

May 9, 2003

Office of Science Policy and Public Liaison  
National Center for Research Resources  
National Institutes of Health  
MSC 7965, Suite 5046  
6705 Rockledge Drive  
Bethesda, MD 20892-7965

**Re: National Center for Research Resources 2004 Strategic Plan, 68 FR 4503-4**

The following comments are submitted on behalf of the Association of American Medical Colleges (AAMC), the Association of American Universities (AAU), and the National Association of State Universities and Land-Grant Colleges (NASULGC), together representing the nation's medical schools, teaching hospitals, leading research universities and public institutions of higher learning.

We are grateful to NCRB for this opportunity to contribute to the development of its strategic plan for 2004 and beyond. Our respective associations, which represent nearly all the academic institutions performing NIH-sponsored research, have elected to join together in these comments to emphasize the importance and indispensability of NCRB's programs in supporting the nation's biomedical research infrastructure. We have encouraged investigators and the leadership of our constituent campuses to respond directly to NCRB on their thoughts concerning the future directions, opportunities, and needs of biomedical research, as well as to share their views with us. Our comments here respond to the questions posed by the NCRB in the *Federal Register* and are based on these and other communications with our member institutions.

*(A) What are the most important research trends that will drive biomedical research?*

We believe that the following are among the most significant and prominent trends in biomedical research:

- Increasing complexity and sophistication of biomedical research. Much of this research relies on advanced technologies, informatics, and other 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 growing need for investigative teams with diverse and specialized skills and capabilities.

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

*(B) What research resources and technologies will be critical in addressing these trends and meeting biomedical investigators’ needs?*

Critical resources include:

- **General Clinical Research Centers.** While often viewed as havens for clinical research within an increasingly constrained health-care delivery system, GCRCs in fact provide optimal venues and essential infrastructure for integrating bio medical science with patient care and thus serve as portals to 21<sup>st</sup> Century medicine.
- **Animal Facilities and Veterinary Scientists.** The role of non-human primates<sup>1</sup>, recombinant animals, and invertebrates and other non-mammalian species as models of human disease is essential. Equally essential is the training of a cadre of academic veterinary scientists capable of enabling and facilitating animal research and ensuring proper handling of research animals.
- **Core facilities.** New approaches are needed to integrate instrumentation, technology, and technical support staff and make these available to many investigators with a common research focus. Support of core facilities should augment, but not supplant, the range of other useful mechanisms used to support shared instrumentation grants, “high-end” instrumentation, biotechnology centers, and other resources.
- **New and renovated research facilities.** The expanded base of NIH-funded biomedical research projects requires more high quality space and facilities. Moreover, many types of biomedical research rely on specialized research facilities or otherwise require more stringent accommodation for environmental, health, security, or other protection.<sup>2</sup>

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<sup>1</sup> Funding for primate centers, in particular, has been relatively flat for nearly a decade.

<sup>2</sup> The current national need and recommendations for extramural research facilities were detailed in the report of the NIH Working Group on Construction of Research Facilities, available at <http://www.nih.gov/about/director/061901.htm> accessed April 15, 2003.

*(C) What strategies will eliminate barriers to progress and enhance access to research resources and technologies?*

The next several years will be decisive in determining how to build most effectively on the momentum of doubling the NIH budget, and will challenge NCRR and NIH to utilize and leverage available resources most effectively to serve the public health mission.

- NCRR should continue to examine and revitalize the GCRC program, building upon its admirable record of achievement. Efforts should be accelerated to see that GCRC-based research extends to centers of ambulatory care and other venues within academic health networks. NCRR should seek new opportunities to integrate GCRCs with other major research resources, as has been undertaken by the Biomedical Informatics Research Network (BIRN), to use GCRCs as venues for clinical research training and career development, and to incorporate the needs of underserved communities (such as in collaboration with the RCMI<sup>3</sup> program). A more visionary, but we believe attainable, goal would be to integrate GCRCs and the NIH Clinical Center into a national system dedicated to cutting-edge translational research.
- Concerns about the supply of physician-scientists and the conduct of patient-centered clinical research have been voiced for several decades. Recently, partly in response to the Nathan Panel's work and report<sup>4</sup>, NIH has taken several important steps to begin to address these problems, primarily at the level of training and educational loan forgiveness, and has made incremental efforts toward mid-career stabilization. However, remaining to be addressed is the establishment within awardee institutions of a supportive clinical research infrastructure to enable clinical research, comparable to the specialized and core research support facilities that NIH has long promoted to enable basic research. Included among these needs is a program of designated, competitive grants to help "establish" clinician-scientists in their academic research careers.<sup>5</sup> We urge that NCRR as a matter of high priority convene a select extramural committee to evaluate these needs and the status of current programs, and provide recommendations that would enable the Center to address this very important issue.
- The historic doubling of the NIH budget completed this year has been undertaken without a commensurate increase in direct NIH funding for new or renovated extramural research facilities. Facilities and research space remain a significant constraint for new research.<sup>6</sup> Funding for renovation and construction of research facilities in general, and for research

