NATIONAL CANCER INSTITUTE

Clinical Trials and Translational Research Advisory Committee (CTAC)

MEMBERS' MANUAL

U.S. Department of Health & Human Services | National Institutes of Health

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, 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, which has been constituted to advise NCI on the national clinical trials and translational research enterprise.

Since its inception in 2007, CTAC has overseen the restructuring of NCI's early- and late-phase clinical trials networks, encouraged the establishment of new timelines for initiating clinical trials, harmonized guidelines across NCI-funded programs, and evaluated clinical trials portfolios as NCI enhanced its already-productive clinical trials programs. In all that we do, 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 CTAC is to provide broad scientific and programmatic advice on the investment of taxpayer dollars in clinical trials and translational research across NCI. Our goal is to foster a collaborative system, involving all the critical stakeholders, that is integrated and efficient, yet innovative and responsive enough to move discoveries to benefit cancer patients in a timely manner.

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

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CLINICAL TRIALS AND TRANSLATIONAL RESEARCH ADVISORY COMMITTEE

ORIGIN

The National Cancer Advisory Board (NCAB) established the Clinical Trials Working Group (CTWG) in 2004 to advise 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. In 2005 the CTWG released a report containing recommendations that resulted from its deliberations (**www.cancer.gov/about-nci/organization/ccct/about/ctwg-report.pdf**). One of the recommendations of the report was to establish a permanent federal body to provide extramural advice on the implementation of CTWG initiatives and the ongoing conduct of clinical trials across NCI. This recommendation led to the formation of the Clinical Trials and Translational Research Advisory Committee (CTAC) in 2007.

DESCRIPTION

CTAC provides broad scientific and programmatic advice on the investment of taxpayer dollars in clinical trials and translational research across NCI. The goal is to foster an open, collaborative system, involving all the critical stakeholders, that is integrated and efficient, yet innovative and responsive enough to move discoveries to benefit cancer patients in a timely manner.

MEMBERSHIP

CTAC is chaired by the NCI director or a designee appointed by the NCI director, as specified in the CTAC charter (see **Appendix A**). Its membership is composed of up to 25 voting individuals (see **Appendix B**) who are appointed by the NCI director to serve for terms of up to five years. Members include leading authorities in clinical trials and translational research. When necessary, five members will hold concurrent membership on the Board of Scientific Advisors (BSA), Board of Scientific Counselors (BSC), National Council of Research Advocates (NCRA), or NCAB. Ex officio members include the following officials or their designees: the NCI deputy directors and directors of the Division of Extramural Activities (DEA) and the Division of Cancer Treatment and Diagnosis (DCTD); an intramural scientist engaged in clinical research; and representatives from the Food and Drug Administration(FDA), Centers for Medicare & Medicaid Services (CMS), U.S. Department of Defense, and U.S. Department of Veterans Affairs. The director of the Coordinating Center for Clinical Trials (CCCT) serves as the executive secretary for CTAC, and CCCT staff members facilitate operations.

CTAC MEMBER ROLES AND RESPONSIBILITIES

The roles and responsibilities of CTAC include:

- Overseeing implementation of the 2005 CTWG and other working group recommendations and initiatives, including evaluation;
- Providing strategic advice and direction for NCI clinical trials and translational research programs;
- Advising NCI on policies, procedures, and processes related to clinical trials and translational research;
- Providing oversight for the scientific initiatives developed in response to the Recalcitrant Cancer Research Act of 2012; and
- Providing a forum for the clinical trials and translational research communities to give advice to the NCI director.

CONFLICT OF INTEREST POLICIES AND ETHICS RULES FOR CTAC MEMBERS

Each CTAC member is appointed as a Special Government Employee (SGE) and covered by the conflict of interest policies and ethics rules of the executive branch, although in a somewhat less restrictive manner than full-time government employees. Detailed ethics rules that govern the conduct of SGEs are provided in **Appendix C**.

CTAC MEETINGS

CTAC meets approximately three times each year, usually in March, July, and November. Meetings are open to the public and are announced in the Federal Register (**www.federalregister.gov**). In the event that a meeting or portion of a meeting is closed to the public, a notice will be published in the Federal Register. CTAC is governed by provisions in the Federal Advisory Committee Act (or FACA; see **Appendix D**).

Additional information related to CTAC meetings, including meeting dates, agendas, and meeting summaries, can be found at **http://deainfo.nci.nih.gov/advisory/ctac/ctac.htm**.

CTAC SUBCOMMITTEES AND WORKING GROUPS

To facilitate CTAC's work, subcommittees or working groups composed of both CTAC and non-CTAC members may be established to provide additional advice and oversight on specific topics or initiatives. Subcommittee meetings are open to the public and announced in the Federal Register. Working groups may be formed to provide in-depth analysis and recommendations for discussion and approval by CTAC.

CURRENT WORKING GROUPS

CTAC is tasked with the oversight of NCI activities in response to the **Recalcitrant Cancer Research Act of 2012** (or RCRA, **www.congress.gov/bill/112th-congress/house-bill/733/text**). The RCRA called upon NCI to "develop scientific frameworks" to assist in making "progress against recalcitrant or deadly cancers." In response to the legislation, the NCI director identified pancreatic ductal adenocarcinoma (PDAC) and small cell lung cancer (SCLC) as two recalcitrant cancers. Two CTAC working groups were formed to track progress on PDAC and SCLC. Progress is to be reported to Congress at baseline and then every five years. Interim updates are provided to CTAC.

The **Progress in PDAC Research Working Group** was formed in November 2014 to oversee the progress on the new PDAC initiatives proposed in the Scientific Framework for Pancreatic Ductal Adenocarcinoma (PDAC), **http://deainfo.nci.nih.gov/advisory/ctac/workgroup/pc/PDACframework.pdf**, which was submitted to Congress in 2014. The PDAC initiatives are:

- Initiative 1: Understanding the biological relationship between PDAC and diabetes mellitus;
- Initiative 2: Early detection and biomarkers development;
- Initiative 3: Identification of new therapeutic strategies in immunotherapy; and
- Initiative 4: Development of RAS therapeutics.

This work was the outgrowth of CTAC's **Pancreatic Cancer Working Group**, which was convened in 2012 to develop strategies and recommendations for NCI on ways to reduce the incidence and mortality rates of adenocarcinoma of the pancreas. The working group developed precise near-term goals as well as high-level recommendations that became the basis for the scientific framework.

Similarly, the **Progress in SCLC Working Group** was formed in 2015 with the primary objective of advising NCI on the progress on the new SCLC initiatives proposed in the Scientific Framework for Small Cell Lung Cancer (SCLC), which was presented to Congress in 2014 (**http://deainfo.nci.nih.gov/advisory/ctac/workgroup/SCLC/SCLC%20Congressional%20Response.pdf**).

The SCLC initiatives are:

- Initiative 1: Building better research tools;
- Initiative 2: Expanding comprehensive genomic profiling studies;
- Initiative 3: Investigating new diagnostic approaches for high-risk populations;
- Initiative 4: Focusing therapeutic development efforts on specific molecular vulnerabilities; and
- Initiative 5: Examining mechanisms underlying both the high initial rate of response and the rapid emergence of drug and radiation resistance.

The foundation for this work was provided by the **SCLC Working Group**, which was created in 2013 to develop strategies and recommendations to advise NCI on the development of a scientific framework to advance research in small-cell lung cancer.

CTAC continues to receive updates from these two RCRA Progress Working Groups and will review their assessment of the scientific progress as the initiatives mature.

Another area of CTAC oversight is the implementation of NCI clinical trials informatics initiatives. To obtain extramural expertise and advice on this topic, the **Clinical Trials Informatics Working Group** (CTIWG) was formed in 2015. Its goals are to:

- Minimize the burden of cancer clinical trials data management;
- Improve the value of cancer clinical trials data; and
- Increase the impact of clinical trials by streamlining initiation, conduct, data analysis, and reporting as originally envisioned in the 2005 CTWG report.

CTAC recently recommended the formation of two new working groups to provide advice on the scientific direction and operations of NCI's late-phase clinical trials enterprise. The **Clinical Trials Strategic Assessment Working Group** will review the individual steering committee clinical trials portfolio self-assessments and their strategic priorities, and assess the activities of the NCI Clinical Trials Network (NCTN) across the system. The **NCTN External Evaluation Working Group** will assess the scientific contributions of the NCTN. The working group will also make recommendations to enhance the scientific and operational functioning of the NCTN.

CTAC ACCOMPLISHMENTS—THE FIRST DECADE

CTAC's first task was to provide extramural advice on NCI's implementation of the CTWG initiatives and the ongoing conduct of clinical trials across NCI. The CTWG recommendations addressed four critical themes for designing a more efficient national system for clinical trials conducted or supported by NCI: (1) better coordination, (2) prioritization based on science and the needs of patients, (3) standardized tools and procedures, and (4) improved operational efficiency. These four themes provided a framework for 22 initiatives recommended by the working group.

In July 2015, CTAC reviewed these initiatives and assessed whether progress was achieved, partially achieved, or not achieved. Additional details can be found at **http://deainfo.nci.nih.gov/advisory/ctac/0715/DoroshowCTWG.pdf**. Implementation of these initiatives is coordinated by CCCT.

The following initiatives were achieved:

- *Establish a permanent federal body to provide extramural advice on the implementation of the CTWG initiatives and the ongoing conduct of clinical trials across NCI*. This led to the charter of CTAC in 2007.
- *Establish a standing internal operations committee to provide ongoing integration, coordination, and oversight of clinical trials activity across NCI*. This led to the formation of the Clinical and Translational Research Operations Committee (CTROC) in 2007.
- *Facilitate collaboration and cooperation across the NCI-funded clinical trials system*. This led to the revision of guidelines, starting in 2009, for the Specialized Programs of Research Excellence (SPORE), NCI-Designated Cancer Centers, and NCTN. The Cancer Clinical Investigator Team Leadership Awards were initiated in 2009 to incentivize mid-career clinical investigators to promote a culture of clinical trials at their cancer centers. This initiative also led to the formation of the NCTN Group/NCI Leadership Management Committee in 2014. These activities continue to be monitored by CTAC.
- *Develop commonly accepted clauses for clinical trials contracts with industry to facilitate clinical trials initiation*. Standard Terms of Agreement for Research Trials (START) Clauses were developed in 2008. The START clauses can be found at **www.cancer.gov/about-nci/organization/ccct/resources**.

- *Restructure NCI's dedicated clinical trials programs to improve patient accrual and cost-effectiveness*. In 2014, NCI restructured three clinical trials programs: the NCTN, which consolidated NCI's clinical trials network into four adult groups and one pediatric group, the NCI Community Oncology Research Program (NCORP) and the Experimental Therapeutics Clinical Trials Network (ETCTN). These clinical trials networks continue to be monitored by CTAC.

- *Identify and address barriers to timely trial initiation*. In 2010, target opening dates and absolute deadlines for opening NCTN and ETCTN trials were established. These are detailed in the Operational Efficiency Working Group report, which can be found at **http://deainfo.nci.nih.gov/advisory/ctac/workgroup/OEWG-Report.pdf**.

- *Promote adoption of the facilitated review process of NCI's Central Institutional Review Board*. In response to this initiative, the CIRB obtained accreditation from the Association for the Accreditation of Human Research Protection Programs, Inc. (AAHRPP) and is now used by all NCTN and NCORP sites for NCI-sponsored trials. CIRBs also were formed for pediatric, cancer control and prevention, and early phase clinical trials.

- *Obtain broad extramural scientific and clinical input into strategic directions for the Cancer Therapy Evaluation Program (CTEP)-funded phase 1 and phase 2 trials*. The Investigational Drug Steering Committee (IDSC) was established in 2005 to provide input on NCI's early phase clinical trials. The IDSC has provided input on drug development plans for more than 40 agents.

- *Obtain broad scientific and clinical input from academic disease experts, practicing oncologists, patient advocates, and NCI staff on the development and selection of NCI-funded late-phase trials*. To address this initiative, 15 Scientific Steering Committees (SSCs) were established to review concepts for late-phase clinical trials.

- *Ensure that adequate funding is available for clinical trials involving biomarkers, imaging, and quality of life*. The Biomarker, Imaging and Quality of Life Studies Funding Program (BIQSFP) was established in 2008 to provide timely access to such funds. The program eliminates the need to apply for investigator-initiated grant funds to support integral and integrated clinical trials-associated markers and studies. As of July 2016, 58 clinical trials with a total of 66 BIQSFP studies have been approved, for a total of more than $58 million in funding.

- *Establish quality control standards for laboratory assays and imaging procedures used in association with NCI-funded clinical trials*. The Program for the Assessment of Clinical Cancer Tests (**https://cdp.cancer.gov/scientific_programs/pacct/default.htm**) developed assay and imaging performance standards for integral and integrated assays conducted in association with clinical trials.

The following ongoing initiatives were partially achieved:

- *Enhance information sharing concerning the status and results of NCI-funded clinical trials*. NCI developed the Clinical Trials Reporting Program (CTRP), which contains data on national, peer-reviewed, institutional, and industrial trials open to accrual on or after January 2009.

- *Enhance interactions with the FDA and the CMS to promote coordination of regulatory and reimbursement policies with the scientific enterprise*. NCI, FDA, industry, and academia continue to meet on the use of molecular diagnostics for clinical decision-making. These interactions led to the launch of major target-based clinical trials, including ALCHEMIST (Adjuvant Lung Cancer Enrichment Marker Identification and Sequencing Trials), Lung MAP (Lung Cancer Master Protocol), and MATCH (Molecular Analysis for Therapy Choice). NCI continues to participate in meetings with the CMS concerning medical care coverage for clinical trials.

- *Create interoperable, standards-based information technology tools to facilitate the collection, management, and analysis of clinical trials data*. A number of electronic links have been established among NCI-Designated Cancer Centers and the CTRP, Cancer Trials Support Unit (CTSU), NCTN, and ETCTN.

- *Develop standard case report forms incorporating common data elements that use standard vocabularies*. Common data elements and standard case report form modules were created. In 2015, an NCTN committee was convened to address the use of standard questions and a set of standard response values.

- *Build a standard credentialing system for investigators and sites to avoid duplicative credentialing for every trial*. Software for a central repository for Form FDA 1572 was developed in 2013 but has not yet been implemented.

- *Analyze the status of patient accrual to NCI clinical trials and develop strategies to improve accrual rates as well as patient and public awareness and understanding of clinical trials*. This topic was addressed at a 2010 Clinical Trials Accrual Symposium, resulting in the development of accrual best practices and identification of areas of research to improve accrual. NCI assembled a Network Accrual Core Team to address accrual rates and public awareness and understanding of clinical trials.

The only CTWG initiative that was characterized as not achieved and in need of reassessment is the following:

- Increase minority patient access to clinical trials to improve the participation of underserved and underrepresented populations. A pilot program of administrative supplements between 2006 and 2010 did not change overall minority accrual trends. In 2011, NCI concluded that the program should not continue in its original form. Other options to address this initiative are under consideration.

