

National Institutes of Health Bethesda, Maryland 20892

Advisory Committee to the Director (ACD) Teleconference Meeting Summary American Recovery and Reinvestment Act NIH Implementation Plans April 16, 2009

Dr. Raynard S. Kington, Acting Director of the National Institutes of Health (NIH), thanked the advisory committee for their participation in the teleconference and provided some background regarding the NIH's role in creation of the economic stimulus package. During numerous discussions with the Congress, it became clear that stimulus dollars are intended to be used to support biomedical research in ways that the NIH would not normally do. The American Recovery and Reinvestment Act (ARRA) funds will carry unprecedented oversight as funding agencies and recipients need to justify initiatives and report outcomes and advances with greater frequency and a high level of scrutiny.

The NIH is very appreciative to the President and to the Congress for their trust in the NIH as a steward of medical and behavioral research for the Nation. The NIH understands that ARRA funds are intended to:

- Create or save jobs
- Re-infuse the biomedical career pipeline
- Stimulate and accelerate biomedical research and discovery
- Meet these objectives within the time that ARRA funds are made available.

It is hoped that this rapid influx of funds from the entire stimulus package will jumpstart the economy and reverse current economic trends.

Dr. Lawrence A. Tabak, Acting Deputy Director of NIH, outlined current NIH implementation plans using ARRA funds. The majority of the \$10.4 billion will fund extramural scientific research, with the National Center for Research Resources receiving \$1.3 billion to fund extramural repair, improvement and construction projects, and scientific equipment purchases.

NIH is taking a two-pronged approach to distributing ARRA funds by:

- 1) Stimulating and accelerating biomedical research with existing mechanisms, including funding of meritorious grant applications that have already been peer reviewed, approved by IC Councils, and have projects which can be completed within 2 years.
- 2) Expanding science with new programs, such as Challenge Grants, Grand Opportunities ("GO") Grants, and the New Faculty Recruitment awards, to enhance research capacity, and a Summer Jobs program for students and teachers to work in science labs.

Additional IC-specific and Common Fund ARRA proposals and programs are also under development.

The NIH also received an additional \$400 million of the \$1.1 billion appropriated for Comparative Effectiveness Research (CER) under ARRA. A CER Federal Coordinating Committee has been developed, and an NIH CER Coordinating Committee will provide advice to the NIH Director on the best use of the CER stimulus funds, implementation of CER rules and definitions, etc. It is anticipated that CER funds will be used to support meritorious CER-specific Challenge Grant and GO Grant submissions. ACD members were encouraged to visit the NIH Recovery Act Website, http://www.nih.gov/recovery, as new ARRA postings are announced frequently.

Ms. Colleen Barros, NIH Deputy Director for Management, provided an overview of risk management considerations associated with ARRA. The Office of Management and Budget (OMB) has issued guidance associated with the Recovery Act to ensure that Federal agencies meet objectives including awarding funds in a prompt, fair and reasonable manner; reporting of funds in a transparent, accurate, and timely manner; avoiding fraud, waste, error and abuse; and achieving and reporting of program goals and outcomes. To meet these objectives, risk management activities will be put in place at all levels of the agency and will touch on all areas of NIH grant accountability.

For NIH funding recipients, special terms and conditions will be attached to every ARRA award and additional reporting requirements will be in place, including documentation of jobs created and retained. The Department of Health and Human Services Office of Inspector General will conduct audits of NIH programs and activities funded by ARRA and the NIH internal process.

ACD members thanked the NIH for developing a broad implementation plan of existing and newly-developed programs for use of ARRA funds. Specific questions and comments focused on:

- Management of the Influx of Applications: Challenge Grants have generated tremendous interest, and the NIH plans on using a modified editorial board model for review of these applications.
- Public Accountability: The NIH should highlight specific examples to give the public a sense of what ARRA funds have bought. It is hoped that academic institutions also publicize the impact that this funding has on their local communities.
- Applicant Pool: There was concern for what will happen with the applicant pool in 2 years, after ARRA funds have been exhausted. Under any scenario, stimulus funds will lead to future applications as funding stimulates and, hopefully, accelerates research discovery. There will be an impact, but the NIH has tried to be careful in not creating large future commitments.
- Flexibility in Institutional Review Board (IRB) Approval: Members asked if there would also be some flexibility regarding the just-in-time window of 3 days for IRB approval.
 Dr. Kington responded that the NIH would explore this issue.

- Distribution of ARRA Funds: The NIH will follow its usual procedures of funding based on scientific merit, research opportunities and priorities. However, ARRA funding decisions will also include the NIH being mindful of funding decisions impacting geographic regions, basic versus clinical research, investigator-initiated versus targeted research, and grants versus contracts. The NIH has some flexibility in decision-making to try to balance the portfolio and recognizes that ARRA funds are intended to stimulate the economy.
- Comparative Effectiveness Research: As an evolving discipline, care needs to be taken
 in how CER is defined as too broad or narrow a definition could have significant impact
 on the types of research supported.
- Bioethics: The NIH recently began efforts to provide support for bioethics, recognizing
 the important niche of this discipline in current biomedical research and discovery. The
 Recovery Act presented a unique opportunity to accelerate research in this field.

Teleconference Participants

ACD Members:

Mary Beckerle
Colleen Conway-Welch
Catherine DeAngelis
Maria Freire
Karen Holbrook
Thomas Kelly
Mary-Claire King
Beatriz Luna
John Nelson
James Thrall
Barbara Wolfe
Keith Yamamoto

NIH Staff:

Raynard Kington Lawrence Tabak Colleen Barros John Burklow

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I hereby certify that, to the best of my knowledge, the foregoing minutes are accurate and complete.

Lawrence A. Tabak, D.D.S., Ph.D. Executive Director, Advisory Committee to the Director Acting Deputy Director, NIH

Raynard S. Kington, M.D., Ph.D. Chairman, Advisory Committee to the Director Acting Director, NIH