The NCI Consumers'

Guide to Peer Review

NATIONAL® CANCER INSTITUTE

Division of Extramural Activities

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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 in the Peer Review of applications that support extramural clinical/population-based research conducted by Cancer Centers, Cooperative Groups, Program Projects, and projects submitted in response to Requests for Applications (RFAs) and Program Announcements (PAs).

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 between 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 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 composed of experts in the scientific field under study. The peer review mechanism helps ensure that NCI uses its resources wisely and funds research that has the potential to make a significant contribution to advancing science.

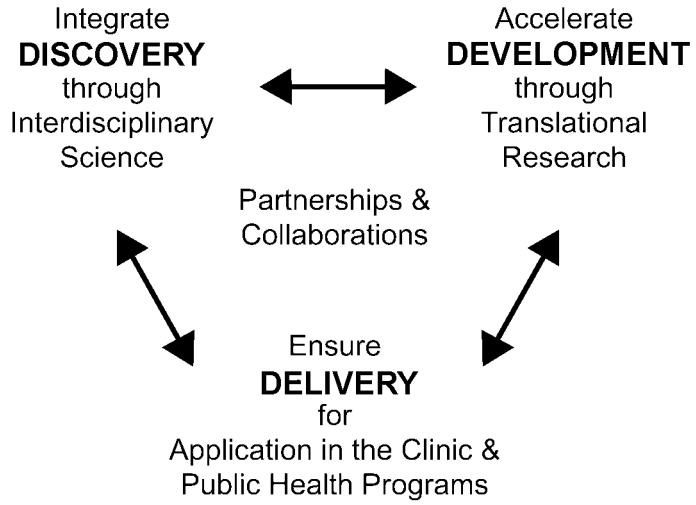
Consumer participation augments scientific merit review by including the patient perspective in the assessment of scientific excellence. Including the patient perspective is consistent with the research agenda of the NCI. In addition to funding basic science, the NCI funds programs that encompass prevention, 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 decision-making process. ***Thank you for agreeing to participate in this very important process. Your views will be welcomed and respected.***

The NCI and Its Research Programs

Mission and Goal

The paramount mission of the National Cancer Institute (NCI) is to support the development of a scientific knowledge base that can be translated and applied to the general population to reduce the burden of cancer. The goal of the NCI is to eliminate the suffering and death due to cancer by 2015. To achieve this goal, the NCI is dedicated to stimulating and supporting programs in three crucial areas of cancer research: discovery, development, and delivery. This approach will enhance and increase our understanding of cancer as a disease process and ultimately result in the prevention and elimination of many cancers and our ability to control others.

Figure 1. Three Crucial Areas of Cancer Research: Discovery, Development, and Delivery



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.

