National Cancer Institute

Orientation

for the Clinical Trials and Translational Research Advisory Committee (CTAC)

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Foreword

Please accept my sincerest congratulations on your appointment to the Clinical Trials and Translational Research Advisory Committee (CTAC). As noted in the Committee's charter, the CTAC is governed by the provisions of the Federal Advisory Committee Act, which sets forth standards for the formation and use of advisory committees. The National Cancer Institute (NCI) is honored that you have joined this oversight committee that has been constituted to advise the NCI on the national clinical and translational research enterprises.

Since its inception in 2007, the CTAC has been an invaluable resource to the NCI's efforts to implement the Clinical Trials Working Group's recommendations spearheaded by the NCI Coordinating Center for Clinical Trials. In all that we do, the NCI is committed, first and foremost, to cancer patients and those who care for them. Thank you for assisting in this important mission.

The primary task of the CTAC is to provide advice to the NCI Director, NCI Deputy Directors, and the Director of each NCI Division within the NCI-supported national clinical trial enterprise. The goal is to build an infrastructure that will foster the development of the best scientific clinical trials by bringing together a broadly developed and engaged coalition of stakeholders involved in the clinical trials process.

We are pleased to provide you with this CTAC Orientation Book that has been prepared to provide new members of the CTAC with an overview of the mission, history, and activities of the National Institutes of Health and the National Cancer Institute. I hope you will find it helpful as you fulfill your responsibilities as a member of the CTAC and look forward to working with you in the years ahead.

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Clinical Trials and Translational Research Advisory Committee

Description

The Clinical Trials and Translational Research Advisory Committee (CTAC) provides broad scientific and programmatic advice on the investment of taxpayer dollars in clinical trials and supportive science. In addition, the Committee makes recommendations regarding the effectiveness of NCI's translational research management and administration program, including needs and opportunities across disease sites, patient populations, translational developmental pathways, and the range of molecular mechanisms responsible for cancer development. The Committee advises on the appropriate magnitude for dedicated translational research priorities and recommends allocation of translational research operations across organizational units, programs, disease sites, populations, developmental pathways, and molecular mechanisms. The Committee ensures that appropriate emphasis is placed on rare cancers, medically underserved populations, and historically lower resourced pathways to clinical goals. The goal is to foster an open, collaborative system involving all the critical stakeholders in the prioritization process, bringing diverse institutions and individuals together into an integrated and efficient, but innovative and responsive effort, thus moving therapies to patients.

The Committee is chaired by the NCI Director or a designee appointed by the NCI Director. Members include leading authorities in clinical trials and translational research. The Director of the Coordinating Center for Clinical Trials (CCCT) serves as the Executive Secretary for the CTAC; the CCCT staff facilitates operations.

Membership

The Committee is composed of 25 voting members (see **Appendix A**) who are appointed by the NCI Director. As specified in the CTAC charter (see **Appendix B**), at least five members hold concurrent membership on either the National Cancer Advisory Board (NCAB), Board of Scientific Advisors (BSA), Board of Scientific Counselors (BSC), or Director's Consumer Liaison Group (DCLG). Members are authorities knowledgeable in the fields of community oncology; surgical oncology; medical oncology; radiation oncology; patient advocacy; extramural clinical investigation; regulatory agencies; the pharmaceutical industry; public health; clinical trials design, management, and evaluation; drug development and developmental therapeutics; cancer education; cancer information services; community outreach; vaccine development; cellular oncology; molecular oncology; pediatric oncology; clinical, basic, and translational research; cancer center administration; cancer biology and diagnosis; cancer epidemiology; chemotherapy; community outreach; oncology health care provision; pharmacology; pathology; biostatistics; quality of life; pain management; cancer treatment and restorative care; and education of health professionals. Members and the Chair are invited to serve for terms up to 4 years.

Ex officio members include the following officials or their designees:

- NCI Deputy Directors
- Director, Division of Extramural Activities (DEA), NCI
- Director, Division of Cancer Treatment and Diagnosis, (DCTD), NCI
- An intramural scientist engaged in clinical research
- Representatives from the Food and Drug Administration (FDA), Centers for Medicare and Medicaid Services (CMS), Department of Defense (DOD), and Department of Veterans Affairs (VA).

CTAC Members' Roles and Responsibilities

Roles and responsibilities of the CTAC include:

- Overseeing implementation of the Clinical Trials Working Group (CTWG) and Translational Research Working Group (TRWG) recommendations and initiatives, including evaluation systems
- Providing strategic advice regarding NCI's entire clinical trials and translational research portfolios
- Advising NCI on policies, procedures, processes, and tools that should be developed and implemented for prioritization, management, coordination, and administration of NCI-funded clinical trials and translational research
- Advising the NCI Director on the status of NCI clinical trials and translational research projects

across all Divisions, Offices, and Centers, and making recommendations for needed improvements

- Providing a forum for the clinical trials and translational research communities to give advice directly to the NCI Director.

CTAC Subcommittees and Working Groups

To facilitate the CTAC's work, subcommittees, ad hoc or standing, as well as working groups may be established to provide additional advice and oversight on specific topics or initiatives.

Working groups may be formed to provide in-depth analysis and recommendations for discussion and approval by the full CTAC. These working groups are usually convened for a defined purpose and disbanded when their purpose has been achieved.

CTAC Meetings

The Committee meets three times each year, usually in March, July, and November. CTAC meetings are open to the public and are announced in the *Federal Register*, http://www.gpoaccess.gov/fr/index.html. In the event that a meeting or a portion of a meeting is closed to the public, a notice will be published in the *Federal Register*. The Committee is governed by provisions in the Federal Advisory Committee Act (FACA; see **Appendix C**), which provides guidance as to when meetings/discussions can and cannot be closed to the public. Additional information related to the charge of the Committee and its meetings can be found at http://deainfo.nci.nih.gov/advisory/ctac/ctac.htm.

Conflict of Interest Policies and Ethics Rules for Special Government Employees Serving on Advisory Committees

As a Special Government Employees (SGE), each CTAC member is covered by the Executive Branch's conflict of interest policies and ethics rules in a somewhat less restrictive manner than full time Government employees. Detailed ethics rules that govern the conduct of SGEs are provided in **Appendix D**.

Clinical and Translational Research Operations Committee

As part of its clinical trials and translational research restructuring efforts, NCI formed the internal Clinical and Translational Research Operations Committee (CTROC). The Committee membership includes representatives from each of NCI's Divisions/Offices/Centers that support clinical trials and translational research.

CTROC's primary goals are to provide oversight of NCI's clinical trials and translational research portfolio, including related information technology programs; advise the NCI Director on the conduct of all clinical trials funded and/or conducted by the Institute; develop a defined NCI organizational structure to coordinate and manage the entire clinical trials enterprise supported by NCI; and monitor progress, review, and prioritize efforts to implement the recommendations of Working Groups, such as the CTWG

Coordinating Center for Clinical Trials

Background

The Coordinating Center for Clinical Trials (CCCT) was established in 2006 as a new office within the NCI Office of the Director. The creation of CCCT was prompted by the 2005 National Cancer Advisory Board (NCAB) Clinical Trials Working Group (CTWG) report, which called for the development of a coordinated organizational structure within the NCI to manage the entire clinical trials enterprise supported by the Institute. Responsibilities were expanded to include oversight of the TRWG recommendations in 2007.

CCCT Mission and Activities

CCCT's overarching goal is to coordinate and strengthen the execution of NCI's clinical trials and translational research enterprises. These are cooperative endeavors that draw upon the strongest components of the Institute's clinical research system and scientific infrastructure, and the constant engagement of critical stakeholders. Specifically, CCCT oversees and supports implementation of the 22 initiatives recommended by the CTWG and the 15 initiatives recommended by the TRWG. This is achieved through continuing dialogue with NCI leadership

and scientific staff, clinicians, researchers, advocates, policymakers, industry, and foundations in order to enhance the effectiveness of our nation's cancer clinical research enterprise.

CCCT, in conjunction with all NCI Divisions, Offices, and Centers, facilitates collaborations that expedite translational and clinical cancer research by:

- Supporting the implementation of the CTWG and TRWG recommendations
- Facilitating prioritization of the NCI's most important clinical trials by Scientific Steering Committees (SSCs) working with NCI clinical programs, such as those in the Division of Cancer Treatment and Diagnosis (DCTD), the Division of Cancer Prevention (DCP), and the Center for Cancer Research (CCR).
- Partnering with the NCI's Center for Biomedical Informatics and Information Technology (CBIIT) to establish the Clinical Trials Reporting Program (CTRP), a comprehensive database with up-to-date information on all NCI-funded clinical trials
- Managing the NCI Clinical and Translational Research Operations Committee (CTROC) and the CTAC, which advise NCI leadership on translational science and clinical trials.

History

The National Cancer Advisory Board (NCAB) established the Clinical Trials Working Group (CTWG) in 2004 to advise the National Cancer Advisory Board on whether and in what ways the National Cancer Institute's (NCI) clinical trials enterprise should be restructured to realize the promise of molecular medicine for advancing clinical practice in the 21st century. The Translational Research Working Group (TRWG) was established in 2005 to advise on the future course of NCI's translational research. Each Working Group released a report with recommendations that resulted from its' deliberations.

Clinical Trials Working Group

The CTWG recommendations, http://transformingtrials.cancer.gov/files/ctwg-report.pdf, published in 2005, address four critical goals for designing a more efficient national system for clinical trials conducted or supported by NCI: (1) better coordination; (2) prioritization based on solid science and the needs of patients; (3) standardized tools and procedures; and (4) improved operational efficiency. These four goals provide a framework for 22 initiatives recommended by the Working Group. The initiatives are organized into six broad categories.

Coordination Initiatives: to improve coordination and cooperation among the functionally diverse components of the current system, including industry and Federal regulatory agencies.

Prioritization/Scientific Initiatives: to improve prioritization and scientific quality by developing an open and transparent process for the design and prioritization of clinical trials that are science-driven and meet the needs of patient care.

Standardization Initiatives: to improve standardization of tools and procedures for trial design, data capture, data sharing, and administrative functions to minimize duplication of effort, and to facilitate development of a shared infrastructure to support an integrated national cancer clinical trials network.

Operational Efficiency Initiatives: to improve operational efficiency by increasing the rate of patient accrual and reducing operational barriers so that trials can be initiated and executed in a timely, cost-effective manner.

Enterprise-Wide Initiatives: to enhance coordinated leadership of the clinical trials enterprise by addressing ongoing NCAB oversight of clinical trials and an integrated NCI organizational structure for clinical trials management.

Informatics Initiatives: to define, design, build, and deliver a comprehensive clinical trials informatics infrastructure that will serve all of the critical stakeholders.

Translational Research Working Group

The report of the TRWG, http://www.cancer.gov/researchandfunding/trwg/order-final-report, published in 2007, was intended to complement and extend the work of the preceding CTWG Report. While the CTWG Report focused primarily on late translation (Phase III trials), the TRWG focused on early translation activities, including partnerships and collaborations with government, academia, and industry; intervention development; and early-stage trials. Similar to the CTWG, the TRWG was constituted as a broad and inclusive panel of translational research experts, including academic scientists and

clinicians, representatives from industry and foundations, patient advocates, and NCI staff.

Each of the 15 TRWG initiatives address one of the common themes derived from the TRWG. Taken together, these initiatives will strengthen and transform the NCI-supported early translational research enterprise into a national effort that integrates the individually strong components of the existing system into a coordinated and collaborative endeavor.

Coordinated Management: to improve coordination and collaboration and instill a culture of active, goal-oriented management for both individual projects and the enterprise as a whole.

Tailored Funding Programs: to tailor both new and existing funding programs to facilitate early translational research progress and incentivize researcher participation.

Operational Effectiveness: to enhance the operational efficiency and effectiveness of early translational research projects and the many supporting activities essential to the enterprise, including the participation of patients and advocacy groups.

Selected Clinical and Translational Research Implementation Activities

Since 2006, NCI, in collaboration with the many stakeholders of the National Cancer Program (NCP), which includes the members of the NCI CTAC, has made significant progress on the implementation of the CTWG and TRWG report recommendations. Key activities and initiatives are described below.

CTWG Steering Committee System

The Steering Committees strive to enhance the National Cancer Clinical Trials Enterprise. Scientific Steering Committees (SSCs) are composed of leading cancer experts and advocates from outside the Institute as well as NCI senior investigators who meet regularly to:

- Increase the transparency and openness of the trial design and prioritization process
- Enhance patient advocate and community oncologist involvement in clinical trial design and prioritization
- Convene Clinical Trial Planning Meetings (CTPMs) to identify critical questions and unmet needs, prioritize key strategies, and facilitate innovation and collaboration among the broad oncology community activity in the specific cancer study.

Individual SSCs may establish one or more Task Forces and/or Working Groups that focus on specific diseases or scientific areas of interest. Currently, there are 12 Disease-Specific Steering Committees (DSSCs), a Clinical Imaging Steering Committee (CISC), an Investigational Drug Steering Committee (IDSC), a Symptom Management and Health-Related Quality of Life Steering Committee (SxQOL SC), and a Patient Advocate Steering Committee (PASC). (A list of SSCs can be found at http://transformingtrials.cancer.gov/steering/overview.)

Disease Specific Steering Committees (DSSCs)

DSSCs are intended to provide analysis of proposed clinical trials concepts and facilitate the sharing of ideas among a broad range of investigators, basic and translational scientists, NCI staff, community oncologists and patient advocates. Each DSSC member is expected to regularly participate in the decision-making activities through teleconferences and face-to-face meetings. The major goal of all DSSCs is to evaluate and prioritize clinical trials based on their scientific merit and increase the efficiency of clinical trial collaboration, reduce trial redundancy, and increase information exchange at an early stage of trial development. To date, the following DSSCs have been established:

- Brain Malignancies Steering Committee (http://transformingtrials.cancer.gov/steering/brain-malignancies)
- Breast Cancer Steering Committee (http://transformingtrials.cancer.gov/steering-committees/breast-cancer)
- Gastrointestinal Steering Committee (http://transformingtrials.cancer.gov/steering-committees/gastrointestinal)
- Genitourinary Steering Committee (http://transformingtrials.cancer.gov/steering-committees/genitourinary)

- Gynecologic Steering Committee (http://transformingtrials.cancer.gov/steering-committees/gynecologic)
- Head and Neck Steering Committee (http://transformingtrials.cancer.gov/steering-committees/head-neck)
- Leukemia Steering Committee (http://transformingtrials.cancer.gov/steering/leukemia)
- Lymphoma Steering Committee (http://transformingtrials.cancer.gov/steering/lymphoma)
- Myeloma Steering Committee (http://transformingtrials.cancer.gov/steering/myeloma)
- Pediatric and Adolescent Solid Tumor Steering Committee (http://transformingtrials.cancer.gov/steering/pediatric-adolescent-solid-tumor)
- Pediatric Leukemia and Lymphoma Steering Committee (http://transformingtrials.cancer.gov/steering/pediatric-leukemia)
- Thoracic Malignancy Steering Committee (http://transformingtrials.cancer.gov/steering-committees/thoracic-malignancy)

Each committee is designed to leverage current Intergroup, Cooperative Group, Special Projects of Research Excellence (SPORE), and Cancer Center structures; increase information exchange at an early stage of trial development; increase the efficiency of clinical trial collaboration; reduce trial redundancy (Phase II and Phase III); and develop, evaluate, and prioritize concepts or Phase III and large Phase II clinical trials.

Investigational Drug Steering Committee (IDSC)

The IDSC was established in November 2005 and is composed of the Steering Committee, task forces, and working groups. Members of the IDSC include the principal investigators (PIs) of NCI's early drug development grants and contracts, representatives from the Cooperative Groups, a patient advocate, biostatisticians, and NCI staff.

The IDSC provides NCI with broad external scientific and clinical input on the design and prioritization of Phase I and Phase II trials with agents for which the Cancer Therapy Evaluation Program (CTEP) holds an Investigational New Drug (IND) application. The IDSC aims to increase the predictive value of early-phase trials, resulting in the design of more successful Phase III trials.

Additional information can be found at: http://transformingtrials.cancer.gov/steering-committees/investigational-drug

Clinical Imaging Steering Committee (CISC)

This committee was established in December of 2010. Members include imaging representatives from Cooperative Groups and other NCI-sponsored networks, as well as other clinicians, translational scientists, biostatisticians, patient advocates, and NCI staff who support or are involved with cancer clinical imaging research.

Information on the CISC is available at: http://transformingtrials.cancer.gov/steering/clinical-imaging

Patient Advocate Steering Committee (PASC). The Patient Advocate Steering Committee (PASC) works to ensure that advocates involved with the Scientific Steering Committees (SSCs) and their task forces are effectively and consistently integrated with the development, implementation, and monitoring of clinical trials within those groups. PASC membership is composed of the patient advocate members of the SSCs.

The PASC's mission and roster can be found at: http://transformingtrials.cancer.gov/steering-committees/patient-advocate

Symptom Management and Health-Related Quality of Life Steering Committee (SxQOL SC)

The SxQOL SC was established in April 2006. The core committee membership includes representatives from the Community Clinical Oncology Program (CCOP) Research Bases, R01 investigators, community oncologists, biostatisticians, patient advocates, and NCI Staff. The SxQOL SC was designed to:

- Review and prioritize symptom management intervention clinical trial concepts to be conducted through the CCOP mechanism
- Provide input to studies with secondary quality-of-life (QOL) endpoints in Cooperative Group treatment studies
- Develop prioritization criteria for QOL studies that are eligible for proposed Correlative Science/QOL set-aside funds

- Convene Clinical Trial Planning Meetings to identify critical questions and prioritize key strategies related to side effects of cancer, cancer treatment, and patients' quality of life.

Information about the SxQOL SC is available at: http://transformingtrials.cancer.gov/steering-committees/symptom-management

Clinical Trials Reporting Program

NCI's Clinical Trials Reporting Program (CTRP) fulfills a recommendation made in the CTWG Report and reiterated by the Institute of Medicine's report, *A National Cancer Clinical Trials System for the 21st Century: Reinvigorating the NCI Cooperative Group Program*. This comprehensive database of the entire NCI portfolio will help identify gaps in clinical research and duplicative studies, as well as facilitate effective clinical trial prioritization. The technical design of CTRP is state-of-the-art, developed around structured data, and based on NCI Enterprise Services, a set of common, shared information services.

CTRP is fully functional for registration of all NCI-supported interventional clinical trials. NCI-designated Cancer Centers were scheduled to complete initial registration in 2011, and other awardees are expected to complete initial registration in 2012. Submission of information on amendments, updates, and status changes has also been initiated. Reporting of accrual data for these trials is to begin in September 2012.

Additional information about the CTRP is available at: http://www.cancer.gov/clinicaltrials/conducting/ncictrp/about and http://ccct.cancer.gov/clinical-trial-information-management

NCI Central Institutional Review Board Initiative

In 2001, NCI created a Central Institutional Review Board (CIRB) in consultation with the Department of Health and Human Services (DHHS) Office of Human Research Protections (OHRP). The CIRB is designed to help reduce the administrative burden on local IRBs and investigators while continuing a high level of protection for human research participants. The CIRB aims to improve access to NCI-sponsored Cooperative Group clinical trials by enabling local IRBs to rapidly approve trials through the use of a facilitated review process and enhance protection of study participants by providing consistent preliminary expert IRB review at the national level.

Over the succeeding years, as operational efficiencies have been implemented and the benefits of CIRB use have become more widely appreciated, use of the CIRB has grown steadily. However, there remains some resistance to the utilization of the CIRB process for facilitated review.

To enhance adoption of the CIRB, the CTWG recommended that a barrier analysis be performed to better understand the nature of the barriers as well as to identify remaining shortcomings in the CIRB's operation. The analysis, which was completed in 2008, outlined five barriers that can be addressed. These include:

- Inefficiencies in implementing the CIRB process at local sites
- CIRB policies and procedures, including inadequate continuing review procedures, lack of Association for the Accreditation of Human Research Protection Programs, Inc. (AAHRPP) accreditation, and no review of certified consent form translations
- Insufficiencies in CIRB operations, including timeliness of posting materials and responding to local site queries as well as in providing complete review materials
- Inadequate coordination between the NCI Cancer Trials Support Unit (CTSU) and CIRB requirements
- Outreach materials that do not accurately target CIRB advantages.

The implementation of actions to mitigate these barriers is currently under way.

Information on the CIRB Initiative can be found at: http://www.ncicirb.org

Standard Terms of Agreement for Research Trials (START) Clauses

Contract negotiations between clinical trials sponsors (pharmaceutical, biotech, or medical device companies), academic medical centers, and the principal investigators often add months to the process of starting a clinical trial. These delays can add as much as $1 million per day to the overall cost of conducting a trial. To help speed up the initiation of clinical trials and eliminate excessive or repetitive costs, the CTWG recommended establishing commonly accepted language for clinical trial contracts.

To fulfill this recommendation, NCI and the Life Sciences Consortium of the CEO Roundtable on Cancer have

jointly developed a set of common clauses, or START (Standard Terms of Agreement for Research Trials) Clauses, that are accessible for any party to use when initiating a trial. These standard clauses provide common language for use as a starting point in the contract agreements that govern clinical trials.

The START clauses contain model language on the key concept areas of intellectual property, study data, indemnification, subject injury, confidentiality, and publication rights. Use of the START clauses is voluntary; they are designed to serve as a starting point for contract negotiations.

The START Clauses can be found at: http://transformingtrials.cancer.gov/initiatives/ctwg/standardization/highlights-start

CTAC Working Groups

Cost-Effectiveness Analysis Working Group (CEAWG)

The CTAC considered the value of including economic analysis in the NCI funding of cancer-related treatment trials. This led to the formation of a Working Group to address issues related to cost-effectiveness analysis (CEA) and to provide recommendations to the NCI.

The purpose of the CEAWG was to advise the CTAC and the NCI on the development of funding mechanisms and a prioritization process to ensure that the most important cost-effectiveness analyses can be initiated in a timely manner in association with clinical trials. Objectives include developing prioritization criteria for determining the most important cost-effectiveness analyses to conduct in conjunction with clinical trials and recommending possible funding mechanisms for support of high-priority cost-effectiveness analyses.

To be most useful to decision-makers, CEA of new cancer therapies must be timely and have high internal validity. Conducting a CEA alongside a treatment trial can achieve these goals and also offers the benefit of efficiency by utilizing the existing treatment trials structure to collect additional data for the economic analysis. To maximize the feasibility, internal validity and timeliness of CEA alongside treatment trials, it is important to incorporate CEA studies during the design phase of treatment trials. Although conducting cost-effectiveness studies alongside clinical trials offers many advantages, additional funds beyond those needed to conduct the treatment trial itself are needed at the onset to achieve the important goals. It is therefore important to have a process for selecting studies where the timely results of an economic analysis will be maximally useful to the oncology community.

The CEAWG report and recommendations can be found at: http://deainfo.nci.nih.gov/advisory/ctac/workgroup/ctacsupmat.htm

CTWG Evaluation Working Group

In 2010, NCI established the CTWG Evaluation Working Group within CTAC to advise on development of an evaluation plan to assess the impact of initiatives recommended by the CTWG on the performance and outcomes of the NCI clinical trials system. The Working Group included 10 extramural participants and 5 NCI staff, and conducted its deliberations between November 2010 and June 2011. The proposed evaluation plan outlined in a report prepared by the Working Group in July 2011 includes four components:

- System Outcomes
- Disease Steering Committees (includes Symptom Management and Health-Related Quality of Life, Imaging, Pediatrics)
- Investigational Drug Steering Committee
- Collaboration.

The Evaluation Working Group's final report is available at: http://deainfo.nci.nih.gov/advisory/ctac/0711/CTWGrEPORT.pdf

Ad Hoc Guidelines Harmonization Working Group (GHWG)

The GHWG included 11 members from CTAC and NCI staff. The Group's approach was first to define collaboration, illustrated by three model collaborative efforts, and to review the current guidelines of all major NCI mechanisms that support clinical trials, with particular attention to apparent disincentives to collaboration. Disincentives to collaboration include limited reimbursement for patient accrual, lack of professional recognition for collaboration, inconsistent incentives for resource sharing, variability in collaboration across the translational and clinical spectrum, and a need for guidelines and review criteria to be harmonized, strengthened, and implemented across funding mechanisms.

The Ad Hoc Working Group report describes recommendations to (1) revise applicant and reviewer guidelines for NCI clinical support mechanisms (Cancer Centers, SPOREs, Cooperative Groups) to improve collaboration and ensure consistency across and between funding mechanisms, and (2) provide additional incentives with the potential to move novel proposals across translational and clinical research programs. A subsequent report describes an implementation plan to realize the recommendations of the Working Group report.

NCI staff are finalizing proposed revisions of programmatic guidelines. These proposals are presented and discussed with CTROC and the Working Group members, and then presented to CTAC as they are approved. Revisions will be incorporated into programmatic guidelines along with other guideline revisions for final approval by the National Institutes of Health (NIH) and then implementation by programs.

GHWG reports and recommendations can be found at: http://deainfo.nci.nih.gov/advisory/ctac/workgroup/ctacsupmat.htm

Operational Efficiency Working Group (OEWG)

In December 2008, the OEWG was established under the auspices of the CTAC to advise the NCI on strategies to reduce the time required to activate NCI-sponsored Cooperative Group and early drug development trials as well as NCI-designated Cancer Center investigator-initiated trials. In addition, the OEWG was asked to identify strategies to increase the percentage of studies that reach their accrual targets in a timely fashion. The work of the OEWG was divided into two phases, with the first addressing the reduction of trial activation time and the second addressing timely completion of activated studies. The OEWG's report, entitled *Compressing the Timeline for Cancer Clinical Trial Activation*, describes the first phase of the OEWG's activity and presents the recommended initiatives resulting from that phase.

By identifying both the critical steps in the activation of each of NCI's clinical trial categories and the key barriers that delay these steps, the OEWG developed 14 recommendations for shortening activation timelines for Cooperative Group Phase II and III trials, N01 contractor and other early drug development trials, and Cancer Center Investigator-Initiated trials. The OEWG set "target" timelines for concept submission and protocol development processes, and an absolute "drop-dead" date for specific trial categories by which all issues must be resolved; otherwise, protocol development will be terminated. Also included in the 14 recommendations were strategies to enhance and improve NCI's overall clinical trials program.

