

Report of Trans-NIH Research Conducted in Fiscal Year 2016

Report to Congress

National Institutes of Health
Department of Health and Human Services

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I. Introduction

Section 402A(c)(2)(B) of the Public Health Service Act (PHS Act) (42 U.S.C. 282a(c)(2)(B)), added to the PHS Act in Section 103(a) of the National Institutes of Health (NIH) Reform Act of 2006, requires that the Secretary of Health and Human Services submit to Congress an annual report identifying the percentage of funds made available by each research institute and center with respect to conducting or supporting research that involves collaboration between the institute or center (IC) and one or more other national research institutes or national centers. This annual report provides the dollar amounts made available by each IC in fiscal year (FY) 2016 for conducting or supporting research that involves collaboration between that IC and one or more other ICs. In addition, the U.S. House of Representatives Report 109-687 accompanying the NIH Reform Act of 2006 recognizes that there may be collaborative work between ICs that may not be fully demonstrated in budgetary data, such as planning meetings and conferences and exchanging day-to-day information between programs. Accordingly, this report references examples of activities that fall under these categories.

II. Overview of Collaborations within the NIH

The NIH is composed of 27 ICs, each having a distinct mission. Leaders across the NIH recognize that scientific progress often comes at the interface of traditional boundaries. Therefore, there is considerable trans-NIH collaborative activity across IC boundaries at every level of NIH operations. Trans-NIH collaborative activities can be found in all disease areas and across basic, translational, and clinical research. These collaborations can be formal or informal and can involve sharing materials, specimens, or scientific expertise. Collaborations take place at any or all stages of a research project or program, including:

- 1) development of a concept, initiative, or plan;
- 2) funding;
- 3) conduct of the research in intramural laboratories;
- 4) management and administration of the project; and
- 5) assessment of results.

Although some collaborations are the product of highly visible joint activities, such as the NIH Common Fund programs and the NIH Blueprint for Neuroscience Research, the vast majority of collaborative activities takes place day-to-day in the office and in the laboratory. This report includes the activities of 24 of the 27 ICs. For reasons discussed below, the Clinical Center, the Center for Information Technology, and the Center for Scientific Review are not part of this report.

Trans-NIH collaborations represent unique opportunities to build on the scientific expertise, sophisticated technologies, infrastructure, and knowledge base of individual Institutes and Centers and to apply this wealth of information to addressing diseases and complex health conditions. These collaborations provide multi-disciplinary and multi-faceted approaches to critical scientific questions and lead to special initiatives and innovative programs for the

discovery, development, and testing of strategies to diagnose, prevent, and treat a wide range of health conditions. Multi-Institute and Center collaborations also permit the leveraging of crucial resources to ensure precious research dollars are used effectively and efficiently in improving the public health of all Americans.

III. Scope of the Report

Inclusions:

For the purposes of this report, a trans-NIH research collaboration is defined as a formally documented, science-based effort that includes two or more ICs. Within this defined cohort, two types of extramural collaborations are included in the budget figures presented in this report: 1) grants and contracts that are co-funded by two or more ICs, and 2) grants and contracts funded in response to collaborative Funding Opportunity Announcements (FOAs) developed and announced by two or more ICs. FOAs of this type include Requests for Applications, Requests for Proposals, and Program Announcements. A qualifying feature of these extramural collaborative FOAs is the formal participation by multiple ICs at the outset of the activity in developing and issuing the FOA.

The NIH intramural program is also highly collaborative. In addition to collaborating on research, NIH intramural programs also jointly fund specific shared resources (e.g., imaging technologies and instrumentation) to minimize duplicative equipment and to conserve costs. Eligible intramural collaborative research projects are included within the “Total Collaborative Activities” column in Table 1.

