National Cancer Institute

THE NCI CONSUMERS'
GUIDE
TO PEER REVIEW

Division of Extramural Activities

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TO PEER REVIEW

NIH> National Cancer Institute

CONTENTS

Introduction

The NCI Consumers' Guide to Peer Review *has been prepared to serve first as an introduction and orientation to the National Cancer Institute (NCI) and its research programs and second to define your role as a consumer advocate in the peer review of applications that support extramural clinical and population-based research and clinical career development and training by various grant and cooperative agreement mechanisms.*

The NCI is part of the National Institutes of Health (NIH), which is the primary biomedical research arm of the U.S. Department of Health and Human Services (HHS). The NCI is dedicated to the development of a multidisciplinary research agenda across all areas of basic science, clinical science, health care delivery, patient outcomes, and psychosocial support relating to the prevention, detection, treatment, and cure of cancer. These goals reflect the changing landscape of the scientific process as the development of research programs involves increasing collaboration among multiple interests, including scientists, academicians, industry, advocacy groups, and policy makers.

The emergence of consumer advocacy groups and heightened national attention to the role and contributions that they can make have had a great impact on the development of Federal medical research programs and the process of their execution. This is particularly true for cancer research.

Critical to the success of the National Cancer Program is the two-tiered review of research applications, in which scientific and technical merit are evaluated in the first tier, and programmatic relevance is evaluated in the second tier. You will participate in the most critical step in the application and award process: peer review for scientific and technical merit. The high caliber of NCI's research in all settings is maintained through peer review, a "quality control" process in which ideas for research are reviewed by an Initial Review Group (IRG) subcommittee or Special Emphasis Panel (SEP) composed of experts in the scientific field under study. The peer review process helps to ensure that the NCI uses its resources wisely and funds research that has the potential to make a significant contribution to advancing science.

Consumer participation augments scientific merit review by including the patient perspective in the assessment of scientific excellence. Including the patient perspective is consistent with the research agenda of the NCI. In addition to funding basic science, the NCI funds programs that encompass prevention, detection, and treatment of cancer, as well as quality of life and behavioral and social sciences research. Because you may have firsthand experience as a cancer survivor or as a family member of a cancer patient, it is anticipated that you will enhance scientific merit review of these types of research applications by increasing attention to outcomes and patient issues. This allows those who are ultimately affected by advances in cancer research to contribute to the decision making process. *Thank you for agreeing to participate in this very important process. Your views will be welcomed and respected.*

Paulette S. Gray, Ph.D.
Director
Division of Extramural Activities, NCI, NIH

The NCI and Its Research Programs

NCI Mission

The National Cancer Institute (NCI) is committed to dramatically lessening the impact of cancer. The NCI is the primary means of support for America's cancer research enterprise, whether in its own laboratories or in our Nation's research universities. The NCI is dedicated to the understanding, diagnosis, treatment, and prevention of cancer for all people and works toward this goal by providing vision to the Nation, as well as leadership and support for both domestic and international NCI-funded researchers. The NCI also works to ensure that research results are applied in clinical practice and public health-related programs to reduce the burden of cancer for all populations.

Within this framework, NCI researchers work to more fully integrate discovery activities through interdisciplinary collaborations; accelerate development of interventions and new technology through translational research; and ensure the delivery of these interventions for application in the clinic and public health programs as state-of-the-art care for all those in need.

History and Organization

The NCI was established under the National Cancer Act of 1937, and is the Federal Government's principal agency for cancer research and training. The National Cancer Act of 1971 broadened the scope and responsibilities of the NCI and created the National Cancer Program to expand existing scientific knowledge on cancer cause, prevention, and control, as well as on the diagnosis, treatment, and rehabilitation of cancer patients.

Over the years, legislative amendments have maintained NCI's authorities and responsibilities and added new information dissemination mandates as well as a requirement to assess the incorporation of state-of-the-art cancer treatments into clinical practice. The NCI coordinates the National Cancer Program, which conducts and supports research, training, health information dissemination, and other programs with respect to the cause, diagnosis, prevention, and treatment of cancer, rehabilitation from cancer, and the continuing care of cancer patients and the families of cancer patients.

Specifically, the NCI:

- Supports and coordinates research projects conducted by universities, hospitals, research foundations, and businesses throughout this country and abroad through research grants and cooperative agreements.

- Conducts research in its own laboratories and clinics.

- Supports education and training in fundamental sciences and clinical disciplines for participation in basic and clinical research programs and treatment programs relating to cancer through career awards, training grants, and fellowships.

- Supports research projects in cancer prevention and control.

- Supports a national network of cancer centers.

- Collaborates with voluntary organizations and other national and foreign institutions engaged in cancer research and training activities.

- Encourages and coordinates cancer research by industrial organizations with a particular capability for programmatic research.

- Collects and disseminates comprehensive information on cancer.

- Supports construction and renovation of laboratories, clinics, and related facilities necessary for cancer research through the award of construction grants.

- Forms partnerships and engages in collaborations with other government agencies and industrial organizations to leverage and advance cancer research.

All of these activities are focused on three key components required for a strong cancer research enterprise: (1) capitalizing on scientific opportunities; (2) targeting specific public health needs; and (3) maintaining a strong research infrastructure and building capacity for the future.

For more information on a broad range of programs and activities supported by the NCI, please visit: http://cancer.gov.

The current NCI organizational structure is shown in Figures 1 and 2. The Office of the Director serves as the focal point for the National Cancer Program with advice from several external advisory groups that include the President's Cancer Panel, the National Cancer Advisory Board, the Board of Scientific Advisors, the Boards of Scientific Counselors, the Clinical Trials and Translational Research Advisory Committee, the Frederick National Laboratory Advisory Committee, and the Council of Research Advocates. In addition, the actual functions of the Institute are performed by NCI Divisions, Offices, and Centers.

Figure 1. The National Cancer Institute

Board of Scientific Advisors
Executive Secretary
Dr. Paulette S. Gray

Board of Scientific Counselors
Clinical Sciences and Epidemiology
Executive Secretary
Dr. Brian E. Wojcik

Board of Scientific Counselors
Basic Sciences
Executive Secretary
Dr. Mehrdad Tondravi

Frederick National Laboratory
Advisory Committee
Executive Secretary
Dr. Caron Lyman

Office of the Director
Acting Director
Dr. Douglas R. Lowy

President's Cancer Panel
Executive Secretary
Dr. Abby Sandler

National Cancer Advisory Board
Executive Secretary
Dr. Paulette S. Gray

Council of Research Advocates
Ms. Amy Williams

Clinical Trials and Translational
Research Advisory Committee
Executive Secretary
Dr. Sheila Prindiville

Division of Cancer Control
and Population Sciences
Director
Dr. Robert Croyle

Division of Cancer Biology
Director
Dr. Dinah S. Singer

Division of
Extramural Activities
Director
Dr. Paulette S. Gray

Division of Cancer
Epidemiology and Genetics
Director
Dr. Stephen Chanock

Division of Cancer
Treatment and Diagnosis
Director
Dr. James H. Doroshow

Center for Cancer Research
Director
Dr. Tom Misteli

Division of Cancer
Prevention
Director
Dr. Barnett Kramer

Figure 2. The National Cancer Institute

Office of the Director
Acting Director
Dr. Douglas R. Lowy

Acting Deputy Director for Management
Ms. Donna Siegle

Associate Director for Prevention
Vacant

Special Assistant to the Director
Dr. Maureen Johnson

Deputy Director for Clinical and Translational Research
Dr. James H. Doroshow

Acting Deputy Director
Dr. Warren Kibbe

Acting Deputy Director
Dr. Dinah S. Singer

Office of Communications and Public Liaison
Director
Dr. Peter Garrett

Center to Reduce Cancer Health Disparities
Director
Dr. Sanya A. Springfield

SBIR Development Center
Director
Mr. Michael S. Weingarten

Institute Review Office
Chief
Dr. Mehrdad Tondravi

Center for Research Strategy
Director
Dr. L. Michelle Bennett

Office of Advocacy Relations
Acting Director
Ms. Amy Williams

Office of HIV and AIDS Malignancy
Director
Dr. Robert Yarchoan

Center for Global Health
Director
Dr. Ted Trimble

Center for Strategic Scientific Initiatives
Acting Director
Dr. Douglas R. Lowy

Office of Cancer Centers
Director
Dr. Henry Ciolino

Coordinating Center for Clinical Trials
Director
Dr. Sheila Prindiville

NCI-Frederick Office of Scientific Operations
Acting Director
Dr. Kristin Komschlies McConville

