Barbara Alving, MD

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Dr. Barbara M. Alving is the acting director of the National Center for Research Resources (NCRR) at the National Institutes of Health (NIH) and the director of the Women's Health Initiative. She also is a professor of medicine at the Uniformed Services University of the Health Sciences in Bethesda, a master in the American College of Physicians, a former member of the Subcommittee on Hematology of the American Board of Internal Medicine, and a previous member of the US Food and Drug Administration's Blood Products Advisory Committee.

Dr. Alving earned her medical degree cum laude from Georgetown University School of Medicine, where she also completed an internship in internal medicine. She completed residency training in internal medicine and a fellowship in hematology at the Johns Hopkins University Hospital. During her career, she attained the rank of colonel in the US Army, serving as the chief of the Department of Hematology and director of the Division of Medicine at the Walter Reed Army Institute of Research. Subsequently, Dr. Alving served as the director of the Medical Oncology/Hematology Section at Washington Hospital Center in Washington, DC. In 1999, Dr. Alving joined the National Heart, Lung, and Blood Institute, where she served as the director of the extramural Division of Blood Diseases and Resources, deputy director of the Institute, and acting director. In March 2005, she was appointed as NCRR's acting director.

NCRR, in coordination with the other Institutes and Centers at the NIH, recently launched an initiative that is designed to transform the way in which clinical and translational research is conducted at academic health centers (AHCs) across the country. As part of the NIH Roadmap, this initiative is intended to advance the academic standing of clinical and translational science as a distinct discipline and to catalyze the development of an academic home for clinical and translational science. Dr. Alving provided details on the initiative in a recent interview.

JIM: What is the "NIH Roadmap for Medical Research," and what are its objectives?

Dr. Alving: Soon after becoming the director of the National Institutes of Health (NIH), in May 2002, Elias A. Zerhouni, MD, convened a series of meetings to chart a "roadmap" for medical research in the twenty-first century. The purpose was to identify major opportunities and gaps in biomedical research, which no single institute at NIH could tackle alone but that the agency as a whole must address, to make the biggest impact on the progress of medical research. The opportunities for discoveries have never been greater, but the complexity of biology remains a daunting challenge. NIH is uniquely positioned to catalyze changes that must be made to transform our new scientific knowledge into tangible benefits for people.

Developed with input from meetings with more than 300 nationally recognized leaders in academia, industry, government, and the public, the NIH Roadmap provides a framework of the priorities NIH as a whole must address in order to optimize its entire research portfolio. It lays out a vision for a more efficient and productive system of medical research. The NIH Roadmap identifies the most compelling opportunities in three main areas: new pathways to discovery, research teams of the future, and reengineering the clinical research enterprise.

JIM: Recently, the National Center for Complementary and Alternative Medicine announced the cancellation of a request for applications (RFA) for regional translational research center (RTRC) planning grants. Could you detail the shifts in focus that led to this cancellation? Does this event presage changes that are more global than the cancellation of a single RFA?

Dr. Alving: The vision behind the RTRC concept was bold, but it relied on collaborations between institutions. Despite the strength of that vision, feedback continued to surface that more attention was needed to first strengthen resources within the individual institutions before pursuing an effort focused primarily on interinstitutional collaborations. We heard from the community that institutions need help to support clinical research.

We, therefore, re-evaluated how best to transform the environment in order to provide enduring support for clinical

research science. To do this required that we ask a fundamental question: How can we integrate the clinical and translational research efforts at institutions in order to reengineer the clinical research enterprise?

We realized that we needed to fully integrate the initial roadmap and other components into one effort to develop a cohesive, comprehensive enterprise. We needed to offer institutions the opportunity to develop a sustainable program to pursue research throughout the full spectrum of laboratory to patient-oriented research.

JIM: What is the most pressing challenge related to reengineering the clinical research enterprise?

Dr. Alving: Clinical research is the linchpin of the nation's biomedical research enterprise. Yet clinical research has become increasingly difficult to conduct, and it has become clear to the scientific community that the United States must recast its entire system of clinical research if such efforts are to remain as successful as they have been in the past.