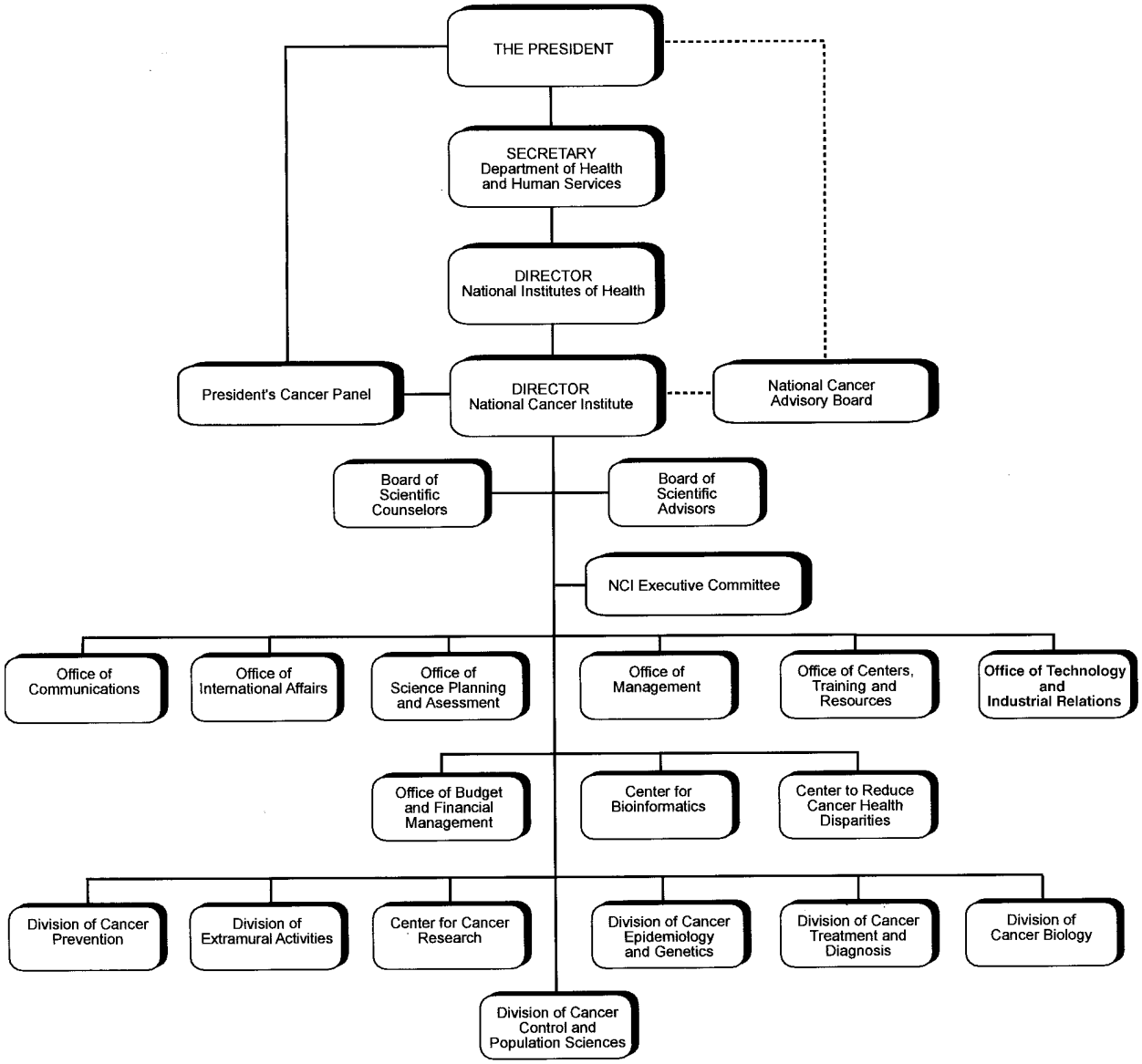
Specifically, the NCI:

- Conducts intramural research with Government scientists in its own laboratories and clinics at the NIH.
- Supports extramural research in basic and clinical programs relating to cancer through career awards, training grants, cancer education grants, and fellowships to non-Government scientists.
- Supports and coordinates research projects conducted by universities, hospitals, state and local governments, research foundations, and commercial organizations, throughout this country and abroad, through research grants and cooperative agreements.
- Supports construction of laboratories, clinics, and related facilities necessary for cancer research through the award of construction grants.
- Supports research projects in cancer prevention, control, and population science.
- Supports a national network of Cancer Centers, Clinical Cooperative Groups, and Specialized Programs of Research Excellence (SPOREs).
- Encourages and coordinates cancer research by industrial concerns where such concerns show a particular capability for programmatic research.
- Collaborates with voluntary organizations and other national and foreign institutions engaged in cancer research and training activities.
- Collects and disseminates information on cancer.

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 2**. The Office of the Director serves as the focal point for the National Cancer Program with advice from several external and internal advisory groups that include the President's Cancel Panel, the National Cancer Advisory Board, the Board of Scientific Advisors, and the Board of Scientific Counselors.

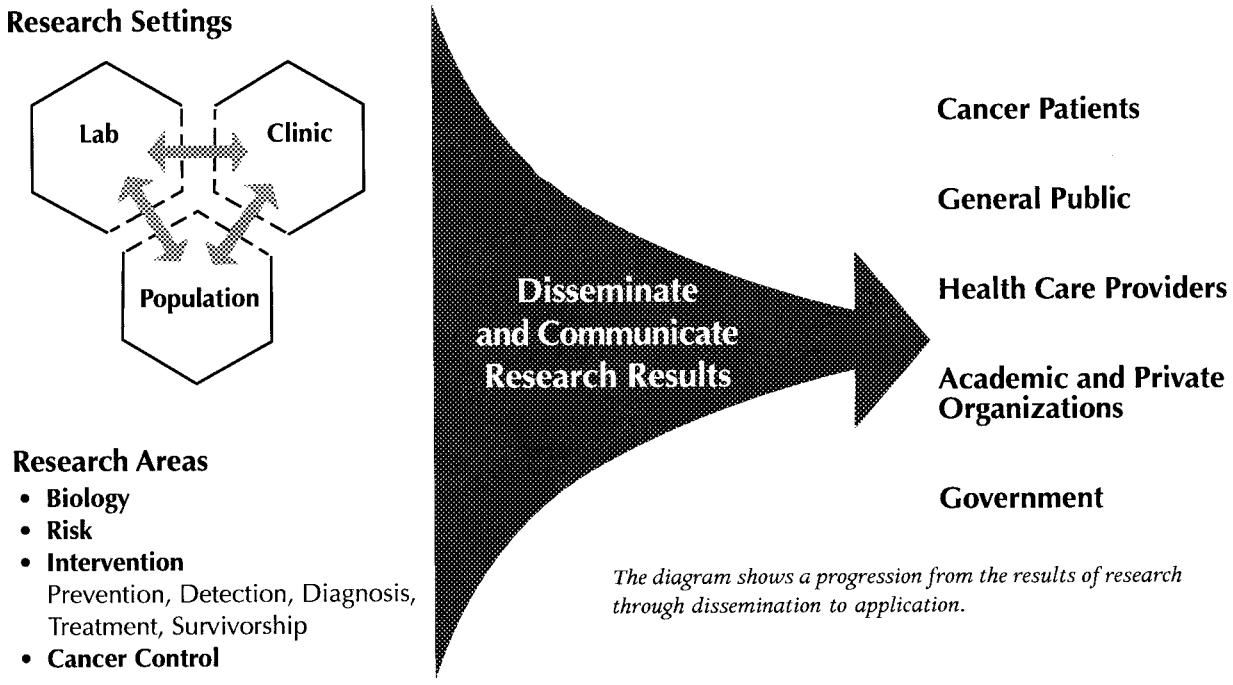
Figure 2. NCI Organization and Advisory Structure