Office of Management
Acting Executive Officer
Ms. Donna Siegle

Center for Cancer Genomics
Director
Dr. Louis Staudt

Center for Cancer Training
Director
Dr. Jonathan Wiest
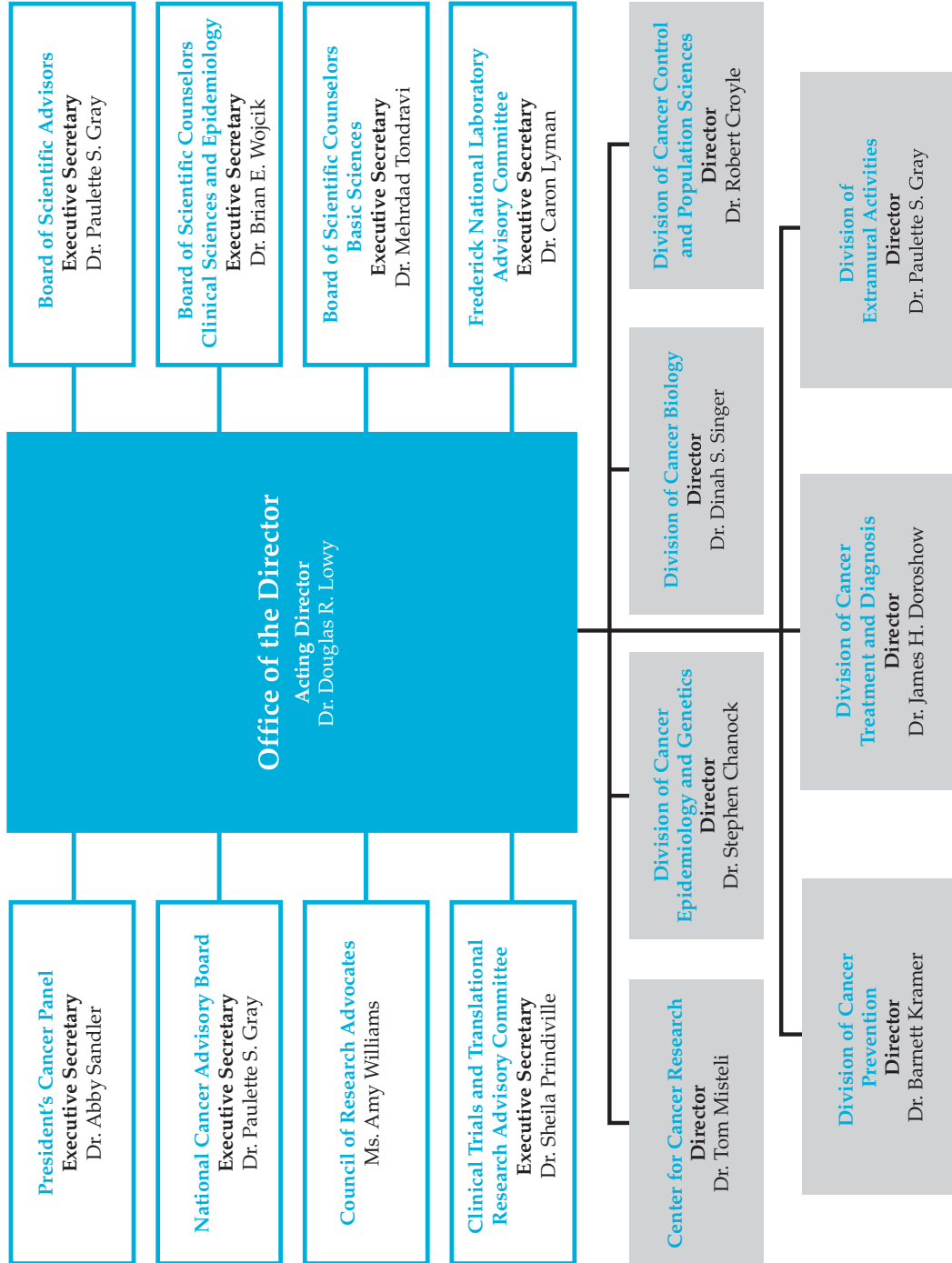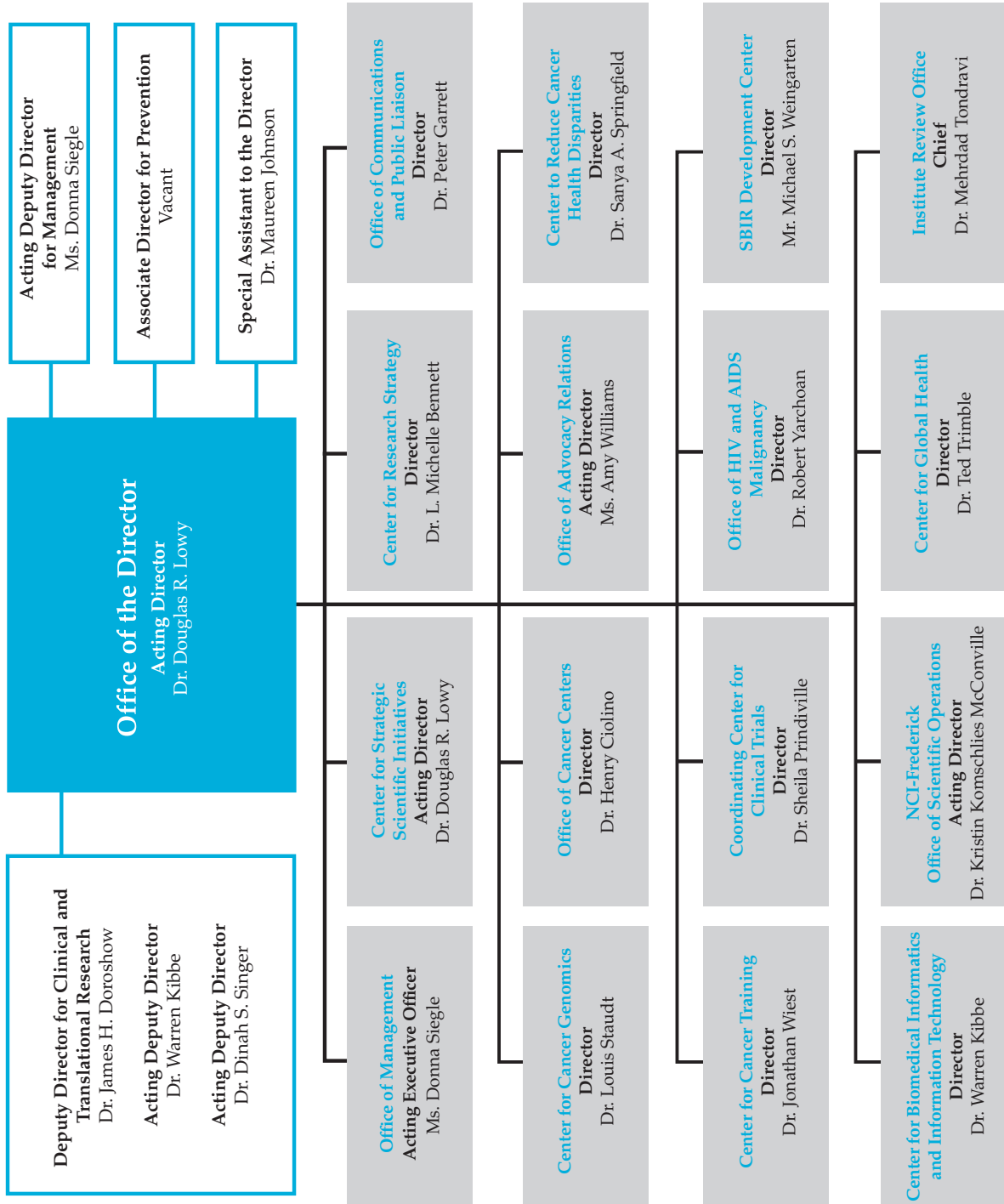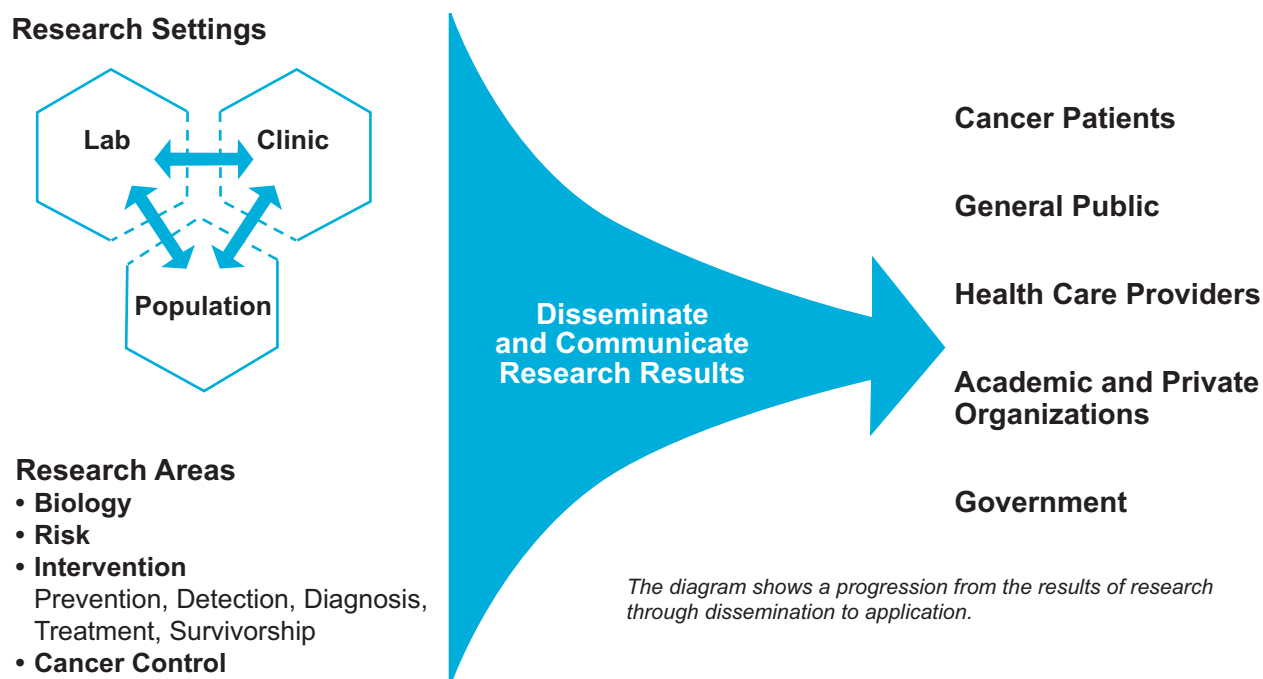
Center for Biomedical Informatics and Information Technology
Director
Dr. Warren Kibbe

Overview of NCI Research Programs

NCI-sponsored *investigator-initiated research* takes place in three settings: the laboratory, the clinic, and the community. In the laboratory, research is pursued on the biology of cancer, the fundamental properties of cancer-causing agents and processes, and the body's defense against and response to cancer. In the clinic, patient-oriented research is conducted in the areas of prevention, detection, diagnosis, treatment, and rehabilitation. In the community, population-based research is performed on the causes, risks, predispositions, incidence, and behavioral aspects of cancer. **Figure 3** shows the progression from the results of research through dissemination to application in the community.

Figure 3. Progression from Cancer Research to Applications in the Community

Research Settings

Lab ↔ Clinic

Population

Disseminate and Communicate Research Results

Cancer Patients

General Public

Health Care Providers

Academic and Private Organizations

Government

Research Areas
- **Biology**
- **Risk**
- **Intervention**
  Prevention, Detection, Diagnosis, Treatment, Survivorship
- **Cancer Control**

The diagram shows a progression from the results of research through dissemination to application.

The NCI supports intramural and extramural research as described in the sections that follow.

Intramural Research

Research performed by NCI employees at the National Institutes of Health (NIH) is called intramural research. The NCI **Intramural Research Program (IRP)** consists of the Center for Cancer Research (CCR) and the Division of Cancer Epidemiology and Genetics (DCEG) and is dedicated to a comprehensive understanding of cancer. IRP government scientists, research fellows, and visiting scientists from around the world conduct basic, clinical, population-based, and prevention studies. They also collaborate with national and international investigators in academia and in the biotechnology and pharmaceutical industries to help expedite the application of new knowledge for the development and delivery of products that will benefit human health.

Extramural Research

Investigator-initiated extramural research is proposed and conducted by non-Government scientists in laboratories and clinical facilities throughout the country. This is an extremely important component of NCI's research program since nearly two-thirds of the Institute's overall budget is devoted to extramural research project grants as well as research and development contracts.

Five extramural research Divisions, six Centers, and two Offices monitor and administer NCI's extramural grant and contract research activities: the Division of Cancer Biology (DCB); the Division of Cancer Control and Population Sciences (DCCPS); the Division of Cancer Prevention (DCP); the Division of Cancer Treatment and Diagnosis (DCTD); the Division of Extramural Activities (DEA): the Center for Strategic and Scientific Initiatives; the Center for Cancer Genomics; the Center to Reduce Cancer Health Disparities; the Center for Global Health; Center for Cancer Training; the Small Business Innovation Research (SBIR) Development Center; the Office of HIV and AIDS Malignancies; and the Office of Cancer Centers. The Division of Extramural Activities (DEA) coordinates the development of new funding initiatives; manages and administers the review of grants and contracts; codes and tracks NCI extramural research; and manages the functions of the National Cancer Advisory Board (NCAB) the Board of Scientific Advisors (BSA), and the Frederick National Laboratory Advisory Committee (FNLAC).

Collectively, NCI extramural research grants and contracts support the full range of basic, clinical, and population-based studies and strive for a "balanced" portfolio of research in biology, cancer etiology, behavior, epidemiology, cancer control, cancer prevention, cancer detection, cancer diagnosis, and cancer treatment, as well as long-term survival/survivorship, rehabilitation, and end-of-life issues. This balance must include attention to all of the distinct diseases collectively referred to as cancer and to all of the various populations that experience these diseases differently.

It also is critical to link the various pieces of the national cancer research effort through translational research. Translational research bridges the gap between basic laboratory research and application of new findings to applied settings involving patients and populations. This interdisciplinary approach involves the bi-directional exchange of results between basic and preclinical and clinical science and is the cornerstone of extramural research to ensure progress against cancer.

We have asked you to participate in the peer review of extramural grant and cooperative agreement applications that support clinical and population-based research and clinical career development and training as described on the following pages.

Grants and Cooperative Agreements

Research grants and cooperative agreements are used by the NCI to provide Federal financial assistance to stimulate and support extramural clinical and population-based research by NCI Cancer Centers, National Clinical Trials Network (NCTN), Specialized Programs of Research Excellence (SPOREs), and Program Projects. A **grant** provides funds to an investigator to perform approved activities with little or no Government involvement. **Cooperative agreements** are grants in which the NCI and extramural scientists/clinicians work together during performance of the research. Under the cooperative agreement mechanism, the NCI and the extramural community share the responsibility for ensuring that the best and most important clinical research is conducted.

Descriptions of the more common grant mechanisms used by the NCI for research funding (e.g., R01, R03, R21) and the specialized grant and cooperative agreement mechanisms used to support centers and clinical and translational research are provided below.

Grants are used when: (1) no substantial programmatic involvement is anticipated between the NCI and the recipient during performance of the financially assisted activities, thus allowing the recipient freedom of action in carrying out the independent research project; and (2) there is no expectation on the part of the NCI of a specified service or end product for use by the NCI other than generating knowledge that moves cancer research and the mission of the NCI forward.

- The **P30 Cancer Center Support Grant** provides support primarily for the research infrastructure of an active and unified center for the purpose of consolidating and focusing cancer-related activities, increasing research productivity, promoting shared use of research resources and improved quality control, stimulating and promoting transdisciplinary and collaborative research, and increasing the rate at which research discoveries are translated into medical benefits. *The NCI-designated Cancer Centers are funded by the P30 grant mechanism.*

- The **P50 Specialized Center** grant supports the full range of research and development from very basic to clinical for a multidisciplinary research group of investigators focused on a common research topic. Applications may include individual projects, shared resources, training components, and developmental funds. *SPOREs are funded by the P50 grant mechanism.* The SPOREs conduct translational research focused on an organ-specific human cancer (e.g., breast cancer) or a highly related group of human cancer types (e.g., gastrointestinal cancers).

- The **P20 Planning Grant** supports planning for new programs, expansion or modification of existing resources, or feasibility studies to explore various approaches to the development of interdisciplinary programs that offer potential solutions to problems of special significance to the mission of the NIH. These exploratory studies may lead to specialized or comprehensive centers.

- The **P01 Program Project Grant** supports an integrated, multiproject research approach involving a number of independent investigators who share knowledge and common resources. This type of grant has a defined central research focus involving several disciplines

or several aspects of one discipline. Each project must contribute or be directly related to the common theme of the total research effort, thus forming a system of research activities and projects directed toward a well-defined research program goal.

- The traditional **R01 Research Project Grants** are investigator-initiated grants that support discrete, specified, circumscribed projects to be performed by investigators in areas representing their specific interest and competencies.

- The **R03 Small Grant** provides limited funding for a short period of time to support a variety of types of projects, including: pilot or feasibility studies; collection of preliminary data; secondary analysis of existing data; small, self-contained research projects; or development of new research technology.

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

- The **R33 Exploratory/Developmental Grant** provides additional support (phase II) to innovative, exploratory, and developmental research activities that were initiated under the R21 mechanism.

- The **R35 Outstanding Investigator Award (OIA)** provides long-term support (up to 7 years) to experienced investigators with outstanding records of cancer research productivity who propose to conduct exceptional research. The OIA is intended to allow investigators the opportunity to take greater risks, be more adventurous in their lines of inquiry, or take the time to develop new techniques.

- The **R50 Research Specialist Award** supports the development of stable research career opportunities for exceptional scientists who want to pursue research within the context of an existing cancer research program, but not serve as independent investigators.