The OEWG report is available at: http://deainfo.nci.nih.gov/advisory/ctac/workgroup/ctacsupmat.htm

Implementation of the report recommendations is an active process described in *Compressing Timelines for CTEP-Supported Cancer Treatment Trials – A Response to the OEWG Report*, available at: http://ctep.cancer.gov/SpotlightOn/OEWG.htm

Immune Response Modifier Pathway Prioritization Working Group and NCI Process to Accelerate Translational Science (PATS) Working Group

Key among the TRWG recommendations was to establish a process to identify a small number of projects "ripe" for translation and to provide the financial resources and the project management required to expedite moving those projects to the point of early-stage clinical trials. This process, referred to as the Translational Research Acceleration Initiative (TRAI), includes:

Collecting information on the breadth of cancer translational research opportunities

- Prioritizing opportunities based on scientific validity, feasibility, and clinical need
- Accelerating the advancement of a small number of high-priority opportunities along the appropriate TRWG Pathway to a Clinical Goal in a coordinated and highly facilitated fashion.

The TRWG identified modulation of the immune response as an important approach to cancer treatment and prevention, and developed the Immune Response Modifier (IRM) Developmental Pathway to a Clinical Goal. The IRM Prioritization Working Group was charged by the CTAC with prioritizing translational research opportunities in the IRM Pathway and recommending several high-priority regimens for funding through the NCI Special Translational Research Acceleration Project (STRAP) program. The report of the IRM Prioritization Working Group can be found at: http://deainfo.nci.nih.gov/advisory/ctac/workgroup/_IRM%20Prioritization%20Working%20Group%20FINAL%20REPORT.pdf

The PATS Working Group process was initiated following the release of the pilot of the STRAP for the Immune Response Modifier Pathway. The Working Group considered the experience of the Immune Response Modifier pilot and provided recommendations on how to best move forward with other TRWG Developmental Pathways. The PATS Working Group report is available at: http://deainfo.nci.nih.gov/advisory/ctac/workgroup/_NCI PATS Working Group FINAL REPORT.pdf

Funding Opportunities

Biomarker, Imaging, and Quality of Life Studies Funding Program (BIQSFP)

The goal of the BIQSFP is to ensure that the most important biomarker, imaging, and quality of life studies can be initiated in a timely manner in association with appropriate trials led by Cooperative Groups and CCOPs.

The BIQSFP supports biological studies, imaging, and quality of life studies embedded in clinical trials that have the potential to modify standard of practice. These tests/assays must be reliable and provide interpretable answers that are of benefit to patients leading to scientific observations that validate targets, reduce morbidity, predict treatment effectiveness, facilitate better drug design, identify populations that may better benefit from treatment, and improve accrual and retention.

SSCs evaluate and recommend the parent Clinical Trial Concept along with the BIQSFP proposal during scheduled SSC meetings. NCI program staff recommend SSC-approved BIQSFP proposals to the CTROC for prioritization and funding approval at their semi-monthly meetings. The CTAC receives periodic updates on the approved funding portfolio.

The BIQSFP also supports cost-effectiveness analysis research developed alongside the clinical trial concept.

Additional information and resources associated with the BIQSFP can be found at: http://biqsfp.cancer.gov/

Cancer Clinical Investigator Team Leadership Award

Designed for midlevel clinical investigators, the 2-year awards provide recognition and $50,000 in funding for those who lead cancer research programs and clinical trials at NCI-designated Cancer Centers. The funding is provided to the recipient's institution and can be applied toward the investigator's salary, fringe benefits, and associated facilities and administrative costs. Recipients are expected to devote 10 to 15 percent of their time to the activities associated with the award. Ultimately, the award, available to investigators at all NCI-designated Cancer Centers that participate in NCI-funded collaborative clinical trials, supports a shared culture in which investigators collaborate freely across disciplines, institutions, and programs to most expeditiously advance the design and conduct of cancer clinical trials.

In 2011, NCI recognized 11 outstanding investigators with 2-year awards to acknowledge and support leaders in clinical care programs at NCI-designated Cancer Centers. This cohort of investigators joined other outstanding clinical investigators who received this prestigious award in 2010.

A list of 2011 awardees is available at: http://www.cancer.gov/ncicancerbulletin/110111/page9/Print

Opportunity for CTSU Support for Collaborative Multi-Center Phase II Trials Led by NCI-designated Cancer Centers and SPOREs

This announcement highlights an opportunity for Cooperative Group, NCI-designated Cancer Center, and SPORE investigators to develop clinical trial collaborations through discussions in NCI's SSCs. Collaboration is an important underpinning of NCI's efforts to harmonize review guidelines across these three grant mechanisms. For clinical trial collaborations requiring multi-center coordinating support that is not otherwise available through existing networks, NCI will prioritize requests for in-kind coordination support through its Cancer Trials Support Unit (CTSU). While most Cooperative Group study PIs are familiar with SSCs and CTSU capability, this announcement provides important details for how study PIs at NCI Designated Cancer Centers and SPOREs can interact with SSCs and request access to CTSU services for highly meritorious clinical trials. It is anticipated that CTSU support will be provided for up to two multi-center Phase II trials per year under this announcement.

The 2011 Program Announcement can be found at: http://ccct.cancer.gov/files/CTSUHarmonizationAnnouncement.pdf

Special Translational Research Acceleration Projects (STRAP)

The STRAP program is a translational research concept theoretically based on a set of developmental pathways

focused on various clinical goals, as defined by the TRWG. Unique components of this program are designed to:

- Help investigators get over the so-called translational research "Valley of Death" where important projects wither away because of gaps in the developmental process or pathway
- Help with projects that are more difficult to fund through the usual one investigator/one project approaches. Collaborations are encouraged and supported
- Assist investigators in mobilizing available NCI resources (e.g., agents, biologics, toxicology)
- Recognize the need for project coordination across investigators, institutions, and programs.

The program provides a unique opportunity to address clinically important translational efforts that have been delayed or are not easily done through usual funding mechanisms. Two projects were funded as pilots in fiscal year (FY) 2010.

Information on the STRAP program, including abstracts of the two pilot projects and funding guidelines, is available at: http://ccct.cancer.gov/STRAP_Program

The National Cancer Institute

NCI Mission

The National Cancer Institute is one component of the National Institutes of Health, one of 11 operating divisions that compose the Public Health Service (PHS) in the Department of Health and Human Services. The NCI, established under the National Cancer Act of 1937, is the Federal Government's principal agency for cancer research and training. The National Cancer Act of 1971 broadened the scope and responsibilities of the NCI and created the National Cancer Program. Over the years, legislative amendments have maintained the NCI authorities and responsibilities and added new information dissemination mandates as well as a requirement to assess the incorporation of state-of-the-art cancer treatments into clinical practice. The National Cancer Institute is committed to dramatically lessening the impact of cancer.

The NCI is the primary means of support for America's cancer research enterprise, whether in its own laboratories or in our nation's research universities. The NCI is dedicated to the understanding, diagnosis, treatment, and prevention of cancer for all people. The NCI works toward this goal by providing vision to the nation and leadership for both domestic and international NCI-funded researchers. The NCI also works to ensure that research results are applied in clinical practice and public-health-related programs to reduce the burden of cancer for all populations. Within this framework, NCI researchers work to more fully integrate discovery activities through interdisciplinary collaborations; accelerate development of interventions and new technology through translational research; and ensure the delivery of these interventions for application in the clinic and public health programs as state-of-the-art care for all those in need.

NCI and the National Cancer Program

As the leader of the National Cancer Program, the NCI provides vision and leadership to the global cancer community. The NCI conducts and supports research, training, health information dissemination, and other programs with respect to the cause, diagnosis, prevention, and treatment of cancer; rehabilitation; and the continuing care of cancer patients. Critical to the success of its programs are collaborations and partnerships that further NCI's progress in serving cancer patients and those who care for them.

The NCI supports a broad range of research to expand scientific discovery at the molecular and cellular levels, within a cell's microenvironment, and in relation to human and environmental factors that influence cancer development and progression. Each year, almost 5,000 principal investigators lead research projects that result in better ways to combat cancer. Intramural research serves as a hub for new development through cutting-edge basic, clinical, and epidemiological research. Extramural program experts provide guidance and oversight for research conducted at universities, teaching hospitals, and other organizations. Proposals are selected for funding by peer review, a rigorous process by which scientific experts evaluate new proposals and recommend the most scientifically meritorious for funding. In addition to direct research funding, the NCI offers the nation's cancer scientists a variety of useful research tools and services: tissue samples, statistics on cancer incidence and mortality, bioinformatic tools for analyzing data, databases of genetic information, and resources through NCI-supported Cancer Centers, Centers of Research Excellence, and the Mouse Models of Human Cancer Consortium (MMHCC).

The NCI also uses collaborative platforms and an interdisciplinary environment to promote *translational research and intervention development*. A newly discovered tool that first helps to understand the underlying mechanism of cancer may eventually be used to help diagnose it, and then may be further developed to help treat it. For example, recent advances in bioinformatics and the related explosion of technology for genomics and proteomics research are dramatically accelerating the rate at which large amounts of information for cancer screening and diagnosis are processed. The largest collaborative research activity is the Clinical Trials Program for testing interventions for preventing cancer, diagnostic tools, and cancer treatments as well as providing access as early as possible to all who can benefit. The NCI supports more than 1,300 clinical trials a year, assisting more than 200,000 patients.

NCI research impacts the delivery of improved cancer interventions to cancer patients and those who care for them. Timely communication of NCI scientific findings helps people make better health choices and advises physicians about treatment options that are more targeted and less invasive, resulting in fewer adverse side effects. NCI researchers also are seeking the causes of disparities

among underserved groups and gaps in quality cancer care, helping to translate research results into better health for groups at high risk for cancer, including cancer survivors and the aging population. In addition, the NCI is fostering partnerships with other agencies and organizations to accelerate the pace for moving targeted drugs through the pipeline of discovery, development, and delivery. Information about NCI's research and activities is available through its public website, http://cancer.gov.

NCI Legislative Authority

The NCI, established under the National Cancer Act of 1937, is the Federal Government's principal agency for cancer research and training. The National Cancer Act of 1971 broadened the scope and responsibilities of the NCI and created the National Cancer Program. Under the National Cancer Act of 1971, the Director of the NCI is authorized to submit, directly to the President, a professional judgment budget reflecting the full funding needs of the National Cancer Program. This budget is referred to as the Bypass Budget.

Bypass Budget

The mandate to produce a "Bypass Budget" is a special authority given to the NCI Director. The Bypass Budget builds on research successes and ensures that research discoveries are applied to improve human health, and allows the NCI Director to express to the President the plans and priorities of the NCI and the National Cancer Program, along with an indication of the associated costs.

Each year, the NCI produces this document to reflect the professional judgment of the nation's top cancer experts about the realities of cancer research and control, and how much money could be spent wisely in the conduct of the entire Program.

The authority to produce the Bypass Budget has many benefits. The extensive strategic planning process that is used to develop the Bypass Budget builds on research successes, supporting the cancer research workforce with the technologies and resources it needs. In addition to being submitted to the President, this comprehensive research plan also is provided to Congress and is used by the greater cancer research community, professional organizations, advisory groups, advocacy organizations, and public and private policymakers. As a result, the Bypass Budget and its development serve as a planning process for the entire National Cancer Program, outlining clearly the areas of highest priority.

In addition to informing the President, the Bypass Budget document also serves as the Institute's strategic plan and has become a powerful communication and priority-setting tool used by constituents across the National Cancer Program. Updated each year, the plan provides a guide for building on research successes, supporting the cancer research workforce with the technologies and resources it needs, and ensuring that research discoveries are applied to improve human health. This strategic plan is based on the authority and the responsibilities entrusted to the presidentially appointed NCI Director to coordinate the research activities of the NCI with the other parts/members of the National Cancer Program.

In so doing, the Director is aided by the National Cancer Advisory Board (NCAB), a group composed of scientists, medical personnel, and consumers from all sectors, public and private, of the cancer enterprise who have the needed expertise and experience to formulate a national agenda in cancer research. The NCAB meets with the President's Cancer Panel (PCP) members to facilitate transfer of PCP observations on the barriers to progress in the NCP and the development of possible solutions. Their deliberations are directly coordinated with other government agencies through the participation of *ex officio* Federal members representing key agencies involved in executing the National Cancer Program. For example, discussions at the NCAB meetings with *ex officio* members representing Department of Defense and Veterans Affairs health care systems directly led to the availability of NCI clinical trials through their health care systems. Close coordination across agencies is critical in the formulation of a strategic plan that takes advantage of the capabilities of each agency and the constituencies it serves.

The ability of the NCI and its partners to address the initiatives in the Bypass Budget is a measure of the success of the NCP. In this way, the Bypass Budget enables efficient strategic coordination of the NCP. As part of the evaluation process, the presidentially appointed PCP is charged to review the implementation of such plans and identify directly for the President and the nation the extent of their success.

NCI Organizational Structure

The NCI's current organizational structure can be seen in **Exhibit I**. NCI's Office of the Director serves as the focal point for the NCP, with advice from the President's Cancer Panel, the NCAB, the Board of Scientific Counselors (Basic Sciences and Clinical Sciences and Epidemiology) (BSC), the Board of Scientific Advisors (BSA), and the

Clinical Trials and Translational Research Advisory Committee (CTAC). The BSA gives final concept approval for extramural Requests for Applications (RFAs) and Requests for Proposals (RFPs), while the BSC conducts intramural laboratory and branch reviews. The Director of the Institute is assisted by several Deputy Directors: Dr. Alan Rabson, Deputy Director of the NCI; Dr. Anna Barker, Deputy Director, Advanced Technologies and Strategic Partnerships; and Mr. Jim Dickens, Acting Deputy Director, Office of Management. The Scientific Program Leaders (SPLs) of the Institute (see **Appendix E**) include the Director, Deputy Directors, Division Directors, and other senior administrative staff. The SPL meets on a regular basis to discuss various matters of NCI policy, including but not limited to, RFA and research and development (R&D) contract concept review and approval before review by the BSA; review of program announcements; development of funding plans; grant payment by exceptions, etc. Five extramural research Divisions, four extramural Centers and one Office, one intramural research Division, and one intramural research Center monitor and administer NCI's cancer research activities through extramural and intramural research programs.

Office of the Director

Examples of some Offices and Centers within the Office of the Director include:

Center for Biomedical Informatics and Information Technology (CBIIT)

The CBIIT helps speed scientific discovery and facilitates translational research by building many types of tools and resources that enable information to be shared along the continuum from the scientific bench to the clinical bedside and back. The CBIIT: (1) coordinates and deploys informatics in support of NCI research initiatives; (2) provides all manner of informatics support, including platforms, services, tools, and data, to NCI-supported research initiatives; (3) participates in the evaluation and prioritization of NCI's bioinformatics research portfolio; (4) conducts or facilitates research that is required to fulfill NCI's bioinformatics requirements; (5) serves as the focus for strategic planning to address NCI's expanding research initiatives' informatics needs; (6) establishes bioinformatics technology standards (both within and outside of the NCI); (7) communicates, coordinates, and establishes bioinformatics exchange standards; (8) provides direct support to four NCI research programs: the Cancer Genome Anatomy Project (CGAP), the Mouse Models of Human Cancer Consortium (MMHCC), the Director's Challenge: Toward a Molecular Classification of Cancer, and the Clinical Trials Program. It also develops core infrastructure to support the integration of these efforts.

Office of Communications and Education (OCE)

The OCE advances the mission of the NCI by disseminating research results to the public to improve the lives of those affected by cancer. Working closely with scientists and partners, the OCE uses effective methods to reach diverse audiences and meet their needs for the latest evidence-based cancer information.

Office of Cancer Content Management (OCCM)

The OCCM in OCE oversees the development, publication, maintenance, and updating of the majority of cancer information products disseminated by the NCI OCE. The OCCM also manages the clearance process for all OCE cancer information products.

Center to Reduce Cancer Health Disparities (CRCHD)

The CRCHD is the keystone of NCI's efforts to reduce the unequal burden of cancer in our society. As the organizational focus for these efforts, the Center directs and supports initiatives that advance the understanding of what causes health disparities. It also supports programs that develop and integrate effective interventions to reduce or eliminate these disparities. The CRCHD, through its Diversity Training Branch (DTB), leads NCI's efforts in the training of students and investigators from diverse populations who will be part of the next generation of competitive researchers in cancer and cancer health disparities research.

Office of Advocacy Relations (OAR)

The OAR engages the advocacy and NCI communities in dialogue about cancer research opportunities and priorities to advance progress and improve outcomes. The OAR: (1) serves as the Institute's expert and central resource for advocacy matters; (2) facilitates dynamic relationships and collaborations to promote mutual goals; and (3) disseminates information and fosters understanding of key cancer issues and priorities.

Center for Strategic Scientific Initiatives

The Center for Strategic Scientific Initiatives (CSSI) directs the planning, development, and implementation of a number of strategic scientific and technology

Exhibit I. *The National Cancer Institute*

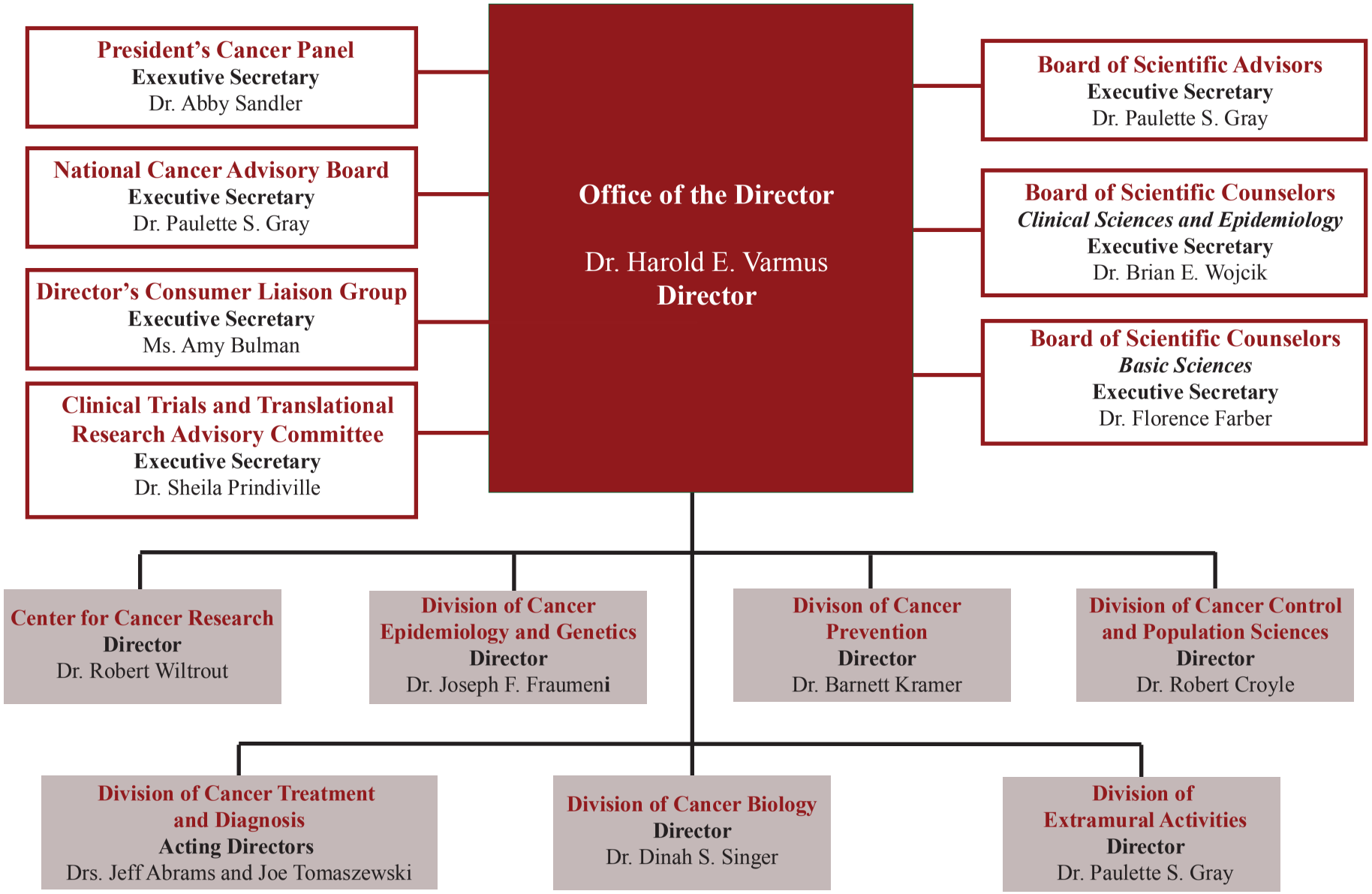
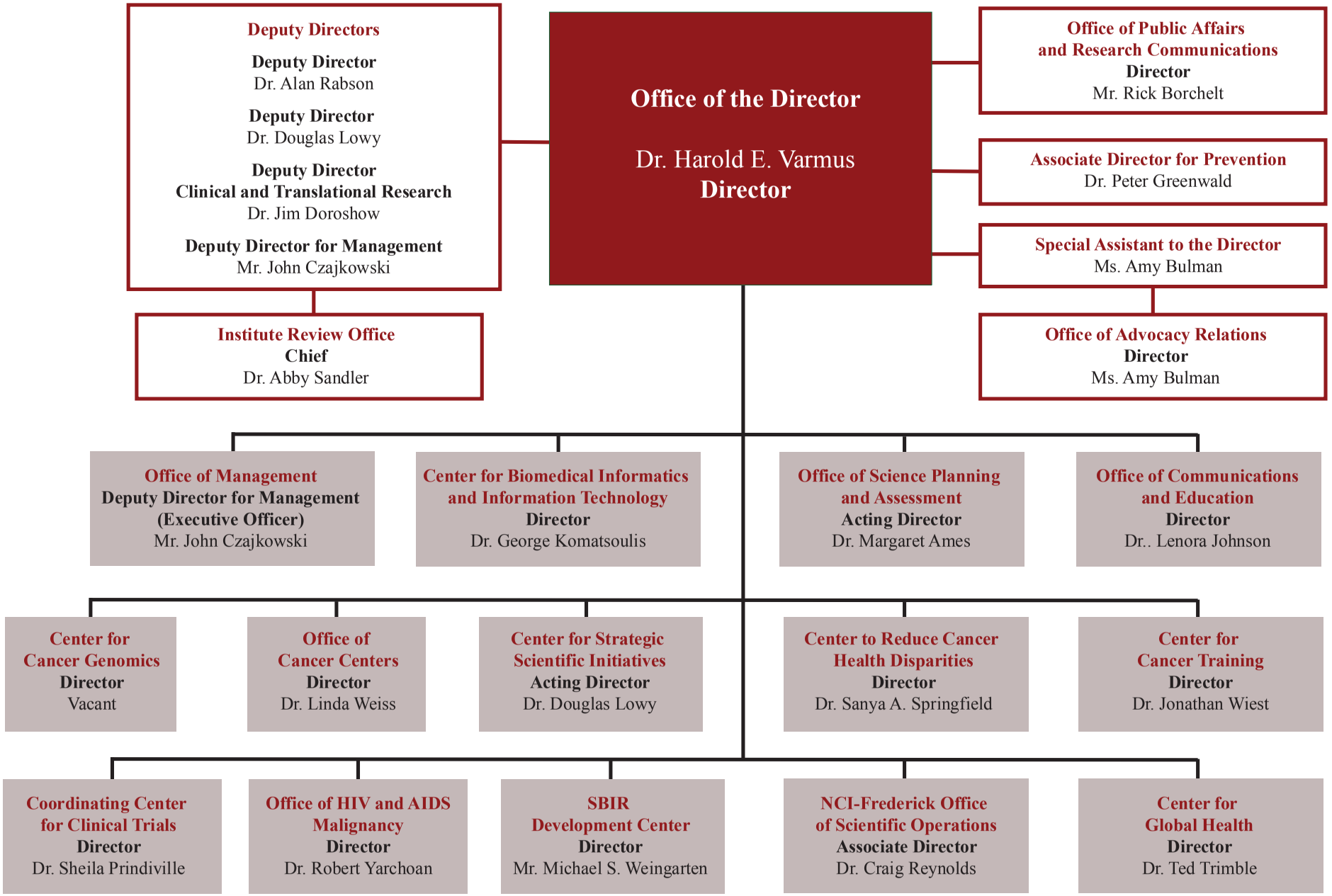


Exhibit I. *The National Cancer Institute (Continued)*



initiatives and partnerships that emphasize innovation, transdisciplinary teams, and convergence of scientific disciplines to enable progress against cancer. These programs also stress the development and application of advanced technologies, the synergy of large-scale and individual-initiated research, novel partnerships, and translation of discoveries into new interventions to detect, prevent, and treat cancer more effectively.

Several offices in CSSI are committed to accelerating the progress of cancer research through its technology-driven initiatives, collaboration with other government programs, and engagement with the private sector in the areas of nanotechnology, proteomics, cancer genomics, and biospecimen resources. By placing a heavy emphasis on advanced technology development, the NCI is accelerating the creation and use of tools that are already facilitating the translation of basic knowledge into clinical advances to benefit patients with a new generation of molecularly based diagnostics and therapeutics. Programs include: Alliance for Nanotechnology in Cancer, Clinical Proteomic Technologies Initiative, Innovative Molecular Analysis Technologies, and Nanotechnology Characterization Laboratory.

Office of Cancer Centers

Currently, the Office supports 66 NCI-designated Cancer Centers nationwide that are actively engaged in transdisciplinary research to reduce cancer incidence, morbidity, and mortality. The NCI-designated Cancer Centers (P30) are a major source of discovery on the nature of cancer and of the development of more effective approaches to cancer prevention, diagnosis, and therapy. Comprehensive Cancer Centers also deliver medical advances to patients and their families, educate health care professionals and the public, and reach out to underserved populations. Cancer Centers are characterized by strong organizational capabilities, institutional commitment, and transdisciplinary, cancer-focused science; experienced scientific and administrative leadership; and state-of-the-art cancer research and patient care facilities.