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 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 3** shows the progression from the results of research through dissemination to application. Research results must be communicated to those who ultimately apply these results in the health care and disease prevention settings, and in the community.

Figure 3. Progression From Cancer Research to Applications



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

The NCI supports research intramurally and extramurally 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)***, which consists of the Center for Cancer Research (CCR) and the Division of Cancer Epidemiology and Genetics (DCEG), is dedicated to the comprehensive understanding of cancer. IRP Government scientists, research fellows, and visiting scientists from around the world conduct basic, clinical, and population-based 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 and contracts.

Four extramural research divisions monitor and administer NCI's extramural grant and contract research activities. The Office of the Deputy Director for Extramural Science (ODDES), which is part of the Office of the Director, coordinates initiatives across NCI's four extramural research divisions: the Division of Cancer Biology (DCB); the Division of Cancer Control and Population Science (DCCPS); the Division of Cancer Prevention (DCP); and the Division of Cancer Treatment and Diagnosis (DCTD). The ODDES also monitors and administers the

Centers, Training, and Resources Program, as well as the grant program supporting minority initiatives. The Division of Extramural Activities (DEA) coordinates the review of grants and contracts, and manages the functions of the National Cancer Advisory Board (NCAB) and the Board of Scientific Advisors (BSA).

Collectively, extramural research project grants and contracts fund the full range of basic, clinical, and population-based studies of cancer etiology, biology, prevention, detection, diagnosis, treatment, and control. The NCI strives for a "balanced" portfolio of research in 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 clinical/population-based research funded by the grant or cooperative agreement mechanisms described below.

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, 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 to identify programmatic relevance. 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.

Cancer Centers are funded by P30 Grants, and Program Projects are funded by P01 Grants.

- **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 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.

- 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 interdisciplinary and collaborative research, and increasing the rate at which research discoveries are translated into medical benefits.

- 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.

Clinical Cooperative Groups are funded by U10 Cooperative Agreements.

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

- 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 are often not available at a single institution, a cooperative study is started that involves investigators in several institutions following common protocols.

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.

