National Cancer Institute

Division of Extramural Activities

THE NCI CONSUMERS' GUIDE TO PEER REVIEW

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Division of Extramural Activities

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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 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 Department of Health and Human Services. 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 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 first-hand experience as a cancer survivor or 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 decisionmaking process. ***Thank you for agreeing to participate in this very important process. Your views will be welcomed and respected.***

Division of Extramural Activities, NCI, NIH

The NCI and Its Research Programs

NCI Mission

The National Cancer Institute is committed to dramatically lessening the impact of cancer. The NCI is the primary means of support for America's cancer research enterprise, whether in its own laboratories or in our Nation's research universities. The NCI is dedicated to the understanding, diagnosis, treatment, and prevention of cancer for all people 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.

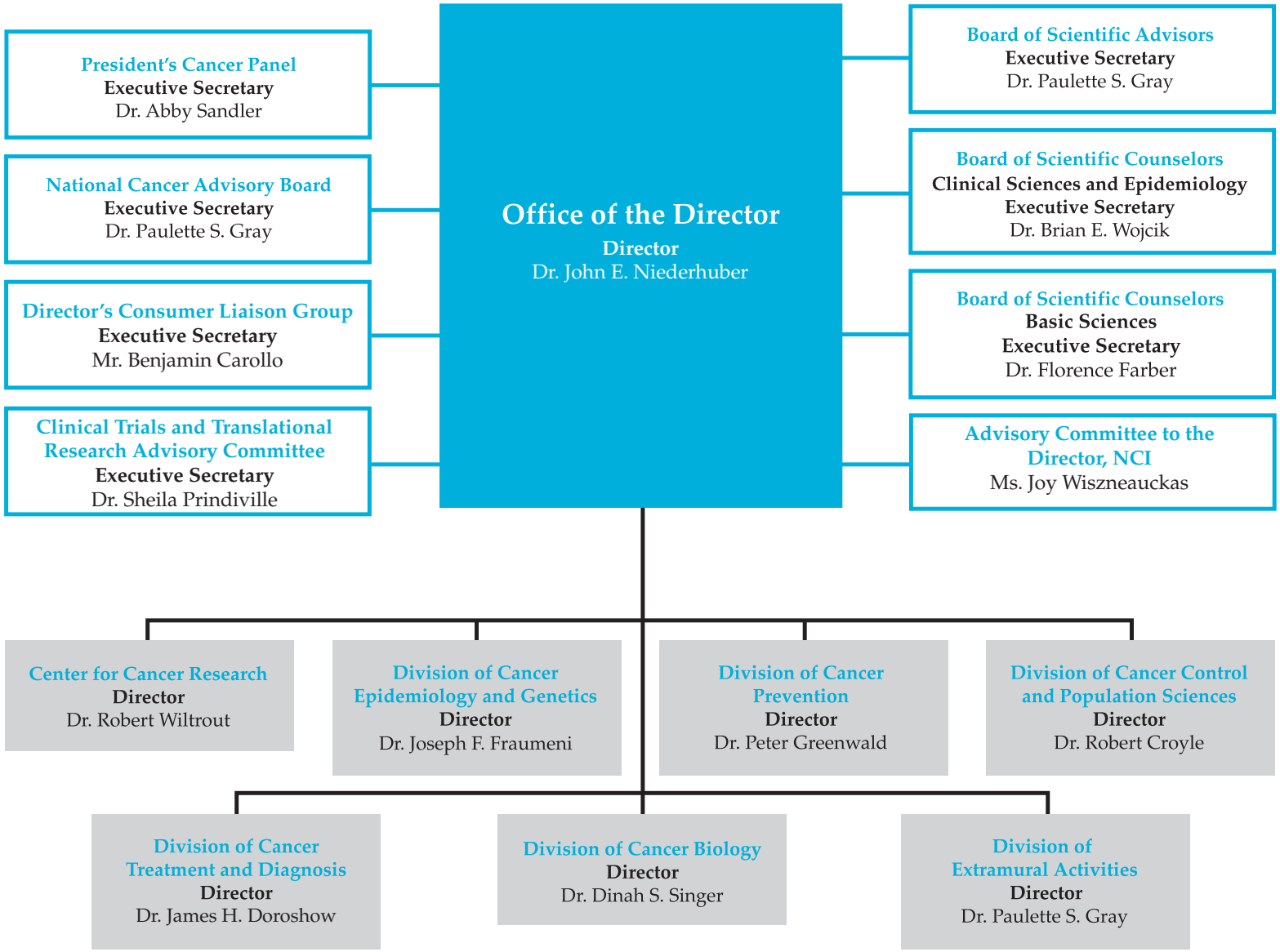
- Supports research projects in cancer prevention and control.
- Supports a national network of cancer centers.
- Collaborates with voluntary organizations and other national and foreign institutions engaged in cancer research and training activities.
- Encourages and coordinates cancer research by industrial 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.