Center for Cancer Training (CCT)

The CCT is responsible for: (1) coordinating and providing research training and career development activities for fellows and trainees in NCI's laboratories, clinics, and other research groups; (2) developing, coordinating, and implementing opportunities in support of cancer research training, career development, and education at institutions nationwide; and (3) identifying workforce needs in cancer research and adapting NCI's training and career development programs and funding opportunities to address these needs.

Coordinating Center for Clinical Trials

The CCCT is central to NCI's efforts to accelerate the delivery of new tools into the clinic through its translational science and clinical trial enterprises. The CCCT facilitates collaborations that expedite translational and clinical cancer research by:

- Supporting the implementation of the Clinical Trials Working Group and Translational Research Working Group recommendations
- Facilitating prioritization of the NCI's most important clinical trials by Scientific Steering Committees working with NCI clinical programs
- Partnering with the NCI's CBIIT to establish the CTRP, a comprehensive database with up-to-date information on all NCI-funded clinical trials.

Office of Cancer Genomics (OCG)

The OCG in CSSI is focused on understanding the molecular mechanisms of cancer, with the ultimate goal of improving the prevention, early detection, diagnosis, and treatment of cancer. To meet this goal, the OCG:

- Provides information, technology, methods, informatics tools, and reagents to serve the needs of the cancer research community.
- Manages the following research programs: the Cancer Genome Anatomy Project (CGAP), the NIH Mammalian Gene Collection (MGC), the Initiative for Chemical Genetics (ICG), the Cancer Genome Atlas (TCGA), Cancer Genetic Markers of Susceptibility (CGEMS), the Clinical Proteomic Technologies for Cancer (CPTC) Program, and Therapeutically Applicable Research to Generate Effective Treatments (TARGET).

Office of Biorepositories and Biospecimen Research (OBBR)

The OBBR in CSSI is responsible for coordinating and developing the Institute's biospecimen resources and capabilities and ensuring that human biospecimens available for cancer research are of the highest quality. This is being accomplished through the development of

a common biorepository infrastructure that promotes resource sharing and team science to facilitate multi-institutional, high-throughput genomic and proteomic studies.

Office of International Affairs (OIA)

The OIA within the Office of Management coordinates NCI's worldwide activities in a number of arenas, including: liaison with foreign and international agencies; coordination of cancer research activities under agreements between the United States and other countries; planning and implementation of international scientist exchange programs; sponsorship of international workshops; and dissemination of cancer information.

Office of Science Planning and Assessment (OSPA)

OSPA's primary responsibilities are to develop and coordinate NCI's scientific planning and evaluation activities. OSPA staff accomplish this through consultation, guidance, analysis, and document preparation in support of various Institute-wide and Division-level programs. These critical activities enable the NCI to identify needs and opportunities for cancer research, establish research goals, and develop sound plans for reaching those goals.

Office of HIV and AIDS Malignancy (OHAM)

The Office of HIV and AIDS Malignancy: (1) coordinates and works with the Divisions and other Offices to manage the portfolio of HIV/AIDS and AIDS malignancy research within the NCI; (2) advises the NCI Director and other NCI managers on issues related to research in HIV/AIDS and AIDS malignancies; (3) coordinates, helps prioritize, and facilitates the NCI research effort in HIV/ AIDS and AIDS malignancies and works with NCI management to redirect the HIV/AIDS and AIDS malignancy research effort, as appropriate, into the highest priority areas; (4) interfaces with the NIH Office of AIDS Research and other Institutes and Centers (ICs) with regard to research in HIV/AIDS and AIDS malignancies in the NCI; and (5) directly manages certain AIDS and AIDS malignancy research programs, such as the AIDS and Cancer Specimen Resource, the AIDS-Associated Malignancies Clinical Trial Consortium (AMC), the NCI Component of the Centers for AIDS Research (CFARS), and the NCI component of the Women's Interagency HIV Study (WIHS).

Small Business Innovation Research (SBIR) Development Center

The SBIR Development Center serves as the NCI focal point for managing Small Business Innovation Research and Small Business Technology Transfer (STTR) activities; implementing pertinent legislation, rules, regulations, and associated matters related to the SBIR/STTR Program consisting of grant and contractor awards; and providing expertise, advice, and services to applicants and NCI programs.

NCI-Frederick Office of Scientific Operations

The NCI-Frederick Office of Scientific Operations: (1) oversees and manages scientific operations at NCI-Frederick and serves as the Project Office for the three main operation and support contracts at NCI-Frederick; (2) directs and develops advanced technologies that are made available to customers of NCI-Frederick; (3) implements programmatic decisions approved by the NCI Director and the Associate Director for NCI-Frederick to transition new efforts to NCI-Frederick by developing contractual requirements and budgets, arranging for needed space, and providing technical and project management advice to the Contracting Officer; (4) works closely with customers (including other NCI and NIH components, the Food and Drug Administration, the Department of Defense, the Department of Agriculture, and the Department of Homeland Security) and contractors to ensure that contractors understand customers' needs and that the customers receive planned outcomes; (5) assists the NCI Associate Director for Frederick with the administrative and business operations of NCI-Frederick; (6) assists the NCI Associate Director for Frederick with planning and prioritizing of space and the maintenance of all buildings and grounds; (7) monitors contractor performance, obtains customer satisfaction feedback, and provides this information to the Management Operations and Support Branch for the award fee processes; (8) tracks and reports funds received and costs associated with all work performed at NCI-Frederick; (9) develops and manages educational, employee outreach, and public outreach programs, including programs for students K-12 and internship opportunities for high school and undergraduate students; (10) coordinates the expansion of student/fellowship mentoring programs at NCI-Frederick; and (11) coordinates NCI-Frederick facility "activities" such as the Spring Research Festival; Take Your Child to Work Day; the Summer Student Seminar Series; Summer Student

Poster Day; the Housing Resources List; speaker requests; and visits for students, teachers, and other interested groups.

Extramural Divisions

The research and research-related activities of the NCI are conducted by five Divisions under the supervision of the Office of the Director. The functions of the Divisions and the major areas of research and research support activities for which each is responsible are:

Division of Cancer Biology (DCB)

The mission of the DCB is to ensure continuity and stability in basic cancer research, while encouraging and facilitating the emergence of new ideas, concepts, technologies, and possibilities. The DCB strives to achieve this goal by promoting a balance between the continued support of existing research areas and selective support of emerging research areas. The DCB provides guidance, advice, funding information, and financial support to grantees and applicants, and encourages the expansion of new research areas through a range of initiatives and funding mechanisms. The scientific discoveries from this research base are critical to the goal of the NCI because they form the intellectual and scientific foundation upon which strategies for the prevention, diagnosis, and treatment of cancer are developed. (http://dcb.nci.nih.gov/)

Division of Cancer Control and Population Sciences (DCCPS)

The DCCPS aims to reduce the risk for, incidence of, and number of deaths from cancer, as well as to enhance the quality of life for cancer survivors. This Division conducts and supports an integrated program of the highest quality genetic, epidemiologic, behavioral, social, applied, and surveillance cancer research. DCCPS-funded research aims to: (1) understand the causes and distribution of cancer in various populations, (2) support the development and implementation of effective interventions, and (3) monitor and explain cancer trends in all segments of the population. Central to these activities is a process of synthesis and decision making, which aids in evaluating what has been learned, identifying new priorities and strategies, and effectively applying research discoveries to reduce the cancer burden at the population level. (http://dccps.nci.nih.gov)

Division of Cancer Treatment and Diagnosis (DCTD)

The DCTD attempts to identify and exploit the most promising areas of science and technology and to initiate, enable, and conduct research that will yield important new knowledge that is likely to lead to better diagnostic or therapeutic interventions in the various childhood and adult cancers. The Division administers grants, contracts, and cooperative agreements, and offers strategically planned workshops and conferences with scientists, clinicians, and public and private partners. It also sponsors a vigorous program of in-house applied research linked to investigators and goals in the extramural community. (http://dctd.cancer.gov/)

Division of Cancer Prevention (DCP)

The DCP plans and conducts programs in basic and applied research and development, technology transfer, demonstration, education, and information dissemination. DCP's programs are designed to: expedite the use of new information relevant to the prevention, detection, and diagnosis of cancer; expedite the use of new information about pretreatment evaluation, treatment, rehabilitation, and continuing care; plan, direct, and coordinate the support of research on cancer prevention at Cancer Centers and community hospitals, and through organ systems programs; support cancer research training, clinical education, continuing education, and career development in cancer prevention; coordinate program activities with other Divisions, Institutes, and Federal and State agencies; and establish liaison with professional and voluntary health agencies, Cancer Centers, labor organizations, cancer organizations, and trade associations. (http://prevention.cancer.gov/)

Division of Extramural Activities (DEA)

The mission and responsibilities of the DEA in some way affect all extramural scientists receiving research or training support from the NCI. The DEA coordinates the review of special initiatives, large grants, and contracts. It is involved in all aspects of grant development and tracking, from the original conception of extramural research and training programs to follow-up after funds are dispersed. In brief, the DEA was established to: provide advice and guidance to potential applicants; receive and refer incoming grant applications to appropriate programs within the NCI; provide the highest quality and most effective scientific peer review and oversight of extramural research; coordinate and administer Federal advisory committee activities related

to the various aspects of the NCI mission, such as the activities of the NCAB and BSA; establish and disseminate extramural policies and procedures, such as requirements for inclusion of certain populations in research, actions for ensuring research integrity, or budgetary limitations for grant applications; and track the NCI research portfolio (more than 7,000 research and training awards) using consistent, budget-linked scientific information to: (1) provide a basis for budget projections and (2) serve as a resource for the dissemination of information about cancer. (http://deainfo.nci.nih.gov/funding.htm)

Intramural Centers and Divisions

Center for Cancer Research (CCR)

As the intramural component of the NCI, the CCR conducts basic clinical investigations at the Bethesda campus. The mission of the CCR is to reduce the burden of cancer through exploration, discovery, and translation. It provides a new forum for cancer research without scientific, institutional, or administrative barriers. The Center is achieving this by conducting outstanding, cutting-edge, basic and clinical research on cancer and translating these discoveries into treatment and prevention. The overall goal is to form a highly interactive, interdisciplinary group of researchers who have access to technology and are able to participate in clinical investigations. The CCR also maintains a foundation of investigator-initiated, independent research. CCR scientists conduct innovative basic and clinical research aimed at discovering the causes and mechanisms of cancer to improve the diagnosis, treatment, and prevention of cancer and other diseases. (http://ccr.nci.nih.gov/)

Division of Cancer Epidemiology and Genetics (DCEG)

The DCEG is an intramural research program in which scientists conduct an international program of population-based studies to identify environmental and genetic determinants of cancer. In carrying out its mission, the DCEG is at the cutting edge of approaches to untangle complex gene-environment and gene-gene interactions in cancer etiology. To conduct these studies, investigators at all levels of their careers work collaboratively to bring together a variety of scientific disciplines. (http://dceg.cancer.gov/)

NCI Programs and Activities

Research Programs

The Institute conducts and leads intensive work to advance knowledge of cancer's biology and processes; to discover and develop new interventions; and to employ a bench-to-bedside approach that strives to rapidly make new treatments—our latest science—available to patients in the communities where they live. Across these complex endeavors, the NCI works to foster the collaborations of government, the private sector, and academia. In addition to the broad range of both basic and applied laboratory and clinical programs that it supports, the NCI provides various research support services, including the development and distribution of critical materials such as viruses, animals, equipment, tissues, and standardized reference bibliographies. These activities are conducted within the Divisions and Centers of the NCI, under the supervision of the Office of the Director.

Cancer Causation

Cancer causation research concentrates on the events involved in the initiation and promotion of cancer. It encompasses chemical and physical carcinogenesis, biological carcinogenesis, epidemiology, chemoprevention, and nutrition research. Studies in this area focus on external agents such as chemicals, radiation, fibers, and other particles, as well as viruses, parasitic infections, and host factors such as hormone levels, nutritional and immunologic status, and the genetic endowment of the individual. FY2009 cancer causation research expenditures totaled about $1.09 billion, accounting for 21.9 percent of the total NCI budget.

Detection and Diagnosis

Detection and diagnosis research includes studies designed to improve diagnostic accuracy; provide better prognostic information to guide therapeutic decisions; monitor the response to therapy more effectively; detect cancer at its earliest presentation; and identify populations and individuals at increased risk for the development of cancer. Areas of emphasis include: improvements in the detection and diagnosis of breast, cervical, uterine, and prostate cancers; the transfer of molecular technologies from the laboratory to clinical practice; the identification of better prognostic markers; increased availability of human tumor samples with associated clinical information; and research to identify genetic alterations involved in tumor pathogenesis and behavior. FY2009

detection and diagnosis research expenditures totaled about $401 million, accounting for 8.1 percent of the total NCI budget.

Treatment

Treatment research is composed of preclinical and clinical research. Preclinical research focuses on the discovery of new antitumor agents and their development in preparation for testing in clinical trials. These agents include both synthetic compounds and natural products. Clinical research involves demonstrating the effectiveness of new anticancer treatments through systematic testing in clinical trials. Phase I trials establish the maximum tolerated dose of a new agent; Phase II trials examine its efficacy against a variety of cancers; and Phase III trials compare the new treatment with the best standard therapy, in terms of improved survival and decreased toxicity. FY2009 treatment research expenditures totaled about $1.15 billion, accounting for 23.2 percent of the total NCI budget.

Cancer Biology

Cancer biology supports a broad spectrum of basic research on cancer and the body's response to cancer. Studies include investigations of cellular and molecular characteristics of tumor cells, interactions among cells within a tumor, and the components of the host immune defense mechanisms. Cancer is the result of genetic damage that accumulates in stages. It is the goal of cancer biology to identify and explain the stepwise progression between the initiating event in the cell and final tumor development. FY2009 cancer biology expenditures totaled approximately $782 million, accounting for 15.8 percent of the total NCI budget.

Cancer Prevention and Control

The NCI conducts Cancer Prevention and Control basic and applied research through both intramural and extramural mechanisms in all phases of cancer prevention and control, as well as cancer surveillance. A key priority of this program is to develop strategies for the effective translation of knowledge gained from prevention and control research into health promotion and disease prevention activities for the benefit of the public. An integrated system of basic research, clinical trials, and applications research is in place and seeks to promote cancer prevention and control activities across the country.

The Cancer Prevention and Control Program includes four components and several subprograms, many of which relate to other program activities of the NCI, including information dissemination, epidemiology, and cancer treatment. The four components are Cancer Prevention Research, Cancer Control Science, Early Detection and Community Oncology, and Cancer Surveillance. FY2009 Cancer Prevention and Control Program expenditures totaled approximately $385 million, accounting for 7.8 percent of the total NCI budget.

Resource Development

Cancer Centers

The Cancer Centers Program consists of a group of nationally recognized, geographically dispersed,individual institutions with outstanding scientific reputations. Each institution reflects particular research talents and special technological capabilities. In FY2009, there were 65 Centers, which received a total of $285 million in support, accounting for 5.8 percent of the total NCI budget.

The NCI uses the Cancer Center Support Grant (CCSG) mechanism (P30) to support centers that conduct research and outreach activities on several different cancers. Cancer Centers are designated as either cancer centers or comprehensive cancer centers.

Cancer Centers have developed in a number of different organizational settings. Some are independent institutional entities entirely dedicated to cancer research (free-standing centers); some have been formed as clearly identifiable entities within academic institutions and promote interactive cancer research programs across departmental and/or college structures (matrix centers); and others involve multiple institutions (consortium centers).

The CCSG is intended to provide support to the peer-reviewed research base of the Cancer Center within the larger institution. The CCSG supports the operational framework (infrastructure) of the center and partially pays for shared laboratory resources and facilities. Research projects themselves are supported through the individual grants and contracts from the NIH and from a variety of other grant-funding agencies and organizations.

Specialized Programs of Research Excellence

The Specialized Programs of Research Excellence (SPOREs) are designed to stimulate translational research from the laboratory to clinical practice. SPOREs, which are funded under the P50 grant mechanism, focus on research

in prevention, detection, diagnosis, and treatment for a single cancer site. These are awarded to institutions that demonstrate the ability to perform significant translational research.

Planning and Development Grants

To encourage the development of cancer research centers in regions not currently served by existing NCI-designated clinical or comprehensive Cancer Centers, the NCI awards Planning and Development Grants, using the P20 mechanism, to help eligible institutions develop the organizational capability to form and/or develop cancer research centers or SPOREs.

Comprehensive Minority Institution/Cancer Center Partnership

NCI's Comprehensive Minority Institution/Cancer Center Partnership (U54) awards are cooperative agreements designed to establish comprehensive partnerships between the minority-serving institutions (MSI) and NCI-designated Cancer Centers. The partnership focuses on cancer research and one or more target areas in cancer research, training and career development, education, or outreach activities designed to benefit racial and/or ethnic minority populations in the region the Cancer Center serves. The partnership also creates a stable, long-term, collaborative relationship between an MSI and NCI-designated Cancer Center and raises awareness about problems and issues relevant to the disproportionate rates of cancer incidence and mortality in minority populations.

Research Manpower Development

The Cancer Training Branch (CTB) in the Center for Cancer Training manages the Institute's extramural research training, career development, and education programs, and provides guidance to the extramural biomedical research community and administration of awards. This assures continued development of well-trained investigators in the basic, clinical, population, and behavioral sciences who are prepared to address problems in cancer biology, causation, prevention and control, detection and diagnosis, treatment, and rehabilitation.

Operationally, the CTB has three functions. The first is the management of NCI-funded grants in research training, career development, and cancer education. The second function is the administration of the Ruth L. Kirschstein National Research Service Award (NRSA) components (F32 and T32) of the CTB grant portfolio. The NRSA program is the major mechanism for providing long-term, stable support to a wide range of promising scientists and clinicians. Individual awards are made directly to postdoctoral fellows (F32), and institutional awards (T32) are made to scientists who, together with a group of faculty-preceptors, administer a comprehensive training program for pre- and postdoctoral trainees. CTB administers a research career development program that supports the training of both scientists and research physicians during the first 3 to 5 years between receipt of a Ph.D., M.D., or other professional degree and receipt of an individual investigator-initiated award. Among the career mechanisms are three additional non-NRSA institutional mechanisms (K12, R25T, and R25E) and six individual career development awards (K-series). The third function is the oversight and coordination of the NIH Loan Repayment Program. Program expenditures in FY2009 totaled approximately $181 million, accounting for 3.7 percent of the total NCI budget.

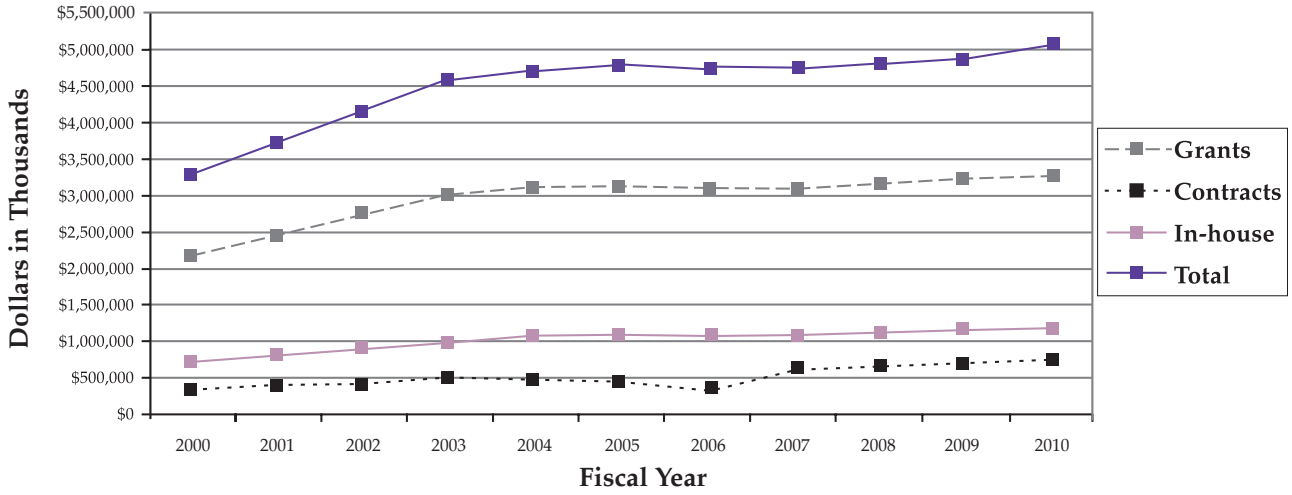
NCI Funding Mechanisms

The NCI supports cancer research, cancer control, and cancer support activities through an extramural program of grants, cooperative agreements, and contracts, and through an intramural program of in-house research. In accordance with NIH tradition, the Institute's extramural programs emphasize grant-supported, investigator-initiated research projects, which are conducted at both nonprofit and for-profit institutions in the United States and abroad. Research contracts are awarded to both nonprofit and for-profit institutions. Intramural funds support continuing investigations by NCI research scientists. The cooperative agreement mechanism, which is a cross between a grant and a contract, became available in 1979 as an additional procurement mechanism. Annual appropriations from Congress provide the funds for all research supported by the NCI.

Exhibit II illustrates the relationship between total NCI obligations and the grant, contract, and intramural/other components of the NCI budget from 2000 to 2010. **Exhibit III** shows the 2006-2010 budget for various research areas. **Exhibit IV** summarizes the FY2010 budget obligations by mechanism. **Exhibit V** shows Research Project Grant (RPG) awards by activity code and presents the number of grants awarded, the total dollars awarded, and the average cost of a grant for the period 2000–2010. **Exhibit VI** depicts NCI's integrated approach to management of clinical trials.

Exhibit II. *NCI Funding History*

	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010
Grants	$2,204,716	$2,488,627	$2,790,485	$3,047,650	$3,171,792	$3,251,216	$3,227,919	$3,174,713	$3,145,011	$3,182,832	$3,289,368
Contracts	361,355	411,588	437,610	532,760	514,602	504,798	492,822	558,510	586,883	618,062	621,682
In-house	745,010	853,50	948,606	1,011,936	1,037,499	1,038,730	1,026,484	1,059,392	1,095,658	1,166,033	1,187,097
Total	3,311,081	3,753,721	4,176,701	4,592,346	4,723,893	4,794,744	4,747,225	4,792,615	4,827,552	4,966,927	5,098,147



Source: *NCI Fact Book,* FY2010.

Grants

Research Project Grants

Research Project Grants are awards for investigator-initiated research applications. Several types of awards are made in this category; they vary by type of mechanism, type of applicant, total amount of support, and length of time. FY2008 Research Project Grant expenditures totaled approximately $2.089 billion, accounting for 43.3 percent of the total NCI budget.

P01 Research Program Project Grant
Research Program Project Grants (P01s) support an integrated, multiproject research approach involving a number of independent investigators who share knowledge and common resources. A P01 has a defined, central research focus involving several disciplines or several aspects of one discipline. Each individual project should contribute or be directly related to the common theme of the total research effort, thus forming a system of research activities and projects directed toward a well-defined research program goal.

R01 Research Project Grant
Research Project Grants (R01s) support a discrete, specified research project to be performed by the named investigator(s) in an area representing his/her specific interest and competencies. This is generally referred to as a "traditional Research Project Grant."

R03 Small Research Grant
Small Research Grants (R03s) provide research support that is limited in time and amount for studies in categorical program areas. Small Research Grants provide flexibility and are generally used to initiate studies for preliminary, short-term projects. These grants are nonrenewable.

R21 Exploratory/Developmental Grant
Exploratory/Developmental Grants support the development of new research activities in categorical program areas. Support generally is restricted in terms of the level of support and time.

R33 Exploratory/Developmental Grant—Phase II
Phase II Exploratory/Developmental Grants provide additional support to innovative, exploratory, and developmental research activities that were initiated under the R21 mechanism.

R37 Method to Extend Research in Time (MERIT) Award MERIT Awards
These awards provide long-term grant support to investigators whose research competence and productivity are distinctly superior and who are highly

likely to continue to perform in an outstanding manner. Investigators may not apply for a MERIT Award. After initial review, NCI staff and the NCAB review competing R01 applications to select MERIT awardees. An initial 5-year MERIT Award is followed by possible extensions of 1 to 5 more years of support. Extensions are based on an expedited review of the investigator's accomplishments during the initial period.

R41 Small Business Technology Transfer (STTR) Grant—Phase I

Phase I STTR Grants support cooperative research and development projects between research institutions and small, domestic, for-profit organizations. R41s are limited in time and amount and are used to establish the technical merit and feasibility of ideas that have a potential for commercialization. Generally, support for Phase I STTR awards may not exceed $100,000 for direct and indirect costs and a fixed fee for a period normally not to exceed 1 year. Note: Phase I award levels and project periods are statutory guidelines. Therefore, applicants are encouraged to propose a budget and project period that are appropriate for completion of the research project. Deviations from the guidelines must be well justified.

R42 Small Business Technology Transfer Grant—Phase II

These grants support in-depth development of cooperative research and development projects between research institutions and small, domestic, for-profit organizations. They are limited in time and amount, and applicants must have established during Phase I their projects' feasibility and potential for commercialization. Generally, support for Phase II awards may not exceed $500,000 for direct and indirect costs and a fixed fee for a period normally not to exceed 2 years. Note: Phase II award levels and project periods are statutory guidelines. Therefore, applicants are encouraged to propose a budget and project period that are appropriate for completion of the research project. Deviations from the guidelines must be well justified.

