Notes from briefing by NIH Acting Director Raynard Kington,
Wednesday, February 18, 2009 at AAAS Auditorium.

No handouts.

Dr. Kingston hosted a briefing for the health care and biomedical research community on the funding provided in the American Recovery and Reinvestment Act (HR1), popularly called the “stimulus bill.” The statutory and conference report language that is relevant to the NIH funding follows these notes.

Dr. Kingston said he would brief on the funding in the stimulus bill in the “broadest possible terms” because NIH is still formulating its plans to obligate the funding. He would provide no specifics.

There are two criteria for the spending (1) the short-term economic impact of the funding and (2) the long-term investment of the funding. The NIH provides support for some 3,000 institutions around the country.

There is a total of $8.4 billion available under the ARRA which will remain available for expenditure through the end of FY 2010. It is two year money. NIH is working to develop a range of options getting the money out the door and is consulting with the Administration and Congress.

A total of $8.2 billion is available for research projects. Of that total $7.4 billion is to be distributed to Institutes and Centers proportionate to their stake in the budget. Some funding will go from the Office of the Director to the Common Fund.

The Office of the Director will retain $800 million for a range of scientific efforts with no formula for allocation other than it will be based on scientific priorities. An additional $1 billion will go to the National Center for Research Resources (NCRR) for extramural construction. An additional $300 million will be used by NCRR for acquisition of shared instrumentation and other scientific equipment. A total of $500 million will go to facilities on the NIH campus for repair and construction.

Finally, the Agency for Healthcare Research and Quality will pass $400 million in funding it is scheduled to receive under the ARRA on to NIH for comparative health effectiveness research. (See below.)

Dr. Kington said NIH intends to move as “quickly and wisely” as it can. He stressed that these are not the “usual dollars” NIH receives for biomedical and behavioral research. It is money that is intended for “stimulus.” There will be an unprecedented level of reporting above the usual NIH reporting requirements with a focus on the number of jobs created and preserved. This is not “business as usual.” There will be a real focus on transparency and impact, especially impact on local economies. He hopes NIH will be able to show the downstream impact of this research funding. NIH will have a “fair degree of flexibility” in obligating the funding.
He is giving a broad explanation today because NIH is in the early stages of planning with no specifics or details available. NIH will have to prioritize the research agenda. He divided the funding into three “buckets.”

**Bucket 1:** The primary mechanism for this bucket will be the R01 (Research Project Grants) and related research mechanisms for meritorious research. Approximately 14,000 such grants have been reviewed and approved. These grants will serve as a starting point. Funding will be for two years rather than the usual four years. Funding will not be done in a “formulaic way.” This funding will not be used for “restoring cuts” in research grants.

There may be some new R01s added. Expectations are that (a) funding will be for two years, (2) research will make advanced, and (c) no commitments for out-year funding.

**Bucket 2:** Some of the funding will be used to supplement existing grants to expand research related to the original goal of a proposal. Some of these supplements will be awarded competitively. Some supplements will be awarded administratively. There might be supplements for themes such as training slots and equipment.

**Bucket 3:** A new program -- the NIH Challenge Grant program. These will be awarded in areas identified by institutes and centers for cross-cutting research. Grants will be $500,000 a year for two years in scientific and public health areas. There will be a new RFA (Request for Applications) with a shortened application process but with peer review.

Dr. Kington emphasized that the peer review process will inform NIH’s decision-making. He said they were thinking in the range of $100 million to $200 million for the Challenge Grants but also said this would be a floor amount.

NIH is setting up the process of setting priorities. NIH will be sensitive to geographic distribution of the grants because this is supposed to be “stimulative” of the whole nation’s economy. He said, again, “this is not business as usual.” This is not a “formulaic process.” This is not “restoring cuts.” We need to start the process quickly.

He asked everyone to express appreciation to Congress and the Administration.

**Questions from the audience:**

**Construction:** On the subject of construction, he said that the language in the bill is controlling as far as new construction versus existing construction. The bill says renovation, improvements and construction and Dr. Kingston said NIH has the authority to implement all three. NIH will have to develop a new solicitation. NCRR will work with the community and the centers to set priorities, but it will include new construction.
** He discussed comparative effectiveness research. NIH already does work with AHRQ and the Office of the Secretary in this field. This will be an iterative process.