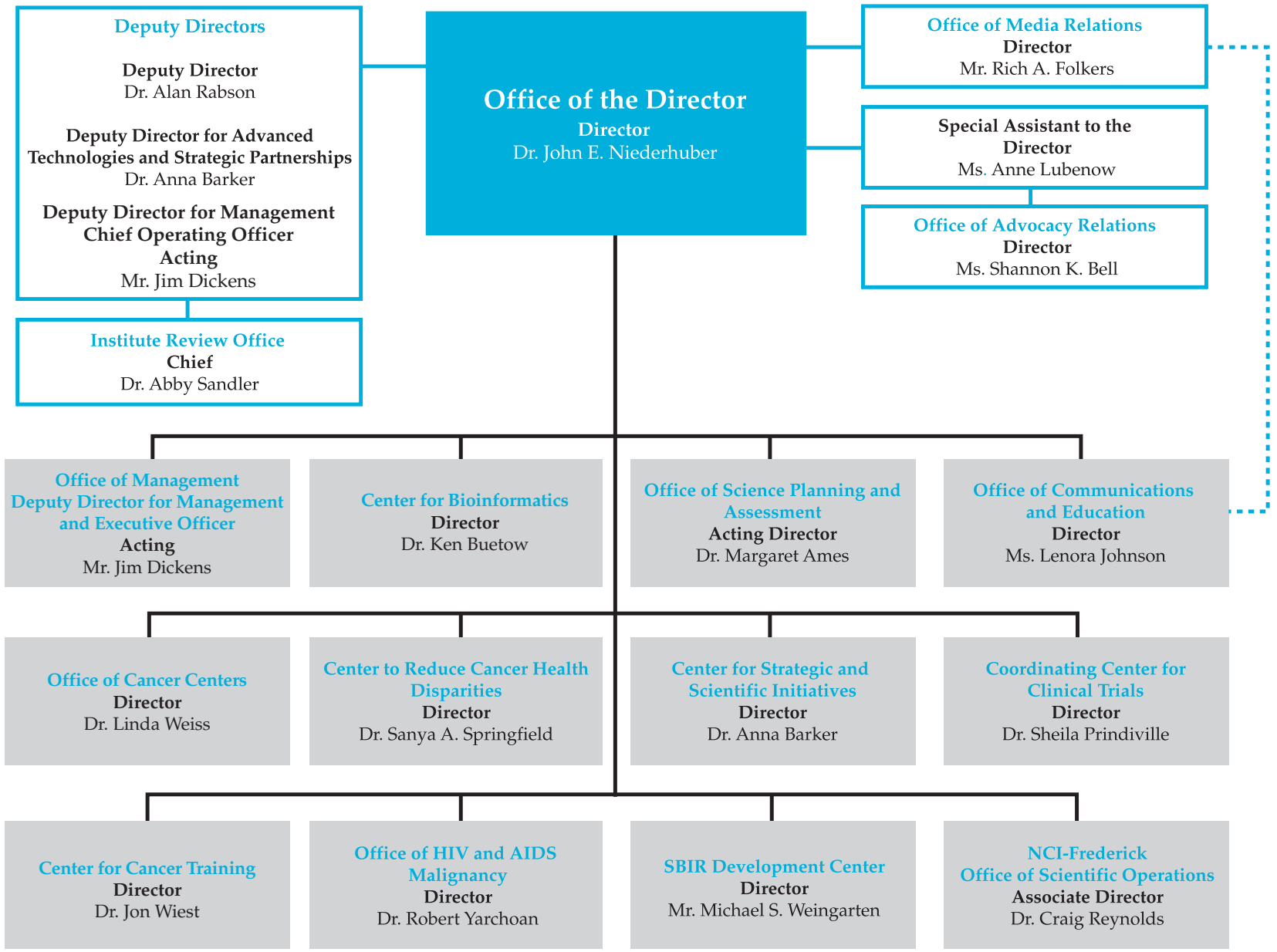
The current NCI organizational structure is shown in Figure 1. The Office of the Director serves as the focal point for the National Cancer Program with advice from several external advisory groups that include the President's Cancer Panel, the National Cancer Advisory Board, the Board of Scientific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

*Figure 1. The National Cancer Institute**



*Source: NCI Fact Book FY2008.

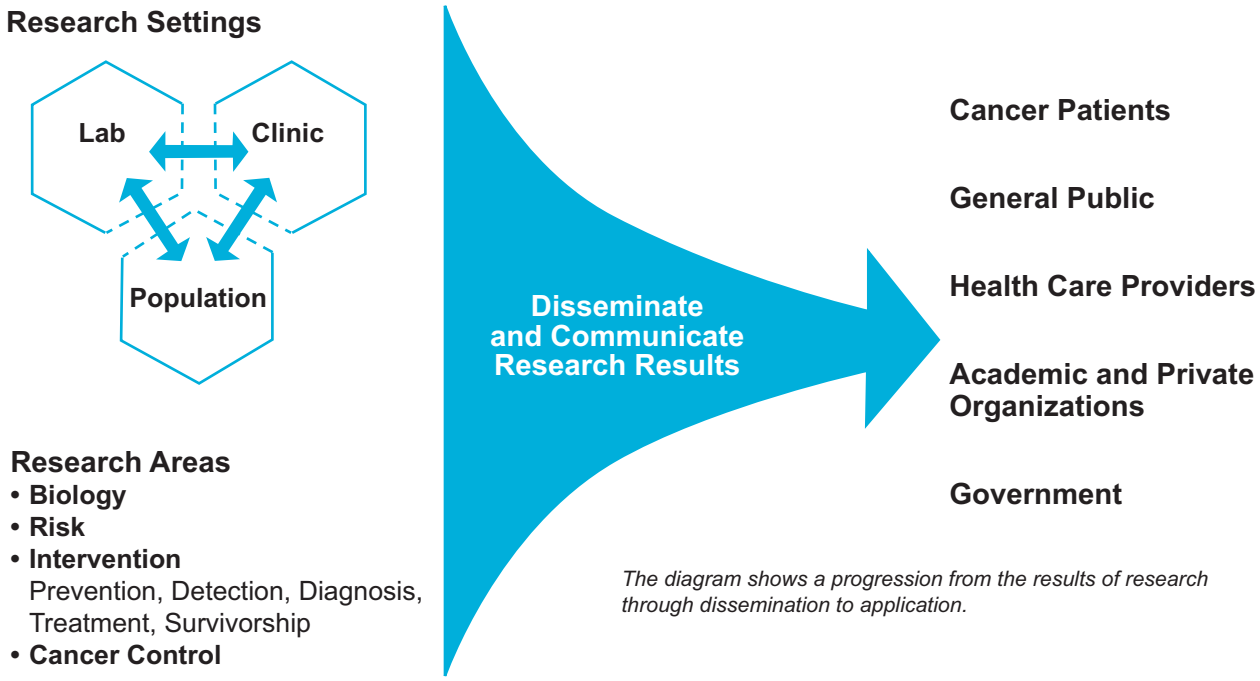
Figure 1. The National Cancer Institute (continued)



