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{ REPORT
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MILITARY CONSTRUCTION AND VETERANS
AFFAIRS AND RELATED AGENCIES APPROPRIATIONS ACT, 2012

CONFERENCE REPORT

TO ACCOMPANY

H.R. 2055



DECEMBER 15, 2011.—Ordered to be printed

The Office of the Director (OD) shall ensure, as practicable, the programs and offices within OD receive increases proportional to the overall increase, unless otherwise specified. The conferees request quarterly notification on obligations from the NIH Director's Discretionary Fund to the Committees on Appropriations of the House of Representatives and the Senate.

The conferees expect NIH to continue the long-standing policy for Common Fund projects to be short-term, high-impact awards, with no projects receiving funding for more than 10 years. The conferees recognize that certain investigator-initiated programs such as Pioneer Awards may be exceptions to the 10-year limit. Any other proposed exceptions should be explained in the fiscal year 2013 congressional budget justification.

The conference agreement includes language to eliminate the National Center for Research Resources (NCRR) and create the National Center for Advancing Translational Sciences (NCATS).

NCATS will study steps in the therapeutics development and implementation process, consult with experts in academia and the biotechnology and pharmaceutical industries to identify bottlenecks in the processes that are amenable to re-engineering, and develop new technologies and innovative methods for streamlining the processes. In order to evaluate these innovations and new approaches, NCATS will undertake targeted therapeutics development and implementation projects. In all of these efforts, the conferees expect that NCATS will complement, not compete with, the efforts of the private sector.

While the conferees welcome the creation of NCATS, they were disappointed by the way the administration requested it. The President's proposed budget for fiscal year 2012 included a vague description of NCATS but did not formally request funding for the restructuring or provide any details about which components of NIH would be consolidated into the new Center. The failure to do so caused unnecessary uncertainty about the proposal and contributed to the impression that it was being rushed. The conferees are also aware of concerns that the NIH process for evaluating the merits of the NCATS reorganization did not comply with the NIH Reform Act of 2006 with respect to the role of the Scientific Management Review Board (SMRB).

Lessons learned with NCATS should guide NIH as it considers another proposed restructuring, one that would involve consolidating NIDA, NIAAA and components of other Institutes and Centers (ICs) into a new Institute devoted to research on substance use, abuse and addiction. The conferees understand that NIH plans to adopt a more deliberate approach in evaluating the need for this Institute. The conferees strongly recommend that this approach should include full consideration by the SMRB and that if the administration ultimately decides to seek such a restructuring, it should provide sufficient details in a formal budget request to Congress.

The following table provides the specific funding levels for the institutes and centers and displays the comparable adjustments related to the reorganization.

(Dollars in thousands)	FY 2011 Enacted*	Reallocation of resources	FY 2011 Reorganization comparable	FY 2012 Enacted
National Cancer Institute (NCI)	\$5,058,577	- 4,163	\$5,054,414	\$5,081,788
Therapeutics for Rare and Neglected Disease (TRND)		- 4,163		
National Heart, Lung, and Blood Institute (NHLBI)	3,069,723	- 1,489	3,068,234	3,084,851
Clinical Research Resources		+995		
Biotechnology Research Resources		+29		
Research Management & Support		+14		
TRND		- 2,527		
National Institute of Dental & Craniofacial Research (NIDCR)	409,608	- 337	409,271	411,488
TRND		- 337 0		
Nat. Inst. of Diabetes & Digestive & Kidney Diseases (NIDDK)	1,792,224	- 1,476	1,790,748	1,800,447
TRND		- 1,476		
National Institute of Neurological Disorders and Stroke (NINDS)	1,622,003	- 1,335	1,620,668	1,629,445
TRND		- 1,335		
National Institute of Allergy and Infectious Diseases (NIAID)	4,478,668	- 3,689	4,474,979	4,499,215
TRND		- 3,689		
National Institute of General Medical Sciences (NIGMS)	2,033,782	+338,010	2,371,792	2,434,637
Institutional Development Awards (IDeA)		+226,480		
Biotechnology Research Resources		+97,114		
Research Infrastructure		+8,853		
Research Management & Support		+7,237		
TRND		- 1,674		
Nat. Inst. of Child Health and Human Development (NICHD)	1,317,854	- 1,085	1,316,769	1,323,900
TRND		- 1,085		
National Eye Institute (NEI)	700,828	- 577	700,251	704,043
TRND		- 577		
National Institute of Environmental Health Sciences (NIEHS)	683,724	- 555	683,169	686,869
TRND		- 555		
National Institute on Aging (NIA)	1,100,481	- 906	1,099,575	1,105,530
TRND		- 906		
Nat. Inst. Arthritis & Musculoskeletal & Skin Diseases (NIAMS)	534,349	- 440	533,909	536,801
TRND		- 440		
Nat. Inst. on Deafness & Other Communication Dis- orders (NIDCD)	415,155	- 341	414,814	417,061
TRND		- 341		
National Institute of Mental Health (NIMH)	1,476,294	- 1,215	1,475,079	1,483,068
TRND		- 1,215		
National Institute on Drug Abuse (NIDA)	1,050,542	- 865	1,049,677	1,055,362
TRND		- 865		
National Institute on Alcohol Abuse and Alcoholism (NIAAA)	458,286	- 377	457,909	460,389
TRND		- 377		
National Institute of Nursing Research (NINR)	144,381	- 119	144,262	145,043
TRND		- 119		
National Human Genome Research Institute (NHGRI) ..	511,497	- 421	511,076	513,844
TRND		- 421		
National Institute of Biomedical Imaging and Bio- engineering (NIBIB)	313,802	+23,370	337,172	338,998
Biotechnology Research Resources		+22,977		
Research Management & Support		+651		
TRND		- 258		
National Institute on Minority Health and Health Dis- parities (NIMHD)	209,714	+65,757	275,471	276,963
Research Centers in Minority Institutions		+58,686		
Biotechnology Research Resources		+1,784		
Research Infrastructure		+2,578		
Research Management & Support		+2,882		

