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Re: National Center for Research Resources 2009 Strategic Plan, 72 FR 37034-5

The Association of American Medical Colleges (AAMC) is grateful for this opportunity to provide input for development of the National Center for Research Resources' (NCRR) 2009-2013 strategic plan. The following comments are provided on behalf of the AAMC's member organizations, including all 126 U.S. allopathic medical schools, nearly 400 teaching hospitals, and 89 academic societies comprising more than 100,000 faculty.

NCRR fills a critically unique role in creating, supporting and sustaining research resources and infrastructure that broadly serve biomedical research, which is distinct from the topical focuses of most other NIH institutes and centers.[1] The importance and distinctness of this role must be respected and protected in all planning and future programming. Our responses to the questions posed by NCRR are made below in the context of this central theme.

1. What are the most significant trends, developments, and/or needs in biomedical research that are likely to materialize over the next five years, and what can NCRR do to be prepared to respond to them?

The AAMC noted several trends in comments on the 2004-2008 strategic plan and we believe these trends remain central to current discussions:

- Increasing complexity and sophistication of biomedical research. Much of this research relies on advanced technologies, informatics, and emerging tools, as well as on shared research resources that often require dedicated professional staff.

- Growth in multi- and cross-disciplinary research, the emergence of new disciplines, and the increasing need for investigative teams with diverse and specialized skills and capabilities.

- The accelerating translation of basic science advancements to clinical research and applications (and vice versa). Moreover, the "horizons" of clinical research now extend

[1] While recognizing that other ICs, e.g., NCI, NHGRI, NIBIB, etc., also substantially contribute to infrastructure.

to public health and health security, the needs of underserved communities, and other areas well beyond the traditional "clinical" environment.

- Finally, the revolution in structural and functional genomics and related sciences has brought new potential for understanding "systems-level" biology and increases investigators' needs for access to research animals and other models of disease.

The Association is gratified that these trends, which were widely noted by many other stakeholders as well, were comprehensively incorporated within the most recent NCRR strategic plan. Several of these trends were also subsequently reflected in the NIH Roadmap initiatives. There has already been much progress in orienting NCRR toward addressing these trends, which we believe should continue.

2. From the standpoint of achieving the broadest impact among investigators, what new or expanded research resources and/or animal models should be developed over the next five to eight years?

The AAMC expects that two central concerns will, unfortunately, constrain future planning for NCRR programs and NIH in general, at least in near term. The first and principal concern is for expected, continuing erosion of purchasing power in the NIH's budgets due to increasing constraints on federal discretionary appropriations.[2] The second concern is for deepening confrontation in priority- and goal-setting within NIH and other agencies as the community responds to budgets that do not provide support even for maintenance of current services. We, of course, hope that federal funding will always be sufficient to protect the vitality and integrity of the NIH's broad research portfolio. Nevertheless, pressures will increase from various constituencies jostling to adapt to the new constrained fiscal environment, and many NCRR programs are particularly vulnerable in such circumstances because they lack broad, powerful constituencies to support them, even though these programs are indisputably central to the common good.

Therefore, it is especially important that the new strategic plan emphatically reassert the core focus of NCRR on shared resources and infrastructure, and the need for balance across all programs including clinical and translational research; animal resources; support for minority institutions, under-represented communities, regional development (IDeA), etc., and informatics, facilities, and instrumentation. Shared resources will be critical in helping research institutions adapt to the foreseeable fiscal circumstances. NCRR's strategic planning must retain its focus on resources and infrastructure that support many investigators and wide arrays of research projects. We believe that regional resources and national hubs connected by informatics networks will become especially important to the nation's biomedical research infrastructure. The Clinical and Translational Science Awards (CTSAs), animal research facilities, and the BIRN program are already exemplars of this approach and must be fully supported.

[2] Heinig SJ, Krakower JY, Dickler HB, Korn D. Sustaining the engine of U.S. biomedical discovery. *New England Journal of Medicine*, 2007 357;10:1042-7.

3. The recently-introduced CTSA (Clinical and Translational Science Award) Program seeks to transform the local, regional and national environment for clinical and translational science, thereby increasing the efficiency and speed of clinical and translational research. What considerations will be most crucial to the long-term success of this initiative?

The CTSA program is one of the most significant initiatives in NIH's history. The AAMC fully supports the CTSA's goal to transform the organizational environment for support of clinical and translational science and training, which parallels the recommendations of the Association's recent task force on clinical research.[3] In supporting this goal, we are especially mindful of our community's inability, across more than four decades, to increase substantially annual numbers of new physicians establishing careers as independent clinical investigators.[4]

The AAMC reiterates its earlier recommendations to permit more flexibility in the organization and administration of CTSA programs (for example, please see AAMC letter to Dr. Anthony Hayward, June 28, 2006).[5] These recommendations were based on constituent feedback reflecting a remarkable variety of organizations and collaborations that already exist within many states, but which do not appear to readily fit the organizational schema anticipated by the two CTSA RFAs issued to date.

NCRR should also clarify expectations for the CTSA programs in addressing the so-called "second translational block" (T2), referring to the organizational and socio-cultural barriers that inhibit the transfer of validated findings from clinical research into actual medical practice and public health. The NIH's expectations for T2 research within the CTSAs appear less clearly articulated than other elements for clinical and translational research and training. Constituents have voiced concerns that they are uncertain how effectively a strong proposal for T2 research influences the success of an application.