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 carried out in the areas of prevention, detection, diagnosis, treatment, and rehabilitation. In the community, population-based research is carried out on the causes, risks, predispositions, incidence, and behavioral aspects of cancer. Figure 2 shows the progression from the results of research through dissemination to application in the community.

Figure 2. Progression From Cancer Research to Applications in the Community



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 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 the most important component of NCI's research program; nearly two-thirds of the Institute's budget is devoted to extramural research project grants as well as research and development contracts.

Five extramural research Divisions, four 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 Center for Strategic and Scientific Initiatives; the Center to Reduce Cancer Health Disparities; the Small Business Innovation Research (SBIR) Development Center; the Center for Cancer Training; 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, administers the review of grants and contracts, codes and tracks NCI extramural research, and manages the functions of the National Cancer Advisory Board (NCAB) and the Board of Scientific Advisors (BSA).

Collectively, NCI extramural research project grants and contracts fund 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 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 applications that support clinical and population-based research and career development and training by grant or cooperative agreement mechanisms 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 Cancer Centers, Cooperative Groups, 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.

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 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. ***Specialized Programs of Research Excellence*** (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 **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 named 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, development of new research technology, etc.

- 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 the NCI and the 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 **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 Clinical Trials Cooperative Groups and the Cancer Community Oncology Program (CCOP) are funded by U10 cooperative agreements.***

- The **U54 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 Minority Institution/Cancer Center Partnerships 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.

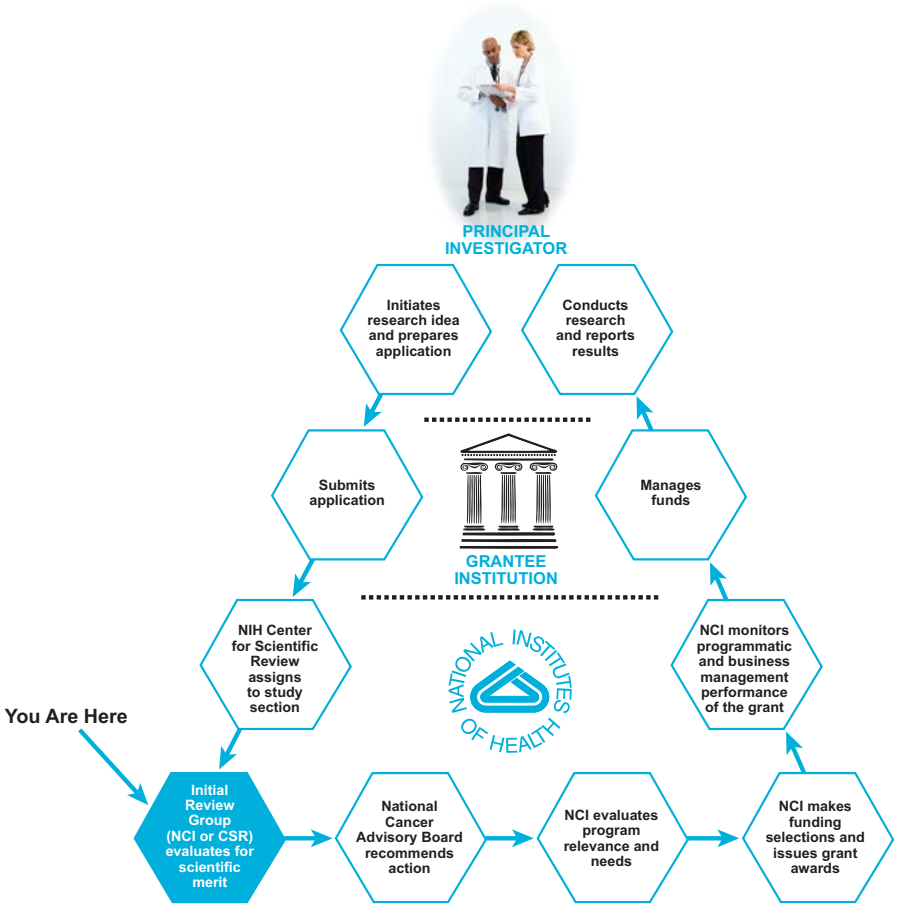
- The **Principal Investigator (PI)**, or Project Director/Principal Investigator (PD/PI) is defined as the individual(s) judged by the applicant organization to have the appropriate level of authority and responsibility to direct the project or program supported by the grant. The applicant-grantee institution 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, 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 the Grants Administration Branch Web Site at http://www3.cancer.gov/admin/gab/.

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 assistance mechanisms, which are used to support and stimulate research, 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 publication deals only with grants and cooperative agreements because these are the mechanisms used to fund extramural clinical and population-based research and 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 National Cancer Advisory Board (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.