PAST WORKING GROUPS

CTWG-Related Working Groups

A number of CTAC working groups assisted in the implementation of CTWG initiatives over the past decade.

The **NCTN Strategic Planning Working Group** was charged with assessing the strength and balance of the active NCTN clinical trials and NCORP symptom management and health-related quality of life trials both within and across portfolios and recommending future strategic priorities and directions. Over the course of a year beginning in 2012, the clinical trials portfolios of 14 SSCs were assessed. Those assessments resulted in cross-portfolio recommendations aimed at improving the overall portfolio as well as comments related to individual portfolios (**http://deainfo.nci.nih.gov/advisory/ctac/0714/Sledge.pdf**).

The working group's recommendations, published in 2014, were grouped into the following broad categories:

- Innovative science-driven trials;

- Reallocation of NCTN resources;

- Coordination of strategic planning and collaborative efforts;

- Evaluation criteria; and

- Optimization of steering committee processes.

The **Cost-Effectiveness Analysis (CEA) Working Group** was formed to advise CTAC and NCI on the development of a prioritization process and funding mechanisms to ensure that the most important cost-effectiveness analyses be conducted in association with NCI-sponsored clinical trials. CTAC accepted the CEA Working Group report in 2010 (**http://deainfo.nci.nih.gov/advisory/ctac/workgroup/CEA-WG%20Recommendations%20to%20CTAC%20%28FINAL%29.pdf**).

The report accomplished the following objectives:

- Developed prioritization criteria for determining the most important clinical trials for including parallel cost-effectiveness analyses;
- Identified possible funding mechanisms for support of high priority cost-effectiveness analyses; and
- Developed a CEA review, funding, and evaluation process.

Following acceptance of this report, the opportunity to submit proposals for the CEA studies was added to the BIQSFP announcement (**http://biqsfp.cancer.gov/eligible/cea.asp**).

The **Operational Efficiency Working Group** (OEWG) was established in 2008 to advise 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. Its report was accepted by CTAC in 2010 (**http://deainfo.nci.nih.gov/advisory/ctac/workgroup/OEWG-Report.pdf**).

The OEWG report:

- Set targets for opening NCI-sponsored trials;
- Set absolute deadlines for cancelling an unopened CTEP trial; and
- Recommended 14 initiatives for achieving trial target activation time.

CTAC approved the formation of a **CTWG Evaluation Working Group** in 2007 to examine issues involving the CTWG Evaluation Plan. The plan developed an evaluation structure to assess the impact of implementation of the CTWG-recommended initiatives on the NCI-funded clinical trials enterprise.

A baseline feasibility analysis was completed in 2008 to determine the feasibility of data collection and to report on certain measures of the state of the system prior to implementation of the CTWG initiatives.

The final report of the CTWG Evaluation Working Group was accepted by CTAC in 2011 (**http://deainfo.nci.nih.gov/advisory/ctac/archive/0711/CTWGrEPORT.pdf**).

The **Guidelines Harmonization Working Group** was formed in 2008 to provide overall guidance and recommendations for the harmonization of NCI's clinical trials program guidelines (NCI-Designated Cancer Centers, SPORE, and Cooperative Groups) to eliminate redundancy and duplication while proactively encouraging collaboration.
The working group presented its report with recommendations to CTAC in 2009. The recommendations support a two-pronged approach with the goal of moving the current clinical trials system to a seamless continuum of translation from basic studies to applications that benefit people (**http://deainfo.nci.nih.gov/advisory/ctac/workgroup/GHWG%20Report_Rev.9-2009_FINAL.pdf**).

The working group recommended the following actions:

- Revise guidelines for NCI clinical research support mechanisms to improve collaboration and ensure consistency across and between funding mechanisms; and
- Develop incentives for collaboration.

The **NCI Implementation Working Group** for the Guidelines Harmonization Working Group Report presented a progress report to CTAC in 2010 (**http://deainfo.nci.nih.gov/advisory/ctac/workgroup/GHWGimplementationReport.pdf**).

The report highlights included the following:

- Key proposed guidelines changes incorporated collaborations across clinical trials and translational science mechanisms with separate sections in the SPORE and Cooperative Group Guidelines.
- Key proposed guidelines also integrated multiple sections within the NCI-Designated Cancer Centers Guidelines.
- Incentives for collaboration were identified.

The SPORE Guidelines were published in 2011 and incorporated incentives to collaboration as recommended by the Guidelines Harmonization Working Group. Similarly, the NCTN Guidelines and the Cancer Center Support Grant Guidelines, both updated in 2012, reflect these changes.

Translational Research Working Groups

Translational research is also under CTAC's purview. Over the past decade, several CTAC working groups were convened and provided recommendations regarding NCI's translational research programs.

The **SPORE Program Evaluation Working Group**, which was created in 2012, had a dual charge. First, the working group was asked to provide expert input on the value of the SPORE program to NCI and the overall cancer research enterprise. Secondly, the working group was asked to recommend ways in which the future of the SPORE program could be enhanced.

The SPORE Program Evaluation Working Group report, released in 2014 (**http://deainfo.nci.nih.gov/advisory/ctac/workgroup/spore/report27jan14.pdf**), outlines conclusions and recommendations related to program requirements as well as specific program features. The working group members were unanimous in recommending that the SPORE Program Announcement be re-issued, with the program continuing in its current configuration with minor modifications.

The **Process to Accelerate Translational Science (PATS) Working Group** was formed to develop Special Translational Research Acceleration Projects and further translational research in clinical trials. The PATS Working Group report and recommendations were accepted by CTAC in 2010 (**http://deainfo.nci.nih.gov/advisory/ctac/workgroup/_NCI%20PATS%20Working%20Group%20FINAL%20REPORT.pdf**).

The recommendations were meant to:

- Enhance scientific collaborations across NCI and assist NCI in identifying the most promising scientific opportunities ripe for translation; and
- Develop a process to ensure that the most promising concepts enter a defined developmental pathway and then advance into the clinic in a rapid, efficient, and effective manner.

The **Immune Response Modifier (IRM) Pathway Prioritization Working Group** was formed to advise NCI on the development of a prioritization process for translational research opportunities and provide input on funding strategies. The working group's recommendations were presented to CTAC in 2009 (**http://deainfo.nci.nih.gov/advisory/ctac/workgroup/_IRM%20Prioritization%20Working%20Group%20FINAL%20REPORT.pdf**).

The report prioritized translational research opportunities across the IRM Pathway and recommended several high-priority options for funding. Two pilot projects were funded in 2010.

BACKGROUND

NCI established the Coordinating Center for Clinical Trials (CCCT) in 2006 in response to the 2005 National Cancer Advisory Board, Clinical Trials Working Group (CTWG) report. The CTWG recommended the creation of an organization within NCI to coordinate the integration of the entire clinical trials enterprise supported by NCI.

THE CCCT'S MISSION AND ACTIVITIES

The CCCT facilitates the integration of NCI's clinical trials programs and associated translational research, including the (1) NCI National Clinical Trials Network (NCTN) and Early Therapeutics Clinical Trials Network (ETCTN) treatment trials, for which the Division of Cancer Treatment and Diagnosis (DCTD) is responsible; (2) NCI Community Oncology Research Program (NCORP) trials for supportive care and cancer care delivery research, for which the Division of Cancer Prevention (DCP) and the Division of Cancer Control and Population Science (DCCPS) are responsible; (3) trials taking place through NCI's Center for Cancer Research; and (4) trials taking place with NCI support, either in NCI-Designated Cancer Centers or through NCI-funded grants.

These programs are cooperative endeavors that draw upon the strongest components of NCI's clinical research system and scientific infrastructure.

The CCCT, in conjunction with all NCI divisions, offices, and centers, facilitates the integration of activities that expedite cancer clinical trials and associated translational research by:

- Facilitating the prioritization of NCI's most important clinical trials by the Scientific Steering Committees working with NCI clinical programs, such as those in DCTD, DCP, and DCCPS;
- Partnering with NCI's Center for Biomedical Informatics and Information Technology to enhance and maintain NCI's Clinical Trials Reporting Program (CTRP), a comprehensive database with up-to-date information on all NCI-supported clinical trials;
- Managing NCI's Clinical and Translational Research Operations Committee (CTROC) and the Clinical Trials and Translational Research Advisory Committee (CTAC), which advise NCI leadership on clinical trials and associated translational science.

CLINICAL AND TRANSLATIONAL RESEARCH OPERATIONS COMMITTEE

The Clinical and Translational Research Operations Committee (CTROC) is key in the internal integration of NCI's clinical trials enterprise. Committee membership includes representatives from each NCI division, office, and center that supports clinical trials and translational research (see **Appendix E**). Members meet twice monthly to:

- Provide oversight of NCI's clinical trials and translational research portfolios, including related information technology programs;
- Advise the NCI director on the conduct of all clinical trials funded or conducted by NCI; and
- Monitor progress and prioritize efforts to implement the recommendations of CTAC subcommittees and working groups.

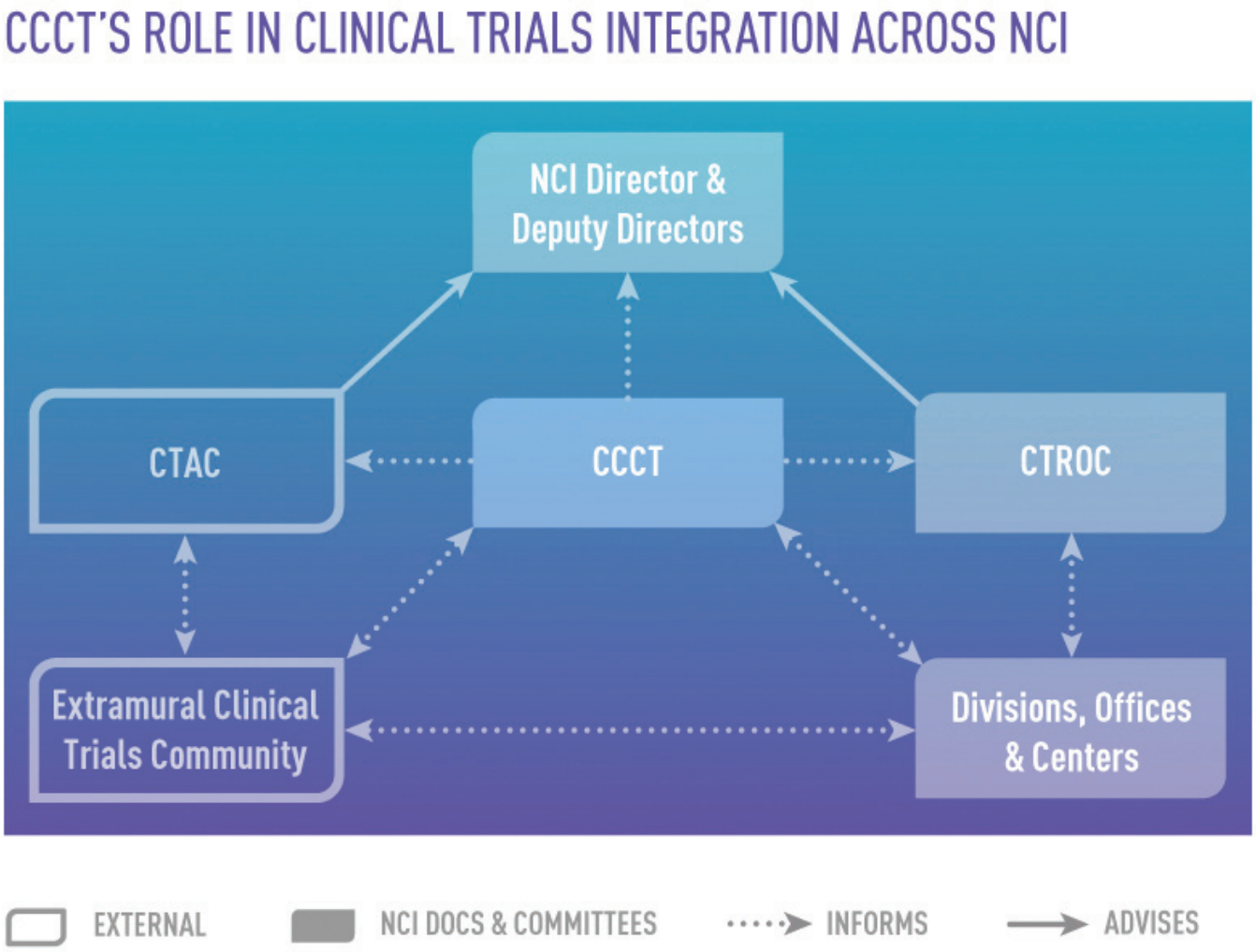
SELECT CLINICAL RESEARCH ACTIVITIES HOUSED IN THE CCCT

In the past decade, NCI has made significant progress on the CTWG report recommendations. Key activities and initiatives directly overseen by the CCCT are described below.

SCIENTIFIC STEERING COMMITTEES

Scientific Steering Committees (SSCs) are composed of leading cancer experts, community oncologists, biostatisticians, translational scientists, and patient advocates, as well as NCI senior investigators. The **NCTN Steering Committees** review concepts for large phase 2 or phase 3 treatment or imaging trials conducted in the NCTN. A concept is a proposal describing key design elements of a study.

Exhibit I - The Interactions Between CTROC, CTAC, and the NCI's Office of the Director



CCCT facilitates the integration of clinical trials activities among the NCI's various divisions, offices, and centers, represented by CTROC, and the extramural clinical and translational research communities, represented by CTAC.

The **Investigational Drug Steering Committee** works with NCI in the design and prioritization of early-phase drug development trials to be conducted in the Experimental Therapeutics Clinical Trials Network (ETCTN). The **NCORP Cancer Control Steering Committees** review concepts for clinical trials related to cancer care delivery, treatment side effects, and the control of cancer symptoms. The **Patient Advocate Steering Committee** works to ensure that advocates involved with SSCs are integrated in the development, implementation, and monitoring of clinical trials. A list of SSCs can be found at **www.cancer.gov/about-nci/organization/ccct/steering-committees**.)

NCTN STEERING COMMITTEES

Disease-Specific Steering Committees

The NCTN Disease-Specific Steering Committees (DSSCs) analyze proposed clinical trials concepts and facilitate the sharing of ideas among a broad range of clinical investigators, basic and translational scientists, NCI staff, community oncologists, and patient advocates. DSSC members participate in decision-making activities through teleconferences and face-to-face meetings. The major goals of the DSSCs are to evaluate and prioritize phase 3 and large phase 2 treatment clinical trials based on their scientific merit, increase the efficiency of clinical trials collaboration, reduce trial redundancy, and increase information exchange at an early stage of trial development. The DSSCs also convene Clinical Trial Planning Meetings to identify critical questions and prioritize key treatment strategies for their diseases. Each committee is designed to leverage the current NCTN Group, SPORE, and Cancer Center structures. To date, the following DSSCs have been established:

- Brain Malignancies Steering Committee
- Breast Cancer Steering Committee
- Gastrointestinal Steering Committee
- Genitourinary Steering Committee
- Gynecologic Cancer Steering Committee
- Head and Neck Steering Committee
- Leukemia Steering Committee
- Lymphoma Steering Committee
- Myeloma Steering Committee
- Pediatric and Adolescent Solid Tumor Steering Committee
- Pediatric Leukemia and Lymphoma Steering Committee
- Thoracic Malignancy Steering Committee.

