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Darrell G. Kirch, M.D.
President

November 13, 2007

Barbara Alving, M.D.
Director
National Center for Research Resources
National Institutes of Health
6701 Democracy Boulevard
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Bethesda, MD 20892-4874

Dear Dr. Alving:

I would like to thank you and your staff for visiting the AAMC on October 29, and for the excellent discussion about the progress and outlook for the CTSA program and other elements of NCRRT's portfolio. I would also like to thank you and Dr. Anthony Hayward again for attending the October 24 meeting of our Advisory Panel on Research. As promised, and at the urging of the Advisory Panel, I am writing to convey the chief recommendations arising from the APR's deliberations.

As you know, the AAMC fully supports the goals of the CTSA program as articulated by Dr. Zerhouni. However, given current fiscal constraints, together with the stated intention to make 60 awards by 2012, the AAMC is concerned that awardee institutions will not be able to accomplish the full array of challenging objectives expected of them in the RFA and proposed in their applications because of the limitations of support. AAMC is also concerned about the long-term sustainability of the CTSA program under circumstances of constrained NIH funding. Realistically, the program probably cannot depend even on annual budget increases sufficient to compensate fully for BRDPI inflation.

In response to these concerns, the APR and others have suggested an alternative strategy for accomplishing the CTSA vision that would explicitly plan for the creation of designated "core resource centers" that build upon the different strengths of applicant institutions. Concordantly, the RFA instructions would be modified to make clear that each applicant institution need not attempt to accomplish every element of the RFA specifications through its own capabilities. This alternative approach would explicitly promote the establishment of consortial arrangements, some regional, others national in scope, and would facilitate the establishment of a truly interactive and cooperative national clinical research enterprise.

Under this proposal, the inevitable funding of CTSA awards at levels substantially below applicants' expectations would be more tolerable, since certain, often expensive, components of

CTSA infrastructure would be supplied by regional or national cores that would serve multiple awardee institutions. Each awardee, then, could focus on specific strengths and not attempt to replicate facilities already served by an accessible core. Moreover, by stewarding CTSA funds in a manner that more realistically reflects foreseeable federal fiscal limitations, NCCR should be able to provide the supplementary funds that would be needed to scale up the designated core resources appropriately.

The current funding strategy is to award all CTSA the pre-existing funding from GCRCs, K30s, and Roadmap K12s and T32s plus approximately 40 percent. In order to provide the supplementary funds necessary to fund the proposed cores, it will be necessary to revise this formula such that the additional funding for each CTSA is a lesser sum, commensurate with a reduced scope of work. It might also be possible to amortize costs of shared resources across all CTSA that use these functions.

Examples of such cores could be in bioinformatics, proteomics, DNA sequencing or biostatistics, as only a partial list. Establishment of cores within the clinical research network would eliminate expensive redundancy and might well improve the technical quality of the services provided. Bioinformatics is perhaps an obvious example of an area where many institutions are struggling to cope with the scope of work outlined in the CTSA RFA. It is tremendously expensive to build bioinformatics that is highly functional for investigator use, and one could argue it is just not practical, or sensible, for many of the 60 centers to attempt to create the platforms for this research de novo. Beyond the first priority of supporting all 60 CTSA awardees, regional or national cores could be scaled over time to support non-CTSA clinical research institutions as well. Indeed, this prospect might induce other NIH ICs to lend their support to the effort, either by supplementary funding or by agreeing to share their own core resources already in planning or operation, and to incorporate such integration in their own strategic planning.

Nothing in our proposal would change the fundamental requirement for all CTSA institutions to provide comprehensive homes for clinical and translational research, with oversight of strengthened programs for training and career development of new clinical investigators.

We believe the strategy would be most effective the sooner implemented, considering that one-third of CTSA awards have already been funded and the majority of awards will likely be selected by the end of the next cycle. Obviously, the strategy would require changes in the RFA that could be discussed further (we note that certain elements could be grafted from the earlier proposal for regional clinical and translational centers that was, we believe, correctly supplanted by the CTSA program). AAMC believes that a strategy to strengthen planned, inter-institutional collaborative research and sharing of expensive core research resources will serve not only the objectives of the CTSA program, but will be critical in the future for sustaining much other biomedical research.

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The Association hopes that we can discuss the implications of this proposal more fully with you and, given the magnitude of the request, with the leadership of NIH. I have asked David Korn, M.D., (202-828-0509, dkorn@aamc.org) to contact you to follow up on this correspondence.

Sincerely,

Darrell G. Kirch, M.D.

cc: Elias Zerhouni, M.D.
Anthony Hayward, M.D. Ph.D
David Korn, M.D.
AAMC Advisory Panel on Research