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.

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

NCI Initial Review Group (IRG). The IRG, composed of six chartered subcommittees, reviews grant and cooperative agreement applications for cancer centers, cooperative group research projects, 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 4 years or as "temporary" members with all the rights and obligations of 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 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 Executive Committee. The NCI Executive Committee, which includes NCI division and center directors and other key senior NCI advisors to the NCI Director meets regularly to make major policy, funding, and operating decisions for the Institute.

Advisory Committee to the Director (ACD). The ACD serves as the official channel through which findings and recommendations of various planning and advisory groups are submitted to the NCI leadership for consideration.

Director's Consumer Liaison Group (DCLG). In 1997, the NCI established the first all-consumer advisory committee at the NIH. The Director's Consumer Liaison Group (DCLG) consists of 16 consumers selected through a national nomination process. This diverse group represents the face of cancer consumer advocacy across the United States. The three-fold purpose of the DCLG is to:

- Serve as a primary forum for discussing issues and concerns and exchanging viewpoints that are important to the broad development of NCI program and research priorities from a consumer perspective,

- Help develop and establish processes, mechanisms, and criteria for identifying appropriate consumers to serve on a variety of NCI program and policy committees, and

- Establish and maintain strong collaborations between the NCI and the cancer advocacy community to reach common goals.

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 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 Nation, 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 DCLG, created the **Consumer Advocates in Research and Related Activities (CARRA) Program** so that the consumer perspective can be incorporated into NCI programs and activities. The CARRA program, 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. Recently, 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 Cancer Centers, Cooperative Groups, Community Clinical Oncology Program, 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 members of special underserved population groups, is a high priority for the Institute. Several programs help ensure that all populations are well represented. The Minority-Based Community Clinical Oncology Program, 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. Grant programs have been established to support research on ways to include more women and minority participants in cancer prevention and screening studies. The

Institute 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/programs-resources/programs/ccop**.

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 prove 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 phases:

- **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-five research-oriented institutions throughout the Nation have been designated 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 Clinical 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 an 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 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 a ***Comprehensive Cancer Center***, 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.

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://cancercenters.cancer.gov**.

Clinical Trials Cooperative Group Program

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 Clinical Trials Cooperative Group Program, a national network consisting of a number of consortia (cooperative groups) 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. Cooperative Groups consist of researchers at separate institutions affiliated with the Groups, who jointly develop and conduct cancer treatment clinical trials in multi-institutional settings. Cooperative 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. Administered by Cancer Therapy Evaluation Program staff, they are a major component of the extramural research effort of the Division of

Cancer Treatment and Diagnosis, NCI. This kind of cooperation makes it possible to centralize administration and data collection for trials taking place at a large number of sites all over the country in the Group Headquarters and Data Management Offices. Current Cooperative Groups differ in structure and research organization, but they share the common purpose of developing and conducting large-scale trials in multi-institutional settings. Many new anticancer drugs are tested in patients for the first time under NCI ***Investigational New Drug (IND)*** sponsorships through the Cooperative Group Program. The Cooperative Group Program involves more than 1,700 institutions that contribute patients to group-conducted clinical trials. Thousands of individual investigators also participate in NCI-supported cooperative group studies. Almost 200 investigational agents or treatment strategies, ranging from new chemotherapy drugs and cancer vaccines to agents that prevent tumor blood vessel development (angiogenesis), are currently being studied under NCI INDs. Approximately 22,000 new patients participate in Cooperative Group clinical trials each year, principally in large Phase III trials that help establish the state of the art for cancer therapy. Thousands of individual investigators participate in Cooperative Group protocols. For more information, please visit: **http://www.cancer.gov/cancertopics/factsheet/NCI/clinical-trials-cooperative-group**.

Community Clinical Oncology Program (CCOP)

The Community Clinical Oncology Program is a network that provides the infrastructure to link community cancer specialists and primary care physicians with clinical Cooperative Groups and Cancer Centers. In addition, CCOPs support scientific development and the implementtation of ongoing cancer prevention, control, and treatment clinical trials among community Cooperative Group members and Cancer Centers. 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://prevention.cancer.gov/programs-resources/programs/ccop**.

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 on 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://spores.nci.nih.gov**.

Program Projects

The program project grant is intended solely 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. The value of this approach is exemplified by a large program project centered in Seattle that has led the way in both understanding basic bone marrow transplant biology and developing its clinical application in high-dose chemotherapy regimens for several types of cancer. For more information, please visit: **http://deainfo.nci.nih.gov/awards/p01.htm**.

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 Cancer Care Outcomes Research and Surveillance (CanCORS) Consortium; Centers for Population Health and Health Disparities; Centers of Excellence in Cancer Communication Research; Pediatric Phase I/Pilot Consortium; Early Detection Research Network; *In Vivo* Cellular and Molecular Imaging Center; and AIDS-Associated Malignancies in Clinical Trials. 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. For more information, please visit: **http://deais.nci.nih.gov/Public/**.