See **www.cancer.gov/about-nci/organization/ccct/steering-committees/nctn/** for the committee rosters.

Clinical Imaging Steering Committee

The Clinical Imaging Steering Committee (CISC) was established in 2010. The CISC is a forum to enable the extramural imaging and oncology communities to provide strategic input to NCI regarding its significant investment in imaging activities in clinical trials. The committee is charged with identifying and promoting the best science in clinical oncology research by addressing the design and prioritization of phase 3 and large phase 2 trials focused primarily on cancer imaging. In addition, CISC members provide valuable imaging expertise for other steering committees' evaluations of therapeutic concepts and discussions that include an imaging component. CISC facilitates the exchange of ideas among a broad range of investigators interested in cancer clinical imaging research. Members include imaging experts from the NCTN 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 **www.cancer.gov/about-nci/organization/ccct/steering-committees/clinical-imaging**.

INVESTIGATIONAL DRUG STEERING COMMITTEE

The Investigational Drug Steering Committee (IDSC) was established in 2005. The IDSC provides NCI with broad external scientific and clinical input on the design and prioritization of phase 1 and phase 2 trials with agents for which the Cancer Therapy Evaluation Program (CTEP) holds an Investigational New Drug application. The IDSC aims to increase the predictive value of early-phase trials, resulting in the design of more successful phase 3 trials. Members of the IDSC include the principal investigators of the ETCTN, representatives from the NCTN Groups, a patient advocate, biostatisticians, and NCI staff. In addition to the steering committee, task forces and project management teams provide scientific input on CTEP's drug development plans.

Additional information can be found at **www.cancer.gov/about-nci/organization/ccct/steering-committees/investigational-drug**.

NCORP CANCER CONTROL STEERING COMMITTEES

Cancer Care Delivery Research Steering Committee

The Cancer Care Delivery Research Steering Committee (CCDRSC) was established in 2015. The core committee membership includes representatives from NCORP Research Bases, Research Project Grant (R01) investigators, community oncologists, biostatisticians, patient advocates, and NCI staff. The role of the CCDRSC is to review and prioritize cancer care delivery research concepts to be conducted through NCORP.

Studies under the purview of the CCDRSC include:

- Descriptive observational studies to document the prevalence and variability of specific cancer care delivery models, approaches, and processes;
- Analytic observational studies to understand how the multilevel characteristics of care delivery models, approaches, and processes influence quality, outcomes, and access; and
- Intervention studies, including randomized, controlled trial designs, to test new models, approaches, and processes of care delivery to improve quality, outcomes, and access.

Information about the CCDRSC is available at **www.cancer.gov/about-nci/organization/ccct/steering-committees/ncorp/cancer-care**.

Symptom Management and Health-Related Quality of Life Steering Committee

The Symptom Management and Health-Related Quality of Life Steering Committee (SxQOLSC) was established in 2006. The core committee membership includes representatives from NCORP Research Bases, R01 investigators, community oncologists, biostatisticians, patient advocates, and NCI staff. The SxQOLSC was designed to:

- Evaluate and prioritize symptom management intervention clinical trials concepts to be conducted through NCORP;
- Evaluate studies with co-primary quality of life (QOL) endpoints in NCTN treatment studies;
- Develop criteria for concepts that are eligible for the Biomarker, Imaging, and Quality of Life Studies Funding Program; and
- Convene Clinical Trial Planning Meetings to identify critical questions and prioritize key strategies related to side effects of cancer, cancer treatment, and patients' QOL.

Information about the SxQOLSC is available at **www.cancer.gov/about-nci/organization/ccct/steering-committees/ncorp/symptom-management**.

PATIENT ADVOCATE STEERING COMMITTEE

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

PASC's mission and roster can be found at **www.cancer.gov/about-nci/organization/ccct/steering-committees/patient-advocate**.

BIOMARKER, IMAGING, AND QUALITY OF LIFE STUDIES FUNDING PROGRAM

The goal of the Biomarker, Imaging, and Quality of Life Studies Funding Program (BIQSFP) is to ensure that the most important biomarker, imaging, and QOL studies can be initiated in a timely manner in association with appropriate trials led by the NCTN Groups and NCORP research bases. The BIQSFP supports studies that are embedded in clinical trials that have the potential to modify standards of practice. Clinical assays that are used to assign or significantly modify a patient's treatment in the proposed clinical trial must have undergone rigorous analytic validation and sufficient clinical validation to warrant inclusion in a clinical trial. The program is an attractive alternative to applying for investigator-initiated grants to support clinical trials tests and assays. The BIQSFP also supports cost-effectiveness analysis (CEA) research developed alongside the clinical trials concept.

On behalf of the study team, the NCTN Groups or NCORP research bases submit requests for the BIQSFP funds. The SSCs evaluate and recommend the parent clinical trials concept along with the BIQSFP proposal during regularly scheduled meetings. NCI program staff members recommend the SSC-approved BIQSFP proposals to CTROC for prioritization and funding approval at their semi-monthly meetings. CTAC receives periodic updates on the approved funding portfolio.

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

CANCER CLINICAL INVESTIGATOR TEAM LEADERSHIP AWARD

The Cancer Clinical Investigator Team Leadership Award (CCITLA) is an administrative supplement award that recognizes and supports clinical investigators with an outstanding record of developing and promoting a culture of successful clinical research. CCITLA is intended to support mid-level clinical investigators at NCI-Designated Cancer Centers who are participating extensively in NCI-funded collaborative clinical trials and clinical research efforts. The award is also intended to retain clinical investigators in academic clinical research careers. Ultimately, CCITLA supports a shared culture in which investigators collaborate freely across disciplines, institutions, and programs to expeditiously advance the design and conduct of cancer clinical trials.

The 2-year award provides recognition and $60,000 annually 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, benefits, and associated facilities and administrative costs. Recipients are expected to devote 15 to 20 percent of their time to the activities associated with the award.

Since 2009, NCI has made 79 awards. A list of awardees is available at **www.cancer.gov/about-nci/organization/ccct/funding/ccitla/2016AwardeeList**.

STANDARD TERMS OF AGREEMENT FOR RESEARCH TRIALS CLAUSES

Contract negotiations between clinical trials sponsors (pharmaceutical, biotechnology, or medical device companies), academic medical centers, and principal investigators often add months to the process of starting a clinical trial. These delays can add 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 trials contracts.

To fulfill this recommendation, NCI and the Life Sciences Consortium of the CEO Roundtable on Cancer (a nonprofit organization) jointly developed a set of common clauses known as the Standard Terms of Agreement for Research Trials (START) clauses. These standard clauses contain common language that provides a starting point for clinical trials contract negotiations between academic institutions and clinical trials sponsors.

The START clauses provide language on intellectual property, study data, indemnification, subject injury, confidentiality, and publication rights. Use of the START clauses is voluntary.

The START clauses can be found at **www. cancer.gov/about-nci/organization/ccct/resources**.

CLINICAL TRIALS REPORTING PROGRAM

The Clinical Trials Reporting Program (CTRP) fulfills a recommendation made in the CTWG report and reiterated by the Institute of Medicine (IOM) report, "A National Cancer Clinical Trials System for the 21st Century: Reinvigorating the NCI Cooperative Group Program." The CTRP is a comprehensive database of regularly updated information, including accrual, on all NCI-supported clinical trials. This database of the NCI portfolio helps identify gaps in clinical research and duplicative studies and facilitates effective clinical trials prioritization. The CTRP is the source of the clinical trials abstracts presented on the NCI website, Cancer.gov, providing the public with updated information regarding trials supported by NCI.

Additional information about the CTRP is available at **www.cancer.gov/about-nci/organization/ccct/ctrp**.

The CTRP supports regulatory compliance with registration and results reporting of applicable clinical trials in ClinicalTrials.gov, which is required by Section 801 of the Food and Drug Administration Amendments Act (FDAAA) for trials in which NCI is the sponsor, as defined by FDAAA. Other trial sponsors can access their CTRP records through ClinicalTrials.gov and use them for ClinicalTrials.gov registration, thus decreasing the burden of duplicative reporting.

SELECT CLINICAL TRIALS PROGRAMS HOUSED IN OTHER NCI DIVISIONS

NCI NATIONAL CLINICAL TRIALS NETWORK

After several years of extensive consultation and coordination with many stakeholders, NCI transformed its longstanding Cooperative Group program into the new National Clinical Trials Network (NCTN) in 2014, guided by the recommendations of the 2005 CTWG report and the 2010 IOM report. The design and implementation of the NCTN incorporated feedback from Cooperative Group investigators, NCI Comprehensive Cancer Center directors, several NCI working groups, leading cancer researchers, industry representatives, and patient advocates. The NCTN is housed in the NCI Division of Cancer Treatment and Diagnosis. The NCTN is composed of five Network Groups, 30 Lead Academic Participating Sites, 7 Network Integrated Translational Research Sites, a Network Imaging Center, and a Canadian Network Group.

For a detailed review of the new NCTN and its goals, please see **www.cancer.gov/research/areas/clinical-trials/nctn**.

NCI COMMUNITY ONCOLOGY RESEARCH PROGRAM

The NCI Community Oncology Research Program (NCORP) was established in 2014. It built upon the strengths of the Community Clinical Oncology Program, guided by the CTWG and IOM reports. NCORP designs and conducts cancer prevention, control, screening, and post-treatment surveillance trials; conducts cancer care delivery research, including comparative effectiveness research; and integrates disparities research questions into clinical trials and cancer care delivery research. NCORP is composed of 7 Research Bases, 34 Community Sites, and 12 Minority/Underserved Sites bringing clinical research to individuals in their communities. NCORP is housed in the Division of Cancer Prevention and the Division of Cancer Control and Population Sciences. For more information about NCORP, see **http://ncorp.cancer.gov**.

EXPERIMENTAL THERAPEUTICS CLINICAL TRIALS NETWORK

The Experimental Therapeutics Clinical Trials Network (ETCTN), also established in 2014, transformed the NCI-sponsored cooperative experimental therapeutics clinical trials program from a series of separate organizations conducting early-phase cancer treatment trials into a consolidated, integrated network. The ETCTN is composed of 12 grantees dedicated to new agent developmental efforts, with an emphasis on early-phase clinical trials. The ETCTN awards provide for rapid, efficient, and systematic evaluation and determination of optimal doses and schedules for specific agents and combinations of investigational agents in NCI's investigational agents portfolio. Members of the ETCTN work on agent-specific trans-network project teams to define the drug development plans and conduct

experimental therapeutic clinical trials. The ETCTN sites extensively characterize patients' tumors on a molecular level to select appropriate patients for specific treatments and explore mechanisms of resistance and response to assist in defining follow-on treatment or determining future combination therapies. The ETCTN is housed in the Division of Cancer Treatment and Diagnosis. More information can be found at **http://ctep.cancer.gov/initiativesPrograms/etctn.htm**.

NCI CENTRAL INSTITUTIONAL REVIEW BOARD INITIATIVE

In 2001, NCI created the Central Institutional Review Board (CIRB) Initiative in consultation with the U.S. Department of Health and Human Services Office of Human Research Protections. The CIRB is designed to help reduce the administrative burden on local institutional review boards (IRBs) and investigators while continuing a high level of protection for human research participants.

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 to be addressed, including:

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

Over the years, as operational efficiencies were implemented and the benefits of the CIRB became more widely appreciated, use of the CIRB grew steadily. In 2012, the CIRB became accredited by the AAHRPP. With the launch of the NCTN in 2014, clinical sites were required to use the CIRB as their IRB of record. In 2013, the Adult CIRB—Early Phase Emphasis was established. In 2015, the Cancer Prevention and Control CIRB was established.

The CIRB is housed in the Division of Cancer Treatment and Diagnosis and the Division of Cancer Prevention. Information on the CIRB Initiative can be found at **www.ncicirb.org**.

THE NATIONAL CANCER INSTITUTE

MISSION

The National Cancer Institute (NCI) is a component of the National Institutes of Health (NIH) and one of 11 operating divisions that compose the Public Health Service in the U.S. Department of Health and Human Services. Established under the National Cancer Act of 1937, NCI is the federal government's principal agency for cancer research and training. The National Cancer Act of 1971 broadened the scope and responsibilities of NCI and created the National Cancer Program (NCP). Over the years, legislative amendments have maintained 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.

NCI is committed to dramatically lessening the impact of cancer. 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. NCI is dedicated to the understanding, diagnosis, treatment, and prevention of cancer for all people. NCI works toward this goal by providing vision to the nation and leadership for both domestic and international NCI-funded researchers. NCI also works to ensure that research results are applied in clinical practice and in 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 the development of interventions and new technology through translational research; and ensure the delivery of these interventions for application in clinics 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 NCP, NCI provides vision and leadership to the global cancer community. 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.

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, NCI offers the nation's cancer scientists a variety of useful research tools and services, including tissue samples, statistics on cancer incidence and mortality, bioinformatics tools for analyzing data, databases of genetic information, and resources through NCI-Designated Cancer Centers, Specialized Programs of Research Excellence, and the Mouse Models of Human Cancer Consortium.

NCI also uses collaborative platforms and an interdisciplinary environment to promote translational research and intervention development. For example, a newly discovered tool that initially helps scientists understand the underlying mechanism of cancer may eventually be used to help diagnose it, and this tool may be further developed to help treat cancer. 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, which conducts tests on interventions for preventing cancer, diagnostic tools, and cancer treatments, and provides access as early as possible to anyone who can benefit. NCI supports more than 2,900 clinical trials each year, assisting more than 142,000 patients.

NCI research affects 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 to determine 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, NCI is fostering partnerships with other agencies and organizations to accelerate the movement of targeted drugs through the pipeline of discovery, development, and delivery.

Information about NCI's research and activities is available through its public website at **www.cancer.gov**.

LEGISLATIVE AUTHORITY

Under the National Cancer Act of 1971, the NCI director is authorized to submit a professional judgment budget reflecting the full funding needs of the NCP directly to the president. 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 it allows the NCI director to express to the president the plans and priorities of NCI and the NCP, along with an indication of the associated costs. Each year, NCI produces the Bypass Budget 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 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 is provided to Congress and updated yearly. It is a powerful communication and priority-setting tool used by constituents across the NCP as well as 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 NCP, clearly outlining the areas of highest priority.

Throughout the planning process, 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 members of the President's Cancer Panel (PCP) to facilitate transfer of the panel's 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 NCP. For example, discussions at the NCAB meetings with ex officio members representing the health care systems of the U.S. Department of Defense and the U.S. Department of Veterans Affairs led directly 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 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, PCP members are charged with reviewing the implementation of such plans and identifying the extent of their success for the president and the nation.

The Annual Plan and Budget Proposal can be found at **www.cancer.gov/about-nci/budget/annual-plan**.