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<sup>3</sup> Research Centers in Minority Institutions.

<sup>4</sup> Report of the NIH Director's Panel on Clinical Research to the Advisory Committee of the NIH Director, NIH, 1997. <http://www.nih.gov/news/crp/97report/index.htm> accessed May 8, 2003.

<sup>5</sup> Even here, NCRR has resourcefully begun to address this concern through the Clinical Research Feasibility Fund (CRFF) supporting pilot projects locally awarded through GCRCs. However, the program's size, \$20,000 per GCRC, cannot alone accomplish necessary systemic change.

<sup>6</sup> See for example, National Science Foundation, Division of Science Resources Statistics, *Scientific and Engineering Research Facilities: 2001*, NSF 02-307, Project Officer, Leslie Christovich (Arlington, VA 2002).

facilities for non-human primates, recombinant rodents, and other animals in particular, should be a priority of the NCRR.

- Related to the point above, academic institutions have assumed the predominant burden for construction of new facilities.<sup>7</sup> We support the recommendation of the NIH Working Group on Research Facilities<sup>8</sup> to create a federal loan guarantee program for new facility construction. Such a program would, with minimal cost to federal partners, improve opportunities for financing new facilities at PHS grantee institutions. Creation of this program requires federal legislation and, of course, could not be accomplished by NCRR or NIH directly.
- Limited access to state-of-art instrumentation, and 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.
- In the important area of bioinformatics and computer technology, NCRR should continue efforts to expand national resources. NCRR has endeavored to develop collaborative funding mechanisms for large projects, such as the Biomedical Informatics Research Network, noted above, and should continue to build on these programs. Despite limited funding for individual research projects, NCRR grants can be leveraged to enable investigators who have passed NIH peer review to approach the private sector for funding with a respected "stamp of approval."
- Additionally, in respect to clinical informatics, NCRR should work closely with the NIH Clinical Center and the GCRCs on the development of a single set of specifications for clinical information systems that academic health centers could adopt, allowing commercial vendors to focus on systems development.<sup>9</sup>
- 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. The goal would be to promote access to resources for NIH-funded and other investigators from across relevant disciplines in a focused research program. A secondary goal would be to reform the "stovepipe" organization that investigators confront in many institutes. Similarly, there may well be more opportunities for coordinated support and use of facilities across

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<sup>7</sup> AAMC data.

<sup>8</sup> NIH working group, *op cit*.

<sup>9</sup> Please see AAMC *Report on Information Technology Enabling Clinical Research*, forthcoming.

federal science agencies (the use of DOE-funded synchrotron radiation facilities to support biological investigations is a model in such regard). Efforts should be made to develop proposals or options to strengthen coordination of investment in merit-reviewed, cross-disciplinary research infrastructure. NCRR and NIH could initiate such efforts, and should also encourage academic institutions to identify opportunities for regional research resources that can be shared among multiple institutions.

- Finally, the administration of biomedical research has become exponentially more complicated, in part due to a progressive increase in obligations to comply with new regulations and guidance (consider, for example, the implementation of the new medical information privacy regulations within academic medical centers). Under current OMB costing policy, the 26% cap on administrative indirect cost recovery means that the burden of such relentless administrative expenses falls squarely upon awardee institutions and siphons away discretionary resources, thereby making it more difficult to respond nimbly to emerging research needs and opportunities. The NIH currently retains authority to support the administration of biomedical research programs at academic institutions—to help seed new programs, provide bridge support, help establish physician-scientists and other new faculty in research, and otherwise assist management of the complex operations of a research program. We urge NCRR to use that authority to make grants that institutions can use to improve research administration, while remaining fully accountable to the NIH and the research community.

Sincerely,

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