A relatively new model of collaboration for several intramural programs is the National Center for Advancing Translational Sciences (NCATS). NCATS, established in December 2011, focuses on addressing challenges associated with translating observations in the laboratory, clinic, and community, into interventions that improve the health of individuals and the public. To accomplish its broad mission, every NCATS program fosters collaborations, partnerships, and team science. Some of these programs do not fit neatly within the definitions of this report as typical intramural research collaborations or sharing of resources, but programs such as the Therapeutics for Rare and Neglected Diseases, Bridging Interventional Development Gaps, and Molecular Libraries are recognized as qualifying for budgetary reporting in this report. These programs match NCATS’ uncommon intramural scientific expertise and technology resources with NIH IC-supported extramural investigators or NIH IC intramural investigators to advance the scientific goals of a project. The unique technological and operational support from NCATS includes a new generation of pharmacological tools, establishment of partnership agreements, regulatory support, and access to contract services. As a result, successful applicants – both intramural and extramural – to these programs benefit from NCATS’ efforts to improve diagnostics and therapeutics development, and make translational science more efficient, less expensive, and less risky. In this way, NCATS complements the work of the private sector and the other NIH ICs. These collaborations are not necessarily co-funded by other ICs and do not involve the exchange of funds; rather, they operate by “in-kind” contribution of unique resources in scientific collaboration and have a formal process for project selection, entry, and progress reporting.

Trans-NIH collaborations reflected in Table 1 provide crucial support for projects and programs in a wide-range of scientific disciplines of biomedical, behavioral, and social science research; clinical trials evaluating strategies to prevent and treat diseases; observational cohort studies involving individuals with infectious or chronic diseases; and training programs designed to mentor the next cadre of basic and clinical biomedical researchers. Multi-IC funding of FOAs also permits leveraging of resources so that additional highly meritorious grants and projects can be supported and critical science is advanced.

In addition to the collaborations reflected in Table 1, there are many informal collaborative activities resulting in multi-IC sponsored workshops, research priority setting task forces, scientific working groups, topic focused scientific interest groups, and guidelines panels. These collaborations do not involve the exchange of funds; rather, they operate by “in-kind” contribution of unique resources in scientific collaboration and provide formal processes for information sharing on new initiatives, scientific advances, and identifying future directions to advance NIH research programs.

Exclusions:

“Parent Announcements” are excluded as collaborative FOAs. These FOAs are general announcements of guidelines for grant mechanisms (e.g., R01 grants) and do not address scientific areas. Therefore, they are outside the scope of the collaborative FOAs included in this report. However, ICs that provide shared resources for grants funded under Parent Announcements, i.e., they are co-funded, are included in this report.

This report also excludes collaborative activities initiated and/or led through or funded by offices within the Office of the Director (OD), such as the Division of Program Coordination, Planning, and Strategic Initiatives (DPCPSI). This is consistent with this report’s definition of a trans-NIH collaboration and with NIH’s interpretation of the legislative language. Trans-NIH collaborations are central to the missions of all DPCPSI offices, and their efforts are critical to the synergy of inter-IC collaborations of all types. The six DPCPSI offices are as follows:

- The Office of Strategic Coordination oversees collaborative efforts across the NIH to plan, implement, and manage the programs funded via the NIH Common Fund. These programs are not included because they are the subject of a separate report, the Common Fund Strategic Planning Report. All NIH ICs participate in these programs, and some ICs have contributed additional funds from their own appropriations. The IC funds are represented in this report, but the dollars appropriated to the Common Fund within the OD appropriation are not.
- The Office of Behavioral and Social Sciences Research (a) leads the development of priorities for increasing the scope of and support for behavioral and social science research and training at the NIH; (b) coordinates research in the behavioral and social sciences across the 27 ICs; (c) develops and facilitates new initiatives in partnership with the ICs; (d) provides leadership in disseminating findings from behavioral and social sciences research and communicating the importance of such research in the acquisition, treatment, and prevention of disease and disability; and (e) advises key NIH officials on matters relating to behavioral and social science research.