** Operations of facilities are the responsibility of the institutions.

** There are no plans for a set aside for HBCUs or smaller institutions though there may be supplements for existing programs.

** The issue of geographic distribution is not new. NIH will not compromise standards of science in addressing this issue.

** Kington stressed, again, there will be no restorations of cuts in already awarded grants. This process is “starting from now,” not looking back at what was cut in the past. Don’t even think about recouping cuts. “This is not going to be done in a formulaic way.”

** SBIR: the bill does not require an SBIR/STTR set aside. Some institutes and centers might chose to do SBIRs but this is probably not a priority.

** Clinical and Translational Research: We’re going to rack results, but there has been no explicit decisions about clinical and translational research versus basic research. He understands that clinical and translational research doesn’t lend itself to a two-year research grant. He mentioned clinical trials specifically

Look at the two year clock. Certain types of programs cannot get the money "out the door" in two years.

Take advantage of existing grant applications. Noted that NIH doesn’t have an existing program for buildings and renovations.

** When can we expect an announcement of what’s going to be done? “Soon.” Probably will have solicitation by May, but still need to develop. There will be themes within the agency and themes within institutes and centers.

** Doesn’t think there will be a specific formula for HIV/AIDS research because it’s not mentioned in the bill, but HIV/AIDS research proposals will be welcome.

** Cannot make out year commitments with ARRA package of funding.

** They understand fellows are looking for jobs. Mentioned Pathways for Independence. Maybe the program will have something for post-docs, fellows and new investigators.

** In answer to a question about revisions in the peer review system, he acknowledged that peer review system is undergoing changes. They’re trying to improve the system, but will use the system in place.
** The Common Fund was reauthorized in 2006. NIH will follow the outlines of that legislation.

** Renewals of grants may be eligible for funding under the stimulus bill. This is a possibility, but they haven’t made decisions yet.

More details to come. Stressed that the clock is ticking and this money is designed to be used in two years. You must be able to make a compelling case for completing projects in two years. If you don’t think you can obligate and expend the funding in two years, don’t apply.

---

**From House Report 116-16, the conference to accompany the American Recovery and Reinvestment Act:**

National Institutes of Health

The conference agreement provides $10,000,000,000 for the National Institutes of Health (NIH) as proposed by the Senate instead of $3,500,000,000 as proposed by the House. The components of this total are as follows:

National Center for Research Resources

The conference agreement includes $1,300,000,000 for the National Center for Research Resources (NCRR) instead of $1,500,000,000 as proposed by the House and $300,000,000 as proposed by the Senate. Bill language identifies $1,000,000,000 of this total for competitive awards for the construction and renovation of extramural research facilities. The conference agreement also provides $300,000,000 for the acquisition of shared instrumentation and other capital research equipment. The conference agreement includes bill language proposed by the House for extramural facilities relating to waiver of non-Federal match requirements, primate centers, and limitation on the term of Federal interest. The conference agreement includes language proposed by the House mandating several reporting requirements on the use of the funds. The conferees expect that NCRR will give priority to those applications that are expected to generate demonstrable energy-saving or beneficial environmental effects.

Office of the Director

(Including Transfer of Funds)

The conference agreement provides $8,200,000,000 for the Office of the Director instead of $1,500,000,000 as proposed by the House and $9,200,000,000 as proposed by the Senate. Of this amount, $7,400,000,000 is designated for transfer to Institutes and Centers and to the Common Fund instead of $7,850,000,000 as proposed by the Senate. The conference agreement adopts the Senate guidance that, to the extent possible, the $800,000,000 retained in the Office of the Director shall be used for purposes that can be completed within two years; priority shall be placed on short-term grants that focus on specific scientific challenges, new research that expands the scope of ongoing projects, and research on public and international health priorities. Bill language is included to permit the Director of NIH to use $400,000,000 of the funds provided in this account for the flexible research authority authorized in section 215 of Division G of P.L. 110-161. The funds available to NIH can be used to enhance central research support activities, such as equipment for the clinical center or intramural activities, centralized information support systems, and other related activities as determined by the Director. The conferees intend that NIH take advantage of scientific opportunities using any funding mechanisms and authorities at the agency's disposal that maximize scientific and health benefit. The conferees include bill language indicating that the funds provided in this Act to NIH are not subject to Small Business Innovation Research and Small Business Technology Transfer set-aside requirements.
The conference agreement provides $500,000,000 for Buildings and Facilities as proposed by the House and the Senate. Bill language permits funding to be used for construction as well as renovation, as proposed by the Senate. The House language permitted only renovation. These funds are to be used to construct, improve, and repair NIH buildings and facilities, including projects identified in the Master Plan for Building 10.