NCI ORGANIZATIONAL STRUCTURE

NCI's current organizational structure can be found in ***Exhibit II***. The NCI Office of the Director serves as the focal point for the NCP, with advice from the PCP, NCAB, Board of Scientific Advisors (BSA), Board of Scientific Counselors (BSC): Basic Sciences and Clinical Sciences and Epidemiology, CTAC, and the NCI Council of Research Advocates. The BSA gives final concept approval for extramural Requests for Applications (RFAs) and Requests for Proposals, while the BSC conducts intramural laboratory and branch reviews. The NCI director is assisted by several deputy directors, including James Doroshow, Warren Kibbe, and Dinah Singer.

The Scientific Program Leaders committee (SPL) see **Appendix F** and **www.cancer.gov/about-nci/leadership** includes the director, deputy directors, division directors, and other senior scientific staff. The SPL meets on a regular basis to discuss various matters of NCI policy, including but not limited to review and approval of the RFA and research and development contract concepts before review by the BSA, review of program announcements, approval of funding plans, and payment of grants by exceptions. NCI's cancer research activities are monitored and administered through several extramural and intramural divisions, offices, and centers.

Exhibit II - The National Cancer Institute

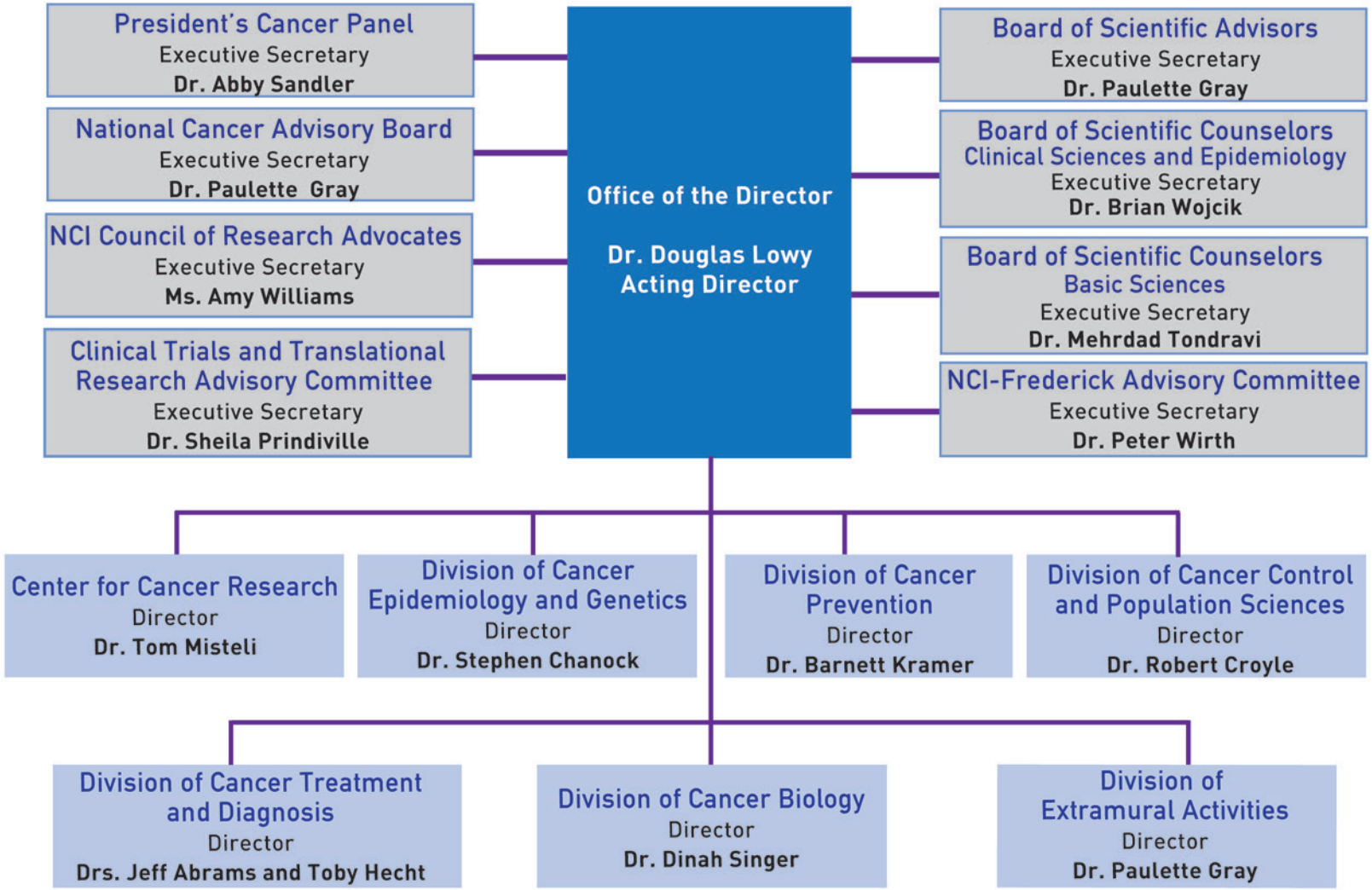
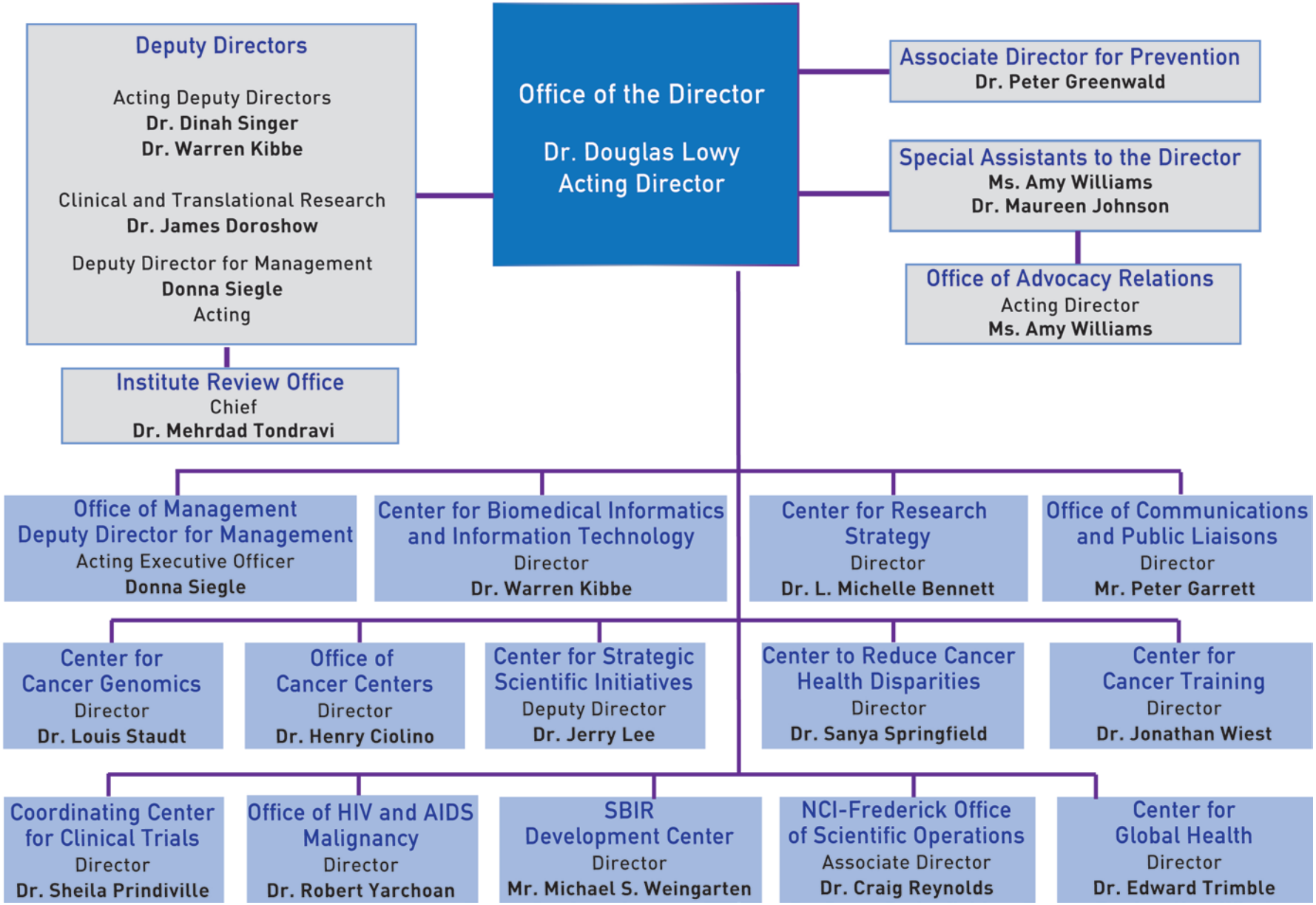


Exhibit II - The National Cancer Institute (continued)



OFFICE OF THE DIRECTOR

Examples of offices and centers within the Office of the Director include:

- **Center for Biomedical Informatics and Information Technology (CBIIT): http://cbiit.nci.nih.gov/**

  Collaborates across NCI to plan, provide, and coordinate technology, standards, and scientific computing in support of the NCI mission.

- **Center for Cancer Genomics (CCG): www.cancer.gov/about-nci/organization/ccg**

  Unifies NCI activities in cancer genomics by aiming to synthesize research in different fields of cancer genomics—structural, functional, and computational—to improve patient outcomes.

- **Center for Cancer Training (CCT): www.cancer.gov/grants-training/training**

  Provides funding to support training and career development at institutions nationwide and manages training programs at NCI laboratories, clinics, and research groups to develop a 21st-century workforce capable of advancing cancer research.

- **Center for Global Health (CGH): www.cancer.gov/about-nci/organization/cgh**

  Provides assistance and guidance to nations as they develop and implement cancer control plans; trains international investigators; and strengthens U.S. national, regional, multilateral, and bilateral collaboration in health research, cancer research, and cancer control to advance global cancer research, build expertise, and reduce cancer deaths worldwide.

- **Center to Reduce Cancer Health Disparities (CRCHD): www.cancer.gov/about-nci/organization/crchd**

  Conducts basic, clinical, translational, and population-based cancer disparities research; trains the next generation of competitive cancer researchers from diverse populations; and creates regional cancer health disparities networks to reduce the unequal burden of cancer in our society.

- **Center for Research Strategy (CRS): www.cancer.gov/about-nci/organization/crs**

  Develops recommendations for addressing scientific opportunities, identifying funding gaps, and managing funding mechanisms, while monitoring the direction and application of scientific knowledge and resources.

- **Center for Strategic Scientific Initiatives (CSSI): http://cssi.cancer.gov/**

  Creates and implements exploratory programs focused on emerging scientific discoveries and innovative technologies to accelerate the pace of cancer research and the translation of research results into new therapies, diagnostics, and preventive agents.

- **Coordinating Center for Clinical Trials (CCCT): www.cancer.gov/about-nci/organization/ccct**

  Facilitates efforts across NCI to enhance the effectiveness of NCI's clinical trials enterprise through collaboration and harmonization among NCI programs and extramural stakeholders.

- **National Cancer Institute at Frederick (NCI-F): https://ncifrederick.cancer.gov/**

  Conducts basic, translational, and preclinical cancer and AIDS research to develop the next generation of cancer tests and treatments. Home to the Frederick National Laboratory for Cancer Research (FNLCR).

- **Office of Acquisitions (OA): http://ncioa.cancer.gov/oa-internet/index.jsp**

  Plans, negotiates, awards, and administers NCI contracts and simplified acquisitions to support a coordinated cancer research program.

- **Office of Advocacy Relations (OAR): www.cancer.gov/about-nci/organization/oar**

  Serves as the cancer advocacy community's primary point of contact and facilitates the involvement of advocates in NCI research activities to help enhance the scientific process and improve patient outcomes.

- **Office of Budget and Finance (OBF): www.cancer.gov/about-nci/organization/obf**

  Advises the Office of the Director and other senior staff on financial and personnel resource management to ensure fiscally responsible and efficient operation of NCI.

- **Office of Cancer Centers (OCC): http://cancercenters.cancer.gov/**

  Supports 69 NCI-Designated Cancer Centers nationwide that are actively engaged in trans-disciplinary research to reduce cancer incidence, morbidity, and mortality.

- **Office of Cancer Clinical Proteomics Research (OCCPR): http://proteomics.cancer.gov/**

  Analyzes protein content in tumor cells through the application of state-of-the-art proteomic technologies and workflows, open-data policies, and community reagents to advance our understanding of proteins derived from cancer genomes in clinical research and medicine.

- **Office of Cancer Nanotechnology Research (OCNR): http://nano.cancer.gov/**

  Accelerates the development of promising molecular discoveries to benefit cancer patients through the development of nanotechnology-based tools for cancer detection, treatment, and monitoring.

- **Office of Communications and Public Liaison (OCPL): www.cancer.gov/about-nci/organization/ocpl**

  Supports NCI by disseminating cancer research findings; providing evidence-based information on cancer for the public, including patients, caregivers, health professionals, researchers, advocates, the news media, and other stakeholders; and disseminating information about cancer clinical trials and funding opportunities.

- **Office of Government and Congressional Relations (OGCR): www.cancer.gov/about-nci/organization/ogcr**

  Informs the NCI community of congressional issues and interests that affect NCI; facilitates relationships between NCI, Congress, and the public; and responds to Freedom of Information Act and Government Accountability Office requests to foster an understanding of the scope and value of NCI's investment in cancer research.

- **Office of Grants Administration (OGA): www.cancer.gov/about-nci/organization/oga**

  Manages all NCI business-related activities associated with the negotiation, award, and administration of NCI grants and cooperative agreements to help financially support cancer research activities throughout the United States and around the world.

- **Office of HIV and AIDS Malignancy (OHAM): http://oham.cancer.gov/**

  Coordinates and oversees HIV/AIDS and HIV/AIDS cancer research; directly manages certain HIV/AIDS-cancer research activities; and acts as a point of contact for the NIH Office of AIDS Research and other institutes and centers to enhance HIV/AIDS and HIV malignancies research efforts across NCI.

- **Office of Management Policy and Compliance (OMPC): www.cancer.gov/about-nci/organization/ompc**

  Advises the Office of Management and other senior staff on the implementation of institute-wide administrative policies and procedures, management controls, and evaluations while ensuring compliance with federal requirements.

- **Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) Programs: http://sbir.cancer.gov/**

  Seeks to increase small business and private sector participation to develop and commercialize novel technologies and products to help advance cancer research, prevention, diagnosis, and treatment.

- **Technology Transfer Center (TTC): https://techtransfer.cancer.gov**

  Builds partnerships and fosters collaboration agreements between NIH scientists, universities, nonprofits, and industry to commercialize NIH inventions; supports research and development that benefits public health.

EXTRAMURAL DIVISIONS

The extramural research and research-related activities of 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 as follows:

- **Division of Cancer Biology (DCB): www.cancer.gov/about-nci/organization/dcb**

  Encourages and facilitates continued support of basic research in all areas of cancer biology to provide the research foundation that enables improved understanding of the disease and may lead to new approaches for prevention, diagnosis, and treatment.