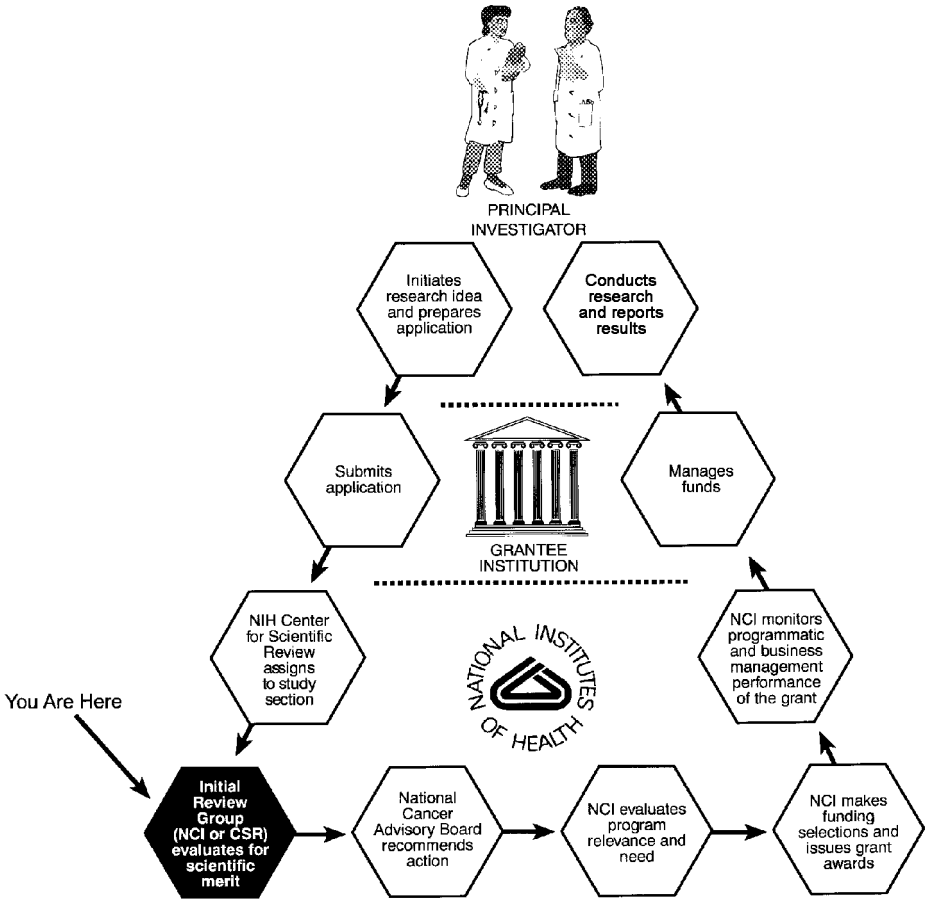
- The **principal investigator** (PI) is designated by the applicant institution to direct the project being supported by the grant. Applications are usually initiated by the PI. They must be

signed by the PI and an authorized official of the applicant institution prior to submission to the NIH. PIs are responsible and accountable to grantee organizational officials for the proper conduct of the project. The PI accepts responsibility for the scientific conduct of the project and submission of progress and any other required reports by signing the grant application.

- 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 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 4**.

Figure 4. 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: **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, which you will be involved in evaluating through peer review.**

Oversight of Research Programs

The NCI maintains several advisory and operating 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 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.

Board of Scientific Counselors (BSC). The BSC advises the Institute leadership on the progress and future direction of NCI's Intramural Research Program. This group of scientific experts from outside the NCI evaluates the performance and productivity of NCI intramural staff scientists through periodic site visits to intramural laboratories, and provides evaluation and advice on the course of intramural research programs.

NCI Initial Review Group (IRG). The IRG, composed of eight subcommittees, reviews grant and cooperative agreement applications for cancer centers, cooperative groups research projects, and research training activities in the areas of cancer cause, prevention, diagnosis, treatment, as well as contract proposals 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 in site visit groups, providing critical information to the chartered advisory committees responsible for initial peer review.

NCI Special Emphasis Panels (SEP). The SEPs advise the Director, NCI, and the Director, DEA, regarding research grant and cooperative agreement applications, contract proposals and concept review relating to basic and clinical sciences, and applied research and development

programs 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 includes NCI division directors and other key senior NCI advisors to the NCI Director and 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 15 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.

- 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 Board's 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 Liaison Activities (OLA)***. Throughout the Nation, hundreds of cancer advocacy and outreach organizations provide education and support to their communities. The OLA is NCI's central point of contact with these national advocacy organizations and, through them, the community-based groups. OLA 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 OLA, 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. For more information on NCI liaison activities, please visit: **http://la.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 National Cancer Program. Conducting clinical trials is a critical step in establishing the best possible means of preventing, diagnosing, detecting, and treating specific cancers. Clinical trials allow the NCI to assess the ability of new cancer treatments 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 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://www3.cancer.gov/prevention/ccop/aboutccop.html.

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 are generally 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. ***You will be involved in the peer review of NCI clinical/population-based research performed by Cancer Centers, Cooperative Groups, Program Projects, or applications for projects submitted in response to an RFA or PA. For more information, please visit:*** **http://www.cancer.gov/clinicaltrials/.**

Cancer Centers Program

More than 50 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 of 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 assure 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 Centers also must have in place effective cancer information, 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 may now 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://www3.cancer.gov/cancercenters/.**

Cooperative Group Clinical Trials 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 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. Close to 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 20,000 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. For more information, please visit: **http://ctep.cancer.gov/resources/coop2.html.**

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 implementation 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, please visit: **http://www3.cancer.gov/prevention/ccop/.**

Specialized Programs of Research Excellence (SPOREs)

These 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 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, brain, skin, head, and neck cancers and lymphomas. In the future, the NCI will increase the use of the SPORE mechanism to include funding for other major cancers. 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 understanding both 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.**