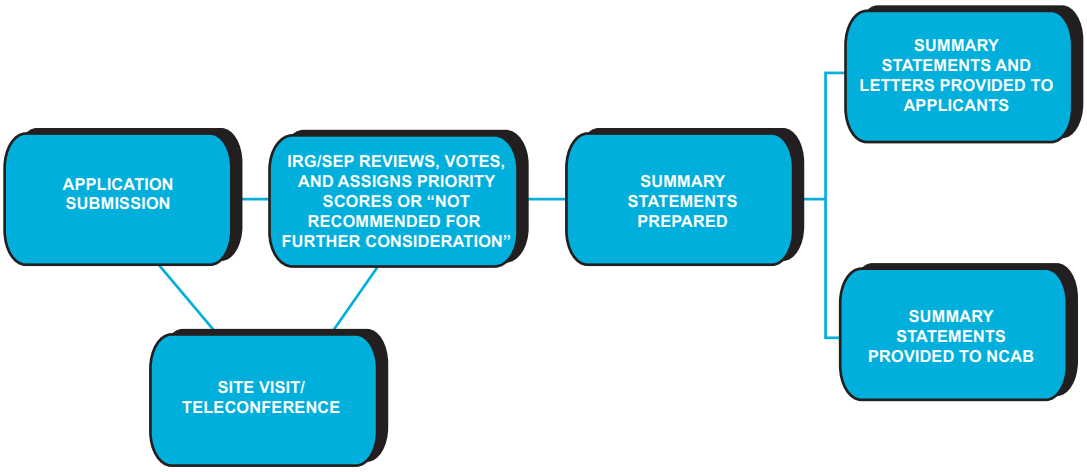
Participating in NCI Peer Review

This second part of the consumer 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 science. You will be involved in the peer review of applications for NCI Cancer Centers, Clinical Cooperative Groups, 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 participation in peer review, consumers should subordinate their 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 merit of research grant/cooperative agreement applications. The second level of review for programmatic relevance is performed by the National Cancer Advisory Board (NCAB).** Figure 4 illustrates steps in the review process.

Figure 4. Review and Evaluation for Scientific Merit



The administration of reviews by an NCI IRG subcommittee or SEP resides in the Division of Extramural Activities (DEA), NCI. **The reviews are managed and administered by Scientific Review Officers (SROs) in the Resources and Training Review Branch (RTRB), Research Programs Review Branch (RPRB), Special Review and Logistics Branch (SRLB), and Program Coordination and Referral Branch (PCRB).**

Portions of the material presented were originally adapted from the U.S. Army Breast Cancer Research Program *Orientation for Consumer Participants in Peer Review*, 1998.

The NCI IRG has six active specialized subcommittees for review of a variety of applications and scientific areas. For example, Subcommittee A reviews Cancer Centers; H reviews Clinical Cooperative Groups; and J reviews Population & Patient-Oriented Training. In addition, SEPs may be formed to review applications in response to RFAs and PAs for a variety of grant and cooperative agreement mechanisms. IRG subcommittee members serve for 4-year fixed 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 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 team. In the discussion that follows, and for the sake of brevity, they will often be referred to as IRG, SEP, and site visit (SV) teams.**

Proper review of Cancer Center and Clinical Cooperative Group applications and applications in response to RFAs and PAs for Program Projects and SPOREs requires participation of consumers and excellent scientists with appropriate expertise: individuals with substantial experience, both scientific and patient related; a broad perspective on cancer research, 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 these multi-component applications with interdisciplinary projects are scientifically detailed and technically sophisticated. The applications outline the scientific question, technical objectives, background information, preliminary data, and methods associated with the proposed research in specialized scientific language. In addition, detailed budgets and research plans identifying project tasks and timelines 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 Scientific Review Officers (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 and Clinical Cooperative Group applications, peer review of these applications usually involves a preliminary review meeting prior to a meeting of the full IRG subcommittee. For Cancer Centers, this preliminary meeting usually consists of a site visit (SV) by reviewers to the applicant institution to evaluate all aspects of the application, and for Cooperative Groups, a site visit to the institution or a teleconference to evaluate only specific parts of the application such as the statistics center. The resulting SV report is then used by the IRG subcommittee in their deliberations. All other applications are reviewed individually by an IRG subcommittee or a SEP and do not involve a site visit.

Electronic Submission and Review of Applications

The implementation of electronic submission and review of grant applications has been a major initiative across all NIH Institutes and Centers. **In 2005, the NIH began the process of transitioning to the electronic (instead 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 electronic submission of all types of grant applications. Some multi-component applications are still in the process of transitioning to electronic submission.

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 process of critique and initial priority score submissions by reviewers via the Internet. Reviewers will be able to electronically submit critiques and view each other's reviews before the actual meeting. As a result, review meetings will include more informed discussions because reviewers can read the evaluations entered by others 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. With the eRA system, the entire process of submitting, accessing, and critiquing applications can be done electronically. 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 SEP are selected to review applications by matching 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:

- SRO
- Government Observers

Descriptions of 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 a scientist (a Government employee) whose function is to serve as the overall IRG, SEP, or site visit administrator. The SRO selects the Chairperson and the members, orients the members, administers the meeting, records application 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 members 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 first-hand experience 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 one's 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 witness 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 decisionmaking process. These individuals are termed ***Program Directors***, and in addition to observing the review proceedings, they will usually make a brief presentation to the review members prior to the formal review of applications and are available to answer questions about NCI program goals.