Exhibit III. *Research Funding for Various Research Areas (Dollars in Millions)*

Disease Area	2006 Actual	2007 Actual	2008 Actual	2009 Actual	2010 Actual
Total NCI Budget	**$4,747.2**	**$4,792.6**	**$4,827.6**	**$4,966.9**	**$5,098.1**
AIDS	253.7	253.7	258.5	265.9	272.1
Brain & CNS	130.3	148.2	153.7	151.5	156.8
Breast Cancer	584.7	572.4	572.6	599.5	631.2
Cervical Cancer	83.3	82.4	76.8	70.8	77.0
Clinical Trials	822.3	843.7	853.2	846.6	852.3
Colorectal Cancer	244.1	258.4	273.7	264.2	270.4
Head and Neck Cancers	71.3	66.2	76.1	76.8	62.7
Hodgkin's Disease	20.9	16.5	17.5	18.2	14.6
Leukemia	223.5	205.5	216.4	220.6	239.7
Liver Cancer	62.7	67.7	74.2	70.3	72.6
Lung Cancer	242.9	226.9	247.6	246.9	281.9
Melanoma	08.0	97.7	110.8	103.7	102.3
Multiple Myeloma	30.3	32.3	41.5	45.2	48.5
Non-Hodgkin's Lymphoma	114.1	113.0	122.6	130.9	122.4
Ovarian Cancer	95.1	96.9	100.0	110.1	112.3
Pancreatic Cancer	74.2	73.3	87.3	89.7	97.1
Prostate Cancer	293.2	296.1	285.4	293.9	300.5
Stomach Cancer	11.5	12.0	12.4	15.4	14.5
Uterine Cancer	19.4	16.6	17.1	18.0	14.2

Source: *NCI Fact Book*, FY2010.

Exhibit IV. *Summary of NCI Obligations by Mechanism, FY 2010 (Dollars in Thousands)**

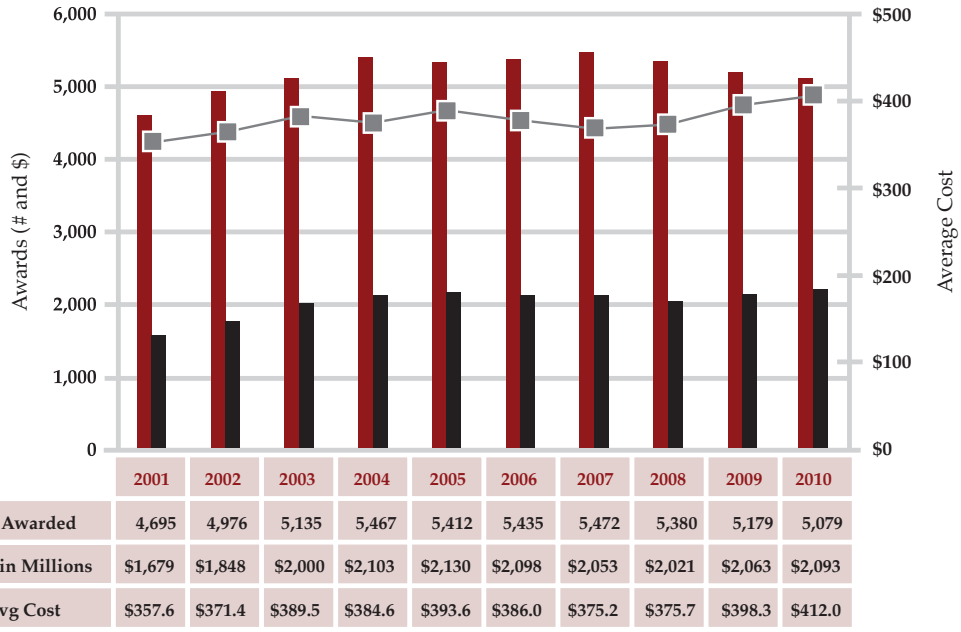
		Number	Amount	% of Total
Research Project Grants	Non-Competing	3,619	1,536,844	30.2%
	Administrative Supplements	(254)	28,947	0.6%
	Competing	1,253	516,598	10.1%
	Subtotal, without SBIR/STTR Grants	4,872	2,082,389	40.9%
	SBIR/STTR Grants	207	85,669	1.7%
	Subtotal, Research Project Grants	**5,079**	**2,168,058**	**42.5%**
Centers & SPOREs	Cancer Centers Grants-P20/P30	66	295,856	5.8%
	SPOREs-P50	63	133,810	2.6%
	Other P50s/P20s	19	38,765	0.8%
	Other Specialized Centers	102	142,702	2.8%
	Subtotal, Centers	**250**	**611,133**	**12.0%**
Other Research	**Career Program**			
	Temin & Minority Mentored Awards-K01	77	10,823	0.2%
	Estab. Inv. Award-K05	21	3,134	0.1%
	Preventive Oncology-K07	97	13,278	0.3%
	Clinical Investigator-K08	83	12,408	0.2%
	Clinical Oncology-K12	18	12,922	0.3%
	Transitional Career Development-K22	30	4,963	0.1%
	Mentored Patient Oriented RCDA-K23	40	5,812	0.1%
	Mid-Career Invest. & Patient Orient. Res-K24	20	3,422	0.1%
	Mentored Quant. Res Career-K25	25	3,311	0.1%
	Inst. Curr. Award-K30	0	0	0.0%
	Pathway to Independence Awards-K99	41	4,841	0.1%
	Subtotal, Career Program	**452**	**74,914**	**1.5%**
	Cancer Education Program-R25	91	35,444	0.7%
	Clinical Cooperative Groups-U10	131	254,487	5.0%
	Minority Biomedical Support-S06	0	466	0.0%
	Res Enhancement-SC1 & Pilot Research-SC2	6	1,348	0.0%
	Continuing Education	6	685	0.0%
	Resource Grants-R24/U24	43	67,144	1.3%
	Explor Coop Agreement-U56	2	862	0.0%
	Global Infect. Disease Rsrch Training Prog-D43	9	5,599	0.1%
	Conference Grants-R13	87	1,664	0.0%
	Subtotal, Other Research Grants	**827**	**442,613**	**8.7%**
Subtotal, Research Grants		**6,156**	**3,221,804**	**63.2%**
NRSA Fellowships	*Trainees:*	**1,428**	**67,564**	**1.3%**
R&D Contracts	R&D Contracts	399	588,742	11.6%
	SBIR Contracts	71	25,020	0.5%
	Subtotal, Contracts	**470**	**613,762**	**12.0%**
Intramural Research	Program		676,730	13.3%
	NIH Management Fund/SSF Assessment		128,602	2.5%
	Subtotal, Intramural Research *FTEs:*	**1,934**	**805,332**	**15.8%**
RMS	Research Mgmt and Support		345,412	6.8%
	NIH Management Fund/SSF Assessment		36,353	0.7%
	Subtotal, RMS *FTEs:*	**1,122**	**381,765**	**7.5%**
Buildings and Facilities			**7,920**	**0.2%**
Construction			**0**	**0.0%**
Total NCI*	***FTEs:***	**3,056**	**5,098,147**	**100.0%**

*Excludes projects awarded with Stamp Out Breast Cancer funds as well as royalty income.
Source: *NCI Fact Book,* FY2010.

Exhibit V. *RPG Awards by Activity Code, FY 2010 (Dollars in Thousands)**

		R01	DP1	DP2	P01	R00	R35	R37	R29	RFA	U01	U19	R03	R21	R33	R15	R55	R56	SBIR/ STTR	TOTAL
2001	#	3,231			178		1	61	210	260	18		122	231	49	3	3		328	4,695
	$	1,008,199			301,115		2,186	26,682	23,738	150,224	14,873		9,024	42,326	23,883	358	300		75,833	1,678,741
2002	#	3,376			173			65	112	267	17		186	308	79	10	9		374	4,976
	$	1,093,908			317,632			29,445	12,471	177,195	17,531		14,115	57,633	39,317	1,477	850		86,367	1,847,941
2003	#	3,573			178			70	14	252	27		203	360	81	21			356	5,135
	$	1,207,387			336,607			35,360	1,584	173,342	31,126		15,207	67,742	37,714	3,086			90,857	2,000,012
2004	#	3,780			177			73	0	233	26		240	425	96	20			397	5,467
	$	1,277,185			344,489			37,888	53	168,539	31,377		18,067	77,970	42,931	4,560			99,579	2,102,638
2005	#	3,848			176			74		254	30	1	223	430	88	20	2	1	265	5,412
	$	1,312,762			338,660			40,007		171,403	34,100	1,049	16,894	76,566	36,250	4,091	200	407	97,775	2,130,164
2006	#	3,909			173			76		273	26	3	218	405	73	14		2	263	5,435
	$	1,293,880			339,616			40,067		173,304	31,292	4,365	16,558	70,650	28,726	2,983		649	96,055	2,098,145
2007	#	3,849			172			73		285	22	3	284	437	48	19		2	278	5,472
	$	1,266,622			326,968			38,232		177,423	24,295	4,212	21,640	78,748	16,739	4,042		495	93,677	2,053,093
2008	#	3,732	2		158	2		70		294	25	3	256	466	36	22		2	312	5,380
	$	1,250,346	1,651		305,250	497		36,287		174,254	20,872	4,366	19,597	92,120	13,770	4,725		302	97,439	2,021,476
2009	#	3,573	3		151	29		63		326	32	2	239	447	25	27	1	0	261	5,179
	$	1,248,939	3,313		302,270	7,186		32,640		218,798	31,320	1,584	18,401	91,537	9,094	5,823	100	79	91,954	2,063,038
2010	#	3,655	5	1	140	55		61		275	43	1	181	415	16	24			207	5,079
	$	1,323,673	6,021	2,512	280,531	13,665		31,498		200,424	36,209	1,252	14,195	83,950	5,583	7,539		8	85,669	2,092,729

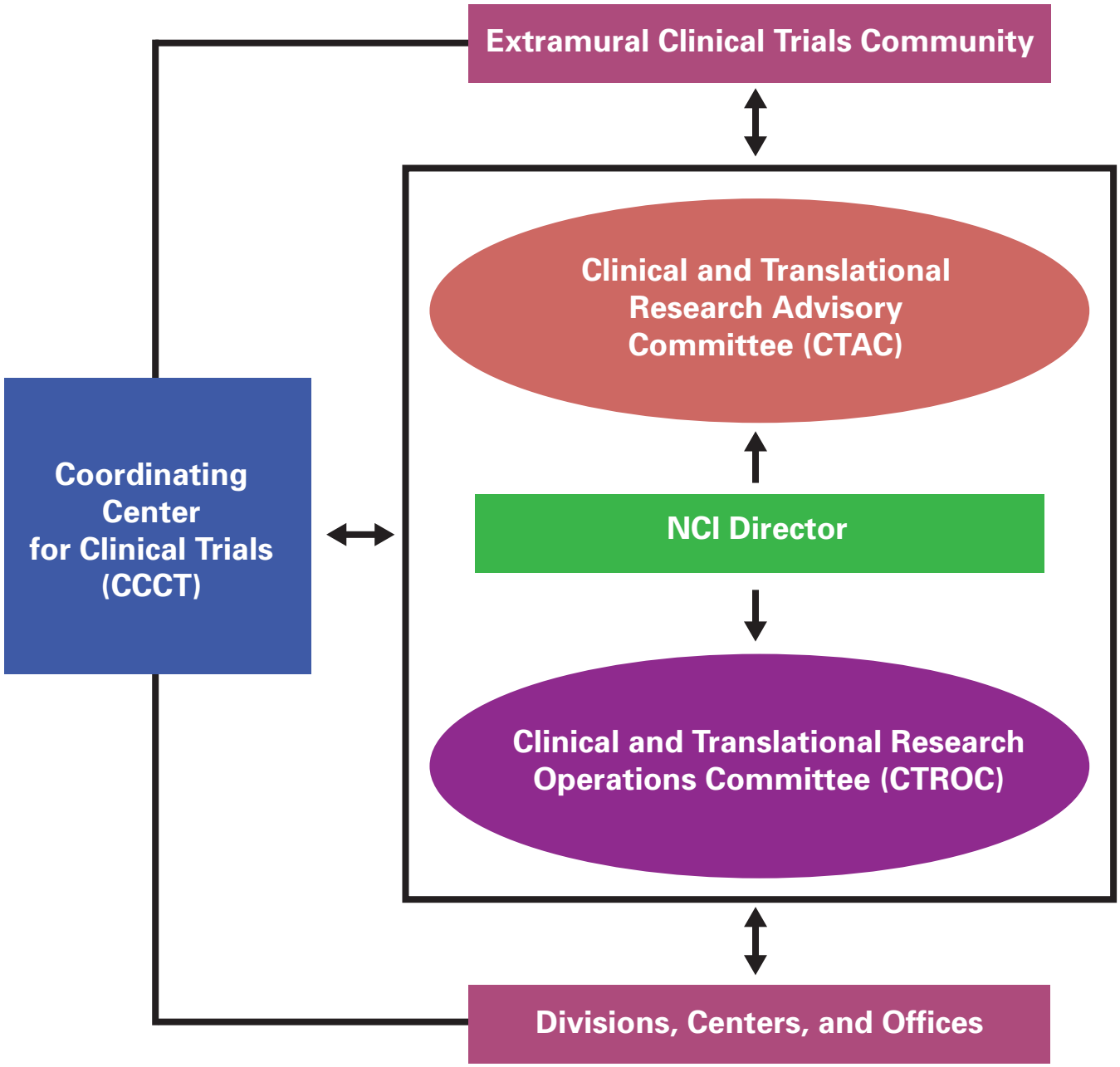
*Research Project Grants and Dollars Awarded FY2001-2010**



	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010
# Awarded	4,695	4,976	5,135	5,467	5,412	5,435	5,472	5,380	5,179	5,079
$ in Millions	$1,679	$1,848	$2,000	$2,103	$2,130	$2,098	$2,053	$2,021	$2,063	$2,093
Avg Cost	$357.6	$371.4	$389.5	$384.6	$393.6	$386.0	$375.2	$375.7	$398.3	$412.0

*Excludes projects awarded with the Stamp Out Breast Cancer Funds and Program Evaluation.
Source: *NCI Fact Book*, FY2010.

Exhibit VI. ***Integrated Management of NCI Clinical Trials***



R43 Small Business Innovation Research (SBIR) Grant—Phase I
Phase I SBIR Grants support research efforts by for-profit, domestic, small businesses. The objectives of this phase are to: (1) establish the technical merit and feasibility of proposed research or research and development (R&D) efforts, and (2) evaluate the performance of the small business awardee organization prior to providing further Federal support in Phase II (R44). Generally, support for Phase I awards may not exceed $100,000 for direct and indirect costs and a fixed fee for a period normally not to exceed 6 months. Note: Phase I award levels and project periods are statutory guidelines. Therefore, applicants are encouraged to propose a budget and project period that are appropriate for completion of the research project. Deviations from the guidelines must be well justified.

R44 Small Business Innovation Research Grant—Phase II
These grants continue R&D efforts started in Phase I (R43). Awards are based on the results of Phase I and the scientific and technical merit and commercial potential of the Phase II application. Only Phase I awardees are eligible for Phase II. Generally, support for Phase II may not exceed $750,000 for direct and indirect costs and a fixed fee for a period normally not to exceed 2 years. Note: Phase II award levels and project periods are statutory guidelines. Therefore, applicants are encouraged to propose a budget and project period that are appropriate for completion of the research project. Deviations from the guidelines must be well justified.

R55 James A. Shannon Director's Award
Applicants do not submit requests for Shannon Awards. Instead, NCI program staff nominate previously reviewed R01 and R03 applications that are beyond the current NCI payline but, because of their merit, are eligible for funding. After each of the three review cycles per year, Shannon Award nominees are administratively reviewed by the NCI according to standard review criteria, then submitted to the Office of Extramural Research, NIH, for expedited review and concurrence prior to funding. Shannon Awards (R55s) provide a limited award to investigators to further develop, test, and refine research techniques; perform secondary analysis of available data sets; test the feasibility of innovative and creative approaches; and conduct other discrete projects that can demonstrate the investigator's research capabilities and lend additional weight to his or her already meritorious application.

R56 High-Priority, Short-Term Project Award
Applicants do not submit requests for a High-Priority Award. Instead, NCI program staff nominate previously reviewed R01 applications that are beyond the current NCI payline but, because of their merit, are eligible for funding. After each of the three review cycles per year, High Priority nominees are administratively reviewed by the NCI according to standard review criteria. The NCI then determines whether any awards are made from NCI funds. High Priority Awards (R56s) provide limited, interim support to enable an applicant to gather additional data for revision of a new or competing renewal application. The R56 will assist early-career scientists trying to establish research careers as well as more experienced scientists who just missed receiving funds.

Cancer Centers and Specialized Programs of Research Excellence

The Cancer Centers, SPOREs, and other specialized centers contain a great diversity of research approaches. In FY2008, expenditures totaled about $477 million, accounting for 9.9 percent of the total NCI budget.

P20 Planning Grant
Planning Grants support planning for new programs, expansion or modification of existing resources, and feasibility studies for new approaches. Such awards have been particularly useful in the development of Cancer Centers and SPOREs.

P30 Cancer Center Support Grant
Cancer Center Support Grants provide support primarily for the research infrastructure of an active and unified Cancer Center, for the purpose of: consolidating and focusing cancer-related activities; increasing research productivity; promoting shared use of research resources and improved quality control; stimulating and promoting interdisciplinary and collaborative research; and increasing the rate at which research discoveries are translated into medical developments.

P50 Specialized Center Grant
Specialized Center Grants support any part of the full range of R&D, from very basic to clinical activities. They also may support ancillary activities, such as the protracted patient care that may be necessary while conducting primary research or R&D. The spectrum of activities comprises a multidisciplinary attack on cancer. These grants differ from Program Project Grants in that they usually are developed in response to an

announcement of the programmatic needs of the NCI and receive continuous attention from its staff. Centers also may serve as regional or national resources for special research purposes. The SPORE grant is one type of Specialized Center. The NCI SPORE is an organ site application, which includes basic and clinical investigation, thus having a significant translational component.

U54 Specialized Center—Cooperative Agreement (see Cooperative Agreement Section)

U56 Exploratory Grant—Cooperative Agreement (see Cooperative Agreement Section)

Other Research Grants

Other research includes the Research Career Program and all other research grants not included in Research Project Grants, Research Centers, and/or Cancer Prevention and Control, except for National Research Service Awards. The NCI Research Career Program includes all "K" awards. Other research also includes the Clinical Cooperative Groups, Cancer Education Program (R25), resource grants (R24/U24), conference grants, and exploratory cooperative agreements (U56). In FY2008, other research expenditures totaled approximately $317.8 million, accounting for 6.6 percent of the total NCI budget.

Career Awards and Cancer Education

K01 Mentored Research Scientist Development Award
Mentored Research Scientist Development Awards provide support and "protected time" for an intensive, supervised career development experience in the biomedical, behavioral, or clinical sciences leading to research independence. Some Institutes/Centers use the K01 to support individuals who propose to train in a new field; for individuals who have had a hiatus in their research careers; or to increase research workforce diversity. The NCI supports the Mentored Research Scientist Development Award to Support Diversity.

K05 Senior Scientist Award
Senior Scientist Awards support outstanding established scientists who have demonstrated a sustained high level of productivity, research accomplishments, and contributions to research in the fields of cancer prevention, control, and population sciences. These awards provide protected time to devote to research and to act as mentors for young investigators. The NCI supports the Established Investigator Award in Cancer Prevention, Control, Behavioral, and Population Sciences Research.

K07 Academic Career Award
Academic Career Awards support junior candidates who are interested in developing academic and research expertise in a specific area. They also support more senior individuals with acknowledged scientific expertise and leadership skills who are interested in improving the curricula and enhancing the research capability within an academic institution. The NCI supports the Cancer Prevention, Control, Behavioral and Population Sciences Career Development Award.

K08 Mentored Clinical Scientist Development Award
Mentored Clinical Scientist Development Awards support the development of outstanding clinical research scientists. These awards provide specialized study for clinically trained professionals who are committed to a career in research and have the potential to develop into independent investigators. The NCI supports two K08 awards: the Mentored Clinical Scientist Development Award and the Mentored Clinical Scientist Development Award to Promote Diversity.

K12 Mentored Clinical Scientist Development Program Award
Mentored Clinical Scientist Development Program Awards help newly trained, appointed clinicians gain independent research skills and experience in a fundamental science within the framework of an interdisciplinary R&D program. The NCI supports the Paul Calabresi Award for Clinical Oncology.

K18 Career Enhancement Award for Stem Cell Research
This program encourages investigators to obtain the training and career development they need to appropriately use stem cells in their research. It is intended to enable investigators to change the direction of their research careers or to take time from their regular professional responsibilities to broaden their scientific background by acquiring new research capabilities, specifically in the use of human or animal embryonic, adult, or cord blood stem cells. The award includes salary and support for career development costs.

K22 Career Transition Award
Career Transition Awards help newly trained basic or clinical investigators to develop their independent research skills through a two-phase program: an initial period involving an intramural appointment at the NIH, and a final period of support at an extramural institution. The award is intended to enable the investigator to establish a record of independent research to sustain

or promote a successful research career. The NCI supports two K22 awards: the Scholars Program and the Transition Career Development Award. The NCI Scholars Program provides an opportunity for outstanding new investigators to begin independent research careers, intramurally, within the special environment of the NCI. It then enables awardees to continue their careers extramurally at an institution of their choice, where they are appointed to junior faculty positions or the equivalent. The NCI Transition Career Development Award is a fully portable mechanism that facilitates the professional advancement of talented clinician cancer scientists, clinicians in patient-oriented cancer research, and researchers in cancer prevention, control, and the population sciences.

K23 Mentored Patient-Oriented Research Career Development Award
Mentored Patient-Oriented Research Career Development Awards provide support for the career development of investigators who focus their research endeavors on patient-oriented research. The mechanism provides support for a period of supervised study and research to clinically trained professionals who have the potential to develop into productive clinical investigators in patient-oriented research.

K24 Mid-Career Investigator in Patient-Oriented Research Award
Mid-Career Investigator in Patient-Oriented Research Awards provide clinicians the opportunity to dedicate time to patient-oriented research and to mentor other clinical investigators in patient-oriented research.

K25 Mentored Quantitative Research Career Development Award
Mentored Quantitative Research Career Development Awards support the career development of investigators with quantitative scientific and engineering backgrounds, outside of biology or medicine, who have made a commitment to focus their research endeavors on behavioral and biomedical research (basic or clinical).

K30 Institutional Curriculum Award
This award supports the development, conduct, and evaluation of curricula that are designed to improve the quality of training for aspiring clinical investigators.

K99/R00 Howard Temin Pathway to Independence Awards in Cancer Research
Howard Temin Pathway to Independence Awards in Cancer Research (K99/R00) support highly promising, postdoctoral research scientists. The initial phase is followed by independent support contingent on securing an independent research position. The goal of this award is to facilitate an investigator receiving an R01 award earlier in his/her research career.

Training (NRSA)

The National Research Service Award (NRSA)
The NRSA is the major mechanism providing long-term, stable support to a wide range of promising scientists and research clinicians. FY2008 NRSA expenditures totaled approximately $69.9 million, accounting for 1.5 percent of the NCI budget.

F31 Predoctoral Individual National Research Service Award
Predoctoral Individual National Research Service Awards provide predoctoral individuals with supervised research training in specified health and health-related areas leading toward a research degree (e.g., Ph.D.).

F32 Postdoctoral Individual National Research Service Award
Postdoctoral Individual National Research Service Awards provide postdoctoral research training to individuals to broaden their scientific background and extend their potential for research in specified health-related areas.

F33 National Research Service Award for Senior Fellows
National Research Service Awards for Senior Fellows enable experienced scientists to take time away from their regular professional responsibilities to: make major changes in the direction of research careers; broaden scientific background; acquire new research capabilities; enlarge command of an allied research field; or increase capabilities to engage in health-related research.

T32 Institutional National Research Service Award
Institutional National Research Service Awards support training opportunities at the predoctoral or postdoctoral level at qualified institutions. Applicants must have the staff and facilities for the proposed program. After the award is made, the institution's training Program Director is responsible for selecting the trainees and administering the program. This program does not support residencies.

D43 International Training Grants in Epidemiology
The International Training Grants in Epidemiology provide support to improve and expand epidemiologic

research and the utilization of epidemiology in clinical trials and prevention research in foreign countries through support of training programs for foreign health professionals, technicians, and other health care workers.

DP1 NIH Director's Pioneer Award (NDPA)
The NIH Director's Pioneer Awards provide support to individuals who have the potential to make extraordinary contributions to medical research. The NIH Director's Pioneer Award is not renewable.

DP2 NIH Director's New Innovator Awards
The NIH Director's New Innovator Awards support highly innovative research projects by new investigators in all areas of biomedical and behavioral research.

Other Grant Mechanisms

R13 Conference Grant
Conference Grants support national or international meetings, conferences, and workshops that are of value in promoting the goals of the National Cancer Program.

R15 Academic Research Enhancement Award (AREA)
Academic Research Enhancement Award (AREA) Grants support small-scale research projects conducted by faculty in primarily baccalaureate-degree-granting domestic institutions. Awards are for up to $75,000 in direct costs (plus applicable indirect costs) for periods not to exceed 36 months.

R24 Resource-Related Research Project Grant
Resource-Related Research Project Grants support research projects that will enhance the capability of resources to serve biomedical research.

R25 Cancer Education Grant
Cancer Education Grants support the development and implementation of programs related to education, information provision, training, technical assistance, coordination, or evaluation. The NCI supports two distinct Cancer Education programs: the Cancer Education and Career Development Program and the Cancer Education Grant Program (CEGP). The NCI Cancer Education and Career Development Program (R25T) is an institutional grant program that supports the development and implementation of curriculum-dependent programs to train predoctoral and postdoctoral candidates in cancer research settings that are highly interdisciplinary and collaborative. The NCI CEGP is a flexible, curriculum-driven program aimed at developing and sustaining innovative educational approaches that ultimately will reduce cancer incidence, mortality, and morbidity. The program also focuses on improving the quality of life for cancer patients. The CEGP awards (R25Es) address a need that is not fulfilled adequately by any other grant mechanism available at the NIH. These awards are dedicated to areas of particular concern to the NCI.

S06 Minority Biomedical Research Support (MBRS) Grant
These grants provide funds to strengthen the biomedical research and research training capability of ethnic minority institutions, thus creating a more favorable milieu for increasing the involvement of minority faculty and students in biomedical research.

S21 Research and Institutional Resources Health Disparities Endowment Grants—Capacity Building
The S21 Research and Institutional Resources Health Disparities Endowment Grants provide support to strengthen the research and training infrastructure of the institution, while addressing current and emerging needs in minority health and other health disparities research.