**Buildings and Facilities**

The conference agreement provides $500,000,000 for Buildings and Facilities as proposed by the House and the Senate. Bill language permits funding to be used for construction as well as renovation, as proposed by the Senate. The House language permitted only renovation. These funds are to be used to construct, improve, and repair NIH buildings and facilities, including projects identified in the Master Plan for Building 10.

**Agency for Healthcare Research and Quality**

Healthcare Research and Quality

(Including Transfer of Funds)

The conference agreement includes $1,100,000,000 for comparative effectiveness research, which is the same level as proposed by both the House and the Senate. The conference agreement uses the term, ``comparative effectiveness research'', as proposed by the House and deletes without prejudice the term ``clinical'', which was included by the Senate. Within the total, $300,000,000 shall be administered by the Agency for Healthcare Research and Quality (AHRQ), $400,000,000 shall be transferred to the National Institutes of Health (NIH), and $400,000,000 shall be allocated at the discretion of the Secretary of Health and Human Services.

The conferees do not intend for the comparative effectiveness research funding included in the conference agreement to be used to mandate coverage, reimbursement, or other policies for any public or private payer. The funding in the conference agreement shall be used to conduct or support research to evaluate and compare the clinical outcomes, effectiveness, risk, and benefits of two or more medical treatments and services that address a particular medical condition. Further, the conferees recognize that a "one-size-fits-all" approach to patient treatment is not the most medically appropriate solution to treating various conditions and include language to ensure that subpopulations are considered when research is conducted or supported with the funds provided in the conference agreement.

**Statutory language from ARRA (HR 1/Public Law 111-XX):**

National Institutes of Health

National Center for Research Resources

For an additional amount for "National Center for Research Resources", $1,300,000,000, of which $1,000,000,000 shall be for grants or contracts under section 481A of the Public Health Service Act to construct, renovate or repair existing non-Federal research facilities: Provided, That sections 481A(c)(1)(B)(ii), paragraphs (1), (3), and (4) of section 481A(e), and section 481B of such Act shall not apply to the use of such funds: Provided further, That the references to "20 years" in subsections (c)(1)(B)(i) and (f) of section 481A of such Act are deemed to be references to "10 years" for purposes of using such funds: Provided further, That the National Center for Research Resources may also use $300,000,000 to provide, under the authority of section 301 and title IV of such Act, shared instrumentation and other capital research equipment to recipients of grants and contracts under section 481A of such Act and other appropriate entities: Provided further, That the Director of the Center shall provide to the Committees on Appropriations of the House of Representatives and the Senate an annual report indicating the number of institutions receiving awards of a grant or contract under section 481A of such Act, the proposed use of the funding, the average award size, a list of grant or contract recipients, and the amount of each award.

Office of the Director
For an additional amount for `Office of the Director', $8,200,000,000: Provided, That $7,400,000,000 shall be transferred to the Institutes and Centers of the National Institutes of Health (``NIH'') and to the Common Fund established under section 402A(c)(1) of the Public Health Service Act in proportion to the appropriations otherwise made to such Institutes, Centers, and Common Fund for fiscal year 2009: Provided further, That these funds shall be used to support additional scientific research and shall be merged with and be available for the same purposes as the appropriation or fund to which transferred: Provided further, That this transfer authority is in addition to any other transfer authority available to the NIH: Provided further, That none of these funds may be transferred to `National Institutes of Health--Buildings and Facilities', the Center for Scientific Review, the Center for Information Technology, the Clinical Center, or the Global Fund for HIV/AIDS, Tuberculosis and Malaria: Provided further, That the funds provided in this Act to the NIH shall not be subject to the provisions of 15 U.S.C. 638(f)(1) and 15 U.S.C. 638(n)(1): Provided further, That $400,000,000 may be used to carry out section 215 of division G of Public Law 110-161.

Buildings and Facilities

For an additional amount for `Buildings and Facilities', $500,000,000, to fund high-priority repair, construction and improvement projects for National Institutes of Health facilities on the Bethesda, Maryland campus and other agency locations.