- The Office of Research Infrastructure Programs (ORIP) is composed of the Division of Comparative Medicine, the Division of Construction and Instruments, and the Office of Science Education/Science Education Partnership Awards. The ORIP (a) provides support for resource activities and research to identify, develop, characterize, and improve animal models and biological materials for the study of human disease; (b) provides high-quality, disease-free animal models and biological materials and specialized animal research facilities for biomedical investigators; (c) supports the development and access to a wide range of research models; (d) supports research activities at National Primate Research Centers and other resources; (e) supports training and career development for veterinarians; (f) provides repositories for the storage and distribution of genetically altered animal models; (g) supports the breeding of and accessibility to animals for biomedical research; (h) supports grants for the acquisition of state-of-the-art instrumentation; (i) supports grants to modernize animal research facilities or construct new biomedical research facilities; (j) assists institutions in complying with the regulations and policies related to care and use of laboratory animals by supporting purchases of equipment for animal research facilities; and (k) collaborates in pre-college science education, workforce diversity, and community health outreach activities at the NIH.
- The Office of Research on Women's Health (a) advises the NIH Director and staff on matters relating to research on women's health; (b) serves as the focal point at the NIH for women's health research and the study of the influence of sex/gender factors in health; (c) promotes, stimulates, and supports efforts to improve the health of women through biomedical and behavioral research that account for the roles of sex and gender in health and disease; (d) ensures that women are appropriately included in clinical studies supported by the NIH; and (e) develops opportunities for the recruitment, retention, re-entry, and advancement of women in biomedical careers and advancement of careers for men and women in women's health research.
- The Office of Disease Prevention (ODP) (a) works to improve the health of the public by increasing the scope, quality, dissemination, and impact of prevention research supported by the NIH; (b) collaborates with the NIH Institutes and Centers as well as other federal agencies, academic institutions, the private sector, non-governmental organizations, and international organizations in formulating prevention research initiatives; and (c) provides scientific leadership and oversight for the continued implementation of the NIH/Food and Drug Administration Tobacco Regulatory Science Program, which addresses priority areas of the Family Smoking Prevention and Tobacco Control Act, including the manufacture, distribution, and marketing of tobacco products. The ODP includes the Office of Dietary Supplements (ODS) as an administrative unit within the organization. The ODS mission focuses on strengthening the knowledge and understanding of dietary supplements by evaluating scientific information, stimulating and supporting research, disseminating research results, and educating the public to foster an enhanced quality of life and health for U.S. populations.
- The Office of AIDS Research (OAR) serves as a unique model of trans-NIH coordination, planning, and management, overseeing all NIH AIDS-related research.

Utilizing its legislative authorities, OAR has established comprehensive trans-NIH planning, portfolio analysis, and budgeting processes to identify the highest priority areas of scientific opportunity, enhance collaboration, minimize duplication, and ensure that research dollars are invested effectively within the highest priorities of AIDS research. The OAR (a) coordinates the scientific, budgetary, legislative, and policy elements of the AIDS research portfolio; (b) develops an annual Strategic Plan and an annual trans-NIH AIDS research budget based on the Strategic Plan; (c) leads trans-NIH Coordination Committees to plan research and share information across each of the specific scientific areas of AIDS research; (d) tracks and monitors all trans-NIH AIDS research expenditures; (e) sponsors reviews or evaluations of research program areas; (f) convenes the Office of AIDS Research Advisory Council and its associated working groups; (g) facilitates international AIDS research and training; (h) identifies specific funding for emerging scientific opportunities and public health challenges that require focused attention; (i) manages and facilitates multi-Institute and trans-Institute activities to address those needs; (j) fosters research and collaboration by designating funds and supplements to ICs to jump-start or pilot program areas; and (k) sponsors scientific agenda setting workshops to identify new cutting-edge initiatives.