SC1 Research Enhancement Award
The SC1 Research Enhancement Awards provide support for individual investigator-initiated research projects aimed at developing researchers at minority-serving institutions to a stage where they can transition successfully to other extramural support (R01 or equivalent).

SC2 Pilot Research Project Grant
The SC2 Pilot Research Project Grants provides support for individual investigator-initiated pilot research projects for faculty at MSIs to generate preliminary data for more ambitious research projects.

Cooperative Agreements

The cooperative agreement is a mechanism to provide funding assistance for a variety of activities. The Federal Grant and Cooperative Agreement Act of 1977 authorized use of the cooperative agreement and formally defined the circumstances under which this mechanism is to be employed by Federal agencies. These instruments are used for situations in which an assistance relationship will exist between the NCI and a recipient and substantial programmatic involvement is anticipated.

U01 Research Project Cooperative Agreement
Research Project Cooperative Agreements support discrete, specified, circumscribed projects to be performed by the named investigator(s) in an area representing his/her specific interest and competencies. This mechanism is

utilized when substantial programmatic involvement is anticipated between the NCI and the recipient.

U10 Clinical Research Cooperative Agreement (Clinical Cooperative Groups)
Clinical Research Cooperative Agreements support clinical evaluations of various methods of therapy and/or prevention in specific disease areas. These represent cooperative programs between sponsoring institutions and participating principal investigators, and usually are conducted under established protocols.

U13 Conference Cooperative Agreement
Conference Cooperative Agreements support international, national, or regional meetings, conferences, and workshops for which substantial programmatic NCI staff involvement is planned to assist the recipients.

U19 Research Program Cooperative Agreement
Research Program Cooperative Agreements support research programs that have multiple projects directed toward a specific major objective, basic theme, or program goal, requiring a broadly based, multidisciplinary, and often long-term approach. Substantial Federal programmatic staff involvement is intended to assist investigators during performance of research activities, as defined in the terms and conditions of the award. This mechanism can provide support for certain basic, shared resources, which facilitate the total research effort, including clinical components.

U24 Resource-Related Research Project Cooperative Agreement
Resource-Related Research Project Cooperative Agreements support projects that help improve the capability of resources to serve biomedical research.

U43 Small Business Innovation Research (SBIR) Cooperative Agreement—Phase I (see R43)
Phase I SBIR Cooperative Agreements support finite projects to establish the technical merit and feasibility of R&D ideas that ultimately may lead to the development of commercial products or services. This mechanism is utilized when an assistance relationship will exist between the NCI and a recipient and in which substantial programmatic involvement is anticipated. Cooperative agreement applications are considered only for the topics specifically listed in the current SBIR Omnibus Solicitation. Note: Phase I award levels and project periods are statutory guidelines. Applicants are encouraged to propose a budget and project period that are appropriate for completion of the research project. Deviations from the guidelines must be well justified.

U44 Small Business Innovation Research Cooperative Agreement—Phase II (see U43 and R44)
Phase II SBIR Cooperative Agreements support in-depth development of R&D ideas for which feasibility has been established in Phase I (U43) and that are likely to result in commercial products or services. Note: Phase II award levels and project periods are statutory guidelines. Applicants are encouraged to propose a budget and project period that are appropriate for completion of the research project. Deviations from the guidelines must be well justified.

U54 Specialized Center Cooperative Agreement
Specialized Center Cooperative Agreements support any part of the full range of R&D, from basic concepts to clinical applications. The U54 may involve ancillary supportive activities, such as the provision of protracted patient care during the primary research or R&D effort. The spectrum of activities comprises a multidisciplinary attack on a specific disease entity or biomedical problem area. The U54s differ from program projects in that they usually are developed in response to an announcement of the programmatic needs of an Institute or Division and subsequently receive continuous attention from its staff. Centers also may serve as regional or national resources for special research purposes, with funding staff helping to identify appropriate priority needs. At the NCI, U54s support comprehensive partnerships between MSIs and NCI-designated Cancer Centers, for the benefit of both. These partnerships focus on cancer research career development at the MSI or cancer research plus one or more target areas in cancer research training. These partnerships also may focus on cancer research and target areas in cancer education for, or cancer outreach to, minority communities.

U56 Exploratory Grant Cooperative Agreement
Exploratory Grant Cooperative Agreements support planning for new programs, expansion or modification of existing resources, and development of feasibility studies to explore the development of interdisciplinary programs that offer potential solutions to problems of special significance to the mission of the NIH. These exploratory studies may lead to Specialized or Comprehensive Centers. Substantial Federal programmatic staff involvement is intended to assist investigators during the performance of the research activities, as defined in the terms and conditions of award.

Solicitation of Grant and Cooperative Agreement Applications

Electronic grant applications must be submitted in response to a Funding Opportunity Announcement (FOA) published on http://www.grants.gov or the *NIH Guide for Grants and Contracts*. "Investigator-initiated" or "unsolicited" applications are submitted to Parent Announcements that are mechanism-specific (e.g., R01, R21, R44, etc.). In addition, the NCI may encourage the submission of grant applications through the publication of additional FOAs using the following types of solicitations:

Program Announcements (PAs)
PAs describe continuing, new, or expanded program interests for which grant or cooperative agreement applications are invited. Applications in response to PAs are reviewed in the same manner as unsolicited grant applications (i.e., by chartered peer review committees or Special Emphasis Panels [SEPs] of the Center for Scientific Review [CSR] or by the NCI).

Program Announcements With Special Receipt/ Review (PARs)
PARs are program announcements that contain special receipt dates, referral guidelines, and review considerations and are reviewed either by CSR or by a specific Institute's initial review group (IRG) or SEP.

Requests for Applications (RFAs)
RFAs are issued to invite grant or cooperative agreement applications in a well-defined scientific area to stimulate activity in NCI programmatic priority areas. Usually, a single application receipt date is specified, and the announcement identifies the amount of funds earmarked for the initiative and the number of awards likely to be funded. Applications are evaluated before review for responsiveness to the RFA. Applications received in response to a particular RFA are reviewed by an appropriate NCI SEP. All PAs and RFAs are published in the *NIH Guide for Grants and Contracts* (http://www.nih.gov/grants/guide/index.html) and, when appropriate, in scientific journals and periodicals.

Contracts

Research and Development Contracts
To stimulate scientific inquiry, direct it toward promising areas of current research, and solve specific research problems, the NCI awards research, development, demonstration, and support contracts to both nonprofit and commercial organizations. The idea for a contract may be generated by the NCI program staff (usually the Project Officer) or may originate from members of the scientific community. The negotiated contract used by the NCI is awarded through a competitive process in which bidders are judged on the basis of technical (scientific) merit, business, and cost factors. The responsibility for reviewing the technical merit of proposals for R&D contracts is lodged in the Special Review and Logistics Branch (SRLB), DEA, NCI. Review responsibility is separated from those responsibilities of the Project and Contracting Officers. After award, the NCI is substantially involved in monitoring the project; this may range from tight control to general surveillance and support. Contracts may be used in support of either research or resource projects. In a research contract, the NCI defines the specific area of research and may identify general approaches. Such a contract usually is used to stimulate work in an area that has been neglected by the private sector.

Loan Repayment Program (LRP)
The LRP was started in 1989 to recruit and retain highly qualified professionals as AIDS researchers. Using the contract mechanism, this program provides for repayment of up to $35,000 (principal and interest) of eligible educational loans for qualified clinical and pediatric investigators for each year of their research service. To be eligible, the awardee must agree to engage in clinical or pediatric research for a minimum of 2 years. Originally confined to intramural researchers, the LRP was expanded in 2002 to include extramural investigators.

L30 Clinical Research Loan Repayment Program
The Clinical Research Loan Repayment Program is for eligible investigators, in exchange for a 2-year commitment to clinical research. To participate in the program, individuals must hold an appropriate terminal degree from an accredited institution, must conduct research for 20 hours per week (based on a 40-hour week), and must conduct research that is supported by a domestic, nonprofit institution or by a U.S. Government entity.

L40 Pediatric Research Loan Repayment Program
The Pediatric Research Loan Repayment Program is for eligible investigators, in exchange for a 2-year commitment to pediatric research. To participate in the program, individuals must hold an appropriate terminal degree from an accredited institution, must conduct research for 20 hours per week (based on a 40-hour week), and must conduct research that is supported by a

domestic, nonprofit institution or by a U.S. Government entity.

NCI Advisory Committees

President's Cancer Panel (PCP)

The PCP (see **Appendix F**) is an NCI Federal advisory committee that reports directly to the U.S. President on the activities of the National Cancer Program. The Panel was established by the Public Health Service Act, as amended by the National Cancer Act (P.L. 92-218), and was chartered in accordance with the Federal Advisory Committee Act (P.L. 92-463). The Panel consists of three members who are appointed by the President for terms of 3 years. One of the members is appointed by the President as Chairperson of the Panel for a 1-year term. At least two members must be distinguished scientists or physicians, and the third may be a lay person. The Panel, which meets at least four times a year, is responsible for monitoring the development and execution of the National Cancer Program, evaluating its efficacy, making suggestions for its improvement, and submitting periodic progress reports to the President.

National Cancer Advisory Board (NCAB)

The NCAB (see **Appendix G**) advises, assists, consults with, and makes recommendations to the Secretary of DHHS and the Director of NCI regarding the activities carried out by and through the Institute as well as policies respecting these activities. The NCAB may make recommendations regarding support grants and cooperative agreements, technical and scientific peer review, and functions pertaining to the NCI as described under sections 405, 406, 413, and 414 of the PHS Act, as amended. The NCAB may implement procedures for expediting en bloc concurrence of Scientific Review Group recommendations. Several members may be selected by the Chair and/or Executive Secretary to provide en bloc concurrence on behalf of the Board. Only those applications that do not require individual consideration are included in this expedited process. A report of the en bloc recommendations is presented at each Board meeting.

Board of Scientific Advisors (BSA)

The BSA (see **Appendix H**) advises NCI's Director, Deputy Directors, and the Director of each NCI Division and Center on a wide variety of matters. Topics include scientific program policy and the progress and future direction of each Division's extramural research program. The BSA's responsibilities include evaluation of NCI-awarded grants, cooperative agreements, and contracts, as well as concept review of those activities that it considers to be meritorious and consistent with the Institute's programs. The advisory role of the Board is scientific and does not include deliberation on matters of public policy. As necessary, the Board and its subcommittees may call upon special consultants, assemble ad hoc working groups, and convene conferences, workshops, or other activities.

Board of Scientific Counselors (BSC)

The BSC (see **Appendixes I and J**) advises the Directors of NCI's Intramural Division of Cancer Epidemiology and Genetics and Center for Cancer Research, and the Director of the NCI, on a wide variety of matters concerning scientific program policy and the progress and future direction of each of the intramural research programs. The BSC evaluates performance and productivity of each Division, including the staff scientists, through periodic site visits to intramural laboratories. It also offers advice on the course of programs comprising DCEG and CCR.

Director's Consumer Liaison Group (DCLG)

The DCLG (see **Appendix K**) provides advice and makes recommendations to the Director of the NCI from the perspective and viewpoint of cancer consumer advocates. The DCLG addresses a wide variety of issues, programs, and research priorities, and serves as a channel through which consumer advocates may voice their views and concerns.

Advisory Committee to the Director (ACD)

The ACD advises and makes recommendations to the NCI Director on oversight and integration of various planning and advisory groups serving the broad programmatic and institutional objectives of the Institute. The Committee serves as the official channel through which findings and recommendations emerging from these groups are submitted to the NCI. The ACD may consider the reports of the various review groups as sources of information, advice, or recommendations, and will help the NCI to identify opportunities to be pursued in cancer research that cut across the intramural and extramural programs. As necessary, at the call of the Chair, the Committee may call upon special consultants, assemble ad hoc working groups, and convene conferences and workshops. These consultants are not members of the Committee and do not participate in any votes or other actions of the Committee.

Initial Review Group (IRG)

The IRG advises the NCI and DEA Directors on the scientific and technical merit of applications for grants for research, research training, research-related grants and cooperative agreements, or contract proposals relating to scientific areas relevant to carcinogenesis, cancer biology and diagnosis, Cancer Center administration, medicine, radiological and surgical oncology, cancer chemotherapy, cancer epidemiology, cancer prevention and control, cancer education, cancer information services, community outreach, cancer detection and diagnosis, cancer treatment and restorative care, dentistry, nursing, public health, nutrition, education of health professionals, medical oncology, surgery, radiotherapy, gynecologic oncology, pediatric oncology, pathology, and biostatistics. The IRG is composed of several chartered subcommittees that primarily review the following applications: Cancer Centers, Clinical Cooperative Groups, Institutional Training Grants, and Career Development Awards.

Clinical Trials and Translational Research Advisory Committee (CTAC)

The CTAC advises, assists, and makes recommendations to the NCI Director, Deputy Directors, and Division Directors on the NCI-supported national clinical trials enterprise. This encompasses oversight of all trials, both extramural and intramural.

The CTAC is described in detail beginning on page 1.

The U.S. Department of Health and Human Services and the National Institutes of Health

The U.S. Department of Health and Human Services

The mission of the Department of Health and Human Services (DHHS) is to enhance the health and well-being of Americans by providing for effective health and human services and fostering strong, sustained advances in the sciences underlying medicine, public health, and social services. The DHHS consists of the Office of the Secretary, which provides leadership; the Program Support Center, which provides centralized administrative support; and 11 operating divisions, which manage more than 300 health-related programs. These operating divisions are:

- Administration for Children and Families (ACF)
- Administration on Aging (AoA)
- Agency for Healthcare Research and Quality (AHRQ)
- Agency for Toxic Substances and Disease Registry (ATSDR)
- Centers for Disease Control and Prevention (CDC)
- Centers for Medicare and Medicaid Services (CMS) [formerly the Health Care Financing Administration (HCFA)]
- Food and Drug Administration (FDA)
- Health Resources and Services Administration (HRSA)
- Indian Health Service (IHS)
- National Institutes of Health (NIH)
- Program Support Center (PSC)
- Substance Abuse and Mental Health Services Administration (SAMHSA).

The ACF is responsible for temporary assistance to needy families; children's welfare, care, and support; disabilities programs; and other services. The AoA serves the elderly. The CMS manages health insurance programs, while the PSC provides products and services to the DHHS and other Federal agencies. NIH, AHRQ, ATSDR, CDC, FDA, HRSA, IHS, and SAMHSA are all devoted to public health and compose the Public Health Service (PHS) (see **Exhibit VII**).

The National Institutes of Health

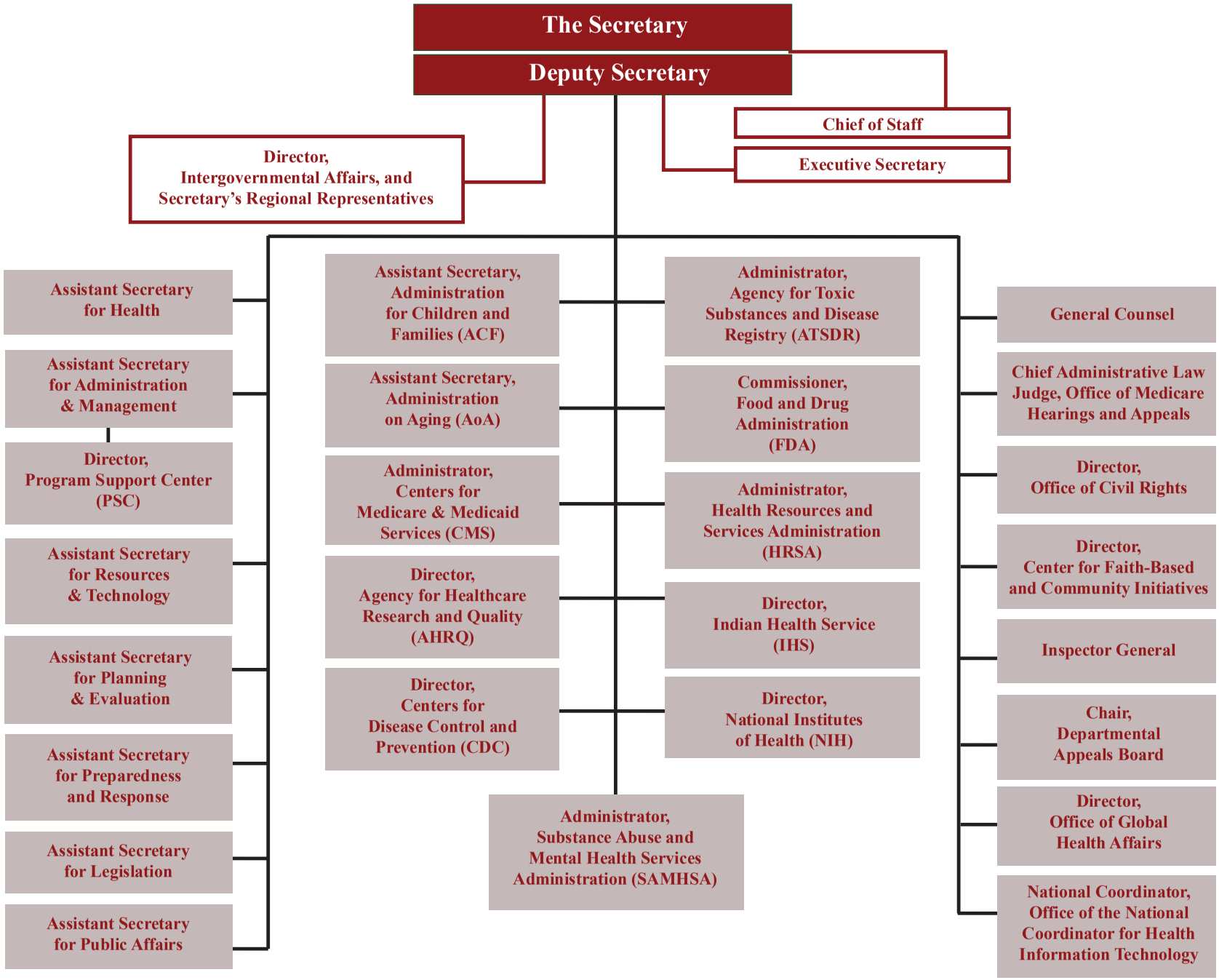
Mission, Organization, and History

NIH's mission is to uncover new knowledge that will lead to better health for everyone. The NIH works toward that mission by conducting research in its own laboratories; supporting the research of non-Federal scientists in universities, medical schools, hospitals, and research institutions throughout the country and abroad; helping to train research investigators; and fostering communication of medical information. NIH's budget has grown from $300 in 1887, when the NIH was a one-room Laboratory of Hygiene, to more than $30.5 billion in 2009 (see **Exhibit VIII**). The NIH is composed of the Office of the Director, 19 Institutes, 7 Centers (4 of which have funding authority), and the National Library of Medicine (NLM); it has 75 buildings located on more than 300 acres in Bethesda, Maryland. An organizational chart for the NIH is presented in **Exhibit IX**. **Exhibit X** is a guide to the Bethesda campus.

Overview of NIH History

NIH is a component of thePHS of DHHS. The PHS traces its origin to "an Act for the Relief of Sick and Disabled Seamen" of 1798 (Stat. L. 604), which authorized the establishment of marine hospitals for the care of American merchant seamen. In 1912, the Public Health and Marine Hospital Service became the Public Health Service. The actual forerunner of the National Institutes of Health was established in 1887 as the Laboratory of Hygiene, located at the Marine Hospital of Staten Island, New York. In 1930, this laboratory was renamed the National Institute of Health. The first of the present Institutes, the National Cancer Institute (NCI), was established in 1937 by an act of Congress. In 1938, the National Advisory Cancer Council approved the first awards for research training fellowships in cancer research. In 1948, the National Heart Institute was established, and the National Institute of Health became the National Institutes of Health (NIH). During the years 1949-2001, the NIH expanded to include 27 Institutes and Centers.

Exhibit VII. *Department of Health and Human Services*



The following timeline chronicles the establishment and evolution of the current NIH Institutes and Centers:

1798 President John Adams signed "an Act for the relief of sick and disabled Seamen," which led to the establishment of the Marine Hospital Service.

1803 The first permanent Marine Hospital was authorized to be built in Boston, Massachusetts.

1836 The Library of the Office of the Surgeon General of the Army was established.

1870 President Grant signed a law establishing a "Bureau of the U.S. Marine Hospital Service" within the Treasury Department. This Bureau, headed by a Supervising Surgeon (later Surgeon General), was given central control over the hospitals.

1887 The Laboratory of Hygiene at the Marine Hospital in Staten Island, New York, was established for research on cholera and other infectious diseases.

1891 The Laboratory of Hygiene was redesignated the Hygienic Laboratory and moved from Staten Island to the Marine Hospital Service headquarters in Washington, DC.

1902 The Advisory Board for the Hygienic Laboratory was established, which later became the National Advisory Health Council. An act of Congress changed the name of the Marine Hospital Service to the Public Health and Marine Hospital Service. The Hygienic Laboratory was authorized by Congress to regulate laboratories that produced "biologicals." The Hygienic Laboratory was expanded to four divisions: Bacteriology and Pathology, Chemistry, Pharmacology, and Zoology.

1912 The Public Health and Marine Hospital Service was renamed the Public Health Service.

1922 The Library of the Office of the Surgeon General was renamed the Army Medical Library.

1930 The Hygienic Laboratory was renamed the National Institute of Health. Congress authorized construction of two buildings for the NIH and a system of fellowships.

1937 Congress authorized the establishment of the National Cancer Institute and the awarding of research grants. Rocky Mountain Laboratory became part of the NIH. The National Advisory Cancer Council held its first meeting.

1938 The NIH was moved to land donated by Mr. and Mrs. Luke I. Wilson, located in Bethesda, Maryland. The cornerstone for the Shannon Building was laid.

1939 The Public Health Service became part of a newly created Federal Security Agency; until that time, it was part of the Treasury Department.

1946 The Division of Research Grants was established to process NIH grants and fellowships to non-Federal institutions and scientists. (Originally established as the Research Grants Office, it was renamed the Research Grants Division and, finally, the Division of Research Grants.)

1948 The National Heart Institute was authorized. Several laboratories (including Rocky Mountain Laboratory) were regrouped to form the National Microbiological Institute. The Experimental Biology and Medicine Institute and the National Institute of Dental Research were established. The National Institute of Health became the National Institutes of Health.

1949 The Mental Hygiene Program of the PHS was transferred to the NIH and expanded to become the National Institute of Mental Health (NIMH).

1950 The "Omnibus Medical Research Act" authorized the establishment of the National Institute of Neurological Diseases and Blindness, as well as the National Institute of Arthritis and Metabolic Diseases. The latter absorbed the Experimental Biology and Medicine Institute.

Exhibit VIII. *NIH FY 2008–2010 Funding*

INSTITUTE/ CENTER	FUNDING (Dollars in Thousands)		
	2008	2009	2010
NCI	4,830,647	4,968,973	5,103,388
NHLBI	2,938,470	3,015,689	3,096,916
NIDCR	391,778	402,652	413,236
NIDDK	1,864,945	1,911,338	1,808,100
NINDS	1,552,113	1,593,344	1,636,371
NIAID	4,288,585	4,702,572	4,818,275
NIGMS	1,946,104	1,997,801	2,051,798
NICHD	1,261,381	1,294,894	1,329,528
NEI	670,664	688,480	707,036
NIEHS	723,215	740,894	689,781
NIA	1,052,830	1,080,796	1,110,229
NIAMS	511,291	524,872	539,082
NIDCD	396,234	407,259	418,833
NIMH	1,412,951	1,450,491	1,489,372
NIDA	1,006,022	1,032,759	1,059,848
NIAAA	438,579	450,230	462,346
NINR	138,207	141,879	145,660
NHGRI	489,368	502,367	516,028
NIBIB	300,233	308,208	316,582
NCRR	1,155,560	1,226,263	1,268,896
NCCAM	122,224	125,471	128,844
NCMHD	200,630	205,959	211,572
FIC	66,912	68,691	70,051
NLM	322,667	330,771	339,716
OD	1,111,735	1,246,864	1,177,300
B&F	118,966	125,581	100,000
TOTAL	29,312,311	30,545,098	31,008,788

Source: *NIH Almanac,* 2010.

1953 The PHS became part of the newly created Department of Health, Education, and Welfare. The Clinical Center opened.

1955 The National Microbiological Institute was renamed the National Institute of Allergy and Infectious Diseases (NIAID). The Laboratory of Biologics Control was renamed the Division of Biologics Standards. The Division of Research Services was created.

1956 The Armed Forces Medical Library was renamed the National Library of Medicine and placed in the PHS.

1957 The Center for Aging Research was established.

1958 The Division of General Medical Sciences was created. The Center for Aging Research was transferred from the National Heart Institute to the Division of General Medical Sciences.

1961 The Center for Research in Child Health was established within the Division of General Medical Sciences.

1962 The NLM was moved to the NIH campus.

1963 The Division of General Medical Sciences was renamed the National Institute of General Medical Sciences (NIGMS). The National Institute of Child Health and Human Development (NICHD) was created.

1966 The Division of Environmental Health Sciences was created.

1967 The National Institute of Mental Health was separated from the NIH and became a separate bureau of the PHS.

1968 The John E. Fogarty International Center (FIC) for Advanced Study in the Health Sciences was created. The Bureau of Health Manpower and the NLM became part of the NIH. The National Eye Institute (NEI) was created. The National Institute of Neurological Diseases and Blindness was renamed the National Institute of Neurological Diseases and Stroke (NINDS).

1969 The Division of Environmental Health Sciences was renamed the National Institute of Environmental Health Sciences (NIEHS). The National Heart Institute was renamed the National Heart and Lung Institute.

1972 The National Institute of Arthritis and Metabolic Diseases was renamed the National Institute of Arthritis, Metabolism, and Digestive Diseases.

1974 The National Institute on Aging (NIA) was created.

1975 The National Institute of Neurological Diseases and Stroke was renamed the National Institute of Neurological and Communicative Disorders and Stroke.

1976 The National Heart and Lung Institute was renamed the National Heart, Lung, and Blood Institute (NHLBI).

1981 The National Institute of Arthritis, Metabolism, and Digestive Diseases was renamed the National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases (NIADDK).