Agency For Healthcare Research and Quality
Healthcare Research and Quality

(Including Transfer of Funds)

For an additional amount for `Healthcare Research and Quality' to carry out titles III and IX of the Public Health Service Act, part A of title XI of the Social Security Act, and section 1013 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, $700,000,000 for comparative effectiveness research: Provided, That of the amount appropriated in this paragraph, $400,000,000 shall be transferred to the Office of the Director of the National Institutes of Health (``Office of the Director'') to conduct or support comparative effectiveness research under section 301 and title IV of the Public Health Service Act: Provided further, That funds transferred to the Office of the Director may be transferred to the Institutes and Centers of the National Institutes of Health and to the Common Fund established under section 402A(c)(1) of the Public Health Service Act: Provided further, That this transfer authority is in addition to any other transfer authority available to the National Institutes of Health: Provided further, That within the amount available in this paragraph for the Agency for Healthcare Research and Quality, not more than 1 percent shall be made available for additional full-time equivalents. In addition, $400,000,000 shall be available for comparative effectiveness research to be allocated at the discretion of the Secretary of Health and Human Services (``Secretary''): Provided, That the funding appropriated in this paragraph shall be used to accelerate the development and dissemination of research assessing the comparative effectiveness of health care treatments and strategies, through efforts that: (1) conduct, support, or synthesize research that compares the clinical outcomes, effectiveness, and appropriateness of items, services, and procedures that are used to prevent, diagnose, or treat diseases, disorders, and other health conditions; and (2) encourage the development and use of clinical registries, clinical data networks, and other forms of electronic health data that can be used to generate or obtain outcomes data: Provided further, That the Secretary shall enter into a contract with the Institute of Medicine, for which no more than $1,500,000 shall be made available from funds provided in this paragraph, to produce and submit a report to the Congress and the Secretary by not later than June 30, 2009, that includes recommendations on the national priorities for comparative effectiveness research to be conducted or supported with the funds provided in this paragraph and that considers input from stakeholders: Provided further, That the Secretary shall consider any recommendations of the Federal Coordinating Council for Comparative Effectiveness Research established by section 804 of this Act and any recommendations included in the Institute of Medicine report pursuant to the preceding proviso in designating activities to receive funds provided in this paragraph and may make grants and contracts with appropriate entities, which may include agencies within the Department of Health and Human Services and other governmental agencies, as well as private sector
entities, that have demonstrated experience and capacity to achieve the goals of comparative effectiveness research: Provided further, That the Secretary shall publish information on grants and contracts awarded with the funds provided under this heading within a reasonable time of the obligation of funds for such grants and contracts and shall disseminate research findings from such grants and contracts to clinicians, patients, and the general public, as appropriate: Provided further, That, to the extent feasible, the Secretary shall ensure that the recipients of the funds provided by this paragraph offer an opportunity for public comment on the research: Provided further, That research conducted with funds appropriated under this paragraph shall be consistent with Departmental policies relating to the inclusion of women and minorities in research: Provided further, That the Secretary shall provide the Committees on Appropriations of the House of Representatives and the Senate, the Committee on Energy and Commerce and the Committee on Ways and Means of the House of Representatives, and the Committee on Health, Education, Labor, and Pensions and the Committee on Finance of the Senate with an annual report on the research conducted or supported through the funds provided under this heading: Provided further, That the Secretary, jointly with the Directors of the Agency for Healthcare Research and Quality and the National Institutes of Health, shall provide the Committees on Appropriations of the House of Representatives and the Senate a fiscal year 2009 operating plan for the funds appropriated under this heading to making any Federal obligations of such funds in fiscal year 2009, but not later than July 30, 2009, and a fiscal year 2010 operating plan for such funds prior to making any Federal obligations of such funds in fiscal year 2010, but not later than November 1, 2009, that detail the type of research being conducted or supported, including the priority conditions addressed; and specify the allocation of resources within the Department of Health and Human Services: Provided further, That the Secretary, jointly with the Directors of the Agency for Healthcare Research and Quality and the National Institutes of Health, shall provide to the Committees on Appropriations of the House of Representatives and the Senate a report on the actual obligations, expenditures, and unobligated balances for each activity funded under this heading not later than November 1, 2009, and every 6 months thereafter as long as funding provided under this heading is available for obligation or expenditure.