- **Division of Cancer Control and Population Sciences (DCCPS): http://cancercontrol.cancer.gov/**

  Conducts and supports an integrated program of genetic, epidemiological, behavioral, social, applied, and surveillance cancer research to reduce risk, incidence, and deaths from cancer and to enhance the quality of life for cancer survivors.

- **Division of Cancer Prevention (DCP): http://prevention.cancer.gov/**

  Conducts and supports research to find ways to prevent and detect cancer and to prevent or relieve symptoms from cancer and its treatments.

- **Division of Cancer Treatment & Diagnosis (DCTD): http://dctd.cancer.gov/**

  Supports the translation of promising research into clinical applications to improve the diagnosis and treatment of cancer in areas of unmet need that are often too risky or difficult for industry or academia to develop alone.

- **Division of Extramural Activities (DEA): http://deainfo.nci.nih.gov/**

  Coordinates the scientific review of extramural research before funding and provides systematic surveillance of that research after awards are made to assist NCI in achieving its goal of a balanced research portfolio.

INTRAMURAL CENTERS AND DIVISIONS

- **Center for Cancer Research (CCR): https://ccr.cancer.gov/**

  Houses a productive community of NCI intramural basic researchers, clinicians, and translational scientists who integrate basic and clinical research discovery to develop novel therapeutic interventions to better treat adults and children with cancer or HIV.

- **Division of Cancer Epidemiology and Genetics (DCEG): http://dceg.cancer.gov/**

  Conducts population and multidisciplinary research to discover the genetic and environmental causes of cancer and ways to prevent it.

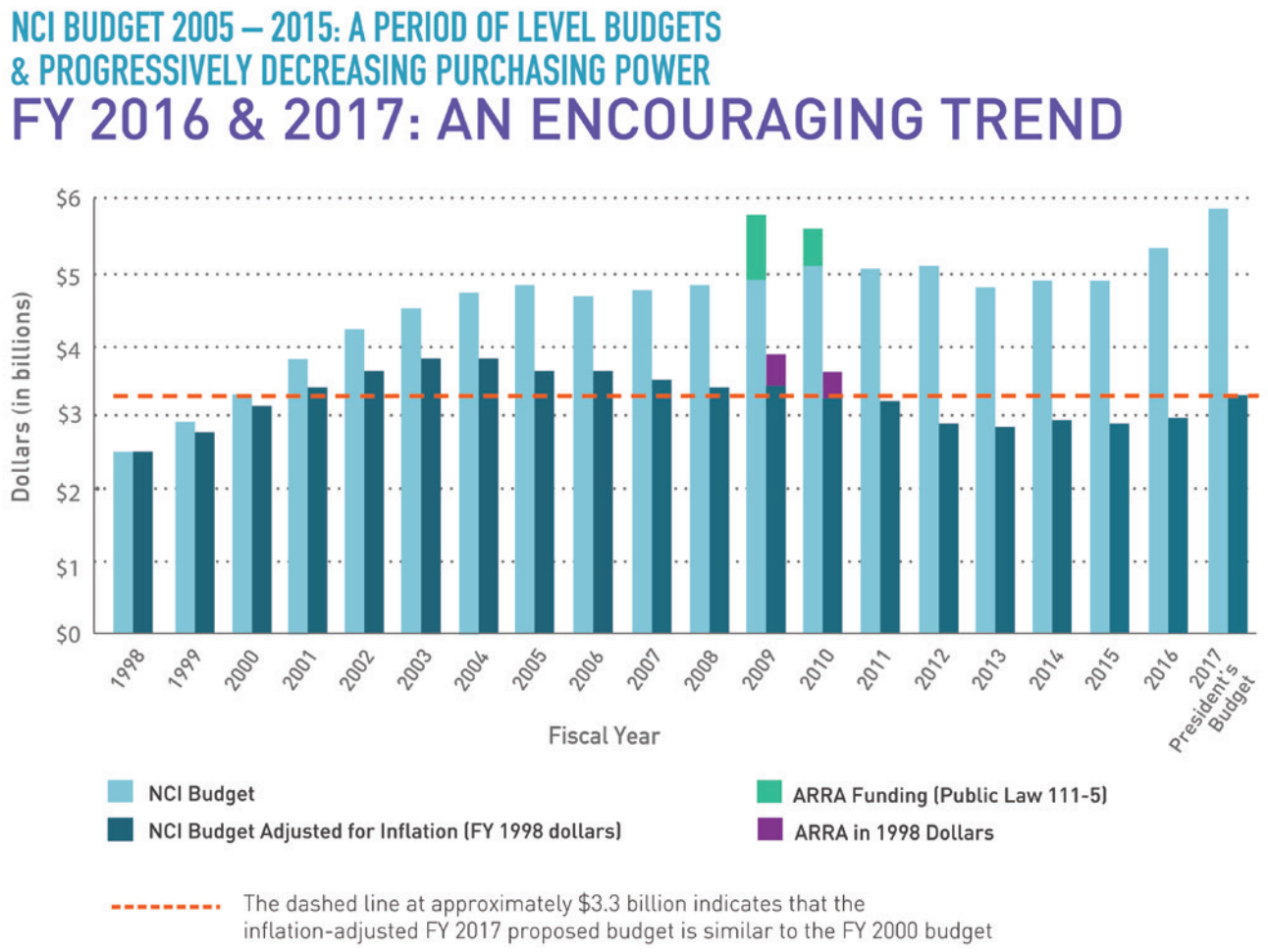
NCI PROGRAMS AND ACTIVITIES

NCI conducts and leads intensive work to advance knowledge of cancer biology; 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, NCI works to foster the collaboration 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, 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 NCI, under the supervision of the Office of the Director.

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 the NIH tradition, NCI'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 funding mechanism. Annual appropriations from Congress provide the funds for all research supported by NCI. **Exhibit III** illustrates the changes in the NCI budget from 1998 to 2017. **Exhibit IV** shows the 2010–2013 budget for various research areas by disease.

Exhibit III - Changes in the NCI Budget from 1998 to 2017



www.cancer.gov
Source: NCI Office of Budget and Finance

Exhibit IV - Research Funding for Various Research Areas

Disease Areas	FUNDING (Dollars in millions)			
	2010	2011	2012	2013
Total NCI Budget	$5,098.1	$5,058.1	$5,067.3	$4,789.0
AIDS	272.1	270.0	271.7	261.6
Brain & CNS	156.8	172.6	177.5	176.8
Breast Cancer	631.2	625.1	602.9	559.2
Cervical Cancer	77.0	81.4	72.6	63.4
Clinical Trials	852.3	877.8	752.8	676.5
Colorectal Cancer	270.4	265.1	256.3	238.3
Head and Neck Cancers	62.7	61.8	71.1	57.6
Hodgkin Disease	14.6	13.4	15.6	14.5
Leukemia	239.7	227.0	234.7	234.9
Liver Cancer	72.6	66.2	64.6	64.0
Lung Cancer	281.9	296.8	315.1	285.9
Melanoma	102.3	115.6	121.2	122.5
Multiple Myeloma	48.5	54.9	61.3	45.4
Non-Hodgkin Lymphoma	122.4	126.4	119.5	113.7
Ovarian Cancer	112.3	110.8	111.7	100.6
Pancreatic Cancer	97.1	99.5	105.4	101.9
Prostate Cancer	300.5	288.3	265.1	255.6
Stomach Cancer	14.5	13.4	12.1	11.2
Uterine Cancer	14.2	15.9	19.1	17.8

Source: www.cancer.gov/about-nci/budget/fact-book/data/research-funding

For a full description of NCI research programs and funding mechanisms, please visit **www.cancer.gov/about-nci/budget/fact-book**.

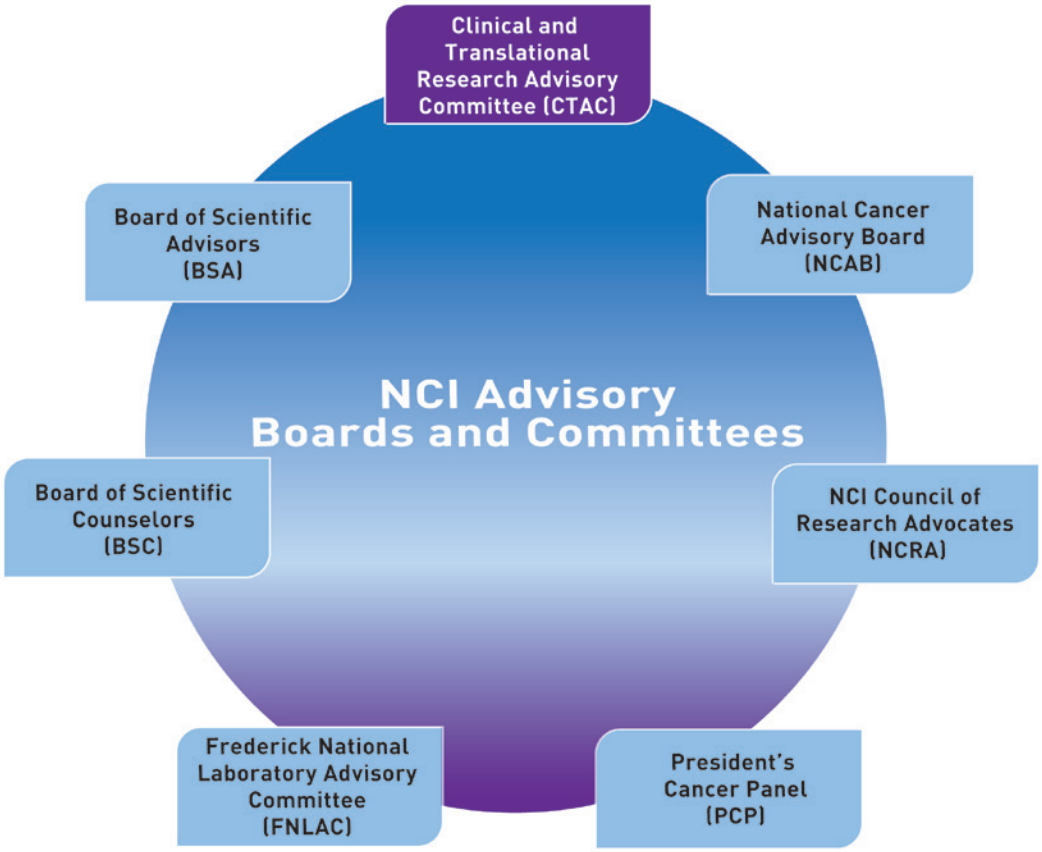
NCI ADVISORY COMMITTEES

As the federal government's lead agency for cancer research, NCI relies on advisory committees to provide objective and expert advice on the coordination of the NCP, NCI scientific priorities, development of major extramural program initiatives, future directions of NCI intramural and clinical trials programs, and the FNLCR.

These advisory committees are formal bodies that are established under the Federal Advisory Committee Act of 1972. The membership and activities of these advisory bodies are coordinated by the NCI Division of Extramural Activities.

Exhibit V lists select NCI Advisory Boards and Committees.

Exhibit V - Select List of NCI Advisory Boards and Committees



PRESIDENT'S CANCER PANEL

The President's Cancer Panel (PCP) is an NCI federal advisory committee that reports directly to the president on the activities of the NCP. 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 PCP consists of three members who are appointed by the president for three-year terms. At least two members must be distinguished scientists or physicians. The president will designate one of the appointed members to serve as chair for a term of one year.

The panel, which meets at least four times a year, is responsible for monitoring the development and execution of the NCP, evaluating its efficacy, making suggestions for its improvement, and submitting periodic progress reports to the president (**http://deainfo.nci.nih.gov/advisory/pcp/index.htm**).

NATIONAL CANCER ADVISORY BOARD

The National Cancer Advisory Board (NCAB) advises, assists, consults with, and makes recommendations to the secretary of the U.S. Department of Health and Human Services and the NCI director regarding the activities carried out by and through NCI, as well as policies related to these activities. The NCAB consists of 18 members appointed by the president and 12 nonvoting ex officio members. The president designates one of the appointed members to serve as chair for a term of two years. Members are invited to serve for overlapping terms of six years. The NCAB may make recommendations regarding support grants and cooperative agreements, technical and scientific peer review, and functions pertaining to NCI as described under sections 405, 406, 413, and 414 of the Public Health Service Act, as amended. Meetings of the full NCAB are held at least four times a year (**http://deainfo.nci.nih.gov/advisory/ncab/ncab.htm**).

BOARD OF SCIENTIFIC ADVISORS

The Board of Scientific Advisors (BSA) makes recommendations on research priorities conducted or supported by NCI. The BSA consists of up to 35 members, including the chair, appointed by the NCI director from authorities knowledgeable in the fields of laboratory, clinical and biometric research, clinical cancer treatment, cancer etiology, and cancer prevention and control, among others. Members are invited to serve for overlapping terms of five years. Board activities include the evaluation of NCI-awarded grants, cooperative agreements, and contracts, and concept review of those activities which it considers meritorious and consistent with NCI programs.

The advisory role of the BSA is scientific and does not include deliberation on matters of public policy. Meetings of the full BSA are held approximately three times a year (**http://deainfo.nci.nih.gov/advisory/bsa/bsa.htm**).

BOARD OF SCIENTIFIC COUNSELORS

The Board of Scientific Counselors (BSC) advises the directors of NCI and its Division of Cancer Epidemiology and Genetics and the Center for Cancer Research on a wide variety of matters concerning scientific program policy and the progress and future direction of each intramural research program. The BSC consists of up to 30 members, including the chair, appointed by the NCI director.

Members are invited to serve for overlapping terms of up to five years. The BSC evaluates the intramural program, including the performance and productivity of tenured and tenure-track principal investigators, senior scientists, and senior clinicians through periodic site visits to intramural laboratories. Meetings of the full BSC are held approximately three times a year (**http://deainfo.nci.nih.gov/advisory/bsc/bs/bs.htm; http://deainfo.nci.nih.gov/advisory/bsc/cse/cse.htm**).

CLINICAL TRIALS AND TRANSLATIONAL RESEARCH ADVISORY COMMITTEE

The Clinical Trials and Translational Research Advisory Committee (CTAC) advises, assists, and makes recommendations to the NCI director, deputy directors, and division directors regarding the NCI-supported national clinical trials enterprise. This work encompasses oversight of all trials, both extramural and intramural. CTAC consists of up to 25 members, including the chair. Meetings of the full CTAC are held approximately three times a year (**http://deainfo.nci.nih.gov/advisory/ctac/ctac.htm**).

NCI COUNCIL OF RESEARCH ADVOCATES

The NCRA makes recommendations to NCI's director, providing informed, non-scientific perspectives relevant to promoting research outcomes that are in the best interest of cancer patients. The NCRA conducts activities with the intent of identifying new approaches, promoting innovation, recognizing unforeseen risks or barriers, and identifying unintended consequences that could result from NCI decisions or actions. The NCRA consists of up to 16 members, including the chair, appointed by NCI's director. Members are invited to serve for overlapping terms of up to four years. Meetings of the full NCRA are held approximately three times a year (**http://deainfo.nci.nih.gov/advisory/ncra/ncra.htm**).