Request 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 or PAs on specific topics. Research topics may include such diverse areas as Clinical Trials in Diagnostic Imaging; Prevention and Cessation of Tobacco Use in Children; Radiation Therapy Clinical Trials Support; Chemoprevention of Genetically Identified High Risk Groups; Pediatric Brain Tumor Clinical Trials Consortium; Diet, Lifestyle, and Cancer in U.S. Populations; AIDS-Associated Malignancies in Clinical Trials; and Cancer Drug Discovery: Diversity Generation and Smart Assays. 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 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://deainfo.nci.nih.gov/extra/rfa/index.htm.**

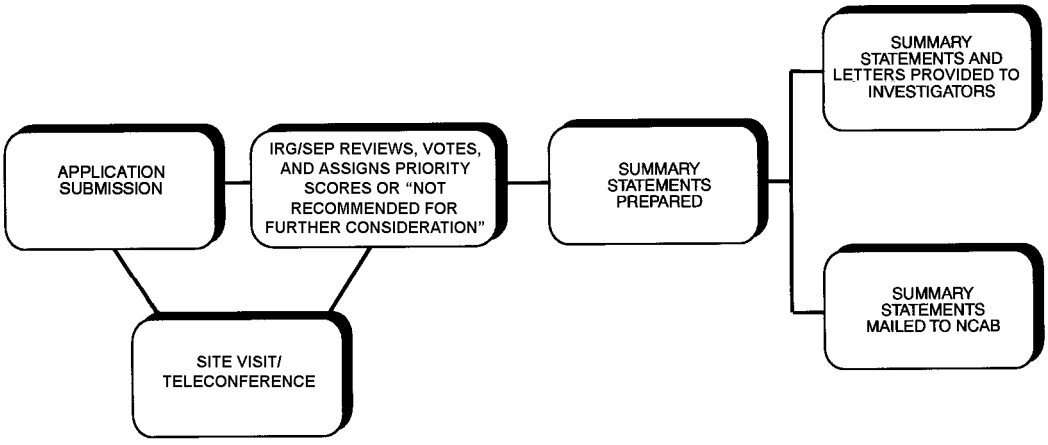
Participating in NCI Peer Review

This second part of the consumer guide will introduce you to the NCI peer review process and help you understand the rationale for including consumers, 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 the National Cancer Program'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, Program Projects, and applications submitted in response to a Request for Applications (RFA). 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 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 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 5** illustrates steps in the review process.

Figure 5. Review and Evaluation for Scientific Merit



The administration of reviews by an IRG subcommittee or SEP resides in the Division of Extramural Activities (DEA), NCI. The reviews are managed and performed by Scientific Review Administrators (SRAs) in the Resources and Training Review Branch (RTRB), Research Programs Review Branch (RPRB), or the Special Review and Logistics Branch (SRLB).

The NCI Initial Review Group (IRG) has eight specialized subcommittees for review of a variety of applications and scientific areas. For example, Subcommittee A reviews Cancer Centers; D reviews Clinical Studies; F, G, and I review Training and Career Development; and H reviews

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

Clinical Cooperative Groups. In addition, Special Emphasis Panels (SEPs) may be formed to review applications in response to RFAs. IRG subcommittee members serve for 4-year fixed terms, attending 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 or as part of a telephone conference conducted preliminary to the IRG subcommittee meeting. This type of meeting is known as a work group or review panel. IRG Subcommittees A, C, D, E, and H regularly have associated work groups whose designated responsibility is the scientific and technical merit assessment of an application(s). For each application, outcomes of the work group discussions are summarized in a draft report that is sent 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 Special Emphasis Panels (SEP) or as a member of a site visit/teleconference team. In the discussion that follows, and for the sake of brevity, they will often be referred to as IRG, SEP, and site visit/teleconference (SV/TC) teams.***

Proper review of Cancer Center, Clinical Cooperative Group and Program Project applications, and applications in response to RFAs and PAs requires participation of consumers and excellent scientists: 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 multicomponent 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 Administrators (SRAs) are responsible for organizing 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 their complexity and multidisciplinary nature, peer review of Cancer Center, Program Project and Clinical Cooperative Group applications usually involves a preliminary review meeting with a review team consisting of selected IRG members and external consultants prior to a meeting of the full IRG subcommittee. This preliminary meeting can consist of either a site visit (SV) by reviewers to the applicant institution, a reverse site visit with the applicant meeting with reviewers in the Washington, DC area, or a teleconference (TC) between all members of the review team and the applicant. At these meetings, a report is written that is subsequently presented to the full IRG. Applications submitted in response to an RFA or PA are reviewed individually by a SEP or an IRG and generally do not involve a site visit.