To accelerate and strengthen the clinical research process, a set of NIH Roadmap initiatives will work toward improving the clinical research enterprise by adopting a systematic infrastructure that will better serve the evolving field of scientific discovery. This effort, which complements the other initiatives that comprise the NIH Roadmap, will provide the necessary foundation for advancing translational and clinical research. Several initiatives are in place to carry forward this goal; at NCRR, we are focusing on an initiative called "Enhancing the Discipline of Clinical and Translational Science."

JIM: In recent presentations, Dr. Zerhouni has outlined a strategy that will seek to reformulate the roles played by the General Clinical Research Centers (GCRCs). Can you speak to the types of shifts that may await the GCRC and the NCRR in the refocusing of resources to address the objectives outlined within the Roadmap?

Dr. Alving: This new initiative will provide an opportunity for qualified institutions to broaden their commitment to clinical research and move clinical research to the next level of research excellence. Academic health centers, including those with GCRCs, will have the opportunity to build on their existing resources and transform into this new integrated program. Over a period of years, GCRCs will have the opportunity to transition into this new broader, more integrated program.

JIM: Could you explain what you mean by "broader" and "more integrated"?

Dr. Alving: The goal is to integrate resources and training in clinical and translational science in a unified institutional environment that allows sustained growth of the discipline and of the emerging clinical and translational workforce. In addition, institutions with the awards will cooperatively address and provide solutions to the national impediments to clinical and translational science. This endeavor will then provide a nurturing environment, locally and nationally, for clinical and translational research, leading to programs similar to a traditional academic department. An institution's program could be housed in a department, center, or institute, depending on local factors. Investigators might hold joint appointments in both the new program and their clinical departments.

JIM: On May 23, you held a meeting to discuss the discipline of clinical and translational science, which more than 300 researchers attended in order to offer suggestions on the implementation of this new initiative. At the meeting, there was a great deal of discussion around the need to define the most appropriate type of "home" for clinical efforts around the country. What has driven this focus?

Dr. Alving: Through dialogue with the clinical research community, NIH has recognized that major shifts in priorities at academic health centers constrain the conduct of clinical research. An exploding demand for clinical services and greatly reduced financial margins have combined to dramatically limit the time clinical scientists have to conduct research and to train the next generation of clinical and translational research scientists. In brief, many of the current problems result from the absence of a true intellectual home for the emerging discipline of clinical and translational science.

NIH also needs to improve its efficiencies to allow for clinical and translational science to flourish at academic institutions.

JIM: What do you anticipate will be the mechanisms that the NIH will use to catalyze a movement to create such clinical research "homes" at AHCs?

Dr. Alving: This new vision will embrace a more systematic, integrated approach to strengthen and accelerate clinical research. Institutions will be provided with the financial resources and flexibility to establish an academic home that will advance the new intellectual discipline of clinical and translational science. This new home will enable these AHCs to create and nurture a robust force of well-trained clinical investigators, as well as to stimulate these institutions to establish or expand degree-granting programs in clinical research. By consolidating, integrating, and strengthening their infrastructure resources, AHCs will be able to synergize clinical research and develop interdisciplinary talent, thereby reducing barriers that impede the transfer of laboratory discoveries into clinical trials. Enhancing and integrating clinical informatics support will further advance the objectives of this new discipline.

The research community continues to be very helpful to this process. We've now reviewed the information gleaned at the May 23 meeting and submitted through the NCRR Web site and are planning to publish details about this new program in the NIH *Guide for Grants and Contracts* in early fall.

We also have a very active Web site devoted to the issues raised at that meeting and the follow-on process: <http://www.ncrr.nih.gov/clinicaldiscipline.asp>.

JIM: Although the NIH recognizes the diversity within the AHCs, what components do you envision will be found within such "homes"? In what areas do you anticipate that differences will persist among the AHCs?

Dr. Alving: To enable this new discipline to develop, we want to create an integrated program that will serve as the institutional focus for clinical and translational science. These awards would likely support research that includes better ways to design clinical studies and trials with respect to protocol development as well as regulatory oversight. Funding would support education, training, and career development, including a clinical and translational science degree-granting program. An effective program would include clinical research informatics and provide data management support. Clini-

cal research resources will include space and personnel for inpatient, outpatient, and community studies and patient recruitment services. Furthermore, these programs would support the core technologies and laboratories required to conduct clinical and translational research.