FREDERICK NATIONAL LABORATORY ADVISORY COMMITTEE

The FNLAC provides advice to the NCI director and the FNLCR associate director on the optimal use of the laboratory to meet the most urgent needs of NCI. The FNLAC consists of up to 16 members, including the chair, appointed by the NCI director. The FNLAC reviews the state of research at the FNLCR and makes recommendations for the best use of its capabilities and infrastructure. Members are invited to serve overlapping terms of up to four years. Meetings of the full FNLAC are held approximately two times a year (**http://deainfo.nci.nih.gov/advisory/fac/fac.htm**).

THE U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

The mission of the U.S. Department of Health and Human Services (HHS) is to enhance and protect the health and well-being of all Americans by providing for effective health and human services and fostering advances in medicine, public health, and social services. The HHS has 11 operating divisions, including eight agencies in the U.S. Public Health Service (PHS) and three human services agencies (see Exhibit VI). The Office of the Secretary (OS), the chief policy officer and general manager of HHS, administers and oversees the organization, its programs, and its activities. The deputy secretary and a number of assistant secretaries and offices support the OS.

The operating divisions of HHS include:

- Administration for Children and Families (ACF)
- Administration for Community Living (ACL)
- 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 & Medicaid Services (CMS)
- Food and Drug Administration (FDA)
- Health Resources and Services Administration (HRSA)
- Indian Health Service (IHS)
- National Institutes of Health (NIH)
- Substance Abuse and Mental Health Services Administration (SAMHSA)

The ACF supports a variety of initiatives that promote the economic and social well-being of families, children, individuals, and communities. The ACL works to maximize the independence, well-being, and health of older adults, people with disabilities across the lifespan, and their families and caregivers. The CMS manages health insurance programs. NIH, AHRQ, ATSDR, CDC, FDA, HRSA, IHS, and SAMHSA are all devoted to public health and compose PHS. (See **Exhibit VI)** for HHS Organization.

NIH'S MISSION AND ORGANIZATION

NIH is the nation's medical research agency. The mission of NIH is to seek fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance health, lengthen life, and reduce illness and disability. NIH works toward its mission by conducting research in its own laboratories; supporting the research of nonfederal 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 is composed of the Office of the Director (OD) and 27 institutes and centers. The OD is the central office at NIH and is responsible for setting policy and for planning, managing, and coordinating the programs and activities of all the NIH components (see **Exhibits VII** and **VIII**). NIH is located in Bethesda, Maryland, and has more than 75 buildings in a campus-like environment of more than 300 acres (see **Exhibit IX**).

The NIH budget has grown from $300 in 1887, when it was a one-room laboratory, to more than $32.3 billion in 2016 (see **Exhibit X**).

Exhibit VI - U.S. Department of Health and Human Services Organization

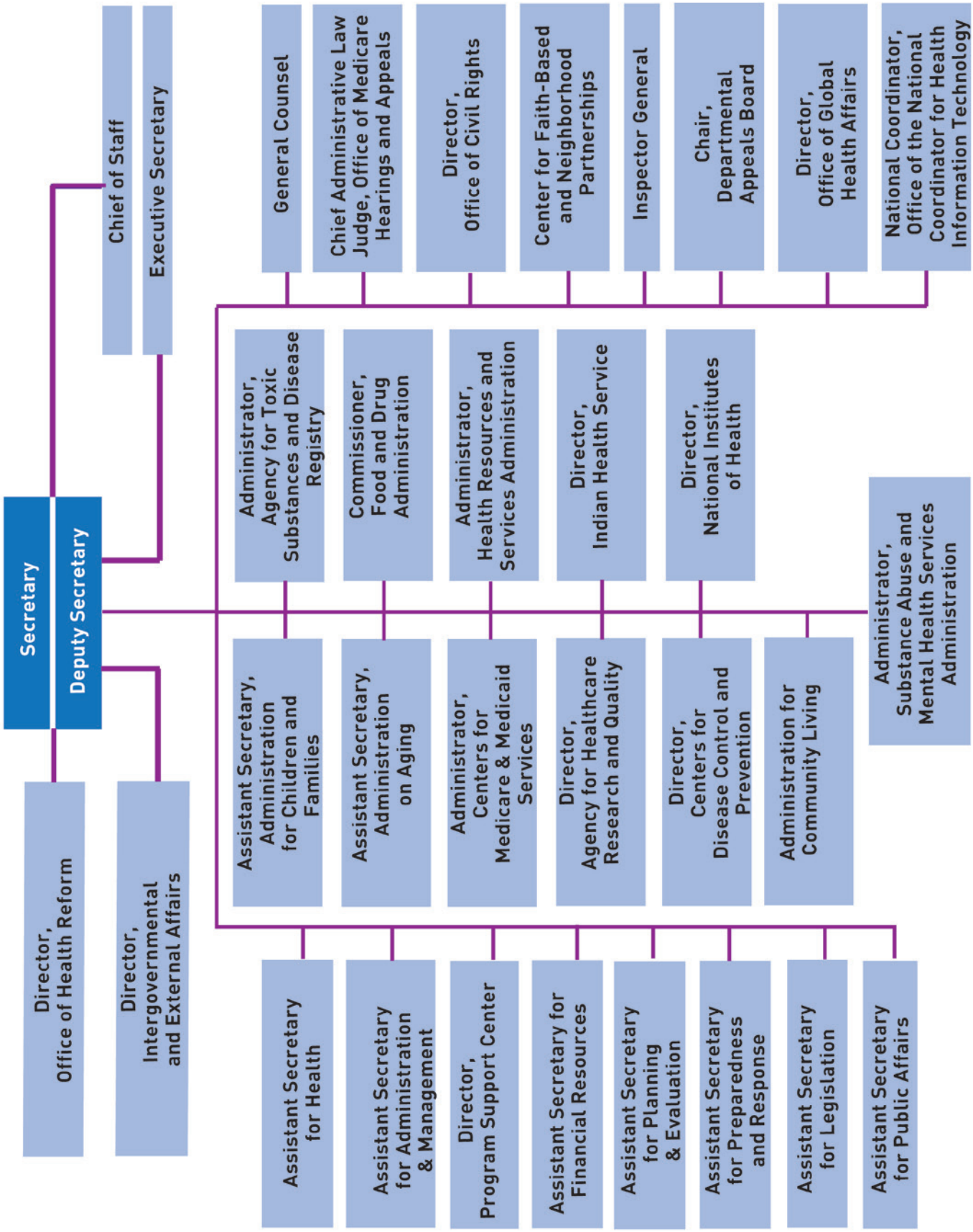


Exhibit VII - National Institutes of Health Organization

National Institutes of Health

National Cancer Institute (NCI)
National Eye Institute (NEI)
National Heart, Lung, and Blood Institute (NHLBI)
National Human Genome Research Institute (NHGRI)
National Institute on Aging (NIA)
National Institute on Alcohol Abuse and Alcoholism (NIAAA)
National Institute of Allergy and Infectious Diseases (NIAID)
National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS)
National Institute of Biomedical Imaging and Bioengineering (NIBIB)
National Institute of Child Health and Human Development (NICHD)
National Institute on Deafness and Other Communication Disorders (NIDCD)
National Institute of Dental and Craniofacial Research (NIDCR)
National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)
National Institute on Drug Abuse (NIDA)
National Institute of Environmental Health Sciences (NIEHS)
National Institute of General Medical Sciences (NIGMS)
National Institute of Mental Health (NIMH)
National Institute on Minority Health and Health Disparities (NIMHD)
National Institute of Neurological Disorders and Stroke (NINDS)
National Institute of Nursing Research (NINR)
National Library of Medicine (NLM)
Center for Information Technology (CIT)
Center for Scientific Review (CSR)
Fogarty International Center (FIC)
National Center for Advancing Translational Sciences (NCATS)
National Center for Complementary and Integrative Health (NCCIH)
NIH Clinical Center (CC)

Exhibit VIII - NIH Office of the Director Organization

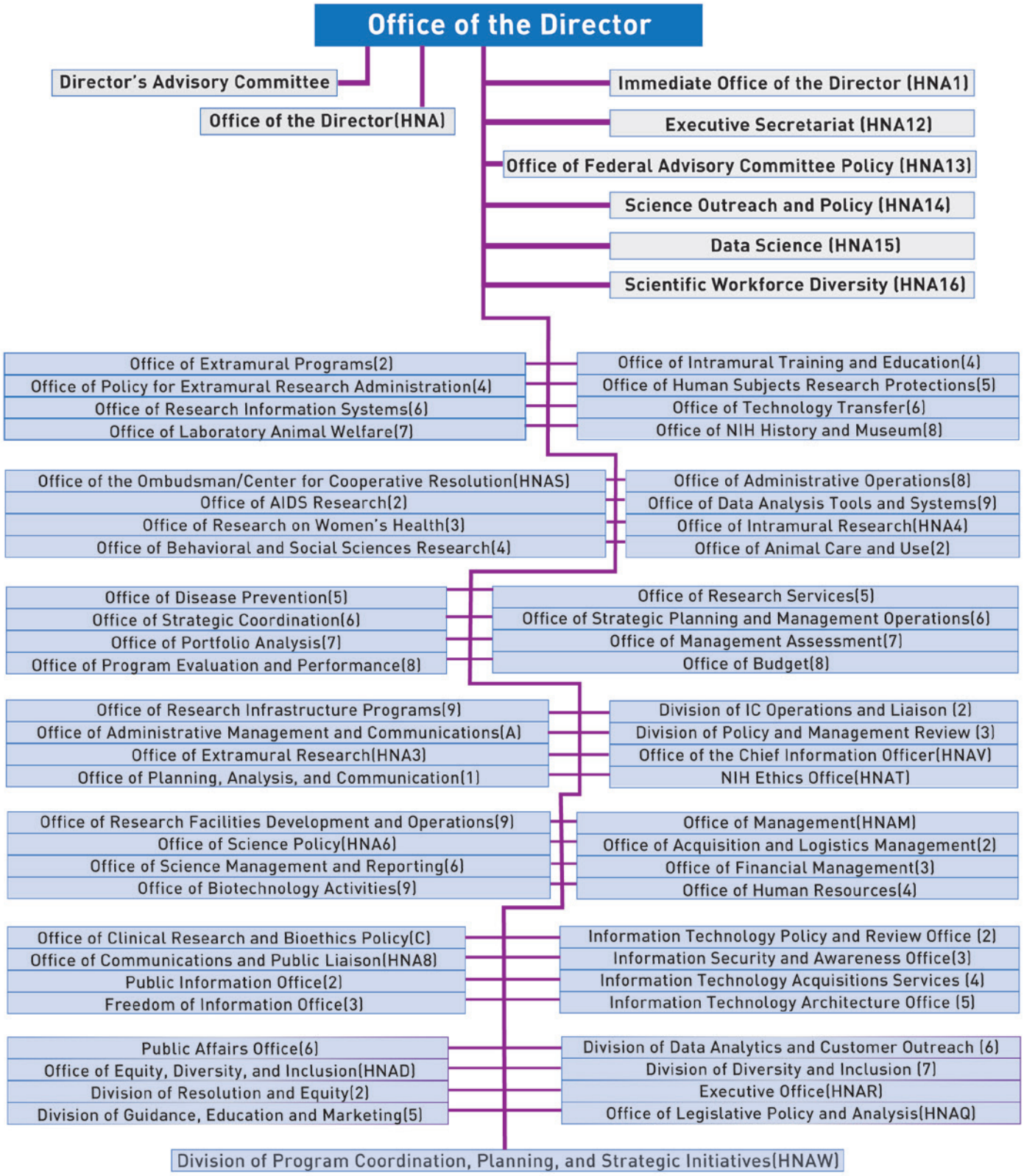
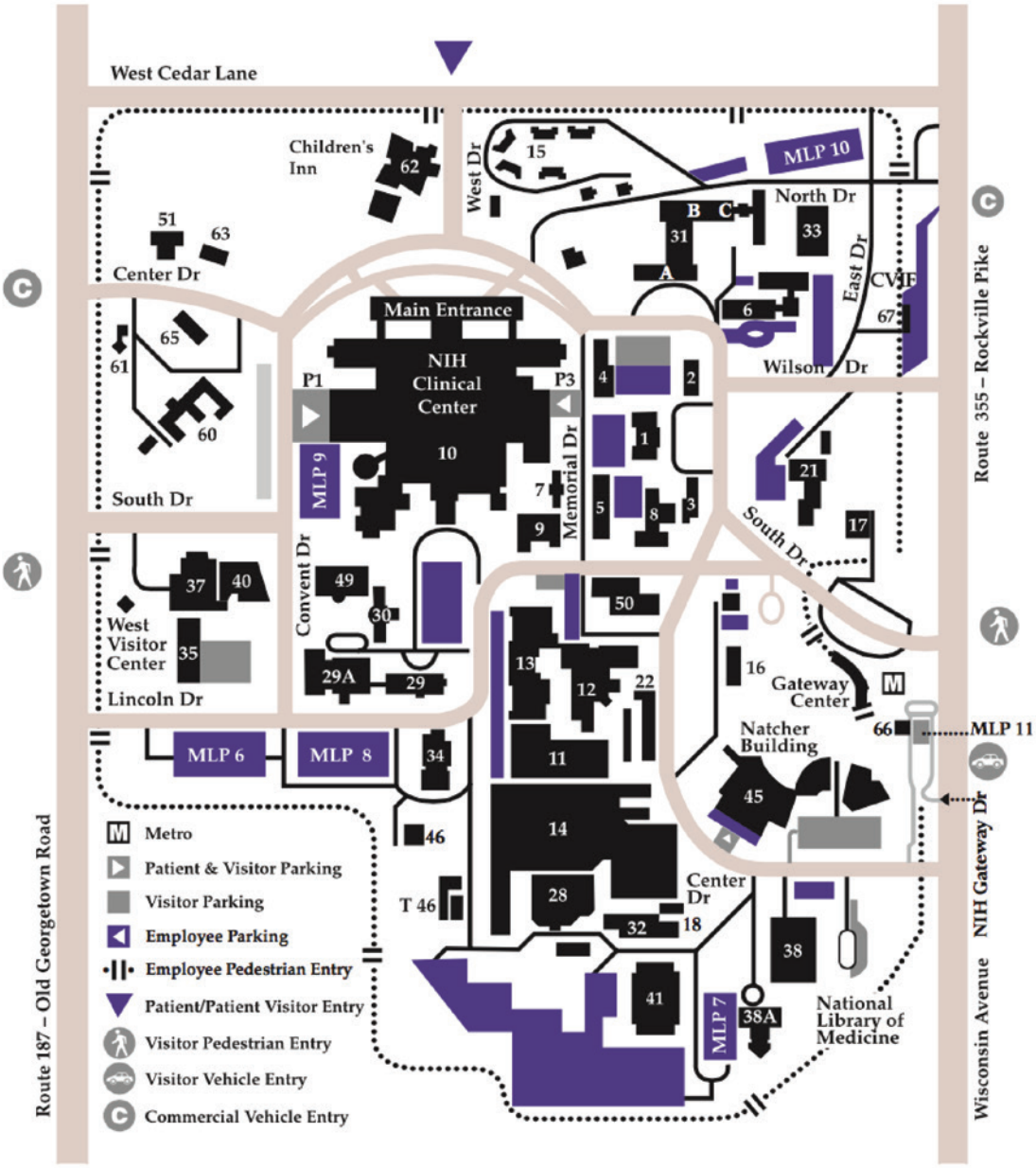