Standards of Conduct in Peer Review

The fundamental goal of the peer review process is to provide an unbiased, independent expert review of scientific merit for consideration by the NCI and the NCAB. All participants must adhere to upholding the highest standards of conduct to ensure that the credibility of this highly visible process and its participants is not compromised. The following discussion is intended to outline 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 list of applications, institution(s) of origin, and collaborators and their institutions will be sent to you in advance, so that you may indicate any obvious conflicts in advance. If a concern about an additional conflict arises at the meeting, the member must notify the SRO. If it is determined by the SRO that a conflict of interest indeed exists, the member must excuse himself/herself from 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 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 applicants that their identity, their applications, and the associated reviews 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 or the reputation of his or her institution in addition to undermining the integrity of the peer review process. For these reasons, review members should 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 sent to each reviewer as part of the review materials package and is certified by the reviewer and returned to the SRO before the 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. Meeting deliberations and outcomes are not to be discussed following the meeting with anyone other than the SRO.***

- ***All applications and review notes should be brought to the meeting and left behind when the meeting concludes.***

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

These guidelines indicate that 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

This peer review process brings together reviewers with different perspectives in the pursuit of a common goal: to identify excellent 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 review deliberations. Scientists have been informed of consumer participation, have been oriented to the role of consumer participants, and have been apprised of the fact that consumers are full and legitimate peer review members deserving the utmost respect. On the other hand, consumers must respect the expertise of scientists and recognize 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 this review activity may perceive some challenges associated with participation in the review process. 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 Web sites for information, a dictionary of frequently used technical terms, and a list of abbreviations are provided.***

To further assist you in preparing for your assignment, the Scientific Review Officer (SRO) will be available as a primary source for specific questions or additional information. As a further aid to you, the SRO and the Consumer Advocates in Research Related Activities (CARRA) program can link you with 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 through World Travel Service (WTS) will be provided to reviewers in the Fact Sheet. Based on the reviewer's preferred itinerary, WTS will provide the most cost and time efficient routing and scheduling options available. Lodging costs and airline transportation 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 assure stringent and fair review of applications from institutions applying for NCI grant support, the DEA provides specific Review Guides with review criteria for reviewers on the site visit team, IRG, or SEP to consider in evaluating the merit of the various applications. Reviewers will score the applications using a new scoring scale of 1 to 9 to assign scores to individual criteria and a final impact/priority score. The Guides are part of the review package you will receive by mail. Instructions for the review of applications submitted in response to an RFA or PA are made available to consumers at the time of review.

Premeeting 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. They 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 review materials are received, you should make sure you promptly attend to the travel and hotel arrangements and electronic reimbursement registration (SPRS), and have everything needed for the meeting and review of the applications. As mentioned in an earlier section, the NIH is transitioning to electronic Internet-Assisted Review (IAR) submission of critiques by reviewers. Your participation in the review will therefore involve either the (1) IAR or (2) hardcopy system. If you are assigned to review an electronic submission (1), you may print your own copy of the relevant application. With (2), reviewers will generally receive a hardcopy of the application they are assigned to review and an encrypted CD containing all applications 3 to 6 weeks before the site visit/teleconference or review meeting. With either system of review, a review package will be sent that includes: a form for the reviewer to sign and return promptly confirming and certifying that he or she understands the confidential nature of review and has no conflict of interest in participating in the review, a 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, a list of the other reviewers, and a Reviewer Assignment Sheet (usually on yellow paper) 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 judged. It is suggested that all reviewers read the general introductory sections of the application(s) to provide a background perspective, and then to focus their attention on the areas assigned to them in the assignment sheet.

Each application or component of an application is assigned to two or 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 should prepare preliminary reports for their assigned application or components of the application, and if applicable, post on the IAR system. Any changes and corrections based on the information obtained from either presentations by the applicant or discussions at the review meeting can be made subsequently.*** 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 will read your assigned application sections in detail, and you may be asked to develop specific comments for presentation 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, please contact the SRO for clarification.***

As you review applications, you may 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 SV meetings is to clarify unclear issues and gather additional information for use by the full 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 can consist of 5 to 25 scientific experts, including a few permanent IRG members, and a consumer. These review meetings last from 1 to 3 days, with time spent meeting at a hotel and a site visit to the applicant institution. Although the details for these meetings may vary somewhat for each mechanism, and each application may differ, the general procedure is described below. **Site visits are often very rigorous and demanding.**

The meetings consist 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 Scientific Review Officer (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 most of the evening.

The Site Visit (SV) at the institution consists of presentations by the applicant 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. If needed, teleconferences are limited to question-and-answer exchanges between the applicant and reviewers to clarify specific points. 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. In the case of a SV, time also should be available, if necessary, for visiting the site of the research activity and the facilities utilized in its completion.

After meeting with the applicant in person, the review team 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 applicant and a visit to the 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. Site visit teams do not vote on overall numerical priority 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 a discussion, the assigned primary reviewers prepare their individual reports that incorporate the 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 the reading 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 assure 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 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.

IRG Review Meeting Procedures Following a Site Visit (SV)

For Cancer Center applications, the draft site visit reports are presented to the full 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 consumers and introduces the consumers to the IRG. The consumers will have seats assigned at the table with the other members. The NCI staff member (Program Director) 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 center or group 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 peer review process 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 priority score for the application.

In the case of Cancer Center applications, the Site Visit (SV) Report serves as the basis of discussion; the input from the permanent IRG members and temporary external consultants who participated in each site visit can assist the full IRG in its deliberations. Copies of the draft report are provided to the applicant, who may submit factual corrections or comments but not appeals for change in rating or budget recommendation or new material. Selected consultant review members and parent IRG subcommittee members 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 to defend the merit rating 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 reports, the oral reports should summarize the written material, not reiterate it in full. It is the role of those reporting the SV to present the consensus view of the SV team, not their own views. The votes on each item are indicated on the summary vote sheets.

It is the responsibility of the SRO to assure that the written report of a section conforms to the rating descriptor voted by the SV team. However, if the IRG believes that the narrative is not consistent with the merit voted or the merit of the application, either too good or too bad, both the vote and the critique can be changed. The comments of the IRG members and temporary SV members can serve as a basis of that change. Also, the individuals reporting 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 some disagreement, it will be assumed that the evaluation in the SV report stands, and the element is not re-voted. There are written minority opinions in some of the reviews; 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 areas where new material was supplied after the SV, and these will be discussed more thoroughly as part of the appropriate review. 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 a priority 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 new scoring scale of 1 to 9 to list their final impact/priority 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 as to the details of the scoring scale prior to the meeting.

