

Reviewed Date: February 29, 2012

Revised Date: June 4, 2010

Frequently Asked Questions (FAQs) for RFA-AR-11-002: Centers of Research Translation (CORT) (P50)

1. The RFA states under **Number of PDs/PIs**: *More than one PD/PI (i.e., multiple PDs/PIs), may be designated on the application.* For which roles among the CORT PI, Project PI, or Core PI is Multi-PI applicable?

The decision to apply for a single PI or a multiple PI grant is the responsibility of the investigators and the applicant organization. Those decisions should be consistent with and justified by the scientific goals of the project. More than one PD/PI (i.e. multiple PDs/PIs) may be designated on the CORT applications as well as on the individual projects and cores that require a “team science” approach and therefore clearly do not fit the single-PD/PI model. All applicants proposing team science efforts are strongly encouraged to contact their NIH program officials at the earliest possible date to discuss the appropriateness of the multiple-PI model for their research projects.

When considering the multiple PD/PI option, 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. Additional information on the implementation plans and 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 electronic Research Administration (eRA) Commons prior to the submission of the application (see <http://era.nih.gov/ElectronicReceipt/preparing.htm> for instructions).

2. In a multiple PI application, what information should be included in a Leadership Plan?

In applications designating multiple PDs/PIs for the overall CORT, the “Multiple PD/PI Leadership Plan” should be presented under the section for Leadership and Organizational Structure in the Research Plan of the Administrative Core (Section III-A-7b(1), Exhibit I, page 29 of the CORT Guidelines http://www.niams.nih.gov/Funding/Funding_Opportunities/CORT_Guidelines.pdf).

In applications designating multiple PDs/PIs for the individual projects or research cores, the “Multiple PD/PI Leadership Plan” should be described under Item 12 in the Research Plan (<http://grants.nih.gov/grants/funding/phs398/fp3.pdf>) for each of the components.

A Leadership Plan should include a rationale for choosing a multiple PD/PI approach. The governance and organizational structure of the leadership team and the research project should be described, including 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. Any requested allocation of funds to components of the project or the associated PIs must be included in the Leadership Plan (See details at http://grants.nih.gov/grants/multi_pi/overview.htm). If an award is made, the requested allocation will be acknowledged in the Notice of Grant Award. Unless limited by a specific term of award, the acknowledgment of the requested allocation will not limit institutional authority to manage the funds nor will it impose additional prior approval requirements. Awards involving PIs at different institutions are managed using subcontracts. The first PI listed must be affiliated with the institution submitting the application and will serve as the contact PI.

3. For roles where Multi-PI is allowable, what would be the minimum effort required for that component?

The level of effort in person-months should appropriately reflect the time commitment required by the proposed project. Because many projects already involve collaborative efforts, the NIH does not expect large increases in the total level of effort required for research projects. Nevertheless, the level of effort should be based on the best estimate of the time required to conduct the proposed project considering the roles and responsibilities described in the Leadership Plan.

In a single PI model, the CORT Director is expected to make a commitment of at least 1.8 calendar months (CM) to the overall administration of the program and the Associate Director is expected to commit 1.2 CM to administration. In a multiple PI model for the CORT, the total time commitment of all the PIs combined should not be less than 3.0 CM.

In a single PI model, a Project PI is expected to commit 2.4 CM to research and a Research Core PI is expected to commit 1.8 CM to the core. In applications designating multiple PDs/PI to the individual research projects and cores, the total time commitment of all PIs should not be less than 2.4 CM for a research project or 1.8 CM for research core.

4. The CORT RFA requires each project and core written within 12 pages for research plan. Is there a page limitation for the Narrative Sections?

The page limit for the Narrative Sections of the CORT application is not specified. However, the applicants should keep in mind the workload of the reviewers who will likely be assigned with multiple applications to evaluate, and keep the sections as succinct as possible without compromising the quality.