The budget figures in Table 1 exclude collaborative efforts coordinated through the NIH Clinical Center because the Clinical Center's budget is funded through a mandatory contribution of a standard percentage of the ICs' intramural budgets. However, it is important to note that the Clinical Center coordinates a broad range of trans-NIH activities, including the highly successful Bench-to-Bedside awards program. In FY 2016, this program was supported by five NIH Offices, in addition to voluntary contributions from two ICs. The Bench-to-Bedside awards program was established to speed translation of promising laboratory discoveries into new medical treatments by encouraging collaborations among basic scientists and clinical investigators. Since the Bench-to-Bedside awards program began over 18 years ago, 238 collaborative projects have received funding, representing partnerships among multiple ICs, and since 2006, extramural NIH grantees can be included as collaborators on awards. Additionally, the Clinical Center is "opening its doors" to the extramural community through an extramural grant mechanism that partners an extramural principal investigator with an investigator in the NIH intramural program who must use the Clinical Center and its resources for at least a portion of its activities outlined in the grant with the goal of conducting collaborative research projects aligned with the NIH mission and its efforts to enhance the translation of basic biological discoveries into clinical applications that improve health. In the first three cycles of this new grant program, *Opportunities for Collaborative Research at the Clinical Center*, 25 awards have been made. Award decisions for the fourth cycle are pending and should be announced in FY 2017. Grant applications for the fifth cycle are due in April 2017.

Other trans-NIH activities are coordinated through centers of excellence established within the Clinical Center to integrate a number of scientific areas or services within the NIH community. The Center for Neuroscience and Regenerative Medicine (CNRM) focuses on the discovery of methods to better intervene and prevent the long-term consequences of traumatic brain injury. The CNRM is a collaboration between the NIH and the Uniformed Services University of the Health Sciences. The goal is discovering new diagnostic tools (especially using imaging at the NIH) and treatment paradigms for both military and civilian brain trauma victims. The Center

for Interventional Oncology, a collaboration involving the Clinical Center and the National Cancer Institute, offers new and expanded opportunities to investigate cancer therapies that use imaging technology to diagnose and treat localized cancers in ways that are precisely targeted and minimally invasive. The Center for Infectious Disease Imaging is a collaborative program that seeks to use advanced anatomic, functional, and molecular imaging methods to identify and assess the manifestations and progression of infectious disease. The Imaging Sciences Training Program provides trainees with a background in state-of-the-art methodology in imaging technology while working collaboratively in a variety of research disciplines between the Clinical Center and various ICs. In addition, the Clinical Center coordinates the development and maintenance of the Biomedical Translational Research Information System (BTRIS), a repository of clinical research data from the Clinical Center's multiple electronic clinical systems and from multiple other ICs. BTRIS serves as a trans-NIH resource that supports intramural access to identified and de-identified data from 1976 to the present for answering research questions.

Another example of a substantial collaborative activity that is not reported in the budget data of Table 1 involves NCATS' Clinical and Translational Science Awards program (CTSA). As NCATS' largest grants program, the CTSA's support a national network of clinical and translational research centers that serve as research hubs by providing expertise, resources, and training with the intent of leveraging these resources by all of the NIH ICs. NCATS fully funds the program of more than 50 centers, thus providing a foundation for NIH ICs to actively encourage their investigators to utilize the infrastructure through formal IC funding announcements and notices.

This report also excludes the following: 1) collaborative efforts coordinated through the Center for Information Technology, whose mission is to provide, coordinate, and manage information technology and to advance computational science; 2) IC mandatory contributions to the development and maintenance of shared databases developed by the National Library of Medicine; 3) the Center for Scientific Review, which has a wholly collaborative mission as the portal for NIH grant applications and their review for scientific merit; 4) activities involving NIH collaboration with other agencies within HHS (these types of activities are included in the Report on NIH Collaborations with Other HHS Agencies); 5) collaborations between individual ICs and private sector partners; 6) awards made using reimbursable dollars; and 7) the Special Statutory Funding Program for Type 1 Diabetes Research and the Superfund Program, which are collaborative efforts by design but not included in Table 1.

