



**Association of
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June 28, 2006

BY ELECTRONIC MAIL: haywarda@mail.nih.gov

Anthony Hayward M.D., Ph.D.
Division for Clinical Research Resources NCRR
6701 Democracy Blvd, Room 906
Bethesda, MD 20892-4874

Re: Notice of Intent to Reissue the Institutional Clinical and Translational Science Award (CTSA) RFA and Request for Comments Regarding CTSA RFA. Notice Number: NOT-RM-06-016

Dear Dr. Hayward:

I appreciate this opportunity to respond on behalf of the Association of American Medical Colleges (AAMC) to the request by the National Center for Research Resources (NCRR) for comments regarding the CTSA RFA. The AAMC represents the nation's 126 accredited medical schools, over 400 affiliated teaching hospitals, and 96 academic medical societies comprising nearly 109,000 faculty members. Our member institutions perform more than half of the extramural research sponsored by NIH, and more than 70 percent of NIH research sponsored at academic institutions.

The AAMC is strongly supportive of the overall goals of the CTSA initiative, namely to strengthen clinical and translational research (C&TR) by providing an "academic home" for such research. Indeed, these goals are entirely congruent with the recommendations of the recent report of the AAMC Task Force II on Clinical Research: "Promoting Translational and Clinical Science: The Critical Role of Medical Schools and Teaching Hospitals" which can be found at:

www.aamc.org/promotingclinicalscience

Nevertheless, the AAMC has comments and suggestions for modifications of the CTSA RFA that we believe would, if adopted, provide clarification as well as improve and strengthen the RFA. These comments and suggestions are based on input we received from 72 medical schools, 17 independent teaching hospitals, and 2 VA hospitals.

Our first suggestions concern the following language: "The program director have authority, perhaps shared with other high-level institutional officials, over requisite space, resources, faculty appointments, protected time, and promotion."

Although some medical schools have or may create a department of clinical research, many others argue strongly that a center or institute should *not* have primary appointment and promotion authority, and such authority would not be possible under their institutional policies. They believe that having secondary appointments, as is done, for example, in most NCI supported Cancer Centers, would provide a C&TR Center director with a sufficient voice in appointment and promotion decisions. Even if faculty positions were to be allocated to the Center, these institutions think that the primary appointment should be in a department, and they request that the language be modified to indicate explicitly that secondary appointment in the C&TR Center would meet the requirement.

Another need for clarification concerns the relationship anticipated between a C&TR Center and other existing centers. For example, NCI-supported Cancer Centers expect their directors to have oversight of Center resources, and those resources always include substantial infrastructure for clinical and translational research.

Suggestions for NIH:

1. Provide clarification that secondary appointments in a C&TR Center or Institute would meet the RFA requirement for “authority” over appointments and promotion. This would permit institutions to have a meaningful choice whether to create a department, center, or institute, as stated in the RFA.

2. Provide guidance on the range of interactions and collaborations permitted between the CTSA and other NIH supported centers that perform C&TR and have C&TR infrastructure.

The next suggestion emanates from concerns regarding the following two statements: "The applicant institution(s) must include a graduate school accredited to award higher degrees in clinical research", and "Therefore, an institution may submit, or be a part of, only a single application in response to this RFA".

These statements, taken together, generate great concern and are widely considered to be too prescriptive given the many different organizational structures and geographic relationships among research institutions. These include:

- Universities affiliated with several independent hospitals, each of which has a GCRC
- University *systems* with multiple medical and other health professions schools that are widely dispersed geographically: in this instance, what is “the institution?”