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

- SRA
- 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 Administrator (SRA)

The SRA is a scientist (a Government employee) whose function is to serve as the overall IRG, SEP, or site visit administrator. The SRA selects the Chairperson, the members, orients the members, administers the meeting, records application scores, and oversees the preparation of summary statements for each application. In addition, the SRA assigns applications to primary and secondary scientific reviewers and consumers.

2. Chairperson

Chairpersons are highly qualified senior scientists, not Federal employees, who offer extensive scientific leadership and research evaluation experience as research program directors and 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. They may also serve as a primary or secondary reviewer on some of the applications. During the meeting, the Chairperson leads the 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 research experience, including experience 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, either as cancer survivors, 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 the assessment of scientific excellence.

While 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.

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 decision-making process. These individuals are termed ***Program Directors***, and in addition to observing the review proceedings, they will usually make a brief presentation to the 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 SRA. If it is determined by the SRA 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 applicants. This includes either personal or professional relationships. 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.

  - 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 their 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 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.***

- ***Applications under consideration and associated meeting deliberations are not to be discussed with anyone other than NCI staff, the SRA, or other review members. This requirement applies at all times before, during, and after meeting deliberations.***

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

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

These guidelines indicate that it is inappropriate to consult professional friends or colleagues for assistance in understanding any application. For occasional technical assistance, you must consult the SRA.

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 debate 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 the science of cancer. 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 administrator (SRA) will be available for specific questions or additional information. As a further aid to you, we are working to link you with consumer mentors who have previously served on peer reviews. These consumer mentors can assist you in some aspects of the review and should be consulted about procedures. Should you require additional help, some of the scientific reviewers can serve as mentors to assist a consumer about scientific issues and preparation of reviews. The SRA will provide you with the names of mentors. Finally, because we have identified resource support to assist you, you are encouraged to use the consumer liaison or mentor assigned to you as the primary or secondary contact for technical information. As the meeting progresses, you are encouraged to develop a sense of confidence and autonomy. The SRA 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. The SRA is also available if your other contacts are unable to provide the information you need.

Review Criteria for Cancer Centers, Cooperative Groups, Program Projects, and Requests for Applications (RFAs) or Program Announcements (PAs)

To assure stringent and fair review of institutions applying for Cancer Center, Cooperative Group, or Program Project support, the NCI provides specific review criteria for reviewers on the site visit/teleconference team, IRG, or SEP to consider in evaluating the merit of the applications and their key sections. These criteria are included in the review package you will receive by mail. For Cancer Center Support Grant (CCSG) applications, the criteria are found under Specific Issues for Review in the ***Cancer Center Support Grant Guidelines***; for Cooperative Groups, criteria are found under Review Criteria in the ***Clinical Trials Cooperative Group Program Guidelines***; and for program projects, criteria are found under Review Criteria in the ***Guidelines for the Program Project Grants***. Instructions for the review of applications submitted in response to an RFA or PA are made available to consumers at the time of review, and are always spelled out in the published announcements of such programs.

Premeeting Activities for Peer Review

Consumers are assigned sections of applications and asked to provide critiques in areas that fall within their expertise, including:

- 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
- 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, adequacy of consent forms
- Inclusion of women/minorities/children in trial.

As soon as review materials are received, you should make sure you attend to the travel arrangements and have everything needed for the meeting and review of the applications. Reviewers generally receive the application and other review materials 3 to 6 weeks before the site visit/teleconference or review meeting. Each review package includes a form for the reviewer to sign and return promptly confirming that he or she has no conflict of interest in participating in the review. Also included, in addition to the application, are a Fact Sheet describing the time and place of the review, and instructions about making travel arrangements to the site of the review and hotel reservations at that location, which should be attended to promptly. A copy of the guidelines 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 component of the application are also included in the package of materials. In some cases, applications are provided on a CD.

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 Guidelines 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 segment is assigned a primary and at least one secondary scientific reviewer. Primary and secondary scientific reviewers are responsible for conducting a detailed review of their assigned component 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 components of the application, subject to any changes and corrections based on the information obtained from either presentation by the applicant or based on discussions with other members of the review team.*** Although a member may review extra components of an application, they are not responsible for preparing written critiques on these but may provide specific comments during discussion. Other reviewers may also choose to read abstracts or review additional applications that are not specifically assigned to them. Informed comments, written or as part of the discussion on any additional components, are welcomed and encouraged.

As a secondary reviewer or a reader, you will read your assigned application sections in detail, and may be asked to develop specific comments for presentation during review proceedings. You may skim sections with technical detail such as laboratory procedures, statistical analysis, 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 formally asked to present in

summary form your comments orally 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, though 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 SRA 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 proposal?*** Be specific.