- The **Career Development Grant** supports scientists and clinicians who wish to develop or enhance a career in biomedical research; activity codes are in the **K series** of grant mechanisms.

Cooperative Agreements are used when: (1) substantial programmatic involvement is anticipated between NCI staff and the grant recipient during the performance of the research activities; and (2) the applicant responds to a specific NCI announcement for cooperative agreements and must tailor the application to the announcement requirements.

- The **U01 Cooperative Agreement** supports a discrete, specified, circumscribed project to be performed by the named investigator(s) in an area representing his or her specific interest and competencies.

- The **U10 Clinical Research Cooperative Agreement** supports prospective clinical research activities utilizing patient volunteers to assess the effect and value of various treatment modalities. Because the clinical resources necessary for the conduct of a major clinical trial

often are not available at a single institution, a cooperative study is started that involves investigators in several institutions following common protocols. *The NCI National Clinical Trials Network (NCTN) and the NCI Community Oncology Research Program (NCORP) are funded by U10 cooperative agreements.*

- The **UG1 Clinical Research Cooperative Agreement** supports single-project applications conducting clinical evaluation of various methods of therapy and/or prevention (in specific disease areas). Substantial Federal programmatic staff involvement is intended to assist investigators during performance of the research activities, as defined in the terms and conditions of the award. NOTE: The UG1 is the single-component companion to the U10, which is used for multiproject applications only. *The NCI National Clinical Trials Network (NCTN) sites are funded by UG1 cooperative agreements.*

- The **UM1 Research Project with Complex Structure** supports cooperative agreements with large-scale research activities with complicated structures that cannot be appropriately categorized into a single component activity code (e.g., clinical networks, research networks or consortia). *The NCORP and the Experimental Therapeutics Clinical Trials Network (ETCTN) are funded by UM1 cooperative agreements.*

- The **U54 Specialized Center Cooperative Agreement** may support any part of the full range of research and development, from very basic to clinical. These differ from program projects in that they are usually developed in response to an announcement of the programmatic needs of an Institute or Division and subsequently receive continuous attention from its staff. Centers also may serve as regional or national resources for special research purposes, with funding component staff helping to identify appropriate priority needs. *The Comprehensive Partnerships to Reduce Cancer Health Disparities are funded by U54 cooperative agreements.*

For new, expanded, and/or high-priority programs, the NCI may encourage the submission of research applications through the use of the following mechanisms:

- **Program Announcements (PAs)** describe continuing, new, or expanded program interests for which grant or cooperative agreement applications are invited. Funds may or may not be set aside for PAs.

- **Requests for Applications (RFAs)** are issued to invite grant or cooperative agreement applications in a well-defined scientific area to stimulate activity in areas of high NCI programmatic priority. RFAs usually are one-time-only competitions with a specified set-aside of funds designated to make awards.

The Grant/Cooperative Agreement Process and Participants

- Grants and cooperative agreements are awarded to nonprofit and for-profit organizations, institutions of higher education, hospitals, research foundations, governments and their agencies, and, occasionally, individuals.

- The **Principal Investigator (PI),** or Project Director (PD) is defined as the individual(s) judged by the applicant organization to have the appropriate level of authority and responsibility to direct the project or program supported by the grant. The applicant-grantee

institution may designate multiple individuals as PDs/PIs who share the authority and responsibility for leading and directing the project, intellectually and logistically. Each PD/PI is responsible and accountable to the applicant organization or, as appropriate, to a collaborating organization, for the proper conduct of the project or program, including the submission of all required reports. When **Multiple PIs** are proposed, the NIH requires identification of one PI who will be designated as the "**Contact PI.**" The Contact PI will be responsible for communication between the PIs and the NIH, but has no special authorities or responsibilities within the project leadership team.

- The **Applicant-Grantee Institution** is, in turn, legally responsible and accountable to the NIH for the performance and financial aspects of the grant-supported activity. In applying for grant support, the applicant institution agrees to administer any grant awarded in accordance with all the regulations and current policies that govern the research grant programs of the NIH.

- The multiple steps in the grants/cooperative agreement process, including application development, submission, peer review, negotiation, funding selection, and grant management, are shown in **Figure 3**.

Figure 3. Overview of the NIH/NCI Grants/Cooperative Agreement Process
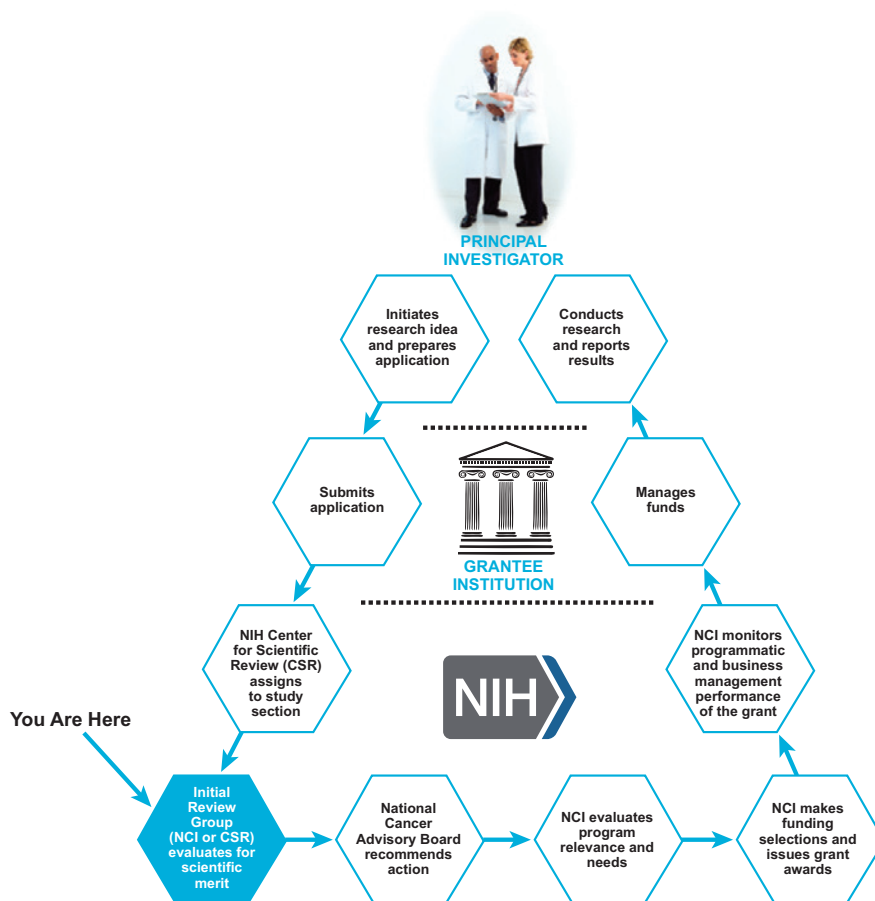
For more information on the grants process and related activities, please visit **http://grants.nih.gov/grants/peer_review_process.htm.**

Contracts

The NCI uses the contract mechanism to acquire cancer research and development efforts and other resources or services needed by the Federal Government. In contrast to grant and cooperative agreement mechanisms, which are used to support and stimulate approved research activities, contracts are a procurement mechanism and are used when the principal purpose of the transaction is to acquire a specific service or end product for the direct benefit of, or use by, the NCI. **The remainder of this *Consumer Guide* deals only with grants and cooperative**

agreements because these are the mechanisms used to fund extramural clinical and population-based research and clinical career development and training, which you will be involved in evaluating through peer review.

Oversight of Research Programs

The NCI maintains several advisory and operational groups for oversight of its scientific programs.

National Cancer Advisory Board (NCAB). NCI's principal advisory body is the Presidentially appointed NCAB. The Board advises and makes recommendations to the NCI Director on all issues related to the entire National Cancer Program and provides a second level of review for grant applications referred to the NCI.

Board of Scientific Advisors (BSA). The BSA, composed of distinguished scientists from outside the NCI and representatives from the consumer advocacy community, advises the NCI leadership on the progress and future direction of the Institute's Extramural Research Program. The BSA periodically evaluates Institute-awarded grant, cooperative agreement, and contract programs, and reviews ideas for new research solicitations to ensure that a concept is meritorious and consistent with the Institute's programs.

Boards of Scientific Counselors (BSC). The BSC for Clinical Science and Epidemiology and the BSC for Basic Sciences advise the Institute leadership on the progress and future direction of NCI's Intramural Research Program. These groups of scientific experts from outside the NCI evaluate the performance and productivity of NCI intramural staff scientists through periodic site visits to intramural laboratories, and provide evaluation and advice on the course of intramural research programs.

NCI Initial Review Groups (IRGs). The IRGs, composed of four chartered subcommittees, review grant and cooperative agreement applications for cancer centers and research training and career development activities in the areas of cancer cause, prevention, diagnosis, and treatment relating to all facets of cancer. Members may be appointed as standing committee members with overlapping terms of up to 6 years or as "temporary" members with all the rights and obligations of full committee membership, including the right to vote on recommendations in which the individual fully participated as a reviewer for a specific meeting. Consultants also may be invited to serve as special experts or *ad hoc* members to provide information or advice. These individuals generally serve *ad hoc* on site visit teams, providing critical information to the chartered advisory committees responsible for initial peer review.

NCI Special Emphasis Panels (SEPs). The SEPs advise the Director, NCI, and the Director, DEA, regarding research grant and cooperative agreement applications and contract proposals of special relevance to the NCI. Membership of an SEP is fluid, with individuals designated to serve for individual meetings rather than for fixed terms. These individuals have all of the rights and obligations of committee membership, including the right to vote on recommendations.

NCI Scientific Program Leaders (SPL). The SPL includes the Director, Deputy Directors, Division Directors, and other senior NCI 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 RFA and research and development contract concepts before review by the BSA; review of program announcements; development of funding plans; and grant payment by exceptions.

NCI Council of Research Advocates (NCRA). The NCRA, formerly the Director's Consumer Liaison Group, provides advice to the Director, NCI, with respect to promoting research outcomes that are in the best interest of cancer patients. The NCRA conducts these activities with the intent to identify new approaches, promote innovation, recognize unforeseen risks or barriers, and identify unintended consequences that could result from NCI decisions or actions. Additionally, the NCRA provides insight into enhancing input, optimizing outreach, and promoting strong collaborations, all with respect to non-scientist stakeholders. The Council consists of up to 16 patient advocates, including the Chair appointed by the Director, NCI.

President's Cancer Panel (PCP). The PCP is an NCI Federal advisory committee that reports directly to the President of the United States on the activities of the National Cancer Program. The Panel consists of three members who are appointed by the President for terms of 3 years. At least two members must be distinguished scientists or physicians, and the third may be a lay person. The Panel, which meets at least four times a year, is responsible for monitoring the development and execution of the National Cancer Program, evaluating its efficacy, making suggestions for its improvement, and submitting periodic progress reports to the President.

Clinical Trials and Translational Research Advisory Committee (CTAC). The CTAC is composed of distinguished clinicians and scientists engaged in a broad spectrum of clinical trials. The Committee provides broad scientific and programmatic advice and recommendations on the conduct, oversight, and implementation of intramural and extramural NCI clinical trials. In addition, the Committee makes recommendations regarding the effectiveness of NCI's translational research management and administration program, including needs and opportunities across disease sites, patient populations, translational developmental pathways, and the range of molecular mechanisms responsible for cancer development. The Committee will advise on the appropriate magnitude for dedicated translational research priorities and recommend allocation of translational research operations across organizational units, programs, disease sites, populations, developmental pathways, and molecular mechanisms. The Committee will ensure that appropriate emphasis is placed on rare cancers, medically underserved populations, and historically lower resourced pathways to clinical goals.

Frederick National Laboratory Advisory Committee (FNLAC). The FNLAC provides advice to the Director, NCI, and the Associate Director, Frederick National Laboratory for Cancer Research (FNLCR) on the optimal use of the Frederick facilities to meet the needs of the Institute. The FNLCR is designated as a Federally Funded Research and Development Center (FFRDC) that provides unique national research within the biomedical research community for the development of new technologies and the translation of basic science discoveries into novel agents for the prevention, diagnosis, and treatment of cancer and AIDS.

For more information on advisory groups, please visit the NCI Advisory Boards' Web page at: http://deainfo.nci.nih.gov/advisory/boards.htm.

Community Input into Research Programs

Input from the cancer community is very important to the NCI. **To strengthen relationships and cooperation with the cancer community, the NCI has established the *Office of Advocacy Relations (OAR)*.** Throughout the United States, hundreds of cancer advocacy and outreach organizations provide education and support to their communities. The OAR is NCI's central point of contact with these national advocacy organizations and, through them, the community-based groups. The OAR engages the advocacy and NCI communities in dialogue about cancer research opportunities and priorities to advance progress and improve outcomes. The OAR maintains ongoing communications and information exchange between the national cancer advocacy organizations and the NCI, encourages input and feedback from these organizations, and cooperates and collaborates with these groups in areas of mutual interest. The office serves as a catalyst and resource to link consumers with NCI programs, working groups, and advisory committees, and helps integrate consumer representatives throughout the NCI. The OAR, in cooperation with the DEA, holds orientation and training meetings for consumers interested in serving as reviewers. For more information on NCI liaison activities, please visit: http://advocacy.cancer.gov.