- A teaching hospital affiliated with 3 different medical schools
- Independent pediatric hospitals
- A medical school located on 4 widely dispersed campuses

Additional concerns related to these organizational requirements include:

- How would a single national laboratory and the NIH intramural program continue their existing research and educational collaborations with multiple institutions generating separate CTSAAs?
- Pediatric GCRCs and other clinical research infrastructure would be subsumed into larger units and fear the loss of focus, control of agenda, and control of resources. This concern is deep-seated and widespread in the children's hospital community and their affiliated academic faculty.
- Some children's hospitals affiliate with multiple medical schools. The RFA language appears to prevent these collaborations from continuing via participation in multiple CTSAAs.
- Where multiple discrete and separately funded assets (e.g., GCRCs) would be rolled up into a single award, there is fear of attrition of resources over time.
- Many of the independent teaching hospitals and children's hospitals have invested substantial institutional funds in building and operating their clinical and translational research infrastructure and are reluctant to cede control of those resources to another organization.
- In circumstances where non-medical health professions schools (e.g., dentistry, pharmacy, veterinary medicine) collaborate with multiple academic medical centers, the RFA language appears to prevent these collaborations from continuing via participation in multiple CTSAAs.

Suggestion 3: Provide flexibility by permitting a degree-granting institution, a national laboratory, the NIH intramural program, non-medical health professions schools, or specialized teaching hospitals to collaborate with more than one CTSA applicant.

The next suggestion relates to the language: "It is expected this individual (the director) would be an established clinician scientist who reports directly to an official with broad trans-institutional authority."

There is a concern that in many universities, the Dean of the School of Medicine, who may or may not carry the additional title of Vice President, is the most appropriate senior institutional official to whom the CTSA director should report.

Suggestion 4: Provide flexibility by allowing the peer review process to determine whether the proposed institutional officer has the authority to implement a “home” for C&TR that may include multiple entities outside the School of Medicine.

The next suggestion concerns the mentoring of the physicians whose C&TR training will be supported by CTSA. There is general agreement that outstanding mentoring is essential to the future success of the trainees as independent C&TR investigators. Thus, it follows that there needs to be salary support for the time that C&TR physician-scientists devote to mentoring.

Suggestion 5: Include, as an allowable cost, salary support for the physician-scientist faculty who serve as mentors to the CTSA trainees.

Our final suggestions relate to concerns, indeed anxiety, about the funding for this initiative, which has a broad and transforming agenda. Many institutions have encountered difficulties in attempting to embrace the entire agenda within the level of funding to be provided. While some institutions have the resources to partner with NIH in accomplishing the goals, others do not, and the initiative needs to be structured such that a broad and diverse range of institutions can provide homes for CTSA. A related concern is whether there will be sufficient additional resources in an era of flat NIH budgets to provide funding beyond that immediately available from rolling up existing awards (GCRC, K30, and roadmap K12 and T32), and where these additional funds will come from, specifically, will support for the CTSA program be at the expense of basic research? Finally, there is a concern that the CTSA initiative will not be fully implemented by the time of the scheduled demise of the GCRC program in 3 years, resulting in the dismantling of programs that currently support clinical and translational research.

Suggestion 6: Provide guidance on how to structure a CTSA where sufficient funds are not available initially to accomplish all aspects of the program.

Suggestion 7: Synchronize the full implementation of the CTSA initiative with the termination of the GCRC program, and make the plans for funding this initiative transparent.

In summary, the AAMC believes that the language of the first CTSA RFA was unnecessarily rigid and prescriptive, and did not permit the flexibility that would allow diverse institutions to best meet the goals of the initiative. Adoption of the suggestions above would strengthen the RFA and create the flexibility needed to accommodate the different organizational and administrative mechanisms that characterize academic medicine. This would in turn empower

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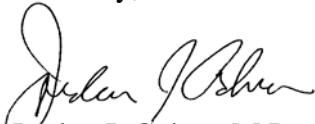
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peer review to determine whether the diverse approaches proposed by applicants would assure the high quality “academic home” for C&TR that NIH is seeking to establish. Transparent and sufficient funding of this initiative in a timely manner is critical for enhancing clinical and translational research.

Sincerely,

A handwritten signature in black ink, appearing to read "Jordan J. Cohen". The signature is fluid and cursive, with a large initial "J" and "C".

Jordan J. Cohen, M.D.

President