- ***Given your experience with cancer, are you aware of any scientific information specifically relevant to the proposal 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…."

Site Visit (SV) and Teleconference (TC) Procedures for Cancer Centers, Cooperative Groups, and Program Projects

For institutions submitting applications for Cancer Centers, Cooperative Groups, or Program Projects, a group of expert reviewers, reflecting the science proposed in the application and under the authority of the SRA, will either site visit the applicant institution or conduct a reverse site visit/teleconference at a meeting location in the Washington, DC area prior to a full IRG meeting. Specifically, for each Cancer Center application, a group of reviewers is assembled to site visit the applicant and institution and hold a meeting at a local hotel (site visit); for each Cooperative Group application, the applicant meets with a group of reviewers in the Washington, DC area (reverse site visit); uniquely, applications to support Program Projects are reviewed in groups of two to four termed "clusters," where the applications contain closely related projects and topics. Each application within the "cluster" is reviewed separately. These "cluster reviews" are conducted by a teleconference between the applicant at the applicant institution and all members of the convened group of reviewers at a hotel in the Washington, DC area (teleconference).

The purpose of these SV/TC meetings is to clarify unclear issues and gather additional information for subsequent 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, multicomponent applications. Depending on the size and scope of the application, the SV/TC review team can consist of 10-25 experts, including a few permanent IRG members, external scientific experts,

and a consumer. These review meetings range from 2 to 3 days, with time spent meeting at a hotel and a site visit, as needed, to the institution. Although the details for these meetings may vary somewhat for each mechanism, and each application may differ somewhat, the general procedure is described below.

The meetings consist of executive sessions at the hotel where review members and NCI staff meet to discuss the application, and formal sessions held with the applicant onsite at the institution, at the hotel, or by teleconference. Generally, the dress at the executive sessions is informal, while business dress is the rule for meetings held with the applicant.

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 Administrator (SRA) 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 session usually lasts for most of the evening.

The site/reverse site visit at the institution or hotel 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. **Teleconferences are limited to question and answer exchanges between the convened review members and each individual applicant whose application is part of the "cluster" review.** 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 should also 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 or by teleconference, 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 vote evaluative judgments on 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/teleconference (SV/TC) teams for Cancer Centers, Cooperative Groups, and Program Projects do not vote 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 the SV/TC 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 SRA into the draft SV/TC Report for distribution to the full IRG. The applicant also receives a copy of this draft report and may provide factual corrections for consideration by the IRG.

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

Review Meeting Procedures for Cancer Centers, Cooperative Groups, and Program Projects

For Cancer Center, Cooperative Group, and Program Project applications, the draft site visit/teleconference (SV/TC) reports are presented to the full IRG, which usually meets in the Washington, DC, area. The meeting will begin with an orientation by the SRA including an overview of specific instructions and meeting policies and procedures. As part of this orientation, the SRA 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 SRA 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, 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 will also 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 would have likely 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/TC teams.

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/TC team appropriately dealt with the review criteria
- Looking at overall application merit in perspective

- Correcting any deviation by SV/TC teams from review criteria or uniform treatment
- Assigning the priority score for the application.

In the case of Cancer Center, Program Project, and Cooperative Group applications, the Site Visit/Teleconference (SV/TC) Report serves as the basis of discussion; the input from the permanent IRG members and temporary external consultants who participated in each site visit/teleconference 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. The IRG and consultant review members who attended an SV/TC are assigned sections of the report to present. In some cases, these assignments are not in areas of direct expertise of the member. Assigned reviewers are asked to briefly summarize the evaluations of the SV/TC team and to defend the merit rating given. They also provide input on the SV/TC teams' 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 to present the consensus view of the SV/TC team, not his or her own view. The votes on each item are indicated on the summary vote sheets.

It is the responsibility of the SRA to assure that the written report of a section conforms to the rating descriptor voted by the SV/TC 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/TC members can serve as a basis of that change. Also, the individual reporting should act as a proponent of the SV/TC 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/TC report stands, and the element is not revoted. There are written minority opinions in some of the reviews, in which case 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 may also be areas where new material was supplied after the SV/TC, 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/TC team.

Following a discussion of each application, the 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. The final score is calculated to one decimal point (i.e., 2.4) on a scale of 1.0 (outstanding) to 5.0 (least acceptable). 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 SRA 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 SRA 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, priority score, budget recommendation, the applicant's description, and the edited consensus reports.

Review Meeting Procedures for RFAs and PAs

Depending upon the subject matter, applications submitted in response to an RFA or PA are reviewed by an IRG or a SEP. Site visits and teleconferences are generally not used. Following an orientation, the SRA will provide an overview of specific instructions and meeting policies and protocols for the RFA or PA. **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 primary and secondary reviewers whether the individual sections of an application 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 SRA.