Support for Clinical Research

Clinical research, or research conducted with cancer patients or those at risk of the disease, is one of the cornerstones of the NCI research program. Conducting clinical trials is a critical step in establishing the best possible means of preventing, diagnosing, detecting, and treating specific cancers. To enhance the process, the NCI established the Clinical Trials and Translational Research Advisory Committee (CTAC). Clinical trials allow the NCI to assess the ability of new cancer treatments and procedures to increase patient survival and to improve quality of life. NCI's designated Cancer Centers, National Clinical Trials Network (NCTN), NCI Community Oncology Research Program (NCORP), Experimental Therapeutics Clinical Trials Network (ETCTN), and Specialized Programs of Research Excellence (SPOREs) provide support for the translation of basic research findings from the laboratory into new preventive interventions, diagnostic tools, and treatments and also are where these findings are first tested for safety and effectiveness. Hundreds of clinical trials are supported through these and other research programs, such as program project grants.

Ensuring Diversity in Clinical Trial Participation

Ensuring participation in clinical research, particularly among women and children and members of underserved population groups, is a high priority for the NCI. Several programs help ensure that all populations are well represented. The Minority-Based Community Clinical Oncology Program (MBCCOP), begun in 1990, has been successful in accruing minority cancer patients to trials and allows for studies in minority populations that may lead to better understandings of the disease process. In 2014, this Program was merged with the NCI Community Oncology Research Program (NCORP) as Minority/Underserved Community Sites. Grant programs have been established to support research on ways to include more women and children and minority participants in cancer prevention and screening studies. The NCI also has funded a number of conferences aimed at sharing current information and strategies to increase

and maintain its good record of gender and minority accrual to clinical trials. For more information, please visit: **http://prevention.cancer.gov/major-programs/nci-community-oncology**.

Clinical Trials

Before a clinical trial of a promising new chemopreventive agent, diagnostic procedure, or treatment can be launched, the agent must undergo rigorous preclinical laboratory testing to demonstrate that it may be beneficial to patients and will be safe to use during testing. The results of the preclinical evaluation must be submitted for approval to the U.S. Food and Drug Administration (FDA) in the form of an ***Investigational New Drug (IND)*** application before a clinical trial can commence. Only then can the researchers recruit volunteers to participate.

Strict entry criteria are developed to help identify patients who are best suited for the trial. ***Clinical trials are designed to answer specific scientific questions.*** Clinical trials generally are conducted in three-four phases:

- **Phase 0.** A Phase 0 (Phase zero) clinical trial is designed to study the pharmacodynamic and pharmacokinetic properties of a drug. Pharmacodynamics describes the biochemical and physiological effects of a drug on the body, including how the drug is absorbed, moves throughout the body, binds to various structures, and interacts with certain molecules within target tissues. Pharmacokinetics describes the activity of a drug in the body over a long period of time. This includes the process by which drugs are absorbed, distributed in the body, localized in the tissues, and excreted. Unlike a Phase I trial, in a Phase 0 trial, a limited number of doses, and much lower doses, of the drug are administered; therefore, there is less risk to the participant.

- **Phase I.** These are small trials designed to tell researchers how best to administer the new intervention and, in studies of new agents, the optimal dose of the drug to give to achieve an anticancer effect while minimizing possible side effects.

- **Phase II.** Using a small number of people, these studies determine if the treatment, delivered at the optimum dose, destroys or prevents cancer and against what types of cancer it works best.

- **Phase III.** Once a therapy has been proven to have an anticancer effect and be safe, it then moves to a Phase III trial to compare the effectiveness of the new therapy with a standard therapy. Phase III trials are often large and may include hundreds or thousands of people from across the country.

As each phase of testing is completed, the data collected are analyzed and the results published. Based on this analysis, the researchers determine whether the agent or procedure is showing enough of a benefit to continue testing. Once a trial has successfully completed these three phases of testing, a ***New Drug Application (NDA)*** is submitted to the FDA. The testing and approval process can take many years; however, it can sometimes be accelerated, particularly if the agent or procedure is beneficial for patients with a form of cancer that has few treatment or prevention options. Occasionally, additional trials (called **Phase IV** trials) are conducted after the approval of the drug to provide longer term safety data or to collect new types of information,

such as quality-of-life assessments. For more information, please visit: http://www.cancer.gov/clinicaltrials.

Cancer Centers Program

Sixty-nine (69) research-oriented institutions throughout the Nation have been designated as NCI-supported Cancer Centers in recognition of their scientific excellence. The Centers are key partners in NCI's efforts to speed the process of discovery and bring the benefits of cancer research directly to the public. Located throughout the country, *each Cancer Center is a hub of cutting-edge research, high-quality cancer care, and medical education for health care professionals and the general public alike.*

When an institution meets the rigorous competitive standards to become a designated NCI Cancer Center, it is awarded a *Cancer Center Support Grant (CCSG).* These funds enable the institution to coordinate multidisciplinary approaches to research questions, to gain access to the most advanced research technologies, and to take rapid advantage of new research opportunities. Support for the Cancer Centers helps to ensure a close association between state-of-the-art research and state-of-the-art patient care activities within the institution. It also allows each Center to develop key collaborations with industrial, community, and state health organizations and link the research capabilities and expertise of scientists within the institution to problems of cancer incidence and mortality in their communities and regions. To be chosen as one of the current 45 *Comprehensive Cancer Centers,* a Center must demonstrate significant scientific strength in basic, clinical, and population studies and strong interdisciplinary collaboration. Comprehensive Cancer Centers also must have in place effective cancer education and outreach activities for the regions and communities they serve. In addition to the 45 *Comprehensive Cancer Centers,* there are 17 *Cancer Centers,* which conduct a combination of basic, population sciences, and clinical research, and 7 *Basic Laboratory Cancer Centers* that conduct only laboratory research and do not provide patient treatment.

Traditionally, Cancer Centers have had broad scientific bases, and most have been developed within a single institution. Recent changes in the program, however, are enabling the planning of new consortia of institutions, often linking free-standing clinical and academic centers with community hospitals, forming networks with tremendous research strength and the ability to deliver quality care in a managed care environment. In addition, Cancer Centers now may have more focused scientific agendas. For example, some Centers are focusing on population sciences and others are concentrating on translational research opportunities within a specific scientific discipline, such as immunology. Overall, such changes in the Cancer Centers program promise to increase the scientific versatility, translational research capabilities, and geographic distribution of NCI-supported Cancer Centers. For more information, please visit: http://www.cancer.gov/research/nci-role/cancer-centers.

National Clinical Trials Network (NCTN)

The sheer number of different types of cancers and the biological complexity of individual cancers make the process of efficiently identifying and evaluating new anticancer or new treatment strategies particularly challenging. *To test potential intervention advances in patients more*

rapidly, the NCI maintains the National Clinical Trials Network (NCTN), a national network consortia consisting of five U.S. cooperative groups (Alliance for Clinical Trials in Oncology, ECOG-ACRIN Cancer Research Group, NRG Oncology, SWOG, and the Children's Oncology Group [COG]) and the Canadian Network Group that seek to define the key unanswered questions in cancer and then conduct clinical trials to answer them. The Program conducts and promotes clinical trials in cancer prevention, early detection, and treatment and explores issues concerning quality of life and rehabilitation during and after treatment for cancer. The NCTN groups consist of researchers at separate institutions affiliated with the Groups, who jointly develop and conduct cancer treatment clinical trials in multi-institutional settings. The NCTN groups frequently work together to conduct large-scale clinical trials, particularly when the cancer in question is so rare that one group working alone would be unable to accrue enough patients to conduct a meaningful study. To help monitor and ensure quality in trials that involve new imaging modalities and/or radiation therapy, the NCTN has established a consolidated Imaging and Radiation Oncology Core (IROC) Group to assist all of the NCTN groups that use these modalities in their trials. Many new anticancer drugs are tested in patients for the first time under NCI *Investigational New Drug (IND)* sponsorships through the NCTN Program. For more information, please visit: http://www.cancer.gov/research/areas/clinical-trials/nctn.

NCI Community Oncology Research Program (NCORP)

The NCI Community Oncology Research Program (NCORP) is a network that provides the infrastructure to link community cancer specialists and primary care physicians with the NCTN and Cancer Centers. NCORP designs and conducts cancer prevention, control, screening and post-treatment surveillance clinical trials and cancer care delivery research studies, including comparative effectiveness research. NCORP also facilitates patient and provider access to treatment and imaging trials from the NCTN; facilitates minority and underserved participation in clinical research; increases integration of disparities research questions across all study types and settings; integrates primary and specialty care providers' health services and behavioral researchers' expertise with oncologists; and accelerates knowledge transfer into clinical practice and health care systems and organizations. This network enables individuals to participate in state-of-the-art clinical research trials at community hospitals without the added burden of traveling to a distant site. By increasing the number of patients and physicians who can participate in clinical trials, the program helps in the transfer of the latest research findings to the community. For more information, visit: http://ncorp.cancer.gov.

Specialized Programs of Research Excellence (SPOREs)

SPORE awards focus on research that is designed to convert novel ideas with the potential to reduce cancer incidence and mortality, improve survival, and improve quality of life into interventions that can help people with cancer or people at risk. Laboratory and clinical scientists work collaboratively to plan, design, and implement interdisciplinary translational research programs that impact cancer prevention, detection, diagnosis, treatment, and control. NCI-designated Cancer Centers and other research institutions are eligible to compete for SPORE awards through specialized Center grants. The NCI currently funds SPOREs at a variety of institutions for: breast, prostate, lung, ovarian, gastrointestinal, genitourinary, gynecologic, leukemia, myeloma, pancreatic, brain, skin, head and neck cancers, and lymphomas. For more information, please visit: http://trp.cancer.gov.

Program Projects

The program project grant is intended for the support of multidisciplinary or multifaceted research programs that have a strong central theme. This allows groups of investigators to interact and to integrate the individual projects in a way that accelerates the acquisition of knowledge beyond that expected from the same projects conducted separately, without combined leadership or a common theme. Individual investigators apply their specialized research capabilities to basic research projects, clinical research projects, cancer control research projects, or combinations of such projects as they relate to the focused, central theme of the overall program project. Groups of researchers who are pursuing thematically related research projects requiring additional shared resources, such as specialized core research facilities, can be supported under a single award. The investigators have access to a much broader range of projects and common access to patients and tissue samples that would be difficult, if not impossible, to arrange in a single project setting. This approach is especially useful in interdisciplinary and translational research in which basic and clinical projects are combined, fostering synergy between the investigators. For more information, please visit: https://deainfo.nci.nih.gov/flash/awards.htm#P01.

Requests for Applications (RFAs) and Program Announcements (PAs)

The NCI stimulates research in programmatic priority areas of cancer causation, detection and diagnosis, treatment, and basic cancer biology through the issuance of RFAs and/or PAs on specific topics. Research topics may include such diverse areas as the Experimental Therapeutics Clinical Trials Network (ETCTN); Centers for Population Health and Health Disparities (CPHHD); Cancer Intervention and Surveillance Modeling Network (CISNET); Phase 0/I/II Cancer Prevention Clinical Trials Program; Early Detection Research Network Pediatric Preclinical Testing Consortium; Children's Oncology Group Pediatric Phase I/Pilot Consortium; and AIDS Malignancies Consortium. The formal announcements are published in the *NIH Guide for Grants and Contracts* (http://www.nih.gov/grants/guide/index.html) and invite grant or cooperative agreement applications in a well-defined scientific area to support specific NCI program initiatives, indicating the amount of funds set aside for the completion and the estimated number of awards to be made. Funds may or may not be set aside for PAs. Applications are evaluated for responsiveness to the RFA/PA before the review. Reviews are conducted by an appropriate NCI IRG subcommittee or a Special Emphasis Panel (SEP) assembled specifically to evaluate the applications for each RFA/PA initiative. Instructions for the review of applications submitted in response to an RFA/PA are made available to consumer participants at the time of review. The procedures are tailored to meet the requirements of the RFA/PA topic under review and the type of award mechanism being used.

Participating in NCI Peer Review

The second part of this *Consumers' Guide* will introduce you to the NCI peer review process and help you understand the rationale for including consumer advocates, define your role and the roles of various review group members and other attendees, outline details of the scientific merit review process, and describe standards of conduct to be followed. The peer review of applications for scientific and technical merit is essential for satisfying one of NCI's main objectives: the funding of excellent and high-impact science. You will be involved in the peer review of applications for NCI Cancer Centers, the NCI National Clinical Trials Network, and applications submitted in response to Requests for Applications (RFA) and Program Announcements (PA) for Program Projects, Specialized Programs of Research Excellence (SPOREs), and other special initiatives. During your participation in peer review, you should subordinate your own disease-specific interests and evaluate the broader issues of health. **It must be emphasized that the peer review process is extremely challenging.**

Overview of Peer Review

The dual peer review system of the NIH/NCI consists of two sequential levels of review mandated by statute. **The first (initial) level of review, which you will be a part of, is performed by an NCI Initial Review Group (IRG) subcommittee or a Special Emphasis Panel (SEP), whose primary function is to review and evaluate the scientific and technical merit of research grant/ cooperative agreement applications. The second level of review is for programmatic relevance and is performed by the National Cancer Advisory Board (NCAB).** Figure 4 illustrates the steps in the review process.