(Dollars in thousands)	FY 2011 Enacted*	Reallocation of resources	FY 2011 Reorganization comparable	FY 2012 Enacted
TRND		- 173		
National Center for Research Resources (NCRR)	1,257,754	- 1,257,754	0	0
National Center for Complementary and Alternative Medicine (NCCAM)	127,713	- 105	127,608	128,299
TRND		- 105		0
John E. Fogarty International Center (FIC)	69,436	- 58	69,378	69,754
TRND		- 58		0
National Library of Medicine (NLM)	336,733	- 277	336,456	338,278
TRND		- 277		0
Office of the Director (OD)	1,166,963	+287,042	1,454,005	1,461,880
Comparative Medicine (incl. Nat'l Primate Res. Centers)		+194,921		
Shared & High-end Instrumentation		+64,114		
Clinical Research Resources		+769		
Biotechnology Research Resources		+8,505		
Research Infrastructure		+6,655		
Research Management & Support		+9,594		
Science Education Partnership Award		+18,480		
Clinical Research Resources		+534		
Biotechnology Research Resources		+552		
Research Management & Support		+716		
Office of Rare Diseases Research		- 17,798		
National Center for Advancing Translational Sciences (NCATS)	0	+563,405	563,405	576,456
Clinical & Translational Science Awards (CTSAs)		+457,700		
Clinical Research Resources		+27,879		
Biotechnology Research Resources		+18,633		
Research Management & Support		+16,316		
NCBI/PA		+1,079		
TRND		+24,000		
Office of Rare Diseases Research		+17,798		
Cures Acceleration Network (CAN)		0		

Note: The FY 2011 enacted level does not include transfers.

Cures Acceleration Network (CAN).—The conferees provide NCATS with up to \$10,000,000 to support the CAN Board and related activities. The conferees expect a high bar for any use of waiver authority for CAN grant matching funds; any use should be extremely limited to maximize funds towards the CAN goals. The conferees encourage the CAN Board to create general principles and measurable outcomes to track success. The conferees request NCATS to charter an Institute of Medicine (IOM) work group to review, evaluate, and identify issues related to the CAN authority and provide a report for use by the CAN Board to help it identify ways to accelerate and expand the number of cures. The report should include a survey and inventory of activities at NIH, FDA, AHRQ, CDC, the Patent and Trademark Office (PTO), and in the private sector that relate to the CAN program. The conferees urge IOM to include balanced participation by the entities listed above as well as the representatives of the pharmaceutical and biotechnology industry and the biotech venture capital community. The report should address patent authority, marketability, use of high-throughput analysis, regulatory timelines, and cost structure issues related to the purpose of CAN.

Accelerating Commercialization of Therapies to Patients.—The conferees understand the need to develop models to assist research universities and institutes on the best ways to leverage and commercialize federally supported basic and applied biomedical re-

search discoveries. This is a key reason why the conferees have agreed to create NCATS. The conferees note the market has started to develop public-private sector models that are beginning to show results in translating basic research far more quickly than traditional models. These types of models use pre-defined technology-licensing terms to rapidly license new products and build a core of options for commercialization partnerships with pharmaceutical and biotechnology companies to establish joint ventures to further advance products to the market. The conferees strongly urge NIH to study and foster these models.

The conferees expect any NIH-supported partnerships to expand translational pharmaceutical development in a manner that does not inhibit creative market models. Top priorities of the Center should include developing tools to improve the “de-risking” process and advancing the drug development process to the point at which it can reasonably be expected to be picked up by the private sector. The conferees suggest the selection of Center projects should consider future market acceptance as one component of the criteria to evaluate and select potential Center projects. The conferees direct NIH to host a trans-NIH workshop with key research organizations, venture capitalists, pharmaceutical firms, the PTO, the FDA, and a sample of research universities and institutes to work together with NIH and the drug development market. The workshop should also consider how existing NIH and government mechanisms can be used to encourage models around the country to speed commercialization of therapies through a market-based approach.

Clinical and Translational Science Awards (CTSAs).—The conferees are encouraged by the success of the CTSA consortium and recommend the program receive full funding as it nears full implementation. The conferees expect the NCATS Director to ensure the current focus on the full spectrum of translational research is maintained, and CTSA resources are not diverted. The inclusion of patient-centered research, community engagement, training, dissemination science, and behavioral research is extremely important to the translation and application of basic science discoveries and success of the CTSAs. CTSAs now represent an investment of half a decade of innovation in translational research. To ensure the benefits of this investment are maintained, the conferees urge NIH to support a study by the IOM that would evaluate the CTSA program and recommend whether changes to the current mission are needed. The review should include stakeholders’ input and be available no later than 18 months after the enactment of this bill.

Therapeutics for Rare and Neglected Disease (TRND) Program.—The conferees continue support for TRND at a level of \$24,000,000 within NCATS. The conferees urge NIH to provide an annual report on the TRND program that identifies the number of projects started each year, cost per project, and the outcome of each project. The first report should be provided to the Committees on Appropriations by July 1, 2012.

Institutional Development Awards.—The conferees provide \$276,480,000 to increase support for the Institutional Development Awards (IDeA) program. The conferees recognize the importance of the Centers of Biomedical Research Excellence (COBRE) and the