1986 The National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases was renamed the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK). The National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) was created. The Center for Nursing Research was transferred from the Health Resources and Services Administration (HRSA) and renamed the National Center for Nursing Research.

1989 The National Institute on Deafness and Other Communication Disorders (NIDCD) was established. The National Institute of Neurological and Communicative Disorders and Stroke was renamed the National Institute of Neurological Disorders and Stroke. The National Center for Human Genome Research was established. The National Center for Biotechnology Information was established within the NLM.

1990 The National Center for Research Resources (NCRR) was created by consolidating the Division of Research Services and the Division of Research Resources.

1992 The National Institute on Alcohol Abuse and Alcoholism (NIAAA), National Institute on Drug Abuse (NIDA), and National Institute of Mental Health (NIMH) were transferred to the NIH from the Alcohol, Drug Abuse, and Mental Health Administration.

1993 The National Center for Nursing Research was renamed the National Institute of Nursing Research (NINR).

1995 The NIH was established as an HHS Operating Division, thereby elevating it to report directly to the Secretary of HHS.

1997 The National Center for Human Genome Research was renamed the National Human Genome Research Institute (NHGRI).

1998 The Division of Research Grants was renamed the Center for Scientific Review. The National Center for Complementary and Alternative Medicine (NCCAM) was established. The National Institute of Dental Research was renamed the National Institute of Dental and Craniofacial Research (NIDCR).

2001 The National Center on Minority Health and Health Disparities (NCMHD) was established. The National Institute of Biomedical Imaging and Bioengineering (NIBIB) was established.

Exhibit IX. *National Institutes of Health*

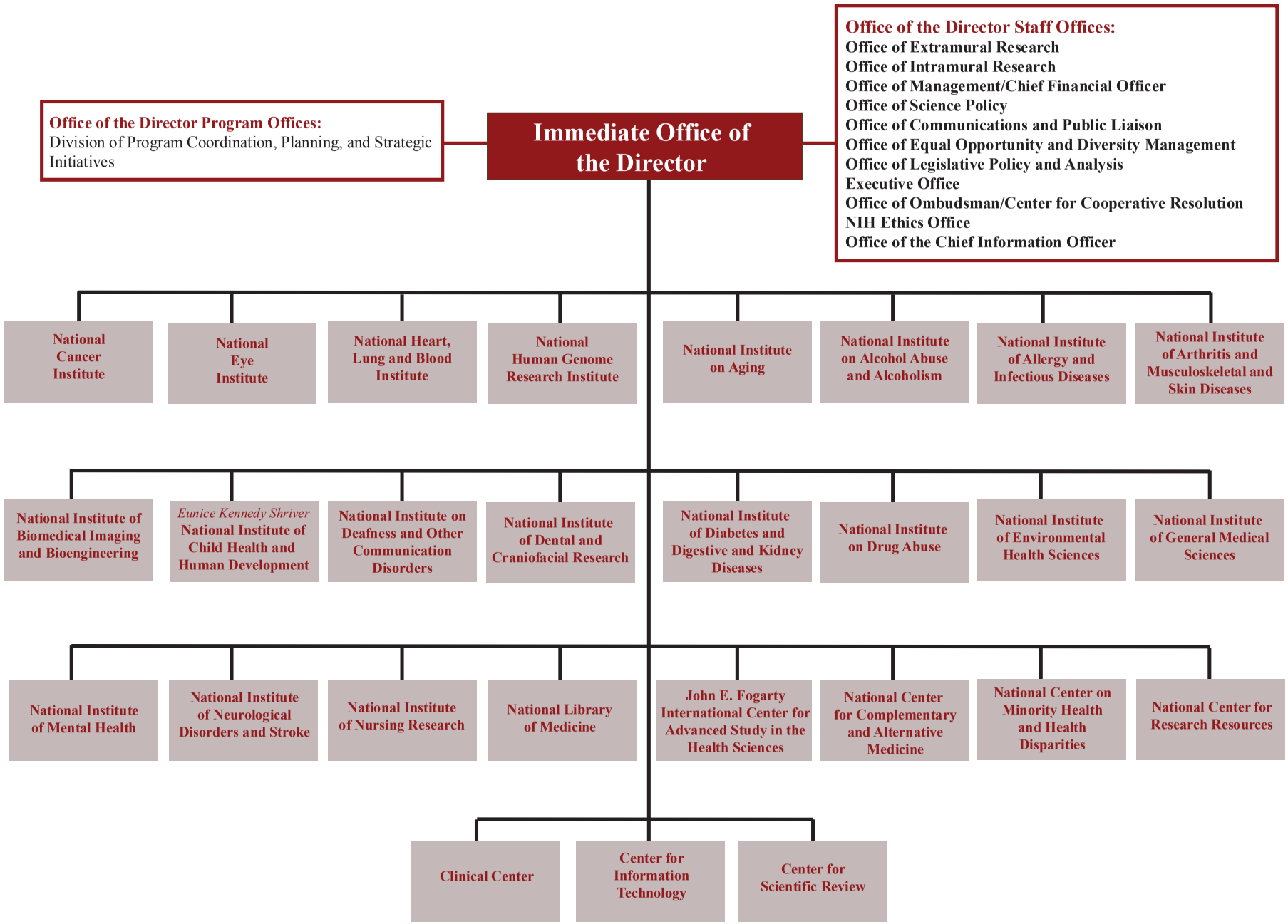
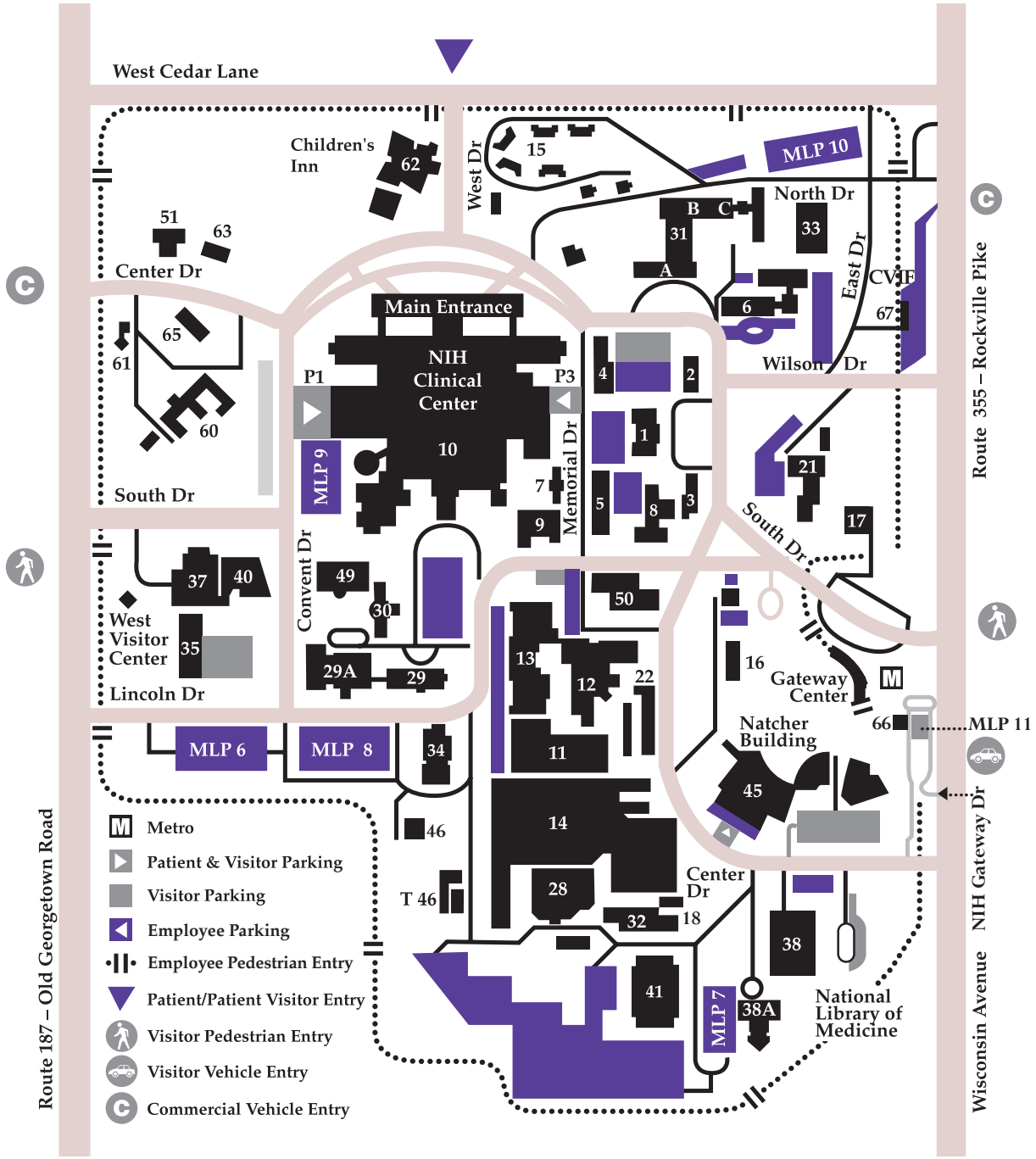


Exhibit X. *NIH Facilities Map*



Building Key

Building 1	James Shannon Building (NIH Administration)	**Building 38**	National Library of Medicine
Building 10	Warren Grant Magnuson Clinical Center; Mark Hatfield Clinical Research Center	**Building 38A**	Lister Hill
		Building 40	Vaccine Research Center
Building 11	Central Utility Plant	**Building 45**	Natcher Building and Conference Center
Building 13	Engineering Services	**Building 49**	Sylvio Conte Building
Building 14	Office of Research Facilities	**Building 50**	Stokes Laboratories
Building 16	Stone House	**Building 60**	Mary Woodard Lasker Center
Building 31	Claude D. Pepper Building (General Office Building)	**Building 62**	The Children's Inn at NIH
Building 36	Lowell P. Weicker Building	**Blue**	**Parking Area**

Appendix A. CTAC Roster

Chair

James L. Abbruzzese, M.D., F.A.C.P. **2012**
Chairman
Department of Gastrointestinal Medical Oncology
The University of Texas
MD Anderson Cancer Center
Houston, TX

Members

Peter C. Adamson, M.D. **2013**
Chair
Children's Oncology Group
Chief
Clinical Pharmacology and Therapeutics
The Children's Hospital of Philadelphia
University of Pennsylvania
Philadelphia, PA

Susan G. Arbuck, M.D., M.Sc., F.A.C.P. **2014**
President
Susan G. Arbuck M.D., LLC
Potomac, MD

Monica M. Bertagnolli, M.D. **2014**
Professor of Surgery
Harvard Medical School
Brigham & Women's Hospital
Dana-Farber Cancer Institute
Boston, MA

Susan G. Braun (DCLG) **2013**
President
The Hale Fund
Executive Director
Commonweal
Bolinas, CA

Curt Civin, M.D. (BSA) **2012**
Associate Dean of Research
Professor of Pediatrics
Director
Center for Stem Cell Biology and Regenerative Medicine
University of Maryland School of Medicine
Baltimore, MD

Kenneth H. Cowan, M.D., Ph.D. **2012**
Director
Eppley Cancer Center
University of Nebraska Medical Center
Omaha, NE

Kevin J. Cullen, M.D. (NCAB) **2015**
Director
University of Maryland Greenebaum Cancer Center
Baltimore, MD

Nancy E. Davidson, M.D. **2015**
Director
University of Pittsburgh Cancer Institute
University of Pittsburgh
Pittsburgh, PA

Olivera J. Finn, Ph.D. **2013**
Distinguished Professor and Chair
University of Pittsburgh School of Medicine
Pittsburgh, PA

J. Phillip Kuebler, M.D., Ph.D. **2015**
Principal Investigator
Columbus Oncology Associates, Inc.
Columbus, OH

Scott M. Lippman, M.D. **2013**
Director
UC San Diego Moores Cancer Center
University of California, San Diego
La Jolla, CA

CTAC Roster, continued

Mary S. McCabe, R.N. **2014**
Director
Cancer Survivorship Program
Memorial Sloan Kettering Cancer Center
New York, NY

Lisa A. Newman, M.D., M.P.H., F.A.C.S. **2014**
Professor of Surgery and Director
Breast Care Center and Multidisciplinary Breast Fellowship Program
University of Michigan Comprehensive Cancer Center
Ann Arbor, MI

Nancy Roach (BSC) **2013**
Consumer Advocate
C3: Colorectal Cancer Coalition
Hood River, OR

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Appendix B. CTAC Charter

AUTHORITY

42 U.S.C. 285a-2(b)(7), section 413(b)(7) of the Public Health Service Act, as amended. The National Cancer Institute Clinical Trials and Translational Research Advisory Committee (Committee) is governed by the provisions of the Federal Advisory Committee Act, as amended (5 U.S.C. app.), which sets forth standards for the formation and use of advisory committees.

MEMBERSHIP AND DESIGNATION

The Committee will consist of 25 members, who may include the Director, NCI as Chair or a designee appointed by the NCI Director will chair the Committee. At least five members will hold concurrent membership on either the National Cancer Advisory Board, Board of Scientific Advisors, Board of Scientific Counselors (Basic Sciences and Clinical Sciences and Epidemiology), or Director's Consumer Liaison Group. Members will be authorities knowledgeable in the fields of community oncology, surgical oncology, medical oncology, radiation oncology, patient advocacy, extramural clinical investigation, regulatory agencies, pharmaceutical industry, public health, clinical trials design, management and evaluation, drug development and developmental therapeutics, cancer education, cancer information services, community outreach, vaccine development, cellular oncology, molecular oncology, pediatric oncology, clinical, basic and translational research, cancer center administration, cancer biology and diagnosis, cancer epidemiology, chemotherapy, oncology health care providers, pharmacology, pathology, biostatistics, quality of life, pain management, cancer treatment and restorative care, and education of health professionals. All non-Federal members serve as Special Government Employees. Members and the Chair will be invited to serve for overlapping four-year terms. A quorum for the conduct of business by the full Committee will consist of a majority of currently appointed members.

Ex officio members include NCI Deputy Directors, the Director, Division of Extramural Activities, NCI, the Director, Division of Cancer Treatment and Diagnosis, an NCI intramural scientist engaged in clinical research, and representatives from the Food and Drug Administration, Centers for Medicare and Medicaid Services, the Department of Defense and Department of Veterans Affairs.

Members of the National Cancer Advisory Board, Board of Scientific Advisors, Board of Scientific Counselors (Basic Sciences and Clinical Sciences and Epidemiology), and Director's Consumer Liaison Group will serve for the duration of their terms as members of their respective Boards/Committees.

A member may serve after the expiration of that member's term until a successor has taken office.

DESCRIPTIONS OF DUTIES

The Committee makes recommendations on the NCI-supported national clinical trials enterprise to build a strong scientific infrastructure by bringing together a broadly developed and engaged coalition of stakeholders involved in the clinical trials process. This encompasses oversight of all trials both extramural and intramural. The Committee will provide broad scientific and programmatic advice on the investment of tax payer dollars in clinical trials and supportive science. This will lead to enormous potential for more specific cancer treatment, coupled with the complexity of evaluating new, highly specific agents integrating knowledge, insights, and skills of multiple fields into a new kind of cross-disciplinary, scientifically-driven, cooperative research endeavor.

In addition, the Committee makes recommendations regarding the effectiveness of NCI's translational research management and administration program, including needs and opportunities across disease sites, patient populations, translational developmental pathways, and the range of molecular mechanisms responsible for cancer development. The Committee will advise on the appropriate magnitude for dedicated translational research priorities and recommend allocation of translational research operations across organizational units, programs, disease sites, populations, developmental pathways, and molecular mechanisms. The Committee will ensure that appropriate emphasis is placed on rare cancers, medically underserved populations, and historically lower-resourced pathways to clinical goals.

The goal is to foster an open, collaborative system involving all the critical stakeholders in the prioritization process bringing diverse institutions and individuals together into an integrated and efficient, but innovative and responsive effort, thus moving discoveries to benefit cancer patients.

ESTIMATED NUMBER AND FREQUENCY OF MEETINGS

Meetings of the full Committee will be held approximately 3 times within a fiscal year. Meetings will be open to the public except as determined otherwise by the Secretary of Health and Human Services (Secretary) in accordance with subsection (c) of section 552b of Title 5 U.S.C. Notice of all meetings will be given to the public. In the event a portion of a meeting is closed to the public, as determined by the Secretary, in accordance with the Government in the Sunshine Act (5 U.S.C. 552b(c)) and the Federal Advisory Committee Act, a report will be prepared which will contain, as a minimum, a list of members and their business addresses, the Committee's functions, dates and places of meetings, and a summary of the Committee's activities and recommendations made during the fiscal year. A copy of the report shall be provided to the Department Committee Management Officer.

Appendix C. Federal Advisory Committee Act

The FACA was established in 1973 as a mechanism for Governmentwide oversight of advisory committees. The Act covers the framework, creation, management, operation, and termination of advisory committees reporting to the Executive Branch. FACA applies to any committee not wholly composed of Federal employees that is established by statute or by the Executive Branch. In principle, FACA promotes Government values such as openness, accountability, and balancing of viewpoints. FACA also allows CTAC to make formal recommendations directly to the NCI Director.

You should be aware that FACA requires:

- Maintenance of information on the nature, functions, and operation of CTAC.
- Meetings that are open to the public, with limited exceptions.
- *Federal Register* publication of meeting notices and agendas to accommodate public participation.
- Assignment of Designated Federal Officials to approve all CTAC meetings and agendas and attend all CTAC meetings.
- Approval of detailed meeting minutes.
- Availability of all CTAC-related documents for public inspection and copying.

Appendix D. Conflict of Interest Policies and Ethics Rules for Advisory Committee Members

Conflict of Interest Policies

Members of the CTAC are Special Government Employees (SGE). By definition, an SGE is an officer or employee in the Executive Branch of the Federal Government who is appointed to perform temporary duties, with or without compensation, for a period not to exceed 130 days during any period of 365 consecutive days. During the term of their appointments, SGEs must be aware of relevant statutes regarding criminal conflicts of interest, and they must follow defined standards of ethical conduct.

The Office of Government Ethics (OGE) has issued the following new conflict of interest guidelines for State multi-campus institutions and private institutions and affiliates.

Policy for State Multi-Campus Institutions

The OGE has provided regulatory waiver under 5 CFR 2640.203© for SGE Federal advisory committee members employed in one university of a State multi-university system to review applications from a separate university of the same system, provided the member has no conflicting multi-institutional duties and responsibilities that affect the entire educational system.

Policy for Private Institutions and Affiliates

In addition, an SGE member of an advisory committee who is employed by a private institution may participate in the review of a grant application submitted by an affiliate of the private institution if the SGE: does not hold a joint appointment with that affiliate, does not have affiliate-wide responsibilities, and has a waiver to do so.

At each Committee meeting, Committee members sign a statement certifying that they did not participate in the discussion of or vote on any application from their own institution or an institution in which they have a financial interest.

Ethics Rules for Special Government Employees Serving on Advisory Committees

As a Special Government Employee (SGE), you are a Federal Government employee. As such, you are covered by the Executive Branch ethics rules, although in a somewhat less restrictive manner than regular Government employees.

The Criminal Conflict of Interest Statutes 18 U.S.C. §§ 203, 205, 207, 208

Financial Conflicts: You are prohibited from participating personally and substantially in any particular matter that directly and predictably affects your own financial interests or the financial interests of certain other persons or organizations: your spouse, minor child, general partner, and outside organizations with which you serve as an officer, director, trustee, or employee, or with which you are negotiating for or have an arrangement for future employment. If your duties would require you to participate in any particular matter that affects your financial interests, you have a conflict of interest which you will have to resolve. Of most concern are reviews of grant proposals or contract applications, or similar funding decisions; recommendations or approvals of scientific studies, projects, clinical trials, and new drug applications; and other actions that involve deliberation, decision, or action affecting the legal rights of identified parties. You might also be prohibited from involvement in Particular Matters of General Applicability; for example, recommendations of regulations, policies, or standards that affect an industry, group of manufacturers, or health care providers.

Divestiture: Sell or otherwise dispose of the financial interest that is creating the conflict.

Waiver: Get written approval from a senior official to continue with your work for the committee despite the conflict. Waivers can be granted where there is a pressing need for a particular individual's services on the committee and this

outweighs the potential for conflict of interest. Specific criteria must be met. This is considered a "general waiver" in that it only allows participation in matters that affect all institutions, or types of institutions, similarly.

Concurrent Representation: While you are serving, there are representational restrictions on contacting the Government on behalf of another—for example, as an agent or attorney—with intent to influence on a specific party matter that you are working on as an SGE.

Post-Employment Representation: You cannot "switch sides" in the private sector and represent back to the Government concerning the same specific party matter—the same contract or grant, for example, that you worked on as an SGE. (Remember also the restrictions resulting from employment negotiations that are covered by the financial conflict statute.)

Standards of Ethical Conduct 5 CFR Part 2635

You are prohibited from receiving compensation for teaching, speaking, or writing about your Government duties or about any topic if the invitation to teach, speak, or write comes from a person substantially affected by the matters on which you work as an SGE. However, you may teach courses about general topics requiring multiple presentations.

You may not accept gifts offered as a result of your advisory committee membership. In many circumstances, you may not participate as an expert witness on any matter or proceeding that you work on as an SGE.

Impartiality: You are prohibited from participating in a specific party matter where a reasonable person would question your impartiality—for example, conducting a review of a grant application submitted by your mentor or someone with whom you have a close relationship—unless authorized by an agency designee to participate.

Misuse of Position—Use of Public Office for Private Gain: This includes the misuse of nonpublic information, government property, and official time. You may not use your position to imply that the Committee endorses your private activities or refer to your Government position for your own private gain.

Employment by, or Gifts from, Foreign Governments: Committee member may not be employed by a foreign government, which includes positions with foreign universities that are government operated. There are also statutory provisions restricting acceptance of gifts including awards, educational scholarships, and travel expenses occurring outside the United States.

Lobbying: In their official capacities or as a group, committee members are prohibited from engaging in any activity which directly or indirectly encourages or directs any person or organization to lobby one or more members of Congress. You may appear for the purpose of informing or educating the public about a particular policy and you may communicate with members of Congress at their request.

Political Activities (Hatch Act): While on Government duty (unlike other rules that always apply during your time of appointment), you may not engage in partisan political activities, run for political office in a partisan election, or solicit contributions from the public. For more information on political activity restrictions, please see the Office of Special Counsel website at http://www.osc.gov.

Ethics for SGEs: Your Responsibilities as a Government Employee

Excerpted from: *Overview of the Ethics Rules for Special Government Employees Serving on an Advisory Committee*, Office of Federal Advisory Committee Policy, NIH (see p. 61).

- Complete the OGE-450 Financial Disclosure Report and submit it for review. You should not attend meetings or participate in committee business until this form is submitted and reviewed.
- Complete the HHS-697 Foreign Activities Questionnaire and submit it for review.
- If conflicts of interest are identified, work with committee managers and ethics officials to resolve them.

- Complete an annual financial disclosure report.
- Complete initial ethics orientation and yearly ethics training—you should have a basic knowledge of the Standards of Ethical Conduct and the Conflict of Interest Statutes.
- Monitor changes in your circumstances that might create new conflicts.
- Be sure to contact your Designated Federal Official (DFO) or ethics officials with any questions.

Financial Conflicts of Interest Office of Government Ethics—OGE 450 Form

Office of Government Ethics (OGE) 450 Form: http://ethics.od.nih.gov/forms/OGE-450-June-08.pdf

Financial Interests to be reported on the form include:

- Stocks, stock options, bonds
- Mutual funds and sector funds (waiver available for biotech/health care sector funds up to aggregate value of $50,000)
- Earned income including salaries, fees, and/or honoraria
- Limited partnerships and venture capital corporations
- Non-Federal research/training support
- Invention rights and royalties
- Real estate, trades and businesses, and partnership interests
- Speaking engagements and consultant work.

At the close of the reporting period, SGEs report assets with a fair market value greater than $1,000 that produced income over $200.

Conflict of Interest and Ethics Web Sites

U.S. Office of Government Ethics:

- Online training on Ethics for Special Government Employees: http://education.oge.gov/training/module_files/ogesge_wbt_07/10.html
- Online training on Completing the OGE Form 450: http://www.oge.gov/Education/Education-Resources-for-Federal-Employees/How-to-file-an-OGE-Confidential-Financial-Disclosure-Form-(OGE-form-450)/

A Guide on the Ethics Rules That Apply to Advisory Committee Members Serving as Special Government Employees:

- http://www.oge.gov/uploadedFiles/Education/Education_Resources_for_Ethics_Officials/Resources/bkServeHonor.pdf

Overview of the Ethics Rules for Special Government Employees Serving on Advisory Committees:

- http://ofacp.od.nih.gov/ethics/pdfs/SGE3.pdf

Ethics Rules for Advisory Committee Members and Other Individuals Appointed as Special Government Employees (SGEs):

- http://ofacp.od.nih.gov/ethics/pdfs/SGETRAININGOCT2004.pdf

NIH Administrative Fact Sheet for Special Government Employees:

- http://ofacp.od.nih.gov/ethics/pdfs/AdminFactSheetforSGEsOct2009.pdf

Foreign Activities:

- U.S. Constitution Emoluments Clause: http://ofacp.od.nih.gov/ethics/pdfs/EmolClause.pdf
- Foreign Activities Questionnaire: http://ethics.od.nih.gov/forms/hhs-697.pdf

Conflict of Interest and the SGE:

- http://ethics.od.nih.gov/topics/OGE-SGE.pdf

NIH Ethics Program:

- http://ethics.od.nih.gov/default.htm
- Bioethics Resources on the Web: http://bioethics.od.nih.gov/conflict.html

To Serve With Honor

A Guide on the Ethics Rules That Apply to Advisory Committee Members Serving as Special Government Employees

U.S. Office of Government Ethics (www.usoge.gov) March 2008

Congratulations on becoming a member of the Government's advisory team! In your new committee position, you may be helping to shape public policy or making other contributions that impact important issues facing our country. Your service on the committee will be a rewarding experience. But, while your membership has it rewards, it also has its ethical obligations. Being a member of the Government's team means you'll have to learn to play by the Government's ethics rules. These ethics rules help promote public confidence and trust in our Government and in the recommendations that your committee will make to the Government. These rules will also help ensure that you serve the Government and your committee honorably.