Exhibit IX - NIH Facilities Map



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 Engineering Services	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 Bldg)	Building 62	The Children's Inn at NIH
Building 36	Lowell P. Weicker Building	***Purple***	***Parking Area***

Exhibit X - National Institutes of Health Budget Overview

INSTITUTE/ CENTER	FUNDING (Dollars in millions)		
	2013	2014	2015
NCI	4,783	4,923	4,931
NHLBI	2,900	2,983	2,988
NIDCR	387	397	397
NIDDK	1,835	1,881	1,893
NINDS	1,532	1,586	1,608
NIAID	4,230	4,393	4,423
NIGMS	2,291	2,362	2,369
NICHD	1,245	1,281	1,283
NEI	656	674	675
NIEHS	721	742	742
NIA	1,039	1,169	1,171
NIAMS	505	519	520
NIDCD	392	403	404
NIMH	1,394	1,417	1,440
NIDA	992	1,016	1,023
NIAAA	433	445	446
NINR	136	140	140
NHGRI	483	497	498
NIBIB	319	326	329
NIMHD	260	268	268
NCCIH	121	124	125
NCATS	542	632	657
FIC	66	67	68
NLM	360	375	381
OD	1411	1,400	1,452
B&F	118	129	129
TOTAL	29,151	30,151	30,362

Source: www.hhs.gov/about/budget/fy2015/budget-in-brief/nih/index.html

THE HISTORY OF NIH

NIH is a component of the HHS Public Health Service (PHS). The PHS traces its origin to "An Act for the Relief of Sick and Disabled Seamen," which was signed into law in 1798 and authorized the establishment of marine hospitals for the care of American merchant seamen. The actual forerunner of NIH was established in 1887 as the Laboratory of Hygiene, located at the Marine Hospital of Staten Island, New York. In 1912, the Public Health and MarineHospital Service became the PHS. In 1930, this laboratory was renamed the National Institute of Health. The first of the present institutes, 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. Between 1949 and 2001, NIH expanded to include 27 institutes and centers.

The following timeline chronicles the establishment and evolution of the current NIH institutes and centers:

1798 President John Adams signed into law "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 renamed 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 to conduct research on cholera and other infectious diseases.

1891 The Laboratory of Hygiene was re-designated 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 National Institute of Health and a system of fellowships.

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

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

1939 The PHS 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 National Institute of Health grants and fellowships to nonfederal 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 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.

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. 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 (NLM) 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. The National Institute of Child Health and Human Development was created.

1966 The Division of Environmental Health Sciences was created.

1967 The NIMH was separated from NIH and became a separate bureau of the PHS.

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

1969 The Division of Environmental Health Sciences was renamed the National Institute of Environmental Health Sciences. 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 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.

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

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

1989 The National Institute on Deafness and Other Communication Disorders 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 was created by consolidating the Division of Research Services and the Division of Research Resources.

1992 The National Institute on Alcohol Abuse and Alcoholism, National Institute on Drug Abuse, and National Institute of Mental Health were transferred to 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.

1995 NIH was established as an HHS operating division, thereby elevating it to report directly to the HHS secretary.

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

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

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

2010 The National Center on Minority Health and Health Disparities was redesignated the National Institute on Minority Health and Health Disparities.

2011 The National Center for Advancing Translational Sciences was established.

2012	NCI-Frederick was renamed the Frederick National Laboratory for Cancer Research.
2014	The National Center for Complementary and Alternative Medicine became the National Center for Complementary and Integrative Health.

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.

OBJECTIVES AND SCOPE OF ACTIVITIES

The Committee will provide advice to NCI's director, deputy directors, and the director of each NCI division, on matters related to the conduct, oversight, and implementation of clinical trials and translational research across NCI.

DESCRIPTION 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. The Committee will advise on translational research opportunities with the greatest potential clinical value and feasibility, strategies for moving high priority translational research opportunities rapidly and efficiently through the development process, streamlining handoffs of translational research projects to early-phase clinical trials programs, and optimizing collaboration and communication among NCI's translational research and clinical trials programs.

The goal is to foster an open, collaborative system involving all the critical stakeholders that is integrated and efficient, yet innovative and responsive, 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.

MEMBERSHIP AND DESIGNATION

The Committee will consist of up to 25 members, including the chair, appointed by the NCI director. When necessary, 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 NCI Council of Research Advocates. 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; health care outcomes; 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 five-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's deputy directors, select division directors, an NCI intramural scientist engaged in clinical research, and representatives from the Food and Drug Administration, Centers for Medicare & Medicaid Services, the U.S. Department of Defense, and the U.S. 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), or NCI Council of Research Advocates 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.

APPENDIX B. CTAC ROSTER AS OF JULY 2016

CHAIR

Nancy E. Davidson, MD, 2018**
Director
University of Pittsburgh Cancer Institute
University of Pittsburgh
Pittsburgh, PA

MEMBERS

David F. Arons, JD (NCRA), 2016
Director of Public Policy
National Brain Tumor Society
Watertown, MA

Susan M. Blaney, MD, 2019
Vice President for Clinical and Translational Research
Vice Chair for Research
Department of Pediatrics
Baylor College of Medicine
Texas Children's Hospital
Houston, TX

Kevin J. Cullen, MD (NCAB), 2016
Director
University of Maryland
Greenebaum Cancer Center
Baltimore, MD

Walter J. Curran, MD, PhD, 2019
Professor and Chairman
Department of Radiation Oncology
Emory University School of Medicine
Atlanta, GA

Gwendolyn A. Fyfe, MD,* 2020
Independent Contractor
San Francisco, CA

David M. Gershenson, MD, 2020
Professor of Gynecology
Department of Gynecologic Oncology and Reproductive Medicine
Division of Surgery
The University of Texas
MD Anderson Cancer Center
Houston, TX

Michael LeBlanc, PhD, 2019
Member
Fred Hutchinson Cancer Research Center
Research Professor
Department of Biostatistics
University of Washington
Seattle, WA

Patrick, J. Loehrer, Sr., MD, 2020
Director
Melvin and Bren Simon Cancer Center
Associate Dean for Cancer Research
Indiana University School of Medicine
Indianapolis, IN

David A. Mankoff, MD, PhD, 2019
Gerd Muehllehner Professor of Radiology
Chief of Nuclear Medicine and Clinical Molecular Imaging
Perelman School of Medicine
University of Pennsylvania
Philadelphia, PA

Mary S. McCabe, RN, 2016
Director
Cancer Survivorship Program
Memorial Sloan Kettering Cancer Center
New York, NY

Edith P. Mitchell, MD, 2016
Clinical Professor of Medicine and Medical Oncology
Program Leader, Gastrointestinal Oncology
Kimmel Cancer Center
Thomas Jefferson University
Philadelphia, PA

Nikhil C. Munshi, MD, 2016
Associate Director
Jerome Lipper Myeloma Center
Dana-Farber Cancer Institute
Professor of Medicine
Harvard Medical School
Boston, MA

Augusto C. Ochoa, MD, 2018
Director
Stanley S. Scott Cancer Center
Professor
Department of Pediatrics
Louisiana State University Health Sciences Center
New Orleans, LA

Gloria M. Petersen, PhD, 2019
Professor of Epidemiology
Department of Education Administration
Mayo Clinic College of Medicine
Rochester, MN

George W. Sledge, Jr., MD, 2016
Chief
Division of Medicine-Oncology
Stanford University School of Medicine
Palo Alto, CA

Chris H. Takimoto, MD, PhD, 2016
Vice President
Translational Medicine Early Development
Janssen Pharmaceuticals, Inc.
Radnor, PA

Miguel A. Villalona-Calero, MD, 2016
Deputy Director and Chief Scientific Officer
Miami Cancer Institute
Baptist Health South Florida
Coral Gables, FL

George J. Weiner, MD, 2016
C.E. Block Chair of Cancer Research
Professor, Department of Internal Medicine
Director
Holden Comprehensive Cancer Center
Iowa City, IA

Louis M. Weiner, MD (BSC), 2017
Director
Lombardi Comprehensive Cancer Center
Francis L. and Charlotte G. Gragnani Chair
Department of Oncology
Georgetown University Medical Center
Washington, DC

EX OFFICIO MEMBERS

William Dahut, MD
Acting Scientific Director of Clinical Research
Center for Cancer Research
National Cancer Institute
National Institutes of Health
Bethesda, MD

James H. Doroshow, MD
Deputy Director
Clinical and Translational Research
Director
Division of Cancer Treatment and Diagnosis
National Cancer Institute
National Institutes of Health
Bethesda, MD

Paulette Gray, PhD
Director
Division of Extramural Activities
National Cancer Institute
National Institutes of Health
Bethesda, MD

Rosemarie Hakim, PhD, MS
Epidemiologist
Centers for Medicare and Medicaid Services
Baltimore, MD

Michael J. Kelley, MD, F.A.C.P.
National Program Director for Oncology
Veterans Health Administration
Department of Veterans Affairs
Washington, DC

Richard Pazdur, MD, F.A.C.P.
Division Director
Division of Hematology and Oncology Products
U.S. Food and Drug Administration
Rockville, MD

EXECUTIVE SECRETARY

Sheila A. Prindiville, MD, MPH
Director
Coordinating Center for Clinical Trials
Office of the Director
National Cancer Institute
National Institutes of Health
Bethesda, MD

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*pending appointment
** Year member's term expires

APPENDIX C. CONFLICT OF INTEREST POLICIES AND ETHICS RULES FOR ADVISORY COMMITTEE MEMBERS

CONFLICT OF INTEREST POLICIES

Members of CTAC are Special Government Employees (SGE). By definition, an SGE is an officer or employee who is retained, designated, appointed, or employed by the federal government 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 your service, please be aware of the relevant statutes regarding criminal conflicts of interest and follow the rules that guide your conduct. These rules are part of the Standards of Ethical Conduct for Employees of the Executive Branch.

ETHICS RULES FOR SPECIAL GOVERNMENT EMPLOYEES SERVING ON ADVISORY COMMITTEES

As an SGE, you are subject to the ethics laws and regulations, although in a somewhat less restrictive manner than regular employees.

THE CRIMINAL CONFLICT OF INTEREST STATUTES 18 U.S.C. § 208, 203, 205, 207

Financial Conflicts (18 U.S.C. §208):): You are prohibited from participating personally and substantially in any particular matter that will have a direct and predictable effect on your financial interest. This includes the financial interest of your spouse, minor child, general partner, or organization in which you serve as an officer, director, trustee, general partner, employee, or any person or organization with whom you are negotiating or have arrangements concerning prospective employment. When you are involved in matters that will have a direct and predictable effect on your financial interest, it is a conflict of interest that will have to be resolved. In addition, a conflict exists when someone whose financial interests are imputed to you, such as a spouse, minor child, or partner, has a financial interest affected by the official matter. Therefore, you must be disqualified from participation in such matters. A recusal or disqualification is a method used to resolve an apparent or actual conflict of interest. Of most concern are specific party matters, for example, reviews of grant proposals, 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.

Exemptions (5 CFR §2640.202): Under the de minimis exemption, you can participate in any particular matter involving specific parties in which the disqualifying financial interest arises from ownership by you, your spouse, or your minor children of securities issued by one or more entities affected by the matter, if: (1) the securities are publicly traded, (2) stock interest involving specific parties does not exceed, $15,000 aggregate, (3) stock interest involving non-parties (competitors) does not exceed, $25,000 aggregate, (4) stock interest involving general matters does not exceed $25,000 in any such entity, and $50,000 in all affected entities, or (5) sector mutual fund interests do not exceed $50,000 aggregate.

RESOLVING FINANCIAL CONFLICTS

Recusal/Disqualification: The most common way to avoid a conflict of interest is to not work on the matter creating the conflict and to isolate yourself from the committee's work on this matter. This remedy is a recusal.

Divestiture: This means to sell down or bring the value to below the de minimis holding amount, or otherwise dispose of the financial interest that is creating the conflict.

Representational Activities (18 U.S.C. § 203 & 205): You are restricted by sections 203 and 205 only in connection with "particular matters involving specific parties." Such matters typically involve a specific proceeding affecting the legal rights of parties, or an isolatable transaction or related set of transactions between identified parties. Examples include contracts, grants, applications, requests for rulings, litigation, or investigations. You may represent others or receive compensation

for representational services in connection with particular matters of general applicability—such as broadly applicable policies, rulemaking proceedings, and legislation—which do not involve specific parties.

Post-Employment Representation (18 U.S.C. § 207): 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.

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 with knowledge of the relevant facts 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. If you are concerned that the circumstances would raise a question regarding your impartiality, you should not participate in the matter.

Misuse of Position—Use of Public Office for Private Gain: If you receive information that has not been made available to the general public, do not use or allow the improper use of that nonpublic information to further any private interest, either your own or anyone else's interest. This includes the misuse of 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.

Activities with Foreign Governments: Under the Foreign Gifts and Decorations Act (FGDA), you are permitted to accept (1) gifts that are $375 or less or (2) gifts of travel and expenses for travel taking place entirely outside of the United States (such as transportation, food, and lodging). However, when you are providing services, traveling within the United States as well as receiving pay for services is permitted. The provisions of the FGDA also apply to your spouse and dependents.

Lobbying: In your official capacity or as a group, you are prohibited from engaging in any activity that directly or indirectly encourages or directs any person or organization to lobby one or more members of Congress. When authorized, you may appear before any individual or group for the purpose of informing or educating the public about a particular policy or legislative proposal. You may also communicate to members of Congress at the request of any representative or senator.

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 **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 Advisory Committees" by the Ethics Division, Office of the General Counsel, U.S. Department of Health and Human Services.

- Complete the Office of Government Ethics (OGE) 450 Confidential Financial Disclosure Report at the start of your term, and quarterly updates thereafter until your term ends. Your OGE 450 report, as well as your quarterly updates must be submitted in order to be cleared to participate in meetings.

- 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 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 or ethics officials with any questions.

Confidential Financial Disclosure Report—OGE 450 Form

The OGE 450 Form is available at **https://www2.oge.gov/Web/OGE.nsf/Resources/OGE+Form+450:+Confidential+Financial+Disclosure+Report** (a form will be sent to you by NCI).

