IOM Clinical Research Roundtable Workshop
"Creating the Infrastructure to Improve the Public's Health"
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Thank you for inviting me to participate in this Roundtable. I wrestled with issues of clinical research first as President of Stony Brook University (1980-94) and later as Director of Brookhaven National Laboratory (1998-2001). At Stony Brook, my first task was to open a brand new tertiary care university hospital, and integrate it with medical school clinical and basic science departments that were expanding along with the health care mission. At Brookhaven, I became closely involved in the management of some very tricky issues involving research on human subjects and the role and operation of Institutional Review Boards. My perspective on clinical research is from the institutional administration point of view, and it is from this perspective that I may be able to add value to your proceedings.

I am going to tell you about a specific initiative that OSTP is undertaking to improve the management environment for all federally funded research, and particularly research that is interdisciplinary, highly regulated, may involve several institutions, and is conducted by teams of investigators. But first I want to speak generally about how OSTP works, and provide some examples that are responsive to the questions the workshop organizers asked in their instructions to speakers.

Facilitating interagency communication and collaboration

OSTP works through the National Science and Technology Council (NSTC), an umbrella arrangement that sanctions the use of agency personnel to facilitate interagency coordination, communication, and collaboration. An excellent example of interagency coordination is the multi-agency Request for Proposals in which multiple agencies draft the Request, review applications and then divvy up the meritorious proposals for funding by relevance to agency missions. This has been done in the areas of Metabolic Engineering and Environmental Biotechnology under the NSTC Committee on Science Subcommittee on Biotechnology. Through this process, agencies agree on goals and terminology and are able to leverage even small amounts of funding to stimulate an area of science.

A more typical kind of interagency coordination is joint planning, in which the same external advisory panel provides input to strategic planning in multiple agencies. There are several good examples where the research community clearly articulates priorities as an important part of agency planning. One is the Astronomy and Astrophysics "Decadal Survey" produced by the National Research Council. The decadal survey focuses principally on tools and facilities for Astronomy. It is developed through a grass-roots process that takes input from across the community in a number of forms (forums at Astronomical conferences, web-based input, submission of white papers) and winnows them down to the highest priorities for the

coming decade. This survey is used by NASA and NSF Astronomy as a guide in program development, and is recognized by the agencies, OSTP and OMB and Congress as the roadmap for science in this area. Although arduous and time consuming, this process pays off in that research in this area is relatively free from arbitrary actions that often occur in the budget process. This brings us to the next topic.

Structured input into research priorities

An important planning approach advocated by OSTP is the development of agency-level facilities plans and roadmaps such as the Department of Energy's recent 20-year facilities plan, or the NIH Roadmap. OSTP tends to support agency projects developed within such high level strategic plans. In the DOE example, the Office of Science asked its external advisory panels to produce a list of the most important facilities for their programs looking over the next two decades. The Director of the Office of Science then used this input to fashion a prioritized list of facilities for this time frame.

Recently the National Academy of Sciences was asked to look at the priority setting mechanisms for large facilities at NSF. Known as the "Brinkman Report," the Academy described a way of prioritizing scientific facilities across the entire NSF through a bottoms-up, community-based approach. This report is a good source for ideas about structured input on research priorities, which brings us to the next topic.

All agencies have advisory committees that bring in public members who express views on research priorities and make recommendations that are reflected in agency budget proposals to the Office of Management and Budget. OSTP works with OMB at multiple levels, all the way up to the Director's review, to formulate the President's budget request to Congress.

Structured output of research results

Most "structured" output from federally sponsored research is in the form of peer-reviewed scientific publications. For clinical research, this is not an ideal form. Unfortunately, such publications are the coin of the realm in research universities, and efforts to change them tend to encounter obstacles at the institutional level. Some of the same cultural biases regarding appropriate research outputs may exist in the peer review process for evaluating clinical grant proposals. I am not sure what the cure is, but one symptom that needs to be addressed is the relatively lower impact of clinical research papers on clinical practice compared with the impact of basic science research papers on the course of scientific research. This is an important issue.

Agencies can certainly encourage "use of research" either by directly requiring it in the grant agreements, by establishing grant programs specifically for "use" activities, or by less direct means. NIH, the Agency for Healthcare Quality Research, the Centers for Disease Control and Prevention and the Department of Veterans Affairs all have a responsibility to transfer knowledge across the health research and health care spectrum -- to identify bottlenecks and address them effectively.

The Research Business Models Subcommittee

OSTP is interested in identifying things the agencies can do to make it easier for investigators to carry out their work. Last year we established an interagency committee under the NSTC umbrella to discover and begin to promulgate best practices for agencies to accommodate their operations to the changing environment in which research is conducted. Called the Research Business Models Subcommittee, this group has solicited input through the Federal Register, conducted hearings across the country, and crystallized findings into a number of actions that would appear to be feasible in a budget neutral way. We suspect these actions will have a favorable budget impact on the investigators and their institutions, and foster behaviors compatible with the opportunities in today's research environment. Some of these behaviors would be consistent with the aims of this Roundtable. Certainly barriers such as terminology that makes it difficult to compare clinical research results, or inconsistent requirements for adverse event reporting across the health care agencies do not need to exist. It is not surprising that agencies that have developed systems for accountability, for research review and funding, or for setting priorities do it differently. But if we want to maximize the utility of research dollars and attack the complexities of human biology in a multidisciplinary research setting, the agencies are going to have to learn to talk to each other in the same language. We hope the RBM will assist in reaching this goal.