In this summary, you will learn more about the ethics laws and rules that apply to your service as a member of a Federal advisory committee. We will highlight some of the ethics rules that are most likely to affect you during your Government service. After you've read this pamphlet, you may want to learn more about specific ethics rules. Agency ethics officials and committee management officials are there to answer any of your questions or to point you in the right direction. They will help you even after your committee has finished its work and your Government service is done.

Whether your time on a committee is short or long, understanding these basic ethics rules will make your Government service more rewarding for you and for your fellow committee members.

Government Employee Status

I will be serving on a committee only for a few days a year. Am I a Government employee just because I am a member of an advisory committee?

Not necessarily. However, if you have been given this pamphlet by the agency sponsoring your advisory committee, it's likely that you are serving as a Special Government Employee (SGE)[1] and are subject to the Government's ethics rules. An agency official should determine your employment status and then inform you whether you are serving on an advisory committee in an employee status.

In general, your status will depend upon what role you will be expected to have on the committee. It is very important for you and every member of your committee to understand your role on the committee before you even start your committee work. If you have not been told, you should ask a committee official or ethics official to explain your status so you will know whether you are subject to any of the Government's ethics rules.

If you are serving in an SGE status, you are considered a Government employee. Your role as an employee will be to provide your best judgment in committee matters that will be presented to you for discussion. As someone serving on a committee in an SGE status, you will be subject to most of the Government's ethics rules. Many of these rules will be discussed in this pamphlet.

Keep in mind that some committee members may be regular Government employees. Other members may not be serving as employees at all. These non-employee members may be serving as representatives of outside organizations. Representative members are not subject to the Government's ethics rules because they are only on a committee to provide the views of outside interest groups or stakeholders.

If you are ever unsure about your role or status on an advisory committee, talk to a committee or ethics official. In some cases, your committee appointment papers will say what your status is and/or the role you will have on the committee. However, don't ever begin your committee work until you know what your status is going to be while serving on a committee.

[1] An SGE is defined as an "officer or employee . . . who is retained, designated, appointed, or employed" by the Government to perform temporary duties, with or without compensation, for not more than 130 days during any period of 365 consecutive days. See Title 18, United States Code, Section 202(a).

Screening for Conflicts of Interest

Is there anything that I should be doing to comply with the Government ethics rules before I begin my committee service?

Yes. You'll need to get an "ethics checkup" before you begin your committee's work. We've all read press stories about athletes having to pass a physical examination before they can start playing for a sports team. One reason that teams require athletes to pass such exams is to make sure they are able to perform to the very best of their ability. In much the same way, the Government wants to ensure that you will be able to perform to the best of your ability when you begin working on one of its advisory committee teams.

Your best service is possible only when you are not affected by conflicts of interests or appearances of conflicts of interest. Conflicts of interest can arise if you have extensive outside activities and financial holdings or other interests that relate to the subject matter of your committee service. An "ethics checkup" or a conflict of interest screening helps the Government ensure that your committee work is done in a manner that will uphold the Government's high ethical standards.

Financial Disclosure Reports

What does an "ethics checkup" involve? Is this exam a one-time event? How will I know if I have passed this ethics checkup?

As with any physical exam, there is always a little bit of paperwork to fill out. In general, one of the first forms you have to complete prior to beginning your committee work is a financial disclosure report. This report collects information about you, your spouse, and dependent children. You will have to fill this report out before you give any advice to the agency and in no event later than your first committee meeting. You will have to complete this report annually if you are reappointed.

As you know, no exam is ever complete without some amount of probing by the doctor. In much the same way, ethics officials will probe and look closely at your report to see if any of your financial interests or affiliations may raise any ethical flags. In some cases, they may have to ask you additional questions about your finances. Keep in mind that this checkup will ultimately benefit both you and your committee's work. An ethics checkup will protect you from unintentionally violating ethics laws and rules. The ethics laws can sometimes carry very serious penalties and fines if you violate them by allowing your conflicts to go untreated. This exam will help the Government ensure that your advice is free from any actual or perceived conflicts of interest.

Your agency ethics official can tell you more about the financial disclosure report, including the type of report you will be required to fill out. Even after you have filed your report, you may want to sit down and talk to your ethics official about your report if you believe your committee is going to work on a matter that may affect one or more of your financial holdings. In some cases, a matter that would raise concerns may not have been apparent during your initial "ethics checkup." You should immediately consult with an agency official about this matter. Remember, an ethics checkup is only as good as the information you provide to your agency.

Financial Conflicts of Interest

I work for a pharmaceutical company, and over the years have received a fair amount of stock in the company. What should I do if the work of my advisory committee will affect my employer?

Generally, you may not work on a committee matter that will affect your own, or your employer's, financial interest. For example, let's say you were serving on an advisory committee that is advising an agency on whether it should continue a health program that provides nutrition information and free vitamins to children. The Government purchases some of the vitamins it distributes from your company. It would be a conflict of interest for you to participate in committee matters relating to the distribution of the vitamins, because you both own stock in, and are employed by, a company that has a financial interest in the issue.

Whether you can be involved in committee matters that relate generally to the agency's nutrition program depends on how the program will affect your company. The agency's ethics official or committee management official will advise you on how to proceed.

Financial Conflicts of Interest—Imputed Interests

Would I still have a conflict of interest if I didn't work for the pharmaceutical company or own any stock, but my spouse owned stock in the company that she bought through her broker?

Yes. The ethics laws treat the financial interests of the following as if they were your own financial interests: your spouse; your minor child; your employer; your general partner; an organization in which you serve as officer, director, trustee, or general partner; or a person with whom you are negotiating or have an arrangement for prospective employment.

So, if your spouse owned stock in the pharmaceutical company described above, you would still have the same conflict of interest concern described in the previous question.

Conflicts of interest concerns that are not addressed can penalize you and your committee's work. Ethics officials or committee officials will work with you to make sure that you can continue to do your committee work ethically and honorably.

Resolving Financial Conflicts of Interests

What steps should I take to avoid violating the Government's ethics rules if I have a conflict of interest?

There are several ways to avoid a conflict of interest while working on a committee matter. The most common way is simply not to work on a particular committee matter if it raises a conflict of interest for you. For example, in the situations discussed above, to avoid what otherwise would be a conflict of interest because of your financial interest in the pharmaceutical company, you could simply not participate in those committee matters that would affect the financial interests of the company. We call this remedy a recusal.

If you have a conflict of interest, you should consult an ethics official because ethics regulations may resolve some of your conflicts of interests. For example, there are some exceptions that apply if the value of your stock is below a certain amount. Another exception may permit you to participate in matters affecting your non-Federal employer in certain cases.

Considering Appearance Issues

Am I required to do anything if I have an outside business relationship that is not a financial conflict of interest, but just looks bad for my committee?

Because you serve the Government, you should always conduct yourself in a manner that is above ethical reproach. So, even if there is no financial conflict of interest, your outside relationships may at times raise questions in the public's mind about how fair you can be while working on a particular committee matter. For example, "appearance" concerns may arise when you are asked to work on a committee matter that you know may affect a member of your household or your former employer or client. In general, you should be alert for situations where a former employer, a client of yours or your spouse, a person or organization with which you have some kind of business or contract relationship, or your spouse's employer will be specifically affected by your committee's activities. In some cases, it may be appropriate for you not to work on a certain committee matter because of appearance concerns.

Because you are part of the Government's team, you are never alone in dealing with these kinds of appearance concerns. If you are not sure whether a potential situation could raise an appearance problem, you should stop your work on that committee matter and contact your agency's ethics official or committee official to discuss your concerns. These officials can help you address possible appearance problems.

Outside Consulting Work

I have an outside consulting business that requires me to represent clients before the Government. Is this O.K.?

In general, you may not represent another person, whether or not you are compensated for the representation, before a Federal agency or court in connection with a matter that you have worked on as an SGE. The types of representational services covered include written and oral communications, as well as making physical appearances on behalf of someone else with the intent to influence or persuade the Government.

Once you have served more than 60 days as an SGE within the previous 365 days, you may not represent anyone on any matter pending in the agency where

you serve. Remember, you should always talk to an agency official if you are thinking about representing a client before the Government on a matter that involves the subject matter of your committee's work or the overall programs of the agency that is sponsoring your committee.

Standards of Ethical Conduct Rules

Are the conflict of interest laws the only ethics rules that I must know before I start my work as a committee member?

There are a number of other important ethics rules that will guide your conduct while you are serving as an SGE. Most of these rules are part of "The Standards of Ethical Conduct for Employees of the Executive Branch (Standards of Conduct)." As a committee member, you are expected to be aware of and follow these basic ethics rules while in Government service. Some of the rules you should know include:

Don't accept improper gifts. Don't ask for or accept gifts that are given because of your committee position or that come from certain "prohibited sources." For example, a company that does business with, or is regulated by, the agency that sponsors your committee is a prohibited source. There are many exceptions to this general rule. Find out more about these gift exceptions by talking to a committee or ethics official.

Don't use public office for private gain. For example, you may not use your committee position, title, or any authority associated with your advisory committee to coerce or induce a benefit for yourself or others.

Don't misuse Government information. If you get information that has not been made available to the general public, don't use (or allow the improper use of) that nonpublic information to further any private interest, either your own or another's. Contact a committee official or agency ethics official if you have any questions about whether you may release certain types of information.

Use Government property and time properly. Always use Government property only for authorized purposes. Government property includes office supplies, telephones, computers, copiers, and any other thing purchased with Government funds. Also, be sure to use your official time to carry out committee work.

Don't accept compensation for teaching, speaking, and writing related to your Government duties. This restriction applies in narrow circumstances to SGEs. It does not apply at all if the compensation is for teaching university courses. And it applies in very limited cases if you are an SGE who is expected to serve less than 60 days. If you intend to receive compensation for teaching, speaking, and writing that is related to the subject of your committee's work, talk to an ethics official first so that you are sure the compensation is acceptable.

Abide by expert witness rules. In general, you cannot be an expert witness in a judicial or administrative proceeding if you participated as a Government employee in the matter that is the subject of the proceeding. Moreover, if you are appointed by the President, serve on a commission established by statute, or have served or are expected to serve more than 60 days in a period of 365 days, this bar applies to any proceeding in which your employing agency is a party or has a direct and substantial interest. The rules that govern service as an expert witness can be very complex, so you should always get advice from an agency ethics official before you agree to serve as an expert.

Other Ethics Rules

Are there any ethics rules that may limit my political activities during my service on a committee?

Yes, a law known as the Hatch Act limits certain political activities of Government employees, including SGEs, when they are engaged in committee work. The law has been substantially amended to allow most Government employees to engage in many types of political activities. However, you should check with your agency ethics official to ensure your activities comply with these laws. You may also want to check the U.S. Office of Special Counsel's website (the agency responsible for enforcing this law) for more information and guidance at www.osc.gov.

Post-Employment Laws

Do any ethics rules apply to me after my service on an advisory committee has ended?

Yes. Post-employment laws may limit the types of communications you may make back to the Government on behalf of another person. For example, you may be permanently barred by a criminal law from representing anyone else before a Federal agency or court on certain matters (such as a contract, grant, or even an investigation) that you worked on while serving on an advisory committee.

There are some other restrictions that could apply to your post-Government activities, depending on your agency and the function you served in on a committee. Your agency's ethics official can help you to understand these and other post-employment rules, either before or after your committee service ends.

Some Final Thoughts

The Government is very grateful for your dedicated service. Your commitment in upholding the integrity of Government service before and even after your committee service ends is important and will help maintain public confidence in the Government's decision making and in the quality of your committee's work.

We hope this summary helps you to understand how some of the Federal ethics rules may apply to you as a Federal advisory committee member serving as an SGE. It is now up to you to ensure that you serve with honor by following this game plan for successful participation on the Government's advisory team.

If you need more information, please talk to a committee management official or your agency ethics official. Like a good coach, these individuals are there to help guide you into becoming the best committee member you can be—one that acts ethically and responsibly before and after his or her service ends. In this way, you can be proud of your service to the Government and to your advisory committee team.

SGE Game Plan for Peak Ethical Performance

1. Don't ever begin your committee work until you know what your role or status is on a committee.
2. Always get an "ethics checkup" before you begin your committee work.
3. Don't work on a committee matter that will affect your financial interests, unless some exception allows you to do so.
4. Always check with an ethics official if you have any concerns about an appearance of a conflict of interest.
5. Improve "your game" by becoming more familiar with Government ethics rules, especially those that are found in the Standards of Conduct and in the Conflict of Interest laws.
6. Talk to your agency ethics official if you anticipate doing some teaching, speaking, or writing as an outside activity for compensation or engaging in representational activity before the Government.
7. Understand the post-employment rules either before or after your advisory committee service ends.
8. Remember that learning more about the Government's ethics rules will help ensure that you serve your committee honorably.

Appendix E. NCI Scientific Program Leaders (SPL) Roster

Dr. Jeffrey Abrams
Division of Cancer Treatment and Diagnosis

Dr. Robert Croyle
Division of Cancer Control and Population Sciences

Mr. John Czajkowski
Executive Officer

Dr. James Doroshow
Office of the Director

Dr. Joseph Fraumeni
Division of Cancer Epidemiology and Genetics

Dr. Paulette Gray
Division of Extramural Activities

Dr. Peter Greenwald
Office of the Director

Dr. Ed Harlow
Office of the Director

Dr. Lee Helman
Center for Cancer Research

Dr. George Komatsoulis
Center for Biomedical Informatics and Information Technology

Dr. Barry Kramer
Division of Cancer Prevention

Dr. Douglas Lowy
Office of the Director

Dr. Alan Rabson
Office of the Director

Dr. Dinah Singer
Division of Cancer Biology

Dr. Sanya Springfield
Center to Reduce Cancer Health Disparities

Dr. Joseph Tomaszewski
Division of Cancer Treatment and Diagnosis

Dr. Ted Trimble
Center for Global Health

Dr. Harold Varmus
Director, National Cancer Institute

Mr. Michael Weingarten
Small Business Innovation Research Development Center

Dr. Linda Weiss
Cancer Centers Program

Dr. Jonathan Weist
Center for Cancer Training

Dr. Robert Wiltrout
Center for Cancer Research

Dr. Barbara Wold
California Institute of Technology

Dr. Robert Yarchoan
Office of HIV and AIDs Malignancy

Executive Secretary

Joy Wiszneauckas
Office of the Director

Appendix F. President's Cancer Panel Roster

Chair

Barbara K. Rimer, DrPH, MPH* 2012
Dean and Alumni Distinguished Professor
Gillings School of Global Public Health
The University of North Carolina at Chapel Hill
Chapel Hill, NC 27599

Member

Owen N. Witte, M.D. 2014
Director
Eli and Edythe Broad Center of Regenerative Medicine and Stem Cell Research
Investigator, Howard Hughes Medical Institute
University of California, Los Angeles
Los Angeles, CA 90095

Executive Secretary

Abby Sandler, Ph.D.
Chief
Institute Review Office
National Cancer Institute, NIH
Bethesda, MD 20892

Appendix G. National Cancer Advisory Board Roster

Chair

Bruce A. Chabner, M.D. 2012
Director of Clinical Research
Massachusetts General Hospital Cancer Center
Massachusetts General Hospital
Boston, MA

Members

Anthony Atala, M.D. 2012
Director
Wake Forest Institute for Regenerative Medicine
Professor and Chairman
Department of Urology
Wake Forest University
School of Medicine
Winston-Salem, NC

Victoria L. Champion, D.N.S. 2014
Associate Dean for Research
Mary Margaret Walther Distinguished Professor of Nursing
Center for Research & Scholarship
Indiana University School of Nursing
Indianapolis, IN

Donald S. Coffey, Ph.D. 2012
The Catherine Iola and J. Smith Michael Distinguished Professor of Urology
Professor of Urology/Oncology/Pathology/Pharmacology and Molecular Science
Johns Hopkins University
School of Medicine
Baltimore, MD

Marcia R. Cruz-Correa, M.D., Ph.D. 2016
Associate Professor of Medicine and Biochemistry
University of Puerto Rico
Basic and Translational Science Director
University of Puerto Rico
Comprehensive Cancer Center
San Juan, PR

Kevin J. Cullen, M.D. 2016
Director
Marlene and Stewart Greenebaum Cancer Center
Professor of Medicine
University of Maryland
Baltimore, MD

William H. Goodwin, Jr., M.B.A. 2014
Chairman and President
CCA Industries, Inc.
Richmond, VA

Waun Ki Hong, M.D. 2014
Professor
Head, Division of Cancer Medicine
Department of Thoracic/Head & Neck Medical Oncology
The University of Texas MD Anderson Cancer Center
Houston, TX

Mr. Robert A. Ingram 2012
General Partner
Hatteras Venture Partners
Durham, NC

Tyler E. Jacks, Ph.D. 2016
Director
Koch Institute for Integrative Cancer Research
David H. Koch Professor of Biology
Massachusetts Institute of Technology
Cambridge, MA

National Cancer Advisory Board Roster, continued

Judith S. Kaur, M.D. **2012**
Medical Director
Native American Programs
Mayo Comprehensive Cancer Center
Professor of Oncology
Mayo Clinic
Rochester, MN

Mary Vaughan Lester **2014**
Board of Directors
University of California,
San Francisco Foundation
Los Angeles, CA

H. Kim Lyerly, M.D. **2014**
Director
Duke Comprehensive Cancer Center
George Barth Geller Professor of
Cancer Research
Professor of Surgery
Duke University Medical Center
Durham, NC

Karen M. Meneses, Ph.D. **2012**
Professor and Associate Dean for Research
University of Alabama at Birmingham
School of Nursing
Birmingham, AL

Olufunmilayo F. Olopade, M.B.B.S., F.A.C.P. **2016**
Walter L. Palmer Distinguished Service
Professor of Medicine and Human Genetics
Associate Dean for Global Health
Director, Center for Clinical Cancer Genetics
University of Chicago
Pritzker School of Medicine
Chicago, IL

Jennifer A. Pietenpol, Ph.D. **2014**
Director
Vanderbilt-Ingram Cancer Center
B.F. Byrd, Jr. Professor of Oncology
Vanderbilt University Medical Center
Nashville, TN

Jonathan M. Samet, M.D., M.S. **2016**
Professor and Flora L. Thornton Chair
Department of Preventive Medicine
Keck School of Medicine
Director, Institute for Global Health
University of Southern California
Los Angeles, CA

William R. Sellers, M.D. **2016**
Vice President/Global Head of Oncology
Novartis Institutes for BioMedical Research, Inc.
Cambridge, MA

National Cancer Advisory Board Roster, continued

Ex Officio Members

Linda S. Birnbaum, Ph.D., D.A.B.T., A.T.S.
Director
National Institute of Environmental Health Sciences, The National Technology Program
Research Triangle Park, NC

Francis S. Collins, M.D., Ph.D.
Director
National Institutes of Health
Bethesda, MD

Margaret A. Hamburg, M.D.
Commissioner
Food and Drug Administration
Silver Spring, MD

John P. Holdren, Ph.D.
Science Advisor to the President
Director
Office of Science and Technology Policy
Executive Office of the President
Washington, DC

John Howard, M.D., M.P.H., J.D., LL.M.
Director
National Institute for Occupational Safety and Health
Washington, DC

Lisa Jackson, M.S.
Administrator
Environmental Protection Agency
Washington, DC

The Honorable Dr. Michael J. Kussman
Under Secretary for Health
Veterans Health Administration
Department of Veterans Affairs
Washington, DC

Anna Palmisano, Ph.D.
Associate Director, Office of Biological and Environmental Research
Department of Energy
Washington, DC

The Honorable Kathleen Sebelius, M.P.A.
Secretary
Department of Health and Human Services
Washington, DC

The Honorable Hilda L. Solis
Secretary
Department of Labor
Washington, DC

Inez Tenenbaum, M.Ed.
Chairman
Consumer Product Safety Commission
Bethesda, MD

Jonathan Woodson, M.D.
Assistant Secretary of Defense for Health Affairs
The Pentagon
Washington, DC

National Cancer Advisory Board Roster, continued

Alternates to *Ex Officio* Members

Michael A. Babich, Ph.D.
Directorate for Epidemiology and Health Sciences
Consumer Product Safety Commission
Bethesda, MD
(Ms. Inez Tenenbaum, CPSC)

Patricia Bray, M.D., M.P.H.
Medical Officer, Office of Occupational Medicine
OSHA/Department of Labor
Washington, DC
(The Honorable Hilda L. Solis, DOL)

Michael Kelley, M.D., F.A.C.P.
National Program Director for Oncology
Veterans Health Administration
Department of Veterans Affairs
Washington, DC
(The Honorable Dr. Michael J. Kussman, VA)

Aubrey Miller, M.D.
Senior Medical Officer
National Institute of Environmental Health Sciences
National Institutes of Health
Research Triangle Park, NC
(Linda S. Birnbaum, Ph.D., D.A.B.T., A.T.S., NIEHS)

Richard Pazdur, M.D.
Division Director
Division of Hematology and Oncology Products
Food and Drug Administration
Rockville, MD
(Margaret A. Hamburg, M.D., FDA)

R. Julian Preston, Ph.D.
Associate Director for Health
Environmental Protection Agency
Research Triangle Park, NC
(Lisa Jackson, M.S., EPA)

Michael Stebbins, Ph.D.
Assistant Director, Biotechnology Office of
Science and Technology Policy
Executive Office of the President
Washington, DC
(John P. Holdren, Ph.D., OSTP)

Marie H. Sweeney, Ph.D., M.P.H.
Chief
Surveillance Branch
Division of Surveillance
Hazard Evaluations & Field Studies
National Institute for Occupational Safety and Health
Cincinnati, OH
(John Howard, M.D., M.P.H., J.D.,
LL.M., NIOSH)

Lawrence A. Tabak, D.D.S., Ph.D.
Principal Deputy Director
National Institutes of Health
Bethesda, MD
(Francis S. Collins, M.D., Ph.D., NIH)

Sharlene Weatherwax, Ph.D.
Director
Biological Systems Sciences Division
Office of Biological and Environmental Research
Office of Science
U.S. Department of Energy
Washington, DC
(Anna Palmisano, Ph.D., DOE)

Executive Secretary

Paulette S. Gray, Ph.D.
Director
Division of Extramural Activities
National Cancer Institute
National Institutes of Health
Bethesda, MD

Committee Management Officer

Claire L. Harris
Division of Extramural Activities
National Cancer Institute
National Institutes of Health
Bethesda, MD

Appendix H. Board of Scientific Advisors Roster

Chair

Todd R. Golub, M.D. 2015
Chief Scientific Officer
The Broad Institute of Harvard University and
Massachusetts Institute of Technology
Cambridge, MA

Members

Francis Ali-Osman, D.Sc. 2011
Margaret Harris & David Silverman
Distinguished Professor of Neuro-Oncology Research
Professor (Tenured) of Surgery
Department of Surgery
Professor of Pathology
Duke University School of Medicine
Duke University Medical Center
Durham, NC

Christine B. Ambrosone, Ph.D. 2012
Professor of Oncology
Chair, Department of Cancer Prevention and Control
Roswell Park Cancer Institute
Buffalo, NY

Sangeeta N. Bhatia, M.D., Ph.D. 2016
John H. and Dorothy Wilson Professor
Division of Health Sciences and Technology and Electrical Engineering and Computer Science
Massachusetts Institute of Technology
Cambridge, MA

Andrea Califano, Ph.D. 2013
Director, Columbia Initiative in Systems Biology
Director, Sulzberger Columbia Genome Center
Associate Director, Herbert Irving Comprehensive Cancer Research Center
Professor of Systems Biology
Department of Biochemistry and Molecular Biophysics, Biomedical Informatics, and Institute of Cancer Genetics
Columbia University Medical Center
New York, NY

Michael A. Caligiuri, M.D. 2012
CEO and Director
The Comprehensive Cancer Center
The Ohio State University (OSUCCC)
Columbus, OH

Arul M. Chinnaiyan, M.D., Ph.D. 2015
S.P. Hicks Endowed Professor
Professor of Pathology and Urology
Director, Pathology Microarry Laboratory
Director, Pathology Research Informatics
Director, Cancer Bioinformatics
Director, Michigan Center for Translational Pathology
University of Michigan
Ann Arbor, MI

Curt I. Civin, M.D. 2012
Director
Center for Stem Cell Biology & Regenerative Medicine
Professor of Pediatrics & Physiology
Associate Dean for Research
University of Maryland School of Medicine
Baltimore, MD

Chi V. Dang, M.D., Ph.D. 2014
Professor of Medicine
Division of Hematology-Oncology
Department of Medicine
Director, Abramson Cancer Center
Director, Abramson Family Cancer Research Institute
Perelman School of Medicine
University of Pennsylvania
Philadelphia, PA

Robert B. Diasio, M.D. 2013
Director
Mayo Clinic Cancer Center
William J. and Charles H. Mayo Professor
Professor of Pharmacology
Department of Molecular Pharmacology and Experimental Therapeutics
Mayo Clinic
Rochester, MN

Jeffrey A. Drebin, M.D., Ph.D., F.A.C.S. **2014**
John Rhea Barton Professor
University of Pennsylvania School of Medicine
Chairman
Department of Surgery
Hospital of the University of Pennsylvania
Philadelphia, PA

Brian J. Druker, M.D. **2016**
Director
OHSU Knight Cancer Institute
Associate Dean for Oncology
JELD-WEN Chair of Leukemia Research
OHSU School of Medicine
Oregon Health and Science University
Portland, OR

Karen M. Emmons, Ph.D. **2016**
Deputy Director
Center for Community Based Research
Dana-Farber Cancer Institute
Professor and Associate Dean for Research
Department of Society, Human Development and Health
Harvard School of Public Health
Boston, MA

Betty Ferrell, Ph.D., R.N., F.A.A.N. **2015**
Professor, Nursing Research and Education
Full Member, Cancer Control and Population Sciences Program
Comprehensive Cancer Center
City of Hope National Medical Center
Duarte, CA