Figure 4. Review and Evaluation for Scientific Merit
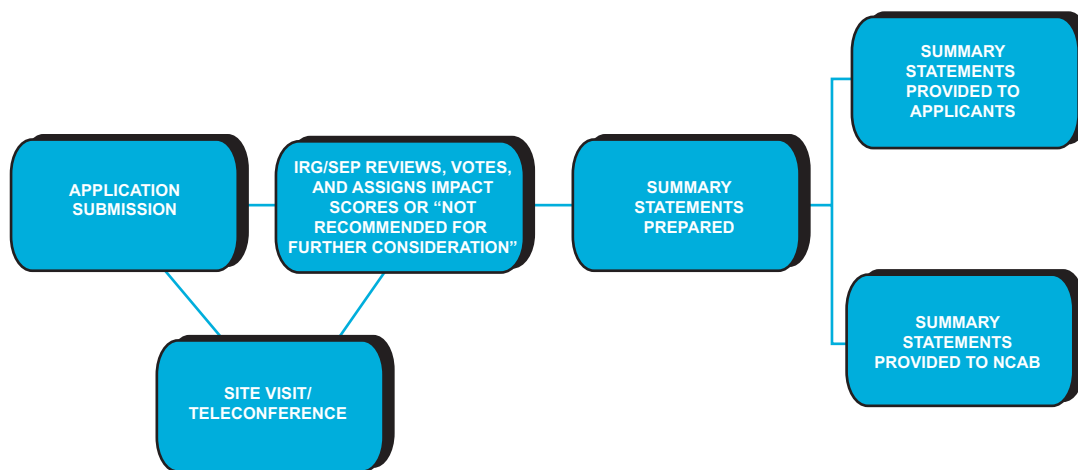
The administration of reviews by an NCI IRG subcommittee or a SEP resides in the Division of Extramural Activities (DEA), NCI. **The reviews are managed by Scientific Review Officers (SROs) in the Resources and Training Review Branch (RTRB), Research Programs Review Branch (RPRB), Special Review Branch (SRB), Research Technology and Contract Review Branch (RTCRB), and Program Coordination and Referral Branch (PCRB).**

The NCI has four specialized IRG subcommittees for review of a variety of applications and scientific areas. For example, **Subcommittee A** manages the review of Cancer Center Support Grant applications; **Subcommittee F** reviews Institutional Training and Education applications; **Subcommittee I** reviews Transition to Independence applications; and **Subcommittee J** reviews Career Development applications. In addition, *ad hoc* SEPs may be formed to review applications and cooperative agreements in response to specific RFAs and PAs. IRG subcommittee members typically serve for 4- to 6-year terms and attend multiple review meetings, whereas SEP members are appointed temporarily for individual review meetings. Consultants with special expertise also may be asked to serve temporarily on a site visit team for the evaluation of Cancer Centers conducted prior to the IRG subcommittee meeting. For each application, outcomes of the site visit discussions are summarized in a draft report that is presented to the IRG subcommittee for use in assessing merit of the application. **Your participation as a consumer in peer review will be associated with one of these IRG subcommittees or SEPs or as a member of a site visit (SV) team. In the discussion that follows, and for the sake of brevity, they will often be referred to as IRG, SEP, and SV teams.**

The review of Cancer Center applications and applications in response to RFAs and PAs for clinical Program Projects, National Clinical Trials Network (NCTN), and SPOREs requires participation of consumers and established scientists with substantial experience, both scientific and patient related; a broad perspective on cancer research, including both basic and clinical; and a high degree of scientific, organizational, and administrative sophistication. Breadth of knowledge is a necessary component of peer review groups. Many of the multi-component applications with interdisciplinary projects are scientifically detailed and technically sophisticated. The applications outline scientific questions, technical objectives, background information, preliminary data, and methods associated with the conduct of the proposed research in specialized scientific language. In addition, detailed budgets and research plans identifying project tasks, timelines, and defined milestones are included. The validity of the evaluative process rests largely with the skill of peer reviewers. Confidentiality is maintained throughout the entire evaluation process. Government-employed SROs are responsible for organizing and managing meetings for the scientific and technical review of the applications, as well as the selection of peer reviewers and the overall administration of the peer review process.

Because of the complexity and multidisciplinary nature of Cancer Center applications, the peer review of these applications usually involves an initial review meeting prior to a meeting of the full IRG Subcommittee A. This preliminary review may consist of a SV by reviewers to the applicant institution to evaluate various aspects described in the written application. The resulting SV report is then provided to the parent Subcommittee A to aid in their final deliberations. The vast majority of other applications are reviewed individually by either an IRG subcommittee or a SEP and do not involve a site visit.

Electronic Submission and Review of Applications

In 2005, the NIH began the process of transitioning to the electronic (in lieu of paper-based) submission of grant applications through **Grants.gov** (http://www.grants.gov), which is the Federal Government's online grant application submission portal. The DEA had a lead role in helping the NCI and its customers' transition to the current electronic submission of all types of grant applications.

The Electronic Research Administration (eRA) Internet-Assisted Review (IAR) system is a Web-based system to manage the process of electronic submission of critiques by reviewers. IAR expedites the scientific review of grant applications by standardizing the current submission process of critiques and initial impact scores by reviewers via the Internet. Reviewers are now able to electronically access applications under review and submit their critiques and view the critiques submitted by other reviewers prior to the actual meeting. As a result, review meetings will include more informed discussions because reviewers can read the evaluations entered by other reviewers prior to the review meeting (except where there is a conflict of interest). It also allows reviewers to update their critiques after the review meeting based on the discussion which occurred during the actual meeting. The SRO will provide you with instructions on the use of the IAR system prior to the review.

Composition of Review Groups

Members of an IRG subcommittee or a SEP are selected to review applications by matching their experience and expertise with the given topic areas of the application under review. Voting members of the group include:

- Chairperson
- Scientists
- Consumers
- Fiscal Consultants

In addition, the following Government employees participate in the review meeting to fulfill administrative and programmatic responsibilities in a nonvoting capacity:

- SROs
- Government Observers (Program Officers/Directors)

The qualifications and responsibilities of the various IRG or SEP members and other attendees are described in detail below.

1. Scientific Review Officer (SRO)

The SRO is an established scientist and serves as the Designated Federal Official (DFO) whose function is to serve as the overall IRG, SEP, or SV administrator. The SRO selects the Chairperson and the review members, orients the review members, administers the meeting, records application impact scores, and oversees the preparation of the summary statement for each application. In addition, the SRO assigns applications to scientific and consumer reviewers.

2. Chairperson

Chairpersons are highly qualified senior scientists and successful grantees, who offer extensive scientific leadership and research evaluation experience as peer review panelists. The Chairperson generally has broad expertise in a relevant scientific area and is responsible for reading all applications prior to the meeting and conducting the formal meeting proceedings. He or she may also serve as a reviewer on some of the applications. During the meeting, the Chairperson

leads the review group process and is responsible for ensuring that all applications receive a fair and competent review.

3. Scientists

Scientific reviewers are selected on the basis of their expertise in relevant areas and achievement as independent scientific investigators. They have extensive basic and clinical research experience, including experience in managing research programs. The IRG or SEP contains a mix of junior, mid-level, and senior scientists to provide a balance of established and emerging scientific perspectives. Most scientists will have previous experience serving in peer review, but some may not. They serve as primary and secondary reviewers.

4. Consumers

Consumers usually have firsthand experience, either as cancer survivors or relatives of cancer patients, or are active in cancer advocacy organizations. You have been selected on the basis of your involvement in the cancer experience; cancer advocacy experience; ability to communicate and advocate a position effectively; ability to think "globally" and to see beyond your personal experience; ability to work well in groups; and membership and active participation in a cancer-related advocacy and/or voluntary organization. Your presence as a representative of patient and public interests is intended to augment scientific merit review by providing the patient/public perspective, in addition to evaluations by scientists/clinicians, in the assessment of scientific excellence.

Although other participants are acquainted with their roles in the review process, as a new consumer member, you may not be. Your responsibilities are outlined as:

- Receive the same orientation material as any other reviewer.

- Read material carefully and review each project to be discussed.

- Vote, prepare written critiques as directed, participate actively in discussions, and present the patient perspective in discussion.

- Increase attention to outcomes and patient issues on the proposed research from the consumer perspective.

5. Fiscal Consultants

Individuals with a business or administrative background may serve on a review group to provide advice or answer questions regarding the business/accounting practices of the institution or issues, for example, related to charges/payment for patient care and testing and possible alternate sources of reimbursement (i.e., insurance coverage). They may vote or comment on relevant sections of the application.

6. Government Observers

Government observers are nonvoting NCI staff who observe the review proceedings. They have experience in a relevant scientific or clinical discipline and are usually the NCI staff person(s) who represent the scientific management and programmatic decision making process. These individuals are usually *Program Officers/Directors*, and in addition to observing the review proceedings, they sometimes make a brief presentation to the review members prior to the formal review of applications and are available and may be asked by the SRO during the review to answer questions about NCI's program goals.

Standards of Conduct in Peer Review

The fundamental goal of the peer review process is to provide a fair, unbiased, and independent expert review of scientific and technical merit of a grant application for consideration by the NCI and the NCAB. All participants must adhere to the highest standards of conduct to ensure that the credibility of this highly visible process and its participants are not compromised. The following discussion outlines each participant's responsibility in preserving the integrity of the peer review process.

Conflict of Interest in Peer Review

An unequivocal requirement of all participants is to avoid both actual conflicts of interest and/or the appearance of conflict. Conflicts of interest exist when a review member or close associate can be viewed as being in a position to gain or lose personally, professionally, or financially from an application under consideration. A composite list of applications, institution(s) of origin, and collaborators and their institutions will be sent to you well in advance of the actual peer review meeting, so that you may indicate any obvious conflicts in advance. If a concern about a previously unidentified conflict arises at the meeting, the participant must notify the SRO immediately in private. If it is determined by the SRO that a conflict of interest does indeed exist, the member must excuse himself/herself for the duration of proceedings for the given application and abstain from voting on that application.

There are two broad categories of conflict for review members:

- The member holds an appointment at the applicant institution. Please note that multiple campuses of a statewide university do not constitute a single institution.

- The member has a relationship with the applicant(s), which can include either personal or professional relationship(s). Examples of this category include the following:

  – A member is named in the application or expects to be invited to participate in the research in any way;

  – A member's spouse, parent, child, business partner, or close personal friend is either named in the application, or the member is aware that this person will be invited to participate in the research;

- A member and the primary investigator are actively collaborating in other research or have had a close professional relationship within the past 3 years (i.e., past collaborations, advisor-student, etc.);

- A member and a primary member of the applicant team have had longstanding professional disagreements that could be considered to affect the reviewer's objectivity; and

- There is the appearance that the member's evaluation of an application could have been influenced by prior actions of the PI or applicant institution.

It cannot be overemphasized that the reviewers themselves bear the responsibility to be vigilant in avoiding actual or apparent conflicts of interest.

Confidentiality in Peer Review

Prior to the review meeting, the NCI has assured all reviewers that their identity and associated review critiques are held in confidence. To provide for this assurance, applications, review materials, and meeting proceedings are for the sole use of reviewers and NCI staff. Any breach of confidentiality is considered unethical. Such unethical conduct has adverse effects on a reviewer's reputation and/or the reputation of his or her institution in addition to undermining the integrity of the peer review process. It may also preclude you from participating in the NIH peer reeview process. For these reasons, review members must adhere to the following practices:

- *Individuals serving as peer reviewers of grant applications and contracts are responsible for reading and agreeing to the "NIH Conflict of Interest, Confidentiality, and Non-Disclosure Rules and Information for Reviewers" and certifying that they have identified any conflicts of interest that might bias their review and that they understand the confidential nature of the evaluation. This information is provided to each reviewer as part of the review materials package and is certified by the reviewer and electronically signed by the reviewer on the IAR site prior to the review meeting*.

- *Applications under consideration and associated meeting deliberations are not to be discussed with anyone other than the SRO or other review members. This requirement applies at all times before, during, and after meeting deliberations. <u>Meeting deliberations</u> <u>and</u> <u>outcomes are not to be discussed following the meeting with anyone other than the SRO</u> <u>managing the review</u>.*

- *All applications and review notes should be brought to the meeting and left behind when the meeting concludes. If these materials are stored on a personal computer, all review-related files should be deleted at the conclusion of the review.*

- *Questions from applicants or representatives of applicant institutions are to be referred to the SRO.*

- *It is inappropriate to consult professional friends or colleagues for assistance in understanding any application.* For technical assistance, you must consult the SRO.

Cooperation in Peer Review

The peer review process brings together reviewers with different perspectives in the pursuit of a common goal: namely, to identify highly meritorious science that promises to make significant strides in the fight against cancer. It is therefore essential that a spirit of teamwork and cooperation prevail during the review process. Scientists have been informed of consumer participation, understand the role of consumer participants, and have been apprised of the fact that consumers are full and recognized peer review members deserving the utmost respect. On the other hand, consumers must respect the expertise of scientists and acknowledge their fundamental commitment and invaluable contribution to those afflicted with cancer. Attention to these issues is critical for maintaining an atmosphere of mutual respect during the discussions that can occur in peer review. Please keep these considerations in mind.