5. Are there examples of research projects that would not be a good fit for the CORT mechanism?

The intent of the CORT program is to foster research translation around a disease-targeted theme with synergy from individual projects, directed at elucidating the relevance of knowledge derived from basic science and engineering to the understanding of human disease and health in an area within the NIAMS mission. The concept of CORT is two way, embracing both the translation of scientific discoveries towards clinical application and clinical findings back to new research. At one end of the translational spectrum, while research involving the use of animal models is not excluded, the model needs to be highly relevant and closely resemble that of human condition. At the other end, health services research, as its primary goals are to identify the most effective ways to organize, manage, finance, and deliver high quality health care; reduce medical errors; and improve patient safety, would be considered beyond the scope of the CORT. In addition, a typical clinical trial project would not be appropriate for a CORT project and the NIAMS uses other mechanisms to support clinical trials. Clinical research to understand the biological bases of treatment responses with a goal to identify novel therapeutic targets or biomarkers of predictive value could be considered under the CORT. The applicants are strongly encouraged to contact their program officials should there be any questions.

6. The RFA states that "A CORT should be focused on one of the disease entities or disorders in the NIAMS mission. The focus cannot be generic, e.g., autoimmune diseases, musculoskeletal disorders, or skin diseases." How will I know if my research projects are within the mission of NIAMS?

The diseases within the NIAMS mission may be found at the following links

http://www.niams.nih.gov/Funding/Funding_Opportunities/Supported_Scientific_Areas/default.asp & http://www.niams.nih.gov/About_Us/Mission_and_Purpose/long_range.asp. Applicants are strongly encouraged to contact their program official should there be any questions.

7. The Guidelines Document states: "Support for research training positions is not to be included." Does this mean that graduate students and postdoctoral fellows would have to find other support to work on the projects of the Center?

No; please disregard that statement in the Guidelines document. The budget for the CORT may include graduate students, clinical fellows and postdoctoral fellows where appropriate. Allowable expenses for graduate students may include tuition and fees in accordance with the policies of NIH (see Compensation of Students in the NIH Grants Policy Statement http://grants.nih.gov/grants/policy/nihgps_2003/NIHGPs_Part6.htm) and the grantee institution.

8. Is it allowed to have foreign institutions involved in my proposed project as a subcontract?

Yes, foreign institutions can be involved in projects in a domestic CORT program through subcontract, although they are not eligible to apply for the CORT RFA as primary institution.

9. Should the individual projects and research cores in a CORT application complete the components following the current PHS398 instructions section “5.5 Content of Research Plan” as applicable?

Yes, as stated under Item 2 of Section IV. Application and Submission Information in the current CORT RFA, all applications should be prepared using the the current PHS 398 application forms and in accordance with the PHS 398 Application Guide (<http://grants.nih.gov/grants/funding/phs398/phs398.html>). Under Section 5.5 of the PHS 398 Application Guide, the research plan for the individual projects and research cores of a CORT application should include the following sections as applicable. Applicants should be advised NOT to use the research plan components found in “Exhibit I: Sample Table of Contents” (p.29-30) of the CORT Guidelines (http://www.niams.nih.gov/Funding/Funding_Opportunities/CORT_Guidelines.pdf) as these headings are from the expired 11/07 PHS398 instructions.

1. Introduction to Application (Resubmission or Revision Applications only)
2. Specific Aims
3. Research Strategy (Significance, Innovation and Approach)
4. Inclusion Enrollment Report (Renewal or Revision Applications only)
5. Bibliography and References Cited/Progress Report Publication List
6. Protection of Human Subjects
7. Inclusion of Women and Minorities
8. Targeted/Planned Enrollment Table
9. Inclusion of Children
10. Vertebrate Animals
11. Select Agent Research
12. Multiple PD/PI Leadership Plan
13. Consortium/Contractual Arrangements
14. Letters of Support (e.g., Consultants)
15. Resource Sharing Plan(s)