Flexibility is key to this process. The program must be tailored to the needs and strengths of individual institutions. AHCs will be able to designate the appropriate sizes, locations, and configurations of their programs. They will need sufficient resources to develop needed infrastructure and receive support for local creativity and adaptability.

JIM: How do you anticipate that such changes will affect the role(s) of the nation's GCRCs?

Dr. Alving: Most GCRCs are linked to academic health centers; thus, they would be central components, or "homes," for clinical and translational science. All institutions with GCRCs will be encouraged to apply and compete. This offers these institutions the opportunity to build upon their existing resources and transform into this new integrated program.

JIM: What changes do you anticipate that such shifts will effect on the clinical research landscape in the coming decade?

Dr. Alving: In 6 to 8 years, we believe we will have created a home for clinical and translational science at academic health centers across the nation. Transforming the clinical and translational science into a new academic discipline will provide greater opportunities for institutions to enhance the creation of dedicated promotion and tenure pathways for clinical researchers, strengthen the infrastructure needed for successful clinical and translational research, and advance the nation's health by rapidly and efficiently moving patient observations and basic discovery research into clinical practice.

JIM: Recent shifts in priorities and funding have been projected to decrease the number of K awards that are to be awarded to young investigators who are to be funded by the NCRR. What effects do you anticipate that this will have on the broader GCRC/NCRR initiatives?

Dr. Alving: First, I'd like to emphasize that the clinical research career development awards—or K awards—are critical to our efforts to attract talented medical students, physicians, dentists, and similar professionals to the challenges of clinical research or to help clinical investigators transition to independent research careers. We believe these awards are an essential component of NCRR's mission. In fact, the number of K awards is expected to stabilize so that NCRR will be supporting about 200 awardees, distributed among the K12, K23, and K24 mechanisms.

JIM: Do you have any final comments?

Dr. Alving: The development of this vision requires that the NIH work closely with the community of researchers and the academic health centers that choose to respond to this opportunity. The process will be initiated soon but will take years to develop fully.

As presaged by Dr. Alving's comments in the preceding interview, on October 12, 2005, the National Institutes of Health (NIH) issued two requests for applications as part of its Roadmap initiative. The first, the Institutional Clinical and Translational Science Awards (CTSA) program, is designed to create "academic homes" for investigators engaged in the practice of clinical and translational science. The second request for applications (RFA) offers planning grants to support the preparation by individual institutions for application for future CTSA grant applications.

The CTSA RFA will assist institutions in creating transformative, novel, and integrative academic homes for clinical and translational science that will have the consolidated resources to:

- captivate, advance, and nurture a cadre of well-trained multi-disciplinary and inter-disciplinary investigators and research teams,
- create an incubator for innovative research tools and information technologies, and
- synergize multidisciplinary and interdisciplinary clinical and translational research and researchers to catalyze the application of new knowledge and techniques to clinical practice at the front lines of patient care.

These efforts are designed to create an entirely new discipline of clinical and translational science that fuses and extends the domains of clinical investigation and translational research. The new entities will serve to concentrate basic, translational and clinical investigators, community clinicians, clinical practices, networks, professional societies, and industry. It is anticipated that these academic homes may take any of a variety of distinct forms, such as centers, departments, or institutes. The RFA intentionally provides for such flexibility. The overriding goal of these programs, however, is to harness the NIH Roadmap resources to promote synergy of existing institutional resources, not necessarily to fund the creation of additional facilities.

The NIH anticipates funding 4 to 7 awards as a result of this RFA, but intends to issue additional solicitations in the future. Awards for this RFA will be up to $6 million annually for 5 years for each institution.

Recognizing that not all institutions are positioned to immediately respond to the present CTSA program RFA, the NIH issued an RFA for institutions still in the planning stage for their institutional clinical and translational science programs. The NIH anticipates funding 50 of these one-year planning grants to provide resources to allow institutions to plan for and manage the necessary organizational and cultural changes needed to implement an institutional Clinical and Translational Science Awards program, in preparation for submission of a subsequent CTSA application.

For more information on this announcement see: <http://www.ncrr.nih.gov/clinicaldiscipline.asp>.