Kathleen M. Foley, M.D. **2013**
Attending Neurologist
Pain and Palliative Care Service
Department of Neurology
Memorial Sloan Kettering Cancer Center
New York, NY

Sanjiv S. Gambhir, M.D., Ph.D. **2012**
Virginia & D.K. Ludwig Professor of Cancer Research
Chair, Department of Radiology
Professor by courtesy, Departments of Bioengineering and Materials Science & Engineering
Director, Molecular Imaging Program at Stanford
Director, Canary Center at Stanford for Cancer Early Detection
Member, Bio-X Program
Stanford University
Stanford, CA

Stanton L. Gerson, M.D. **2016**
Shiverick Professor of Hematological Oncology
Director, Case Comprehensive Cancer Center
Director, National Center for Regenerative Medicine
Case Western Reserve University
Director, Siedman Cancer Center
University Hospitals Case Medical Center
Cleveland, OH

Joe W. Gray, Ph.D. **2013**
Gordon Moore Endowed Chair
Chair, Department of Biomedical Engineering
Director, OHSU Center for Spatial Systems Biology
Oregon Health and Science University
Portland, OR

Mary J. C. Hendrix, Ph.D. **2012**
President and Scientific Director
Children's Memorial Research Center
Medical Research Institute Council Professor
Lurie Comprehensive Cancer Center
Feinberg School of Medicine
Northwestern University
Chicago, IL

Timothy J. Kinsella, M.D. **2012**
Research Scholar Professor
Warren Alpert Medical School of Brown University
Department of Radiation Oncology
Rhode Island Hospital
Providence, RI

Joshua LaBaer, M.D., Ph.D. **2014**
Virginia G. Piper Chair in Personalized Medicine
Director, Virginia G. Piper Center for Personalized Diagnostics
The Biodesign Institute
Arizona State University
Tempe, AZ

Theodore S. Lawrence, M.D., Ph.D. **2016**
Isadore Lampe Professor and Chair
Department of Radiation Oncology
University of Michigan Medical School
University of Michigan
Ann Arbor, MI

Mr. Don Listwin **2014**
Founder and Chairman
Canary Foundation
Palo Alto, CA

Maria E. Martinez, M.P.H., Ph.D. **2015**
Professor
Department of Family & Preventive Medicine
Program Leader, Reducing Cancer Disparities
UC San Diego Moores Cancer Center
La Jolla, CA

James L. Omel, M.D. **2012**
Education and Advocacy
Volunteer, International Myeloma Foundation
Volunteer, Multiple Myeloma Research
Volunteer, Leukemia, Lymphoma, Myeloma Society
Grand Island, NE

Luis F. Parada, Ph.D. **2016**
Chairman
Department of Developmental Biology
Southwestern Ball Distinguished Chair in Neuroscience Research
Director, Kent Waldrep Center for Basic Research on Nerve Growth and Regeneration
Diana & Richard C. Strauss Distinguished Chair in Developmental Biology
University of Texas Southwestern Medical Center
Dallas, TX

Stuart L. Schreiber, Ph.D. **2012**
Morris Loeb Professor
Director, Chemical Biology
The Broad Institute of Massachusetts Institute of Technology and Harvard University
Cambridge, MA

Lincoln Stein, M.D., Ph.D. **2016**
Director
Informatics and BioComputing Platform
Ontario Institute for Cancer Research
Toronto, Ontario, Canada

Bruce W. Stillman, Ph.D. **2012**
President and Chief Executive Officer
Cold Spring Harbor Laboratory
Cold Spring Harbor, NY

Victor J. Strecher, Ph.D., M.P.H. **2012**
Professor
Department of Health Behavior and Health Education
University of Michigan School of Public Health
Ann Arbor, MI

Louise C. Strong, M.D. **2013**
Sue and Radcliff Killam Chair
Professor of Genetics
Department of Genetics
The University of Texas MD Anderson Cancer Center
Houston, TX

Frank M. Torti, M.D., M.P.H. **2014**
Executive Vice President for Health Affairs
Dean
School of Medicine
University of Connecticut Health Center
Farmington, CT

***Gregory L. Verdine, Ph.D.** **2016**
Erving Professor of Chemistry
Department of Stem Cell and Regenerative Biology
Harvard University
Cambridge, MA

Irving L. Weissman, M.D. **2012**
Director
Institute of Stem Cell Biology and Regenerative Medicine
Stanford University
Stanford, CA

Executive Secretary

Paulette S. Gray, Ph.D.
Director
Division of Extramural Activities
National Cancer Institute
National Institutes of Health
Bethesda, MD

* Pending appointment

Appendix I. Board of Scientific Counselors Roster: Clinical Sciences and Epidemiology

Chair

Ethan Dmitrovsky, M.D. 2013
American Cancer Society Professor
Department of Pharmacology and Toxicology
Dartmouth Medical School
Hanover, NH

Members

Edgar Ben-Josef, M.D. 2014
Associate Professor
Department of Radiation Oncology
University of Pennsylvania
Perelman Center for Advanced Medicine
Philadelphia, PA

Arthur W. Blackstock, Jr., M.D. 2016
Professor and Chair
Department of Radiation Oncology
School of Medicine
Wake Forest University
Winston-Salem, NC

Bruce R. Blazar, M.D. 2012
Professor and Anderson Chair
Department of Pediatrics
University of Minnesota
University of Minnesota Hospital
Minneapolis, MN

Tim Byers, M.D. 2015
Interim Director
Department of Preventive Medicine and Biometrics
University of Colorado School of Medicine
Denver, CO

Susan Chang, M.D. 2013
Professor
Department of Neurological Surgery
University of California, San Francisco
San Francisco, CA

William Evans, Pharm.D. 2012
Director and CEO
St. Jude Children's Research Hospital
Memphis, TN

Jo L. Freudenheim, Ph.D. 2012
Chair, Department of Social and Preventive Medicine
University of Buffalo
State University of New York
Buffalo, NY

Judy Garber, M.D. 2012
Associate Professor, Harvard Medical School
Director
Center for Cancer Genetics and Prevention
Dana-Farber Cancer Institute
Boston, MA

Marc Goodman, Ph.D. 2015
Professor and Researcher
Cancer Research Center of Hawaii
University of Hawaii at Manoa
Honolulu, HI

Bernard Harlow, Ph.D. 2014
Mayo Professor and Division Head
Division of Epidemiology and Community Health
University of Minnesota
Minneapolis, MN

Carl June, M.D. 2014
Professor of Pathology and Laboratory Medicine
Department of Pathology
University of Pennsylvania School of Medicine
Philadelphia, PA

Karen Kelly, M.D. 2015
Professor and Phase 1 Clinical Director
UC Davis Medical Center
Internal Medicine/Hematology Oncology
Sacramento, CA

Hongzhe Lee, Ph.D. **2016**
Professor of Biostatistics
Department of Biostatistics and Epidemiology
University of Pennsylvania School of Medicine
Philadelphia, PA

Alexandra M. Levine, M.D., MACP **2015**
Chief Medical Officer and Professor
Hematology/Hematopoietic Cell Transplantation
City of Hope National Medical Center
Duarte, CA

Sanford Markowitz, M.D., Ph.D. **2016**
Professor of Cancer Genetics
Howard Hughes Medical Institute
Wolstein Research Building
Cleveland, OH

Augusto Ochoa, M.D. **2014**
Director, Department of Pediatrics
HealthScience Center
Louisiana State University
New Orleans, LA

Kenneth Offit, M.D., M.P.H. **2016**
Chief, Clinical Genetics Service
Memorial Sloan Kettering Cancer Center
New York, NY

Raphael E. Pollock, M.D., Ph.D., F.A.C.S. **2016**
Head, Division of Surgery
Professor, Department of Surgical Oncology
The University of Texas MD Anderson Cancer Center
Houston, TX

David Poplack, M.D. **2014**
Director, Texas Children's Cancer Center
Head, Pediatric Hematology-Oncology
Department of Pediatrics
Baylor College of Medicine
Houston, TX

Nancy Roach **2013**
Consumer Advocate
C3: Colorectal Cancer Coalition
Hood River, OR

Thomas Rohan, M.D., Ph.D. **2014**
Professor and Chairman
Department of Epidemiology and Population Health
Albert Einstein College of Medicine
Bronx, NY

Thomas Sellers, Ph.D. **2013**
Director, Moffitt Research Institute
H. Lee Moffitt Cancer Center & Research Institute
University of South Florida
Tampa, FL

Darryl Shibata, M.D. **2015**
Professor, Norris Cancer Center
University of Southern California
Los Angeles, CA

Robert Tigelaar, M.D. **2013**
Professor, Department of Dermatology
Yale University
New Haven, CT

Walter Urba, M.D., Ph.D. **2013**
Director, Cancer Research
Robert W. Franz Cancer Research Center
Earle A. Chiles Research Institute
Providence Portland Medical Center
Portland, OR

Elizabeth Ward, Ph.D. **2014**
Vice President
Surveillance and Health Policy Research
American Cancer Society
Atlanta, GA

George Wilding, M.D. **2016**
Director
Department of Medicine
Carbone Cancer Center
University of Wisconsin
Madison, WI

Cheryl Willman, M.D. **2015**
Maurice and Marguerite Liberman
Distinguished Chair in Cancer Research
Director and CEO, Cancer Research and Treatment Center
University of New Mexico
Albuquerque, NM

Executive Secretary

Brian Wojcik, Ph.D.
Institute Review Office
Office of the Director
National Cancer Institute
National Institutes of Health
Bethesda, MD

Appendix J. Board of Scientific Counselors Roster: Basic Sciences

Chair

Joan W. Conaway, Ph.D. **2011**
Investigator
Stowers Institute for Medical Research
Kansas City, MO

Members

Paul D. Bieniasz, Ph.D. **2014**
Associate Professor and Head
Aaron Diamond AIDS Research Center
New York, NY

John C. Cambier, Ph.D. **2015**
Ida and Cecil Green Professor and Chairman
Department of Immunology
University of Colorado
Denver, CO

Lawrence Corey, M.D. **2014**
Professor
Department of Laboratory Medicine
School of Medicine
University of Washington
Seattle, WA

Sara A. Courtneidge, Ph.D. **2016**
Professor
Sanford-Burnham Medical Research Institute
La Jolla, CA

Norman Drinkwater, Ph.D. **2014**
Professor
Department of Oncology
McArdle Laboratory for Cancer Research
University of Wisconsin-Madison
Madison, WI

Errol Friedberg, M.D. **2014**
Senator Betty and Dr. Andy Andujar
Distinguished Professor and Chair
Department of Pathology
The University of Texas Southwestern
Medical School
Dallas, TX

Joanna Groden, Ph.D. **2016**
Professor and Vice Chair for Academic Affairs
Department of Molecular Virology,
Immunology and Medical Genetics
College of Medicine
The Ohio State University
Columbus, OH

Daria J. Hazuda, Ph.D. **2015**
Vice President
Merck Research Laboratories
West Point, PA

Eric Hunter, Ph.D. **2015**
Professor
Departments of Pathology and Laboratory
Medicine
Emory Vaccine Center
Yerkes National Primate Research Center
Atlanta, GA

Chris M. Ireland, Ph.D. **2013**
Professor and Chair
Department of Medicinal Chemistry
University of Utah
Salt Lake City, UT

Alexandra L. Joyner, Ph.D. **2016**
Member
Pediatric Cancer Research
Developmental Biology Program
Member, Memorial Sloan-Kettering
Institute Cancer Center
New York, NY

Marcelo Kazanietz, Ph.D. **2015**
Professor
Department of Pharmacology
University of Pennsylvania School of Medicine
Philadelphia, PA

Board of Scientific Counselors Roster: Basic Sciences, continued

Robert E. Lewis, Ph.D. **2016**
Professor
Eppley Institute for Cancer Research
University of Nebraska Medical Center
Omaha, NE

Jonathan D. Licht, M.D. **2014**
Johanna Dobe Professor of Hematology/Oncology
Robert H. Lurie Comprehensive Cancer Center
Northwestern University
Feinberg School of Medicine
Chicago, IL

Thomas A. Look, M.D. **2013**
Vice Chair for Research
Department of Pediatric Oncology
Dana-Farber Cancer Institute
Boston, MA

Ian Gregory Macara, Ph.D. **2014**
Harrison Distinguished Professor of Microbiology
Markey Center for Cell Signaling
University of Virginia
Charlottesville, VA

Nita Maihle, Ph.D. **2012**
Professor
Departments of Obstetrics/Gynecology and Reproductive Sciences
Yale University School of Medicine
New Haven, CT

Suzanne Ostrand-Rosenberg, Ph.D. **2014**
Professor of Biological Sciences
Robert & Jane Meyerhoff Chair of Biochemistry
Department of Biological Sciences
University of Maryland Baltimore County
Baltimore, MD

Ann Marie Pendergast, Ph.D. **2012**
Professor
Department of Pharmacology and Cancer Biology
Duke University Medical Center
Durham, NC

Thomas L. Poulos, Ph.D. **2015**
Chancellor's Professor
Department of Molecular Biology and Biochemistry
University of California, Irvine
Irvine, CA

James H. Prestegard, Ph.D. **2013**
Professor and Eminent Scholar
Complex Carbohydrate Research Center
University of Georgia
Athens, GA

Kenneth L. Rock, M.D. **2013**
Chairman and Professor of Pathology
Department of Pathology
University of Massachusetts Medical School
Worcester, MA

James A. Wells, Ph.D. **2016**
Chairperson
Department of Pharmaceutical Chemistry
University of California
San Francisco, CA

Wayne M. Yokoyama, M.D. **2016**
Investigator
Howard Hughes Medical Institute
Division of Rheumatology
Washington University School of Medicine
St. Louis, MO

Virginia A. Zakian, Ph.D. **2015**
Harry C. Wiess Professor in the Life Sciences
Department of Molecular Biology
Princeton University
Princeton, NJ

Executive Secretary

Florence E. Farber, Ph.D.
Institute Review Office
Office of the Director
National Cancer Institute
National Institutes of Health
Bethesda, MD

Appendix K. NCI Director's Consumer Liaison Group Roster

Chair

Gwen Darien **2012**
Cancer Advocate
Montclair, NJ

Members

Jeffrey Allen, Ph.D. **2013**
Executive Director
Friends of Cancer Research
Arlington, VA

Susan G. Braun, M.A. **2013**
Executive Director
Commonweal
Bolinas, CA

Adam M. Clark, M.D. **2015**
Health Scientist
Office of the Assistant Secretary for Preparedness and Response
Department of Health and Human Services
Washington, DC

Joya Delgado Harris, M.P.H. **2015**
Cancer Advocate
Atlanta, GA

Linda S. House, M.S., R.N. **2015**
Executive Vice President of Public Affairs
Cancer Support Community
Indianapolis, IN

Cheryl Jernigan, CPA, F.A.C.H.E. **2012**
Advocate and Volunteer
Susan G. Komen for the Cure
Kansas City Area Affiliate
Kansas City, MO

Jeffrey A. Kaufman, M.B.A. **2015**
Co-Founder and Executive Director
Adenoid Cystic Carcinoma Research Foundation
Needham, MA

Michelle McMurry-Heath, M.D., Ph.D. **2014**
Associate Director for Science
Office of the Center Director
Center for Devices and Radiological Health
Food and Drug Administration
Silver Spring, MD

Deborah Morosini, M.D. **2012**
Advocate for Lung Cancer Awareness
Oncology Pathologist
Pharmaceutical Research & Development
AstraZeneca Pharmaceutical, Inc.
Boston, MA

Phyllis Pettit Nassi, M.S.W. **2012**
Manager, Special Populations
Department of Prevention and Outreach
Huntsman Cancer Institute
University of Utah
Salt Lake City, UT

Jon G. Retzlaff, M.P.A., M.B.A. **2012**
Managing Director
Science Policy and Government Affairs
American Association for Cancer Research
Washington, DC

Wendy K.D. Selig **2012**
President and CEO
Melanoma Research Alliance
Washington, DC

Josh Sommer **2014**
Co-Founder and Executive Director
The Chordoma Foundation
Greensboro, NC

Andrea E. Ferris Stern, M.B.A. **2011**
President and Chairman of the Board
Lungevity Foundation
Chicago, IL

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Appendix L. Acronyms and Abbreviations

AAHRPP	Accreditation of Human Research Protection Programs, Inc.
ACD	Advisory Committee to the Director
ACF	Administration for Children and Families
AHRQ	Agency for Healthcare Research and Quality
AIDS	Acquired Immune Deficiency Syndrome
AMC	AIDS-Associated Malignancy Clinical Trials Consortium
AoA	Administration on Aging
AREA	Academic Research Enhancement Award
ATSDR	Agency for Toxic Substances and Disease Registry
BIQSFP	Biomarker, Imaging, and Quality of Life Studies Funding Program
BSA	Board of Scientific Advisors
BSC	Board of Scientific Counselors
CBIIT	Center for Biomedical Informatics and Information Technology
CCCT	Coordinating Center for Clinical Trials
CCOP	Community Clinical Oncology Program
CCR	Center for Cancer Research
CCSG	Cancer Center Support Grant (P30)
CCT	Center for Cancer Training
CDC	Centers for Disease Control and Prevention
CEA	Cost-Effectiveness Analysis
CEAWG	Cost-Effectiveness Analysis Working Group
CEGP	Cancer Education Grant Program
CFARs	Centers for AIDS Research
CFR	Code of Federal Regulations
CGAP	Cancer Genome Anatomy Project
CGEMS	Cancer Genetic Markers of Susceptibility
CIRB	Central Institutional Review Board
CISC	Clinical Imaging Steering Committee
CMS	Centers for Medicare and Medicaid Services
CPTC	Clinical Proteomic Technologies for Cancer
CRCHD	Center to Reduce Cancer Health Disparities
CSR	Center for Scientific Review
CSSI	Center for Strategic Scientific Initiatives
CTAC	Clinical Trials and Translational Research Advisory Group
CTB	Cancer Training Branch
CTEP	Cancer Therapy Evaluation Program
CTPM	Clinical Trial Planning Meeting
CTROC	Clinical and Translational Research Operations Committee
CTRP	Clinical Trials Reporting Program
CTSU	Clinical Trials Support Unit
CTWG	Clinical Trials Working Group
D43	International Training Grants in Epidemiology
DCB	Division of Cancer Biology
DCCPS	Division of Cancer Control and Population Sciences

DCEG	Division of Cancer Epidemiology and Genetics
DCLG	Director's Consumer Liaison Group
DCP	Division of Cancer Prevention
DCTD	Division of Cancer Treatment and Diagnosis
DEA	Division of Extramural Activities
DF	Deferred
DFO	Designated Federal Official
DHHS	Department of Health and Human Services (HHS)
DoD	Department of Defense
DP1	NIH Director's Pioneer Award (NDPA)
DP2	NIH Director's New Innovator Awards
DSSC	Disease-Specific Steering Committee
DTB	Diversity Training Branch
F31	Predoctoral Individual National Research Service Award (NRSA)
F32	Postdoctoral National Research Service Award (NRSA)
F33	National Research Service Award (NRSA) for Senior Fellows
FACA	Federal Advisory Committee Act
FDA	Food and Drug Administration
FIC	Fogarty International Center
FOA	Funding Opportunity Announcement
FY	Fiscal Year
GHWG	Guidelines Harmonization Working Group
HRSA	Health Resources and Services Administration
DHHS	Department of Health and Human Services (DHHS)
I/C	Institute/Center
IAR	Internet Assisted Review
ICG	Initiative for Chemical Genetics
IDSC	Investigational Drug Steering Committee
IHS	Indian Health Service
IND	Investigational New Drug
IRG	Initial Review Group (in NCI)
IRG	Integrated Review Group (in CSR)
IRM	Immune Response Modifier
K01	Mentored Research Scientist Development Award
K05	Senior Scientist Award
K07	Academic Career Award
K08	Mentored Clinical Scientist Development Award
K12	Mentored Clinical Scientist Development Program Award
K18	Career Enhancement Award for Stem Cell Research
K22	Career Transition Award
K23	Mentored Patient-Oriented Research Career Development Award
K24	Mid-Career Investigator in Patient-Oriented Research Award
K25	Mentored Quantitative Research Career Development Award
K30	Institutional Curriculum Award
K99/R00	Howard Temin Pathway to Independence Awards in Cancer Research

L30	Clinical Research Loan Repayment Program
L40	Pediatric Research Loan Repayment Program
LRP	Loan Repayment Program
MARC	Minority Access to Research Careers
MBRS	Minority Biomedical Research Support (S06)
MERIT	Method to Extend Research in Time (R37)
MGC	Mammalian Gene Collection
MMHCC	Mouse Models of Human Cancers Consortium
MSI	Minority Serving Institution
NCAB	National Cancer Advisory Board
NCCAM	National Center for Complementary and Alternative Medicine
NCI	National Cancer Institute
NCMHD	National Center on Minority Health and Health Disparities
NCP	National Cancer Program
NCRR	National Center for Research Resources
NDPA	NIH Director's Pioneer Award (DP1)
NEI	National Eye Institute
NHGRI	National Human Genome Research Institute
NHLBI	National Heart, Lung and Blood Institute
NIA	National Institute on Aging
NIAAA	National Institute on Alcohol Abuse and Alcoholism
NIAID	National Institute of Allergy and Infectious Diseases
NIAMS	National Institute of Arthritis and Musculoskeletal and Skin Diseases
NIBIB	National Institute of Biomedical Imaging and Bioengineering
NICDR	National Institute of Dental and Craniofacial Research
NICHD	Eunice Kennedy Shriver National Institute of Child Health and Human Development
NIDA	National Institute on Drug Abuse
NIDCD	National Institute on Deafness and Other Communication Disorders
NIDCR	National Institute of Dental and Craniofacial Research
NIDDK	National Institute of Diabetes and Digestive and Kidney Diseases
NIEHS	National Institute of Environmental Health Sciences
NIGMS	National Institute of General Medical Sciences
NIH	National Institutes of Health
NIMH	National Institute of Mental Health
NINDS	National Institute of Neurological Disorders and Stroke
NINR	National Institute of Nursing Research
NIOSH	National Institute for Occupational Safety and Health
NLM	National Library of Medicine
NR	Not Recommended for Further Consideration
NRSA	National Research Service Award
OAR	Office of Advocacy Relations
OBBR	Office of Biorepositories and Biospecimen Research

OCCAM	Office of Cancer Complementary and Alternative Medicine
OCCM	Office of Cancer Content Management
OCE	Office of Communication and Education
OCG	Office of Cancer Genomics
OCTR	Office of Centers, Training and Resources
OEWG	Operational Efficiency Working Group
OGE	Office of Government Ethics
OHAM	Office of HIV and AIDS Malignancy
OHRP	Office of Human Research Protections
OIA	Office of International Affairs
OLA	Office of Advocacy Relations
OLAW	Office of Laboratory Animal Welfare
OSO	Office of Scientific Opportunities
OSPA	Office of Science Planning and Assessment
OTIR	Office of Technology and Industrial Relations
P01	Research Program Project Grant
P20	Planning Grant
P30	Cancer Center Support Grant
P50	Specialized Center Grant (SPORE)
PA	Program Announcement
PAR	Program Announcement with Special Receipt
PASC	Patient Advocate Steering Committee
PATS	Process to Accelerate Translational Science
PCP	President's Cancer Panel
PCRB	Program Coordination and Review Branch
PHS	Public Health Service
PI	Principal Investigator
PL	Public Law
PSC	Program Support Center
QOL	Quality of Life
R&D	Research and Development
R01	Research Project Grant
R03	Small Research Grant
R13	Conference Grant
R15	Academic Research Enhancement Award (AREA)
R21	Exploratory/Developmental Grant
R24	Resource-Related Research Project
R25	Cancer Education Grant
R33	Exploratory/Developmental Grant—Phase II
R37	MERIT Award
R41	Small Business Technology Transfer (STTR) Grant Phase I
R42	Small Business Technology Transfer (STTR) Grant Phase II
R43	Small Business Innovation Research (SBIR) Grant Phase I
R44	Small Business Innovation Research (SBIR) Grant Phase II
R55	James A. Shannon Director's Award
R56	High-Priority, Short-Term Project Award
RCB	Research Contracts Branch
RFA	Request for Applications
RFP	Request for Proposals

RO	Referral Officer
RPG	Research Project Grant
RPRB	Research Programs Review Branch
RTRB	Resources and Training Review Branch
S06	Minority Biomedical Research Support (MBRS)
S21	Research and Institutional Resources Health Disparities Endowment Grants—Capacity Building
SC1	Research Enhancement Award
SC2	Pilot Research Project Grant
SAMHSA	Substance Abuse and Mental Health Services Administration
SBIR	Small Business Innovation Research Grant (Phase I R43; Phase II R44)
SEG	Source Evaluation Group
SEP	Special Emphasis Panel
SGE	Special Government Employee
SPL	Scientific Program Leader
SPORE	Specialized Programs of Research Excellence (P50)
SRG	Scientific Review Group
SRLB	Special Review and Logistics Branch
SRO	Scientific Review Officer
SSC	Scientific Steering Committee
START	Standard Terms of Agreement for Research Trials
STRAP	Special Translational Research Acceleration Project
STTR	Small Business Technology Transfer Grant (Phase I R41; Phase II R42)
SxQOLSC	Symptom Management and Health-Related Quality of Life Steering Committee
T32	Institutional National Research Service Award (NRSA)
TARGET	Therapeutically Applicable Research to Generate Effective Treatments
TCGA	The Cancer Genome Atlas
TRAI	Translational Research Acceleration Initiative
TRWG	Translational Research Working Group
U01	Research Project Cooperative Agreement
U10	Clinical Research Cooperative Agreement
U13	Conference Cooperative Agreement
U19	Research Program Cooperative Agreement
U24	Resource-Related Research Project Cooperative Agreement
U43	Small Business Innovation Research (SBIR) Cooperative Agreement Phase I
U44	Small Business Innovation Research (SBIR) Cooperative Agreement Phase II
U54	Specialized Center—Cooperative Agreement
U56	Exploratory Grant—Cooperative Agreement
VA	Department of Veterans Affairs
WIHS	Women's Interagency HIV Study