Assistance for New Consumer Committee Members

Consumers new to the review process may experience some challenges associated with participation in the review-related activities. The most fundamental issue may be the specialized nature of scientific knowledge and its associated jargon. Although it is impossible for anyone to become an expert in a given field of science overnight, you have been chosen to participate in part on the basis of your demonstrated interest in cancer advocacy and in cancer research. Such involvement has likely produced a familiarity with many keywords and phrases of scientific jargon. ***To assist you, a listing of websites for information, a dictionary of frequently used technical terms, and a list of abbreviations are provided in Appendices B and C.***

To further assist you in preparing for your assignment, the SRO will be available as a primary source for specific questions or additional information. As a further aid to you, the SRO and the Office for Advocacy Relations can link you with other consumer advocates who have previously served on peer reviews. The SRO also can provide you with the names of scientific mentors to answer questions of a scientific nature and the preparation of reviews. As the meeting progresses, you are encouraged to develop a sense of confidence and autonomy. The SRO will conduct a follow-up debriefing with you to determine how you view the review experience and what steps can be taken to make the process more efficient.

Registration Process for Reimbursement of Travel Expenses

The NIH requires reviewers to register in eRA Commons to access a secure payment system—the Secure Payee Registration System (SPRS) for reimbursement of travel expenses and honoraria. Information on booking travel to the review meeting through World Travel Service (WTS) will be provided to reviewers in the Meeting Fact Sheet. Based on the reviewer's preferred itinerary, WTS will provide the most cost- and time-efficient routing and scheduling options available. Lodging and transportation (airline, railway, or personal automobile) costs are paid directly by the NIH, whereas reviewers are reimbursed for ground transportation and incidentals by a flat rate reimbursement. Reviewers who participate in a review in person or via teleconference will receive an honorarium of $200 per day.

Criteria for Review of Applications

To ensure stringent and fair review of applications from institutions applying for NCI grant support, the DEA provides Review Guides with specific review criteria for scientific reviewers and consumers participating in a site visit (SV), IRG, or SEP to consider in evaluating the merit of the various applications. Reviewers will score applications using a scoring scale of 1 to 9 to assign scores to the individual review criteria and a final impact score. The Review Guides are part of the review package you will receive prior to the review. Instructions for the review of applications submitted in response to an RFA or PA are also made available to consumers prior to the review. The SRO also will orient you on how to assign a final impact score to an application based on your evaluation, the other reviewer's critiques/evaluations, and the review criteria.

Pre-Meeting Activities for Peer Review

Consumers may be assigned sections of applications and asked to comment on areas that fall within their expertise, in addition to evaluations made by scientists/clinicians. These include:

- Factors that may affect study design;
- Feasibility of plans for recruitment/retention and follow-up of subjects;
- Feasibility of protocols with specific populations (e.g., complexity, compliance);
- Clarity and patient acceptability of protocols;
- Adequacy of consent forms;
- Feasibility of protocols in the context of total patient care;
- Cultural and socioeconomic aspects of protocol implementation;
- Outreach and special challenges (e.g., need for multicultural staff);
- Community Advisory Board (e.g., composition and role);
- Ethical issues;
- Human subject protection;
- Inclusion of women/minorities/children in clinical trials; and
- Areas of individual special expertise.

As soon as you receive the review materials, you should promptly attend to the travel and electronic reimbursement registration (SPRS), and ensure that you have everything needed for the meeting and review of the applications. Immediately upon your acceptance to participate in the site visit/telephone conference/or face-to-face review meeting, the SRO will electronically send to you a Meeting Fact Sheet describing the time and place of the review; instructions about making travel arrangements to the site of the review and hotel reservations at that location; a copy of the Review Guide for the type of application under review; and a password-protected listing of key personnel involved in the applications(s) under review. Approximately 3 to 6 weeks prior to the review, the SRO will activate you in the NIH electronic Internet-Assisted Review (IAR) system, which provides you access to a variety of review-related documents. These documents include a form for you to electronically sign confirming and certifying that you understand the confidential nature of the review and have no conflict of interest in participating in the review; a list of the other reviewers; a fillable critique template to be used

to submit evaluations; and a listing of reviewer assignments indicating which reviewers are responsible for the initial detailed evaluation of each individual application or component of an application. More detailed instructions will be given on the use of the IAR process by the SRO.

In view of the size and complexity of the applications, it is important to begin reviewing these materials as soon as possible after their receipt. New reviewers should read the enclosed Review Guide to understand the criteria by which the application(s) is to be evaluated. It is suggested that all reviewers read the general introductory sections of the application(s) to provide a background perspective, and then focus their attention on the areas assigned to them in the assignment sheet.

Normally, each application or component of an application is assigned to at least three scientific reviewers. These scientific reviewers are responsible for conducting a detailed review of the application and for developing detailed written critiques. The critiques outline the strengths and weaknesses of the proposed research and comment on how the proposed work addresses the relevant evaluation criteria. *Prior to the meeting, assigned reviewers prepare preliminary reports for their assigned application or components of the application, and if applicable, post them on the IAR system. Any changes and corrections based on the information obtained from either following a presentation by the applicant or discussions at the review meeting can subsequently be made.* Review members may provide specific comments on portions of an application not specifically assigned to them during the discussion. Informed comments, as part of the discussion on any additional components, are welcomed and encouraged.

As a consumer reviewer, you need to read your assigned application sections in detail, and you may be asked to provide specific comments during review proceedings. You may skim sections containing technical details, such as laboratory procedures, statistical analyses, and budget requests. You may be asked to submit your comments in written form at the conclusion of the discussion, and you should be prepared, if requested, to present your comments orally in summary form during the review meeting. It should be emphasized that you are not expected to provide detailed scientific critiques in the manner of primary and secondary scientific reviewers, although you may comment on scientific and budgetary issues as desired. Your comments will be most helpful in addressing specific issues, such as outcomes and impact on patients. *If you have any questions or concerns, or require additional information and clarification, please contact the SRO.*

As you review applications, you should consider the following questions:

- *Is the proposed research applicable to cancer in terms of some or all of the following: prevention, cause, detection, treatment, care, quality of life, and/or other pertinent issues?* Describe and explain strengths and weaknesses.

- *Assuming the proposed research is scientifically sound, is it applicable in the near term, or does it lay groundwork for addressing cancer issues in the future?* Explain.

- *Based on your knowledge and experience with cancer, are there any concerns you have with this application?* Be specific.

- *Given your experience with cancer, are you aware of any scientific information specifically relevant to the application under discussion?* If so, please provide.

You may, in some instances, qualify your comments by stating, "The science is unfamiliar to me, but from a consumer's point of view…."

Procedures for Reviews with a Site Visit (SV)

For Cancer Centers, the purpose of the initial SV is to clarify unclear issues identified in the written application and gather additional information for use by the full Subcommittee A IRG in their final evaluations. The information may relate to suitability of the facilities for the work proposed, nature and depth of individual components and interdisciplinary studies, or other aspects of these large, multi-component applications. Depending on the size and scope of the application and the information to be gathered, the SV review team usually consists of 10 to 25 scientific experts, including members from the parent IRG Subcommittee A, a fiscal consultant, and a consumer advocate. SV review meetings typically last from 1 to 3 days, with time spent meeting at a hotel and a visit to the applicant institution. Although the details for these meetings may vary somewhat for each review, and each application may differ, the general procedure is described below. **SVs are often very rigorous and demanding.**

A SV review consists of executive sessions at the hotel or conference center where review members and NCI staff meet to discuss the application and formal sessions held with the applicant onsite at the institution, or by teleconference at the hotel. Generally, the dress at the executive sessions is informal, while business dress is the rule for meetings held with the applicant(s) at the institution.

You should plan to arrive at the hotel in time to have dinner prior to the start of the executive session, which is usually in the evening. At this session, the SRO provides an orientation to the review process and the specific plans and issues for the individual review. Rules and regulations to ensure confidentiality are discussed, and reviewers are asked to affirm their understanding and acceptance of the rules regarding confidentiality and conflict of interest. The bulk of this session is devoted to discussion by the reviewers of the general strengths and weaknesses of the application(s), the individual components, and, more particularly, the issues for discussion with the applicant and the areas where additional information will be sought from the applicant. The evening executive session usually lasts for 3 to 4 hours.

The SV at the institution consists of presentations by the Principal Investigator of the application and members of the applicant team on the science and technical aspects of the application with time allotted for questions on all topics of the application by reviewers. The length of these SV presentations varies depending on the size and complexity of the application, but they generally begin early in the morning. The applicant is instructed to leave adequate time for questions by all of the reviewers. It is essential that reviewers have the opportunity to have their questions answered. Sufficient time also should be available, if necessary, for visiting the site of the research activity and the facilities utilized in its completion. *If the review is conducted using a teleconference, then the format is limited to question-and-answer exchanges between the applicants and reviewers to clarify specific points identified in the written application.*

After the face-to-face or teleconference meeting with the applicants, the review team returns to the hotel and begins to evaluate the application(s) and to address the merit of each component, in light of the formal review criteria for the funding mechanism. Special attention is directed to changes, if any, in the reviewers' preliminary evaluation based on the additional information obtained from the applicants during the reviewers' visit to the applicants' facilities. After thorough discussion by assigned reviewers and other members of the team, reviewers evaluate and score each individual component of the application. Budgetary recommendations also are discussed and voted upon. After all the components are rated, the merit of the overall application is discussed. SV teams do not vote on overall numerical impact scores for the entire application but make evaluative comments on the overall merit of the application for transmission to the full IRG in the form of a report.

Following the round-table discussion of the application, the assigned primary reviewers prepare their individual reports that incorporate the consolidated views of the review team. It is essential that the individual reports represent the consensus of the entire review team, not just the opinions of the report writer.

A final session is devoted to a read-back of all or some of the individual reports, as well as the overall critique of the entire application. This is not a *pro forma* exercise; rather, it is important that each member of the review team listen carefully to the reports being read to ensure that they are accurate in fact and tone and reflect the consensus views and vote of the entire team.

Comments and corrections are encouraged toward that end. The reports on the individual components are compiled by the SRO into the draft SV Report for distribution to the full IRG. The applicant also receives a copy of this draft report and may provide factual corrections or comments for consideration by the IRG, but not appeals for change in the rating or budget recommendation.

At the end of the final review session, reviewers are asked to leave the application and all unpublished materials with the SRO to ensure that they remain confidential. Members are asked to plan their trips home to allow their attendance at the full final session.

Subcommittee A IRG Review Meeting Procedures Following a Site Visit (SV)

For Cancer Center Support applications, the draft SV reports are presented to the full Subcommittee A IRG, which usually meets in the Washington, DC, area. The meeting will begin with an orientation by the SRO, including an overview of specific instructions and meeting policies and procedures. As part of this orientation, the SRO defines the role of consumer(s) and introduces the consumers to the IRG. The consumers will have seats assigned at the table with the other IRG members. The NCI staff member (Program Officer) from the extramural program responsible for the applications to be reviewed is usually present and can be called upon by the SRO for objective background information and clarification of the Guidelines for the type of application under review.

The role of the IRG is to evaluate the applications and to judge the extent to which each applicant has promoted and/or is likely to promote excellence in research that may lead to a

reduction in the incidence, morbidity, and mortality attributable to cancer. Reviewers also will evaluate how well the Cancer Center leadership and administration have facilitated scientific productivity, strengthened research capabilities, and enabled investigators to take advantage of scientific opportunities over and above what likely would have taken place without the support requested. In other words, the IRG will make judgments on the scientific merit and the value-added features of the application. This is a particularly important role of the IRG, as its members may have more experience with the specific type of applications being reviewed than the members of the SV team.

The responsibilities of the IRG include:

- Ensuring equitable, uniform review standards for all applications in a review cycle;

- Serving as the corporate memory for reviews;

- Ensuring uniform treatment across review cycles;

- Ensuring compliance with the review criteria;

- Ensuring that the SV team appropriately dealt with the review criteria;

- Looking at overall application merit in perspective;

- Correcting any deviation by SV teams from review criteria or uniform treatment; and

- Assigning the impact score for the application.

In the case of Cancer Center applications, the SV Report serves as the basis of discussion with input from the permanent IRG members and temporary external consultants who participated in each SV providing assistance in the full IRG in its deliberations. Copies of the draft SV Report are provided to the applicant, who may submit corrections to factual errors in the report or comments, but not appeals for change in the rating or budget recommendation or the submission of new material. Parent IRG subcommittee members and selected consultants who attended the SV are assigned sections of the report to present and represent the views of the entire SV team. Assigned reviewers are asked to briefly summarize the evaluations of the SV team and provide the merit ratings given. They also provide input on the SV team's opinions on the overall merit of the application. Because it can be assumed that all IRG members have read the SV Report, the oral reports should only summarize the written material, not reiterate it in full. It is the role of those reporting to the full IRG to present the consensus view of the SV team, not their own views. Summary vote sheets are provided to the IRG listing the votes on each item.

It is the responsibility of the SRO to ensure that the written description of particular sections in the SV Report conforms to the numerical or adjectival ratings provided by the SV team. However, if the parent IRG believes that the narrative is not consistent with the numerical and/or adjectival descriptor given to the application, either too good or too bad, both the numerical rating and/or the written critique may be revised in response to comments of the IRG members and temporary SV members, which serve as a basis for the changes. The individuals reporting to the parent IRG should act as proponents of the SV team's views, not of the application under review.

