PD/PI must be the PD/PI listed on the supplement request. Administrative supplements cannot change the Multiple PD/PI team or convert a grant from a single PD/PI to a multiple PD/PI grant.
- The remaining items on the face page should be filled out in accordance with the PHS 398 application instructions.

3) **PHS 398 Form page 2** [MS Word](#) [PDF](#)

Note: The project "summary" is that of the administrative supplement, not the parent grant. All other

information requested on Form Page 2 should be provided.

4) **A brief proposal describing the project, including:**

a) **Scope of the overall project and the anticipated contribution of the requested supplement** (not to exceed **five** pages). This section should include a description of the supplement's purpose.

b) The research project plan should discuss the rationale for each of the five eligible activities as discussed in the section "Eligibility" above.

c) **Budget for the supplement with a justification that details the items requested, including Facilities and Administrative costs and a justification for all personnel and their role(s) in this project.** Note the budget should be appropriate for the work proposed in the supplement request. All applications under this notice must include detailed budgets on the PHS 398 Form Pages 4 ([MS Word PDF](#)) and 5 ([MS Word PDF](#)).

d) **Biographical Sketch for all new Senior/Key Personnel.** There is no need to repeat information previously provided for other Senior/Key Personnel. [MS Word PDF](#)

e) **Human Subjects documentation** (if applicable). Include a current Human Subjects/Institutional Review Board (IRB) approval letter, if applicable. Otherwise, this letter will be required at time of funding. All appropriate IRB approvals must be in place prior to a supplement award being made. No significant changes in the approved use of human subjects will be considered for administrative supplements.

f) **PHS 398 Checklist Form** [MS Word PDF](#)

ARRA Terms of Award

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

The terms of the NoA will reference the requirements of the Recovery Act.

In addition to the standard NIH terms of award and those particular to the Groups and ACRIN (as applicable), all funding provided under the Recovery Act will be subject to the HHS Standard Terms and Conditions for American Recovery and Reinvestment Act of 2009 (Recovery Act or ARRA). The full text of these terms approved for NIH awards can be found in the following document: [Standard Terms and Conditions for ARRA Awards](#).

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.

ARRA Reporting

Awarded administrative supplements that include a commitment for funding in FY2010 will be required to submit a separate [Non-Competing Continuation Grant Progress Report \(PHS 2590\)](#) and financial statement as required in the [NIH Grants Policy Statement](#). This will be in addition to any annual progress report required for the parent grant. The funded Recovery Act administrative supplement will also require separate closeout reports.

In addition, grantees must comply with the requirements set forth in the Recovery Act, including, but not limited to, the quarterly reporting requirements of Section 1512 of the Recovery Act as specified in HHS Standard Terms and Conditions for American Recovery and Reinvestment Act of 2009. The full text of these terms approved for NIH awards can be found at the following document: [Standard Terms and Conditions for ARRA Awards](#).

Recovery Act-related reporting requirements will be incorporated as a special term of award.

Inquiries

For scientific or technical questions relating to research that would be supported by this solicitation, contact the Program Director for the parent grant. For technical grant inquiries, please contact the Grants Management Specialist listed on the parent grant. For questions concerning the types of science supported by this solicitation, contact Dr. Mooney (Cooperative Groups), Ms. Barbara Galen (ACRIN), or Dr. Abrams, as indicated below. For administrative programmatic questions, contact Ms. Elise Kreiss, as indicated below. For general fiscal, grant or Recovery Act questions pertaining to this solicitation, please contact Ms. Crystal Wolfrey, as indicated below.

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