After the discussion of each application, reviewers are asked to place 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 applications 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 briefly describing the application and summarizing the recommendations of the IRG, a priority 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 and Cooperative Group applications, most other applications, depending on the subject matter, are reviewed with only an IRG subcommittee or Special Emphasis Panel (SEP) meeting. For example, applications for Training, Education, Career Development, and Population-Patient Oriented Training are reviewed by an IRG subcommittee. 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. **Teleconferences between review panel members and the applicant may be used for clarification of unclear 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 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 carried out; if the application is determined not to be meritorious, an expedited review is given, wherein the application is not discussed formally at the 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 secondary reviewer 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.

- There will be 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, following discussion, whether their scores remain the same.

- The Chair will then ask members to record their merit scores on their individual scoring sheets. Each application is scored in its own right and not in comparison to other applications under consideration. Reviewers will score the applications on five individual core criteria (significance, investigators, innovation, approach, and environment) using a new scoring scale of 1 to 9. They will use the same 9-point scale to list their final impact/priority score. 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. All members will be oriented by the SRO as to 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, priority 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 at http://deainfo.nci.nih.gov

NCI Fact Book at http://fmb.cancer.gov/financial/Factbook.htm

NCAB Orientation Book at http://deainfo.nci.nih.gov/advisory/ncab/orientationbook

BSA Orientation Book at http://deainfo.nci.nih.gov/advisory/bsa/orientationbook

Bypass Budgets at http://plan.cancer.gov

Cancer at http://www.cancer.gov

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

Cancer Centers at http://www.nci.nih.gov/cancercenters

Grants and Contracts at http://www.nih.gov/grants or
NCI Division of Extramural Activities at http://deainfo.nci.nih.gov

NCI Office of Grants Administration at http://www3.cancer.gov/admin/gab/

Surveillance at http://seer.cancer.gov

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

Center for Cancer Training at http://www.cancer.gov/researchandfunding/cancertraining

Appendix B. List of Abbreviations

ACD.....Advisory Committee to the Director
ACOSOG.....American College of Surgeons Oncology Group
ASSIST.....American Stop Smoking Intervention Study
BSA.....Board of Scientific Advisors
BSC.....Board of Scientific Counselors
caBIG.....Cancer Biomedical Informatics Grid
CALGB.....Cancer and Leukemia Group B
CanCORS.....Cancer Care Outcomes Research and Surveillance Consortium
CARRA.....Consumer Advocates in Research and Related Activities
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
CGAP.....Cancer Genome Anatomy Project
CIS.....Cancer Information Service
CIT.....Center for Information Technology
CMO.....Committee Management Office
COG.....Children's Oncology Group
CSR.....Center for Scientific Review
CTAC.....Clinical Trials and Translational Research Advisory Committee
CTEP.....Cancer Therapy Evaluation Program
DCB.....Division of Cancer Biology
DCCPS.....Division of Cancer Control and Population Sciences
DCEG.....Division of Cancer Epidemiology and Genetics
DCLG.....Director's Consumer Liaison Group
DCP.....Division of Cancer Prevention
DCTD.....Division of Cancer Treatment and Diagnosis
DEA.....Division of Extramural Activities
DHHS.....Department of Health and Human Services
DSMB.....Data Safety and Monitoring Board
DoD.....Department of Defense
ECOG.....Eastern Cooperative Oncology Group
EORTC.....European Organization for Research and Treatment of Cancer
eRA.....Electronic Research Administration
FAR.....Federal Acquisition Regulations
FDA.....Food and Drug Administration
FOA.....Funding Opportunity Announcement
GLP.....Good Laboratory Practice
GMP.....Good Manufacturing Practice
GOG.....Gynecologic Oncology Group
IACUC.....Institutional Animal Care and Use Committee
IAR.....Internet Assisted Review
IND.....Investigational New Drug
IRB.....Institutional Review Board
IRG.....Initial Review Group
IRP.....Intramural Research Program
LOI.....Letter of Intent
NCAB.....National Cancer Advisory Board
NCCTG.....North Central Cancer Treatment Group
NCI.....National Cancer Institute
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
OGP.....Office of Governmentwide Policy
OHAM.....Office of HIV and AIDS Malignancy
OHRP.....Office of Human Research Protections
ORI.....Office of Research Integrity
OTIR.....Office of Technology and Industrial Relations
P01.....Program Project Grant
P30.....Cancer Center Support Grant

P50.....Specialized Center Grant
PA.....Program Announcement
PCP.....President's Cancer Panel
PCRB.....Program Coordination and Referral Branch
PD.....Program Director
PDQ.....Physician's Data Query
PI.....Principal Investigator
PRG.....Progress Review Group
PRMS.....Protocol Review and Monitoring System
R01.....Research Project Grant
R03.....Small grant
R21.....Exploratory/developmental grant
RAC.....Recombinant DNA Advisory Committee
RePORT.....Research Portfolio Online Reporting Tool
RFA.....Request for Application
RFI.....Request for Information
RPRB.....Research Programs Review Branch
RTRB.....Resources and Training Review Branch
SBIR.....Small Business Innovative Research Program
SEER.....Surveillance, Epidemiology, and End Results Program
SEP.....Special Emphasis Panel
SIC.....Special Interest Category
SPORE.....Specialized Program of Research Excellence
SPRS.....Secure Payee Registration System
SRO.....Scientific Review Officer
SRLB.....Special Review and Logistics Branch
STTR.....Small Business Technology Transfer Program
SV/TC.....Site Visit/Teleconference
SWOG.....Southwestern Oncology Group
TRP.....Translational Research Program
U01.....Cooperative Agreement
U10.....Clinical Research Cooperative Agreement
U19.....Research Program Cooperative Agreement
WHO.....World Health Organization
WTS.....World Travel Service

Appendix C. Web Sites of Interest

DEA Web Sites

http://deainfo.nci.nih.gov
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/whatsnew/news.htm
Extramural events and updates.