IV. Percentage of Funds Made Available in Fiscal Year 2016 by Each National Research Institute or Center for Conducting Trans-NIH Research

Table 1 presents the percentage of FY 2016 funds made available by each research IC for conducting trans-NIH research. The IC dollar amounts presented in this table represent the sum of collaborative activities in three areas: extramural grants, extramural contracts, and intramural research projects. Intramural collaborations are identified through the NIH Intramural Database (NIDB) available at <http://intramural.nih.gov/index.tml>. As with extramural projects, reporting on intramural projects is limited to formal collaborations between two or more ICs. In each case, the total FY 2016 budget for a collaborative intramural research project is credited wholly to the lead IC because the NIDB does not identify effort or budget from individual ICs.

Examples of collaborative activities across ICs that are not fully demonstrated in budgetary data include committees, working groups, and task forces; conferences, workshops, and meetings; and educational campaigns and clearinghouses. The list, available at <http://dpcpsi.nih.gov/collaboration>, illustrates the range of collaborative extramural and intramural activities but is not intended to be exhaustive.

V. Conclusion

The NIH has a strong commitment to collaborative research among the ICs, as evidenced by joint efforts at all levels. Although many inter-IC collaborative activities are typically not as visible as Common Fund and other high-profile trans-NIH collaborations, Table 1 illustrates that a substantial percentage of the ICs' budgets supports collaborative activities. Because many categories of collaborations are excluded from this report, the obligations presented in Table 1 represent significant underestimates of the actual level of trans-NIH collaborative commitments.

Table 1: IC Collaborative Activity Financial Summary – FY 2016**Dollars in Thousands**TOTAL
2016

Funding IC	Total IC Actual Obligations*	Total Collaborative Activities	Percent for Collaborative Activities
FIC	\$ 69,996	\$ 39,228	56.0%
NCATS	\$ 681,366	\$ 64,849	9.5%
NCCIH	\$ 128,615	\$ 41,373	32.2%
NCI	\$ 5,071,412	\$ 745,811	14.7%
NEI	\$ 696,704	\$ 68,442	9.8%
NHGRI	\$ 497,964	\$ 214,507	43.1%
NHLBI	\$ 3,081,083	\$ 388,404	12.6%
NIA	\$ 1,585,858	\$ 238,546	15.0%
NIAAA	\$ 459,745	\$ 82,079	17.9%
NIAID	\$ 4,722,653	\$ 693,905	14.7%
NIAMS	\$ 533,245	\$ 70,335	13.2%
NIBIB	\$ 341,258	\$ 87,843	25.7%
NICHHD	\$ 1,312,044	\$ 340,658	26.0%
NIDA	\$ 1,040,022	\$ 187,175	18.0%
NIDCD	\$ 417,141	\$ 46,547	11.2%
NIDCR	\$ 403,647	\$ 62,802	15.6%
NIDDK	\$ 1,938,718	\$ 293,770	15.2%
NIEHS	\$ 672,113	\$ 83,301	12.4%
NIGMS	\$ 1,728,715	\$ 130,506	7.5%
NIMH	\$ 1,493,169	\$ 333,041	22.3%
NIMHD	\$ 279,333	\$ 36,403	13.0%
NINDS	\$ 1,670,356	\$ 315,612	18.9%
NINR	\$ 144,508	\$ 29,346	20.3%
NLM	\$ 395,074	\$ 23,303	5.9%
TOTAL**	\$ 29,364,739	\$ 4,617,864	15.7%

* Total IC Actual Obligations exclude certain categories of obligations described in the report text.

**Numbers may not add due to rounding.

An acronym list of NIH ICs can be found at http://grants.nih.gov/grants/acronym_list.htm.