For guidance, contact your ethics official or visit: **https://ethics.od.nih.gov/topics/450-info.htm**

On the OGE 450 Form, you will report assets held for investment with a value greater than $1,000 at the end of the reporting period OR assets held for investment that produced more than $200 in income during the reporting period, including but not limited to:

- Stocks, stock options, bonds, and equity interest;

- Sector mutual funds. Generally, waivers are issued for general matters when interests are in the following categories: pharma/biotech/tobacco/cell phone companies/medical devices and imaging/alcohol and semi-conductor (with wireless component) and other health-related entities. *Please note: For sector mutual funds over $50,000, you will need to recuse yourself from any specific party matters with all health science entities that might be contained in any sector fund you own, as there is no way to definitively know what is owned by sector funds at any one time.*

- Earned income including salaries, fees, and/or honoraria;

- Investment interests in retirement plans that are non-diversified (self and spouse);

- Pension plans that SGE continues to participate in with a former employer;

- Limited partnerships and venture capital corporations;

- Non-federal research/training support;

- Invention rights and royalties for self and spouse;

- Real estate, trades and businesses, and partnership interests;

- Future speaking engagements; and

- Consultant work.

CONFLICT OF INTEREST AND ETHICS WEB SITES

U.S. Office of Government Ethics

"To Serve with Honor: A Guide on the Ethics Rules That Apply to Advisory Committee Members Serving as Special Government Employees (2008)": **https://www2.oge.gov/web/oge.nsf/Resources/To+Serve+With+Honor:+A+Guide+on+the+Ethics+Rules+that+Apply+to+Advisory+Committee+Members+Serving+as+Special+Government+Employees+(2008)**

The HHS Office of Government Ethics
"Overview of the Ethics Rules for Special Government Employees Serving on Advisory Committees": **https://ofacp.od.nih.gov/ethics/pdfs/SGE3.pdf**

NIH Office of Ethics

"Ethics Rules for Advisory Committee Members and Other Individuals Appointed as Special Government Employees": **https://ofacp.od.nih.gov/ethics/pdfs/SGETRAININGOCT2004.pdf**

APPENDIX D. FEDERAL ADVISORY COMMITTEE ACT

The Federal Advisory Committee Act (FACA) was established in 1972 as a mechanism for Government-wide oversight of advisory committees. FACA 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 NCI's 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

Rosters of NCI Advisory Committees can be found here: **www.cancer.gov/about-nci/advisory-boards**.

APPENDIX E. NCI CLINICAL AND TRANSLATIONAL RESEARCH OPERATIONS COMMITTEE ROSTER AS OF JULY 2016

Dr. James Doroshow
Chair
Office of the Director

Dr. Jeffrey Abrams
Division of Cancer Treatment and Diagnosis

Dr. Henry Ciolino
Office of Cancer Centers

Dr. Robert Croyle
Division of Cancer Control and Population Sciences

Dr. William Dahut
Center for Cancer Research

Dr. Leslie Ford
Division of Cancer Prevention

Dr. Paulette Gray
Division of Extramural Activities

Dr. Toby Hecht
Division of Cancer Treatment and Diagnosis

Dr. Warren Kibbe
Center for Biomedical Informatics and Information Technology

Dr. Lori Minasian
Division of Cancer Prevention

Dr. Sheila Prindiville
Coordinating Center for Clinical Trials

Dr. Julia Rowland
Division of Cancer Control and Population Sciences

Dr. Dinah Singer
Division of Cancer Biology

Dr. Sanya Springfield
Center to Reduce Cancer Health Disparities

Dr. Ted Trimble
Center for Global Health

Dr. Robert Yarchoan
Office of HIV and AIDS Malignancy

APPENDIX F. NCI SCIENTIFIC PROGRAM LEADERS ROSTER AS OF OCTOBER 2016

Dr. Douglas Lowy
Acting NCI Director

Dr. Jeffrey Abrams
Division of Cancer Treatment and Diagnosis

Dr. L. Michelle Bennett
Center for Research Strategy

Dr. Stephen Chanock
Division of Cancer Epidemiology and Genetics

Dr. Henry Ciolino
Office of Cancer Centers

Dr. Robert Croyle
Division of Cancer Control and Population Sciences

Dr. William Dahut
Center for Cancer Research

Dr. James Doroshow
Division of Cancer Treatment and Diagnosis

Dr. Dan Gallahan
Division of Cancer Biology

Dr. Paulette Gray
Division of Extramural Activities

Dr. Ed Harlow
Office of the Director

Dr. Toby Hecht
Division of Cancer Treatment and Diagnosis

Dr. Warren Kibbe
Center for Biomedical Informatics and Information Technology

Dr. Barry Kramer
Division of Cancer Prevention

Dr. Jerry Lee
Center for Strategic Scientific Initiatives

Dr. Glenn Merlino
Center for Cancer Research

Dr. Craig Reynolds
NCI Campus at Frederick

Ms. Donna Siegle
Acting Executive Officer

Dr. Dinah Singer
Division of Cancer Biology

Dr. Sanya Springfield
Center to Reduce Cancer Health Disparities

Dr. Lou Staudt
Center for Cancer Genomics

Dr. Ted Trimble
Center for Global Health

Mr. Michael Weingarten
Small Business Innovation Research Development Center

Dr. Jonathan Wiest
Center for Cancer Training

Dr. Robert Wiltrout
Office of the Director

Dr. Robert Yarchoan
Office of HIV and AIDS Malignancy

EXECUTIVE SECRETARY

Ms. Maureen Johnson
Office of the Director

APPENDIX G. SELECT NCI, NIH, AND FEDERAL CLINICAL TRIALS POLICIES, REGULATIONS, AND LAWS

NCI POLICIES

Centralized Data Sharing for the National Clinical Trials Network (NCTN) via the NCTN Data Archive (2015): This plan describes the scope, effective date, and data submission and access processes involved in the centralized sharing of data from clinical trials of the NCTN. For the current plan, see page 224 of the NCTN Program Guidelines at **http://ctep.cancer.gov/initiativesPrograms/docs/NCTN_Program_Guidelines.pdf**.

Cancer Therapy Evaluation Program Slow Accrual Guidelines: In 2015, NCI's Cancer Therapy Evaluation Program (CTEP) set minimum accrual expectations for all early phase trials. At the letter of intent/concept development stage, CTEP and study investigators must agree upon realistic projected accrual rates, as trials may be terminated if the agreed upon accrual projections at the time of study approval are not met. For the full policy, see **http://ctep.cancer.gov/protocolDevelopment/cde_data_policies.htm**. In 2007, CTEP developed minimum accrual expectations for phase III trials. This document explains how CTEP's early stopping guidelines were developed. It can be accessed at **http://ctep.cancer.gov/protocolDevelopment/docs/slow_accrual.pdf**. For the full policy for phase III trials, see **http://ctep.cancer.gov/protocolDevelopment/cde_data_policies.htm**.

Data and Safety Monitoring of Clinical Trials (2014): All clinical trials supported or performed by NCI require some form of monitoring. The method and degree of monitoring should be commensurate with the degree of risk involved in participation and the size and complexity of the clinical trial.

Monitoring exists on a continuum, from monitoring by the principal investigator/project manager or NCI program staff to a data and safety monitoring board. These monitoring activities are distinct from the requirement for study review and approval by an Institutional Review Board (IRB). For the full policy, see **http://deainfo.nci.nih.gov/grantspolicies/datasafety.pdf**.

CTEP Investigator Handbook (2014): This handbook explains the policies and implementing procedures for the conduct of therapeutic clinical trials sponsored by NCI's Division of Cancer Treatment and Diagnosis. This handbook is designed to be useful in practical matters connected with protocol drafting and submissions, reporting requirements, agent accountability, and a host of other subjects. This handbook is written to guide the individual clinical investigator at the clinical trial site working alongside a team of health professionals and research staff. For the full document, see **http://ctep.cancer.gov/investigatorResources/investigators_handbook. htm**.

Change in NCI Policy for Grants Funding Phase III Trials (2013): NCI will no longer use the Research Project Grant (R01) and Research Program Project Grant (P01) activity codes to support investigator-initiated phase III clinical trials for cancer-related medical interventions and/or investigator-initiated phase III clinical trials for cancer imaging modalities.

Accordingly, NCI will no longer accept investigator-initiated R01 and P01 applications proposing such clinical trials. This policy change became effective in 2013. For the full policy, including definitions, see **http://grants.nih.gov/grants/guide/notice-files/NOT-CA-13-012.html**.

NIH POLICIES

NIH Policy on Funding Opportunity Announcements for Clinical Trials: NIH policy requires that all applications involving one or more clinical trials be submitted through a Funding Opportunity Announcement specifically designed for clinical trials. For the full statement, see **https://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-147.html.**

NIH Policy on Good Clinical Practice Training: All NIH-funded investigators and staff who are involved in the conduct, oversight, or management of clinical trials should be trained in good clinical practice. For the full policy, see **https://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-148.html.**

NIH Policy on Dissemination of NIH-Funded Clinical Trial Information: All NIH-funded investigators conducting clinical trials must register their trials at ClinicalTrials.gov and submit results to ClinicalTrials.gov. For the full policy, see **https://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-149.html.**

Final NIH Statement on Sharing Research Data (2003): NIH policy requires that the results and accomplishments of the activities that it funds be made available to the public. For the full statement, see **http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-032.html**.

NIH Policy on Human Subjects Training (2000): NIH requires education on the protection of human research participants for all investigators submitting an NIH application for grants, proposals for contracts, or receiving new or noncompeting awards for research involving human subjects. See **http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html** for more information.

The NIH Policy for Data and Safety Monitoring (1998): It is the policy of NIH that each institute and center should have a system for the appropriate oversight and monitoring of the conduct of clinical trials to ensure the safety of participants and the validity and integrity of the data for all NIH-supported or conducted clinical trials. The establishment of the data safety monitoring boards is required for multisite clinical trials involving interventions that entail potential risk to the participants. For the full policy, see **http://grants.nih.gov/grants/guide/notice-files/not98-084.html**.

FEDERAL LAWS AND REGULATIONS

Food and Drug Administration Amendments Act of 2007, Section 801 (2007): Section 801 lays out requirements for clinical trials registration and results submission, among other items. A link to the complete text of Section 801 is available at **https://www.clinicaltrials.gov/ct2/manage-recs/fdaaa** (see "Section 801 of the Food and Drug Administration Amendments Act").

21 C.F.R. 50: Part 50 lays out the general requirements for informed consent for studies reviewed by the FDA. For the full document, see **www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm**.

21 C.F.R. 56: Part 56 contains the general standards for the composition, operation, and responsibility of an IRB that reviews clinical investigations regulated by the FDA. For the full document, see **www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm**.

45 C.F.R. 46 Protection of Human Subjects (The Common Rule): This 14-page document, last revised in 2009, lays out the basic HHS policy for protection of human subjects in research. For the full document, see **www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html**. In 2016, the HHS is considering comments on proposed changes to the Common Rule. For proposed changes, supporting documents, and comments submitted, see **www.regulations.gov/docket?D=HHS-OPHS-2015-0008**.

APPENDIX H. ACRONYMS AND ABBREVIATIONS

AAHRPP	Accreditation of Human Research Protection Programs, Inc.
AIDS	Acquired Immune Deficiency Syndrome
ALCHEMIST	Adjuvant Lung Cancer Enrichment Marker Identification and Sequencing Trials
BCSC	Breast Cancer Steering Committee
BMSC	Brain Malignancies Steering Committee
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
CCG	Center for Cancer Genomics
CCR	Center for Cancer Research
CCDRSC	Cancer Care Delivery Research Steering Committee
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
CFR	Code of Federal Regulations
CGH	Center for Global Health
CIRB	Central Institutional Review Board
CISC	Clinical Imaging Steering Committee
CMS	Centers for Medicare and Medicaid Services
CRCHD	Center to Reduce Cancer Health Disparities
CRS	Center for Research Strategy
CSSI	Center for Strategic Scientific Initiatives
CTAC	Clinical Trials and Translational Research Advisory Committee
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
DCCPS	Division of Cancer Control and Population Sciences
DCEG	Division of Cancer Epidemiology and Genetics
DCP	Division of Cancer Prevention
DCTD	Division of Cancer Treatment and Diagnosis
DEA	Division of Extramural Activities
DFO	Designated Federal Official
DOD	Department of Defense
DSSC	Disease-Specific Steering Committee

FACA	Federal Advisory Committee Act
FDA	Food and Drug Administration
FDAAA	Food and Drug Administration Amendments Act of 2007
FOA	Funding Opportunity Announcement
FY	Fiscal Year
GCSC	Gynecological Cancer Steering Committee
GISC	Gastrointestinal Cancer Steering Committee
GUSC	Genitourinary Cancer Steering Committee
GHWG	Guidelines Harmonization Working Group
HNSC	Head and Neck Cancer Steering Committee
HHS	Department of Health and Human Services (HHS)
IDSC	Investigational Drug Steering Committee
IND	Investigational New Drug
IRM	Immune Response Modifier
LKSC	Leukemia Steering Committee
LYSC	Lymphoma Steering Committee
MYSC	Myeloma Steering Committee
NCAB	National Cancer Advisory Board
NCATS	National Center for Advancing Translational Sciences
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
NCORP	NCI Community Oncology Research Program
NCTN	NCI National Clinical Trials Network
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
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
NIMHD	National Institute on Minority Health and Health Disparities
NINDS	National Institute of Neurological Disorders and Stroke
NINR	National Institute of Nursing Research
NLM	National Library of Medicine

OAR	Office of Advocacy Relations
OBBR	Office of Biorepositories and Biospecimen Research
OCCAM	Office of Cancer Complementary and Alternative Medicine
OCG	Office of Cancer Genomics
OCPL	Office of Communication and Public Liaison
OEWG	Operational Efficiency Working Group
OGE	Office of Government Ethics
OHAM	Office of HIV and AIDS Malignancy
OHRP	Office of Human Research Protections
P01	Research Program Project Grant
P30	Cancer Center Support Grant
P50	Specialized Center Grant (SPORE)
PA	Program Announcement
PAR	Program Announcement with Special Receipt/Review
PASC	Patient Advocate Steering Committee
PASTSC	Pediatric and Adolescent Solid Tumor Steering Committee
PATS	Process to Accelerate Translational Science
PCP	President's Cancer Panel
PHS	Public Health Service
PI	Principal Investigator
PL	Public Law
PLLSC	Pediatric Leukemia and Lymphoma Steering Committee
QOL	Quality of Life
R&D	Research and Development
R01	Research Project Grant
RFA	Request for Applications
RFP	Request for Proposals
RPG	Research Project Grant
SAMHSA	Substance Abuse and Mental Health Services Administration
SBIR	Small Business Innovation Research Grant (Phase I R43; Phase II R44)
SEP	Special Emphasis Panel
SGE	Special Government Employee
SPL	Scientific Program Leader
SPORE	Specialized Programs of Research Excellence (P50)
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
TARGET	Therapeutically Applicable Research to Generate Effective Treatments
TCGA	The Cancer Genome Atlas
TMSC	Thoracic Malignancy Steering Committee
TRWG	Translational Research Working Group
U10	Clinical Research Cooperative Agreement
UM1	Research Project with Complex Structure Cooperative Agreement
VA	Department of Veterans Affairs

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