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

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

http://deainfo.nci.nih.gov/advisory/ncab.htm
National Cancer Advisory Board charter; subcommittee rosters; meeting agendas.

http://deainfo.nci.nih.gov/advisory/ncabminmenu.htm
Full text of NCAB meeting summaries and presentation slides.

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

http://deainfo.nci.nih.gov/advisory/bsaminmenu.htm
Full text of BSA meeting summaries and presentation slides.

http://deainfo.nci.nih.gov/advisory/bsc.htm
Charter of the Board of Scientific Counselors (BSC).

http://deainfo.nci.nih.gov/advisory/CTAC/CTAC.htm
Charter minutes, members, and agendas of the Clinical Trials and Translational Research Advisory Committee.

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

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

http://deainfo.nci.nih.gov/advisory/joint.htm
Charter of the Advisory Committee to the Director; meeting schedules, agendas, and minutes; members of various Working Groups.

http://deainfo.nci.nih.gov/advisory/dclg/dclg.htm
Charter of the NCI Director's Consumer Liaison Group; meeting schedules, agendas, minutes, and meeting summaries.

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

http://deais.nci.nih.gov/Public/RFA-PA.jsp?nt=P
Active PAs, with links to detailed descriptions.

http://deais.nci.nih.gov/Public/RFA-PA.jsp
Active RFAs, with links to detailed descriptions.

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

http://deainfo.nci.nih.gov/extra/extdocs/Glossary/A.htm
NCI Glossary of Terms.

http://fundedresearch.cancer.gov/
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://deainfo.nci.nih.gov/relatedlinks.htm
Quick links to resources available through the NCI and the NIH.

NCI Web Sites

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

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

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

http://deainfo.nci.nih.gov/funding.htm
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://www3.cancer.gov/admin/gab/2005GPB/GPB05-LowRes.pdf
The document "Everything You Wanted to Know about the NCI Grants Process."

http://resresources.nci.nih.gov/
The NCI Research Resources page lists scientific tools and services designed to enable and expedite the efforts of cancer investigators; searchable by category or keyword.

http://biospecimens.cancer.gov/researchnetwork/default.asp
Office of Biorepositories and Biospecimens is responisible for promoting a common biorepository infrastructure that promotes resource sharing and team science.

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

http://otir.cancer.gov/
NCI's Office of Technology and Industrial Relations (OTIR). OTIR'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.

http://carra.cancer.gov
NCI's Consumer Advocates in Research and Related Activities (CARRA) program site has two pages of detailed information of interest to consumers involved in the NCI peer review process: the **Research Review and Funding** page describes the research review and funding process and the types of research that NCI funds; the **Peer Review Groups** page describes the peer review process and your role as a participant.

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

NCI's Cancer Information Web Sites

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

http://www.cancer.gov
CancerNet provides a wide range of recent and accurate cancer information, including treatment options, clinical trials, ways to reduce cancer risk, and ways to cope with cancer. Resources on support groups, financial assistance, educational materials, and more are available.

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

http://cis.nci.nih.gov
The Cancer Information Service (CIS) is a free public service. The CIS responds to calls in English and Spanish. Through 14 regional offices, the CIS serves the entire United States, Puerto Rico, and the U.S. Virgin Islands. U.S. residents can call the CIS at 1-800-4-CANCER (1-800-422-6237), Monday through Friday, from 9:00 a.m. to 4:30 p.m., local time, to speak with a Cancer Information Specialist. Hearing-impaired callers with TTY equipment may call 1-800-332-8615.

http://www.cancer.gov/clinicaltrials/
The Cancer Trials Web Site 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://seer.cancer.gov/
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://www3.cancer.gov/atlasplus/
The Cancer Mortality Maps and Graphs Web Site 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 1950–1994.

NIH Web Sites

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

http://enhancing-peer-review.nih.gov/guidance_reviewers.html
Overview of recent changes in the peer review system, including videos and slides.

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

http://ofacp.od.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://grants.nih.gov/grants/oer.htm
NIH grants and funding opportunities.

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

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

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

http://forms.cit.nih.gov
Downloadable NIH electronic forms in a variety of formats (e.g., Microsoft Word, PDF).

http://commons.era.nih.gov/commons
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://videocast.nih.gov
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 Web site. Videocasting is the method of electronically streaming digitally encoded video and audio data from a server to a client. (Requires the latest free version of RealPlayer and 150 Kbps LAN or 56 Kbps dial-up bandwidth.)

http://era.nih.gov/ElectronicReceipt/
Information on electronic submission of grant applications.

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

http://grants.nih.gov/grants/guide/index.html
Information on funding opportunities (RFAs and PAs) and notices.

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

General Government-Related Web Sites

http://usa.gov
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://www.gsa.gov
The Office of Governmentwide Policy (OGP) consolidates all of the General Services Administration's governmentwide policymaking activities within one central office. The site contains links to resources on the management of Federal advisory committees and on travel management.

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

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