Translational Research
NIH Submits NCATS Budget and Program Plans to Congress

At its May 11 hearing (see previous page), Senate LHHS Appropriations Subcommittee members also asked Dr. Collins about a plan and budget amendment regarding the proposed National Center for Advancing Translational Sciences (NCATS)—the centralized translational research entity that was officially recommended for implementation by the NIH’s Scientific Management Review Board (SMRB) at its December 8, 2010, meeting. Due to timing, an NCATS budget line item was not included in the administration’s FY2012 budget proposal. Dr. Collins, who spoke with great enthusiasm for NCATS as a means by which to advance the discipline of translational research, responded that NIH would shortly provide program and budget details to ensure that NCATS was initially funded in the FY2012 budget process, rather than waiting for FY2013.

On June 6, Secretary Sebelius wrote to Congressional appropriators about plans to establish NCATS and abolish the National Center for Research Resources (NCRR), moving many of its programs into NCATS and various I/Cs. She requested that these changes be incorporated as the Appropriations Committee proceeds with its FY2012 funding bill, since DHHS intends to implement them within the President’s proposed budget. She attached a table that details the impact of the I/C-specific organizational and budgetary realignment, proposing an NCATS line item of $721.6 million, the majority of which reflects $479.7 million from the Clinical and Translational Science Awards (CTSA) program moved over from the NCRR. Other major NCATS components include the Cures Acceleration Network (CAN), proposed to be funded at $100 million in FY2012 (CAN was not previously funded in FY2011 since it was authorized during the appropriations process), the Therapeutics for Rare and Neglected Diseases (TRND) Program, and the Office of Rare Disease Research.

On June 15, House LHHS Appropriations Subcommittee Chair Denny Rehberg (R-MT) wrote to Secretary Sebelius expressing several concerns about the NCATS proposal, including how abolishing the NCRR may impact management of the CTSA and Institutional Development Award (IDeA) programs. Chairman Rehberg also noted that his office had not yet received a formal budget amendment from the President, especially if NCATS is to be implemented in FY2012, nor answers to questions posed at the March 11 Subcommittee hearing. He also expressed concern that NIH has already taken steps to start searching for an NCATS director in advance of resolution of these issues. At press time, NAEVR understands that DHHS plans to respond. NIH has sought input on the NCATS proposal through its Feedback NIH.gov Web site.

Visit the NIH/NEI funding section of NAEVR’s Web site at www.eyeresearch.org for full details

NEI and FDA Hold Endpoints Symposium

On May 6 on the NIH Campus, the NEI and the Food and Drug Administration (FDA) jointly held the fifth in the series of joint Endpoint Symposia, which are managed by ARVO. Entitled Use of Functional Visual Endpoints in Visual Prosthesis Product Development, the meeting addressed how functional vision-related endpoints for clinical trials of visual prostheses will be analyzed and correlated with objective measures of visual acuity, visual fields, and contrast sensitivity. The FDA currently has draft guidance for industry and FDA staff entitled Investigational Device Exemption (IDE) Guidance for Retinal Prostheses.

Previous joint symposia, which bring together regulators, researchers, and industry representatives, have focused on research into Age-related Macular Degeneration (AMD), Glaucoma, and Diabetic Retinopathy, as well as Patient Reported Outcomes. The symposia grew out of NAEVR-initiated meetings between NEI and FDA and exemplify NEI’s leadership in facilitating the translation of its basic research—an NIH priority.

Dr. Collins Comments on NCATS

As recently as the June 28 NIH Council of Councils meeting, at which the vision community was represented by Mae Gordon, Ph.D. (Washington University School of Medicine), Dr. Collins described the potential transformative power of NCATS. In a July 6 commentary published in the journal Science Translational Medicine and posted on the Director’s section of the NIH Web site, Dr. Collins described the goals and functions of NCATS as it strives to reengineer the process of developing drugs, diagnostics, and devices. NCATS will seek to generate innovative methods and technologies that will enhance the development, testing, and implementation of diagnostics and therapeutics across a wide range of human diseases and conditions with the goal of significantly shortening what currently takes about 15 years from molecular discovery to new therapy.