All participating IRG members, both permanent and temporary, will make the final evaluation on each component of the application. However, unless there is significant disagreement, it will

be assumed that the evaluation in the SV Report stands and that individual components are not re-voted. On occasion, there may be differing opinions expressed, and when a vote is taken, a minority opinion will be included in the summary statement if at least two voters dissent from the majority on an evaluation. There also may be instances where new material was supplied after the initial SV. In this case, the new information will be discussed by the IRG to ensure a more thorough review and final evaluation of the application. Unless there is comment on the budget suggestions, the budget remains as recommended by the SV team.

Following a discussion of each application, the IRG Chairperson will ask IRG members to record their merit scores on their individual scoring sheets. Temporary members, including consumers, also will vote an impact score on those applications in whose discussion they participated. Each application is scored in its own right and not in comparison to other applications under consideration. Reviewers will score the applications using a scoring scale of 1 to 9 to list their final impact score. If a member of the IRG is at major variance with the primary and secondary reviewers as to the merit of the application under discussion, it is important for that person to make his/her opinions known to the full IRG. All members will be oriented by the SRO regarding the details of the scoring scale prior to the meeting.

After the discussion of each application, reviewers are asked to place all review-related materials to the application in boxes or bags for disposal in a manner that assures the confidentiality of the grant application materials. This often results in the tossing of materials into boxes located near the table at which the reviewers are seated. This is not meant as any disrespect for the work involved in preparing the application, but is a method for efficiently disposing of these materials.

Following the review meeting, a summary statement will be prepared by the SRO for each application as an official record of the review. This summary will consist of a resume and summary of discussion briefly describing the application and summarizing the recommendations of the IRG, a final impact score, a budget recommendation, the applicant's description, and the edited consensus reports.

Review Meeting Procedures with Only an IRG or SEP Meeting

Aside from Cancer Center applications, most other applications are reviewed only with an IRG subcommittee or Special Emphasis Panel (SEP) meeting. For example, applications for Institute Training and Education, Transition to Independence, and Career Development are reviewed by a specific IRG subcommittee or SEP. Applications submitted in response to RFAs and PAs, such as SPOREs and Program Projects, are reviewed by a specially constituted SEP based on the subject matter of the applications. **On very rare occasions, a teleconference between review panel members and the applicant may be used for clarification of issues.** Following an orientation, the SRO will provide an overview of specific instructions, meeting policies, and protocols for the group of applications being reviewed.

The review of individual applications is conducted sequentially as follows:

- To focus the discussion of the IRG/SEP on the most meritorious projects of an application, the process of expedited review may be used. In this process, the Chair of the IRG/SEP will determine from the preliminary evaluations of reviewers assigned to application components whether the individual sections are meritorious. If the application is determined to be meritorious, a complete review is conducted. On the other hand, if the application is determined to lack significant merit, then an expedited review is given, wherein the application is not discussed formally at the review meeting. The conditions in which an application is deemed to be of lower merit will be provided by the SRO.

- The primary reviewer will briefly describe the proposed work and cogently discuss the evaluation of its strengths and weaknesses. This discussion will address the appropriate evaluation criteria, include comments on human/animal subjects and associated risks where warranted, and state the rationale for the recommended merit score.

- The subsequent reviewers will provide a summary of his/her critique, elaborating on specific areas of agreement or disagreement with the primary reviewer's critique and offering his/her own novel critical observations. She/he also will recommend a merit score.

- The consumer advocate will provide a concise summary of his/her comments, adding any major points not raised by the primary and secondary reviewers.

- The Chair will then open the meeting for a full IRG/SEP discussion of the application. Deliberations allow members to express their opinions about the merits of the application under consideration. Differences of opinion are not uncommon.

- The IRG/SEP discussion will be summarized by the Chair, who will ask the primary and secondary reviewers for their final recommended impact scores based on their comments and the comments made by the entire panel.

- The Chair will then ask members to record their merit impact scores on their individual scoring sheets, as well as electronically on the IAR site. Each application is scored in its own right and not in comparison to other applications under consideration. Reviewers will base their final impact score for the applications on five individual core criteria (significance, investigators, innovation, approach, and environment) using a scoring scale of 1 (highest) to 9 (lowest). Consistent scoring is important, but each member may vote as he/she sees fit. However, if a member of the IRG/SEP is at major variance with the primary and secondary reviewers as to the merit of the application under discussion, it is important for that person to make his/her opinions known to the full IRG/SEP so these comments can be incorporated into the final summary statement. All members will be oriented by the SRO regarding the details of the scoring scale prior to the meeting. Additionally, the detailed scoring scale will be posted in the meeting room for reference.

- After members have recorded their scores, the Chair will ask the primary and secondary reviewers for budget recommendations based on the requested direct cost budget. The recommendations will be discussed by all members to reach a final recommendation for a funding amount and project duration.

- After the meeting, a Summary Statement will be prepared by the SRO for each application as an official record of its review. This summary will consist of a resume briefly describing the project and summarizing the recommendation of the IRG/SEP, impact score, budget recommendation, the applicant's description of the project, and the minimally edited comments of the individual reviewers. The Summary Statements containing averaged scores are forwarded to applicants and to the NCAB and NCI staff for consideration and final action.

Final Comments

The foregoing discussion identifies the challenges facing any new reviewer. We at the NCI are excited about the continuing involvement of consumers in this rewarding and important experience. This process is evolving constantly and requires patience, commitment, and respect on the part of all participants. Although the responsibilities of all participants, whether consumer or scientist, are great, your responsibilities are particularly challenging as you enter this new arena. Because challenge is not unfamiliar to consumers who have exhibited courage in their fight against cancer and great initiative and responsibility in their involvement in advocacy, we anticipate that your involvement in scientific merit review will be as effective and vital as consumer involvement in other areas of the NCI research program. *We appreciate your enthusiasm in undertaking these efforts, congratulate you on your selection to participate, and wish you success in the endeavor.*

Appendices

Appendix A. Related Documents

DEA Annual Report
http://deainfo.nci.nih.gov

NCAB Orientation Book
https://deainfo.nci.nih.gov/advisory/ncab/orientationbook.pdf

BSA Orientation Book
https://deainfo.nci.nih.gov/advisory/bsa/orientationbook/orientationbook.pdf

NCI Budget Fact Book
http://www.cancer.gov/about-nci/budget/fact-book

Bypass Budgets
http://plan.cancer.gov

Cancer
http://www.cancer.gov

Clinical Trials
http://www.cancer.gov/clinicaltrials

Cancer Centers
http://cancercenters.cancer.gov/

Grants and Contracts
http://www.nih.gov/grants

NCI Division of Extramural Activities
http://deainfo.nci.nih.gov

NCI Office of Grants Administration
http://www.cancer.gov/about-nci/organization/oga

Surveillance
http://seer.cancer.gov

Grant Mechanisms and Descriptions
http://deainfo.nci.nih.gov/flash/awards.htm

Center for Cancer Training
http://www.cancer.gov/grants-training/training/about

Center for Scientific Review (CSR) Reviewer Resources
http://public.csr.nih.gov/reviewerresources/pages/default.aspx

NIH Grant Review Process YouTube Videos
http://public.csr.nih.gov/aboutcsr/contactcsr/pages/contactorvisitcsrpages/nih-grant-review-process-youtube-videos.aspx

eRA Video Series on Navigating the Internet Assisted Review (IAR)
http://public.csr.nih.gov/reviewerresources/toolsandtechnology/pages/newforreviewers IAR.aspx

Appendix B. List of Abbreviations

ACRIN..........American College of Radiology Imaging Network
AIDS.............Acquired Immune Deficiency Syndrome
ASSIST.........American Stop Smoking Intervention Study
BCSC...........Breast Cancer Surveillance Consortium
BSA.............Board of Scientific Advisors
BSC.............Board of Scientific Counselors
CALGB........Cancer and Leukemia Group B
CanCORS....Cancer Care Outcomes Research and Surveillance Consortium
CBIIT...........Center for Biomedical Informatics and Information Technology
CCCT..........Coordinating Center for Clinical Trials
CCOP..........Community Clinical Oncology Program
CCR.............Center for Cancer Research
CCSG..........Cancer Center Support Grant
CDC.............Centers for Disease Control and Prevention
CDP.............Cancer Diagnosis Program
CFR.............Code of Federal Regulations
CGCR..........Center for Global Cancer Research
CGN.............Cancer Genetics Network
CHTN..........Cooperative Human Tissue Network
CIRB............Central Institute Review Board
CIS..............Cancer Information Service
CISNET........Cancer Intervention and Surveillance Modeling Network
CIT...............Center for Information Technology
CMO............Committee Management Office
CMS............Centers for Medicare and Medicaid Services
CNP.............Community Networks Program
COG............Children's Oncology Group
COI..............Conflict of Interest
COMMIT......Community Intervention Trial for Smoking Cessation
CRN.............Cancer Research Network
CSR.............Center for Scientific Review
CTAC...........Clinical Trials and Translational Research Advisory Committee
CTEP...........Cancer Therapy Evaluation Program
CTROC........Clinical and Translational Research Operations Committee
DCB.............Division of Cancer Biology

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
DSMB..........Data Safety and Monitoring Board
DSSC...........Disease Specific Steering Committee
ECOG..........Eastern Cooperative Oncology Group
EDRN..........Early Detection Diagnosis Research Network
EORTC........European Organization for Research and Treatment of Cancer
eRA.............Electronic Research Administration
ETCTN.........Experimental Therapeutics Clinical Trials Network
FAR.............Federal Acquisition Regulations
FDA.............Food and Drug Administration
FNLAC.........Frederick National Laboratory Advisory Committee
FOA.............Funding Opportunity Announcement
FOIA...........Freedom of Information Act
GLP.............Good Laboratory Practice
GMP............Good Manufacturing Practice
GWAS.........Genome Wide Association Studies
HBCU...........Historically Black Colleges and Universities
HHS.............Department of Health and Human Services
HIPAA..........Health Insurance Portability and Accountability Act
HMO............Health Maintenance Organization
IACUC.........Institutional Animal Care and Use Committee
IAR..............Internet-Assisted Review
IC.................Institute or Center
IDSC............Investigative Drug Steering Committee
IND.............Investigational New Drug
IHS..............Indian Health Service
IOM.............Institute of Medicine
IRB..............Institutional Review Board
IRG.............Initial Review Group
IRP..............Intramural Research Program
LOI..............Letter of Intent