NCRR strategic planning should also provide more detail on the anticipated phase-out of the General Clinical Research Centers, and how this will coincide with full implementation of the CTSA program, to help institutions avoid unnecessary disruption and dislocation in many clinical studies.

Finally, NCRR should identify mechanisms, procedures, and partners for dissemination of lessons learned, emerging good practices, and other advice or guidance that develops from the staged implementation of the CTSA program, and include such dissemination in the strategic plan. The AAMC is eager to assist in the active communication and dissemination of such findings from the program.

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[3] Association of American Medical Colleges. *Promoting Translational and Clinical Science: The Critical Role of Medical Schools and Teaching Hospitals*. Report of the AAMC Task Force II on Clinical Research, Stephen Gabbe, M.D., chair. Washington, DC: AAMC, 2006. Available at: http://www.aamc.org/promotingclinicalscience.

[4] Dickler HB, Fang D, Heinig SJ, Johnson E, Korn D. New physician investigators receiving National Institutes of Health research project grants: a historical perspective on the "endangered species." *JAMA* 2007;297:2496-501.

[5] Available at: http://www.aamc.org/advocacy/library/research/corres/2006/062806.pdf. Also, NIH Director Zerhouni's response to AAMC, October 2, 2006.

4. Despite significant progress, research institutions serving predominantly minority and underserved populations face stiff challenges. What can NCRR do to most effectively support the long-term advancement of these institutions?

To support better long-term advancement of predominantly minority and underserved populations, NCRR should:

- Expand funding of Centers of Clinical Research Excellence grantees
- Expand the Stroke Prevention/Intervention Research model to fund more research collaborations between NIH and historically black colleges and universities (HBCUs) or minority-serving institutions to focus on prevention/intervention for chronic conditions that contribute to health and health care disparities
- Fund pipeline initiatives at HBCUs and minority-serving institutions that enhance mentorship, laboratory experiences, and clinical science experiences for underrepresented high school and undergraduate students.
- Fund training and capacity building for clinical research "teams" at HBCUs and minority-serving institutions, including training for allied health professionals and community outreach personnel.

We note further that the AAMC's Task Force II on clinical research identified several academic institutions that have developed programs that serve minority populations, and have a track record for involving neighboring communities in clinical and translational research. These programs should be recognized as models for CTSAs and other programs aimed at increasing such participation.

5. NCRR has worked with many federal and private sector institutions, agencies, and organizations and will continue to do so as we move forward. What organizations should NCRR seek out for future partnerships to most effectively support, expand, and advance its programs and services?

The AAMC strongly supports NCRR planning for coordinated support and use of facilities with other federal science agencies. The extraordinarily productive use of DOE-funded synchrotron radiation facilities to support biological structure investigations is a model in this regard.

Regarding health outcomes, effectiveness, and other behavioral and evaluative research in the CTSAs noted above, NCRR and awardee institutions would considerably benefit from close and coordinated interaction with the Veterans Administration and the Agency for Healthcare Research and Quality, as well as with health insurers and other provider organizations (indeed, several of the awarded CTSA programs have already established such relationships).

In clinical and translational research, and in bioinformatics, NCRR should work closely with the NIH Clinical Center on the development of standards, specifications, and information systems that academic health centers could adopt or adapt, allowing other organizations to focus on systems development.[6]

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[6] AAMC, *Promoting Translational and Clinical Science*, 2006.

Finally, we note that adequate protection and defense for public health and for national and homeland security relies increasingly on animal resources (especially non-human primates) and adequately trained veterinarians. The AAMC recommends that federal agencies with purview for these concerns should also participate in lending support for the development of animal facilities and technical personnel.

6. Is there anything else you would like to add that would be helpful to NCRR?

Limited access to state-of-art instrumentation, particularly so-called high-end instruments (such as MRIs, PET scanners, etc.) remains a major impediment to biomedical research. NCRR's shared instrumentation and high-end instrumentation programs are well designed to address these needs, but have not received adequate support. The shared instrumentation program, for example, has not received any significant increase in funding, in adjusted dollars, from the early 1990s. We note that this recommendation is carried over *verbatim* from our previous 2003 comments, as the situation has changed so little.

Much research infrastructure is supported by other NIH institutes and centers within the purview of their respective research missions. The growth of multi-disciplinary research across biomedical sciences underscores the opportunity for further efforts to coordinate support of infrastructure across NIH. Clearly, identification of appropriate mechanisms for review and support of infrastructure across ICs is a daunting task, but pilot projects might be used to test the feasibility of alternative approaches. Identification of these mechanisms could be a function of the new Office of Portfolio Analysis and Strategic Initiatives.

The AAMC again is grateful for this opportunity to comment, and we have encouraged our member institutions, leaders and faculty also to submit comments. We look forward to other opportunities for participation as the strategic planning process continues.

For further discussion or clarification of our views expressed in this letter, please contact Howard Dickler, M.D. Director for Clinical Research (hdickler@aamc.org, 202-828-0567), or Stephen Heinig, Senior Research Fellow (sheinig@aamc.org; 202-828-0488) in AAMC's Division of Biomedical and Health Sciences Research.

Sincerely,

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