The Research Business Models Subcommittee was established in 2003 as a standing subcommittee of the NSTC's Committee on Science. It addresses policy implications arising from the changing nature of scientific research, and to examine the effects of these changes on business models for the conduct of federally sponsored research. Members include representatives from fifteen Federal departments and agencies that support or are engaged in research activities. The Co-Chairs are Dr. Norka Ruiz-Bravo, Deputy Director for Extramural Research, NIH and Dr. Rodney Brown, Deputy Under Secretary for Research, Education, and Economics, USDA.

Here is a brief history of activities conducted by the RBM Subcommittee:

Request for Information: A Federal Register notice on August 6, 2003 requested comment on ten areas. During the following two months approximately 50 comments were received and posted to the RBM website (http://rbm.nih.gov/)

Regional Workshops: Workshops were held during the last three months of 2003 at Berkeley (aligning funding mechanisms with scientific opportunities), Minnesota (common practices among agencies), North Carolina (costs and accountability issues), and Washington, D.C. (general issues). Approximately 350 faculty and institutional administrators attended the four meetings with about 200 in attendance at the Washington meeting.

RBM Subcommittee Retreat: The RBM Subcommittee and Working Groups members met in January to review and prioritize approximately 45 topics or issues excerpted from both the written and oral public comments. The members selected ten high-priority topics which addressed about 20 of the original 45. The ten topics reflect a good balance among the three Working Groups (Science, Common Practices, and Accountability). The remaining topics may be reexamined at a later date once the initial priorities have been addressed.

Committee on Science: The ten initiatives were presented to the Committee on Science on February 9 which endorsed the ten initiatives with the understanding that the Subcommittee will prepare more detailed implementation-oriented recommendations by early fall. These activities are being closely coordinated with other groups that may already be working on the issues, such as those working on PL106-107, or the Federal Demonstration Partnership. For example, the Education and Workforce Subcommittee of the Committee on Science is taking the lead on the issue on graduate student and postdoctoral support.

Current Status: The 45 topics identified during the hearing process fall into three major categories: Facilitating Collaborative Multidisciplinary Research**;** Improving Consistency of Agency Practice**;** Harmonizing Stewardship and Accountability

Ten Initiatives: Here is a very brief description of the ten initiatives as Endorsed by the Committee on Science:

Facilitating Collaborative Multidisciplinary Research

- **FS-1** Acknowledgement of CO-PIs in proposals and agency information systems
  - Recognize two or more equal scientific collaborators as peer investigators

- **FS-2** Stability and predictability of support for research facilities and instrumentation independent of individual projects. Initial focus is on instrumentation.
  - Address instruments in range of $100K-$4-5M? To be defined.
  - Provide mechanisms for purchase and technical support not tied directly to individual projects

- **FS-3** Support for graduate and postdoctoral students with regard to salary, stipends, tuition, benefits, etc.
  - Provide more consistent <u>forms</u> of support across agencies
  - Allow institutions more flexibility in addressing the status of graduate students, fellows, trainees, and research assistants within the institution

- **FS-4** Collaboration between universities, federal laboratories, and industry
  - Develop templates and model agreements to address collaboration within Federal labs, especially on issues pertaining to access, security, rights in data, publication, etc.

(Some action has occurred on this initiative: The Department of Energy issued a revision to its standard research subcontract on April 7 that should simplify relations with universities.)

Improving Consistency of Agency Practice

- **CP-1** Standard progress and financial reporting procedures.
  - Develop a standard progress report format, for example, progress or scientific “nuggets”
  - Develop standard electronic submission through Grants.gov

- **CP-2** Broader use of the Federal Demonstration Partnership (FDP) model sub-agreement templates
  - Extend use of current FDP templates to all non-FDP institutions

–Streamline and facilitate collaboration among institutions

•**CP-3** Consistent award notices format and terms and conditions
–Facilitates compliance among currently diverse agency formats and eventual electronic exchange thru Grants.gov

Harmonizing Stewardship and Accountability

•**SA-1** A-133 monitoring requirements for A-133 compliant institutions.
–Streamline process for institutions to review other institutions audit findings.
–Longer term solution is to review the current requirement for major research institutions to review and monitor other A-133 "prime" institutions' audit findings

•**SA-2** Consistent Federal-wide policies for Research Conflict of Interest
–Resolve differences between NIH and NSF policies and encourage implementation among others
–Addresses public concern about ad hoc treatment when cases arise relating to agencies that currently don't have policies

•**SA-3** Consistent Federal-wide policies for Research Misconduct
–Implement OSTP policy

What will happen next:

The RBM Subcommittee will submit a status report to the NSTC Committee on Science in July, and we expect detailed recommendations in mid-September. One possible product might be a "guidebook" or "toolkit" for scientific collaboration. Despite everyone's desire for uniformity of practice, "One size fits all" policies are rarely warranted. The idea of a guidebook has been suggested to communicate principles, best practices, case studies, and potential unintended consequences. The audience for such a product would be agency and institutional staff.

OSTP will take the RMB recommendations to the appropriate policy and agency personnel, and define paths forward to achieve implementation as appropriate for each topic.

Clinical research is a good example of a federally funded activity that can benefit from improved management practice at the institutional and agency level. I look forward to working with the clinical community to create a productive working environment that brings new discoveries rapidly into practice where they are most needed.

Thank you for inviting me to participate in this workshop. I would be glad to answer your questions.