MARC ....Minority Access to Research Careers

MBCCOP .....Minority-Based Community Clinical Oncology Program

NCAB ....National Cancer Advisory Board

NCCCP ....NCI Community Cancer Centers Program

NCCTG ....North Central Cancer Treatment Group

NCI ....National Cancer Institute

NCORP ....NCI Community Oncology Research Program

NCRA ....NCI Council of Research Advocates

NCTN ....National Clinical Trials Network

NDA ....New Drug Application

NEXT ....NCI Experimental Therapeutics

NHGRI ....National Human Genome Research Institute

NIAID ....National Institute of Allergy and Infectious Diseases

NIGMS ....National Institute of General Medical Sciences

NIH ....National Institutes of Health

NSF ....National Science Foundation

OAR ....Office of Advocacy Relations

OBBR ....Office of Biorepositories and Biospecimen Research

OCG ....Office of Cancer Genomics

OFACP ....Office of Federal Advisory Committee Policy

OGA ....Office of Grants Administration

OHAM ....Office of HIV and AIDS Malignancy

OHRP ....Office of Human Research Protections

OIA ....Outstanding Investigator Award

ORI ....Office of Research Integrity

P01 ....Program Project Grant

P30 ....Cancer Center Support Grant

P50 ....Specialized Center Grant

PA ....Program Announcement

PBTC ....Pediatric Brain Tumor Consortium

PCOS ....Prostate Cancer Outcomes Study

PCP ....President's Cancer Panel

PCPT ....Prostate Cancer Prevention Trial

PCRB ....Program Coordination and Referral Branch

PD/PO ....Program Director/Program Officer

PDQ ....Physician's Data Query

PI… ....Principal Investigator

PMI ....Precision Medicine Initiative

PNRP ....Patient Navigation Research Network

PRG ....Progress Review Group

PRMS ....Protocol Review and Monitoring System

QCCC ....Quality Cancer Care Committee

QOC ....Quality of Care

QOL ....Quality of Life

R01 ....Research Project Grant

R03 ....Small Grant

R21 ....Exploratory/Developmental Grant

R35 ....Outstanding Investigator Award Grant

R50 ....Research Specialist Award

RePORT ....Research Portfolio Online Reporting Tool

RFA ....Request for Application

RFI ....Request for Information

RPRB ....Research Programs Review Branch

RTCRB ....Research Technology and Contract Review Branch

RTRB ....Resources and Training Review Branch

SAMHSA ......Substance Abuse and Mental Health Services Administration

SBIR ....Small Business Innovative Research Program

SEER ....Surveillance, Epidemiology, and End Results Program

SEP ....Special Emphasis Panel

SIC ....Special Interest Category

SPL ....Scientific Program Leaders

SPORE ....Specialized Program of Research Excellence

SPRS ....Secure Payee Registration System

SRO ....Scientific Review Officer

SRB ....Special Review Branch

STTR ....Small Business Technology Transfer

SV/TC ....Site Visit/Teleconference

SWOG ....Southwestern Oncology Group

TARGET ....Therapeutically Applicable Research to Generate Effective Treatment

TCGA ....The Cancer Genome Atlas Project

TRP ....Translational Research Program

TTC ....Technology Transfer Center

U01 ....Cooperative Agreement

U10 ....Clinical Research Cooperative Agreement

U19 ....Research Program Cooperative Agreement

UM1 ....Complex Structure Cooperative Agreement

WHO ....World Health Organization

WTS ....World Travel Service

Appendix C. Websites of Interest

DEA WEBSITES

DEA home page. Includes links to individual DEA Web pages, the mission of the Division, and contact information for DEA staff.
http://deainfo.nci.nih.gov
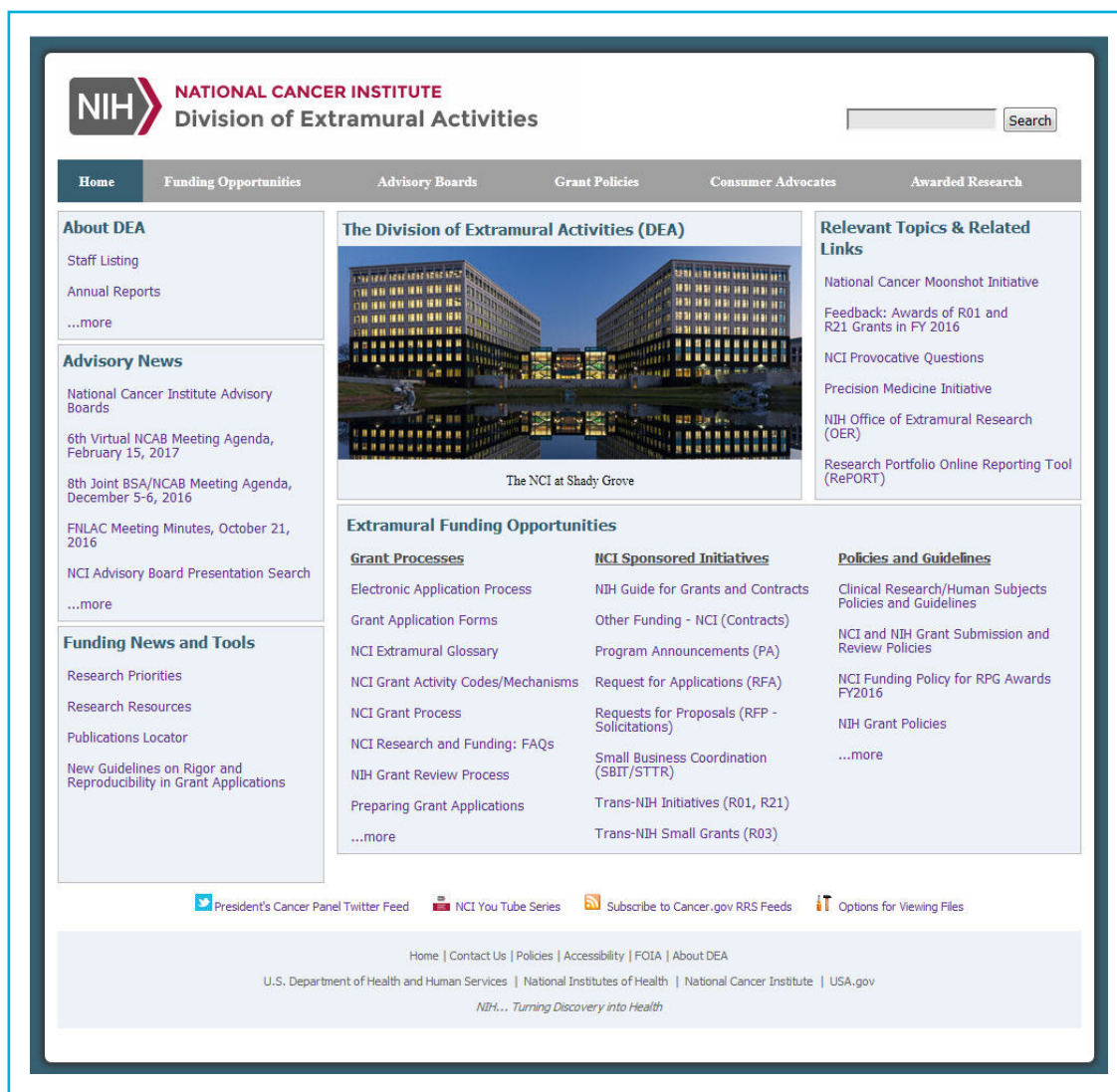
Extramural events and updates.
https://deainfo.nci.nih.gov

Contains links to the home pages of NCI's advisory boards.
http://deainfo.nci.nih.gov/advisory/boards.htm

President's Cancer Panel (PCP) charter; meeting agendas and meeting minutes; annual reports.
https://deainfo.nci.nih.gov/advisory/pcp/index.htm

National Cancer Advisory Board (NCAB) charter; rosters; meeting agendas, minutes, presentation slides.
http://deainfo.nci.nih.gov/advisory/ncab/ncab.htm

Board of Scientific Advisors (BSA) charter; subcommittee rosters; meeting agendas, minutes, presentation slides.
http://deainfo.nci.nih.gov/advisory/bsa/bsa.htm

Charter of the Board of Scientific Counselors (BSC), Clinical Sciences and Epidemiology.
http://deainfo.nci.nih.gov/advisory/bsc/cse/charter.pdf

Charter of the Board of Scientific Counselors (BSC), Basic Sciences.
http://deainfo.nci.nih.gov/advisory/bsc/bs/charter.pdf

Clinical Trials and Translational Research Advisory Committee charter, members, meeting information.
http://deainfo.nci.nih.gov/advisory/CTAC/CTAC.htm

Charter of the Initial Review Group (IRG); subcommittee rosters.
http://deainfo.nci.nih.gov/advisory/irg/irg.htm

Charter of the Special Emphasis Panel (SEP); rosters of recent meetings.
http://deainfo.nci.nih.gov/advisory/sep/sep.htm

Frederick National Laboratory Advisory Committee (FNLAC) charter, members, meeting information.
http://deainfo.nci.nih.gov/advisory/fac/fac.htm

Charter of the NCI Council of Research Advocates; meeting schedules, agendas, minutes, and meeting summaries.
http://deainfo.nci.nih.gov/advisory/ncra/ncra.htm

Links to grant-related NCI and NIH policies, such as guidelines on the inclusion of women and minorities in clinical trials and instructions for evaluating research involving human subjects.
http://deainfo.nci.nih.gov/grantspolicies/index.htm

Comprehensive information about funding for cancer research; lists of active PAs and RFAs; grant policies and guidelines; downloadable application forms.
http://deainfo.nci.nih.gov/funding.htm

Active PAs, with links to detailed descriptions.
https://grants.nih.gov/Grants/guide/search_results.htm?year=active&scope=pa

Active RFAs, with links to detailed descriptions.
https://grants.nih.gov/grants/guide/search_results.htm?year=active&scope=rfa

Grants Guidelines and Descriptions (descriptions of NCI funding mechanisms, with links to Program Announcements, RFAs, guidelines, and supplemental materials).
http://deainfo.nci.nih.gov/flash/awards.htm

NCI Glossary of Terms.
http://deais.nci.nih.gov/glossary

NCI Dictionary of Cancer Terms
https://www.cancer.gov/publications/dictionaries/cancer-terms

NCI's Funded Research Portfolio database contains information about research grant and contract awards for the current and past 5 fiscal years. Searchable by text words in abstracts and by Special Interest Category (SIC) and anatomic site codes.
http://fundedresearch.cancer.gov

NCI WEBSITES

The NCI maintains numerous sites containing information about the Institute and its programs. All NCI websites, including those designed to provide cancer-related information to the general public and physicians, can be reached from the NCI home page.
https://www.cancer.gov

Descriptions of NCI's Divisions, Offices, and Centers.
http://www.cancer.gov/aboutnci/organization

NCI's website for the press, managed by the NCI Office of Media Relations; contains news and information on cancer research and NCI programs and resources.
http://www.cancer.gov/newscenter

A wide variety of information sources on obtaining funding for cancer research, including assistance in applying for grants; descriptions of NCI-sponsored research initiatives; review panel rosters and schedules; training opportunities; and links to other funding resources.
http://deainfo.nci.nih.gov/funding.htm

The essentials of the NCI grants process are available on this website.
http://www.cancer.gov/grants-training/grants-process

The Biorepositories and Biospecimens Research Branch is responsible for promoting a common biorepository infrastructure that promotes resource sharing and team science.
http://biospecimens.cancer.gov/researchnetwork/default.asp

Links to NCI's partnerships with the cancer research, advocacy, and support communities.
http://www.cancer.gov/researchprograms/partners

Technology Transfer Center (TTC). The NCI TTC's mission is to speed the progress of cancer research by encouraging development of new technologies and promoting scientific collaborations between the NCI and the private sector.
https://ttc.nci.nih.gov

The NCI Office of Advocacy Relations (OAR) uses a variety of methods to engage cancer research advocates in NCI activities.
http://www.cancer.gov/about-nci/organization/oar

The Cancer Moonshot initiative aims to make more therapies available to more patients, while also improving our ability to prevent cancer and detect it at an early stage.
http://www.cancer.gov/research/key-initiatives/moonshot-cancer-initiative

NCI'S CANCER INFORMATION WEBSITES

Links to a wide variety of NCI's Web-based information resources for health professionals and the general public.
http://www.cancer.gov/cancerinfo

A comprehensive resource for definitions of cancer-related terms, as well as links to additional online dictionaries of medical and health-related terms.
http://cancer.gov/dictionary

The NCI Contact Center, or Cancer Information Service (CIS), is a free public service providing accurate, up-to-date, and reliable information on cancer that is easy to understand. The Cancer Information Specialists respond to calls in English and Spanish and can be reached at 1-800-4-CANCER (1-800-422-6237). Hearing-impaired callers with TTY equipment may call 1-800-332-8615.
http://www.cancer.gov/contact/contact-center

The Cancer Trials website provides information and news about cancer research studies. The site is designed to answer basic questions about clinical trials; provide resources for people considering participating in clinical trials; help people learn what clinical trials are available; and publish current, accurate information about clinical trial results and advances in cancer care.
http://www.cancer.gov/clinicaltrials

The NCI Surveillance, Epidemiology, and End Results (SEER) Program is the most authoritative source of information on cancer incidence and survival in the United States. Information on more than 2.5 million cancer cases is included in the SEER database, and approximately 160,000 new cases are added each year within the SEER catchment areas.
http://seer.cancer.gov

The Cancer Mortality Maps and Graphs website provides maps, graphs, text, tables, and figures showing geographic patterns and time trends of cancer death rates for more than 40 cancers for the time period 1950–2004.
http://ratecalc.cancer.gov

NIH WEBSITES

National Institutes of Health home page.
http://www.nih.gov

NIH Research Portfolio Online Reporting Tool (RePORT).
http://report.nih.gov

Home page of the Office of Federal Advisory Committee Policy (OFACP). This site features downloadable guidelines, reference tools, and training materials. It also contains advisory committee membership lists; laws, regulations, and policies related to Federal advisory committees; and other resources.
http://ofacp.od.nih.gov

NIH Office of Extramural Research. Includes an overview of the grants process.
http://grants.nih.gov/grants/oer.htm

NIH Guide for Grants and Contracts for NIH grants and funding opportunities.
http://grants.nih.gov/grants/guide/index.html

NIH Center for Scientific Review.
http://www.csr.nih.gov

Definitions of NIH acronyms and glossary.
http://grants.nih.gov/grants/glossary.htm

eRA Commons is an online interface where grant applicants and Federal staff at NIH and grantee institutions can access and share administrative information relating to research grants.
http://commons.era.nih.gov/commons

The Center for Information Technology (CIT) makes special NIH events, seminars, and lectures available to viewers on the NIH network and the Internet from the VideoCasting website.
http://videocast.nih.gov

Information on electronic review of grant applications.
https://era.nih.gov/reviewer/index.cfm

Information on grants policy statements and notices, grant awards and NIH appropriations, policy resources, and other guidance resources.
http://grants1.nih.gov/grants/policy/policy.htm

Information on extramural training mechanisms.
http://grants.nih.gov/training/extramural.htm

The NIH Event Calendar is a scheduling system for cancer-related scientific meetings and events.
http://calendar.nih.gov

The NIH Precision Medicine Initiative Cohort Program will seek to extend precision medicine to all diseases by building a national research cohort of one million or more U.S. participants.
https://www.nih.gov/precision-medicine-initiative-cohort-program

PubMed comprises more than 26 million citations from Medline, life science journals, and online books.
https://www.ncbi.nlm.nih.gov/pubmed

GENERAL GOVERNMENT-RELATED WEBSITES

The official U.S. Government portal to 30 million pages of Government information, services, and online transactions. FirstGov offers a powerful search engine that searches every word of every U.S. Government document. The site also features a topical index, options to contact Government agencies, links to state and local agencies, and other tools, so the user does not have to know the name of the agency to get needed information.
http://usa.gov

The Centers for Disease Control and Prevention.
http://www.cdc.gov

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Notes

An electronic version of this document can be viewed and downloaded from the Internet at http://deainfo.nci.nih.gov/consumer.htm