- 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 will 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 will also 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. The final score is calculated to one decimal point (i.e., 2.4) on a scale from 1.0 (outstanding) to 5.0 (least acceptable). 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 SRA 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 SRA 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 NCI staff and the NCAB 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 prospects for involving consumers in a rewarding and successful experience. This process is constantly evolving 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

Bypass Budgets at **http://planning.cancer.gov/aboutbypass.html**

Cancer at **http://cancernet.nci.nih.gov/**

Clinical Trials at **http://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 Grants Administration Branch at **http://www3.cancer.gov/admin/gab/index.htm**

Surveillance at **http://seer.cancer.gov/**

Training, Education, and Career Development at **http://deainfo.nci.nih.gov/flash/awards.htm#TP**

Appendix B. List of Abbreviations

AB……Antibody
ABMT……Autologous Bone Marrow Transplant
ACD……Advisory Committee to the Director
ACTH……Adrenocorticotropic Hormone
AIDS..... Acquired Immunodeficiency Syndrome
APC……. Adenomatous Polyposis Coli
ARC……. AIDS-Related Complex
ASSIST…….. American Stop Smoking Intervention Study
BAC……. Bacterial Artificial Chromosome
BMR……Basal Metabolic Rate
BSA..... Board of Scientific Advisors
BSC..... Board of Scientific Counselors
CALGB…….. Cancer and Leukemia Group B
CARRA ..... Consumer Advocates in Research and Related Activities
CCOP……Community Clinical Oncology Program
CCR..... Center for Cancer Research
CCSG..... Cancer Center Support Grant
cDNA..... Complementary DNA
CDC……. Centers for Disease Control and Prevention
CDP..... Cancer Diagnosis Program
CEA……. Carcinoembryonic Antigen
CFR……. Code of Federal Regulations
CGAP..... Cancer Genome Anatomy Project
CIS ..... Cancer Information Service
CIT……..Center for Information Technology
CMV ..... Cytomegalovirus
CNS..... Central Nervous System
CSF……Colony Stimulating Factor
CT……Computerized Tomography
CTEP..... Cancer Therapy Evaluation Program
DCB……Division of Cancer Biology
DCC……. Deleted in Colon Carcinoma
DCCPS..... Division of Cancer Control and Population Sciences
DCEG……Division of Cancer Epidemiology and Genetics
DCIS..... Ductal Carcinoma *in situ*
DCLG……Director's Consumer Liaison Group
DCP……. Division of Cancer Prevention
DCTD..... Division of Cancer Treatment and Diagnosis
DEA ..... Division of Extramural Activities
DES……. Diethylstilbestrol
DNA……. Deoxyribonucleic acid
DSMB……Data Safety and Monitoring Board
DoD……. Department of Defense
ECG..... Electrocardiogram
ECOG……Eastern Cooperative Oncology Group
EGF……. Epidermal Growth Factor
EKG……. Electrocardiogram
ELISA……Enzyme-Linked Immunosorbent Assay
EM ..... Electron Microscopy
EORTC…….. European Organization for Research on Cancer
EP……Erythropoietin
ERT……Estrogen Replacement Therapy
FAR ..... Federal Acquisition Regulations
FDA……Food and Drug Administration
FGF……Fibroblast Growth Factor
GAP..... Guanosine Triphosphatase - Activating Protein
GLP……. Good Laboratory Practice
GMP……Good Manufacturing Practice
GOG……Gynecologic Oncology Group
GRB……Grants Review Branch
GVHD……Graft Versus Host Disease
HHV-8……Human Herpes Virus 8
HIV……..Human Immunodeficiency Virus

HLA ..... Human Leukocyte Antigens
HNPCC..... Hereditary Non-Polyposis Colorectal Cancer
HPLC.....High-Performance Liquid Chromatography
HPV ..... Human Papilloma Virus
HRT.....Hormone Replacement Therapy
IACUC..... Institutional Animal Care and Use Committee
IFN..... Interferon
IGF.....Insulin-Like Growth Factor
IL..... Interleukin
IND.....Investigational New Drug
IRB.....Institutional Review Board
IRG ..... Initial Review Group
IRP.....Intramural Research Program
IV.....Intravenous
KS ..... Kaposi's Sarcoma
LCIS ..... Lobular Carcinoma *in situ*
LTF..... Long-Term Follow-Up
MAB/MOAB . Monoclonal Antibody
MDR ..... Multidrug Resistance
MRI..... Magnetic Resonance Imaging
NCAB ..... National Cancer Advisory Board
NCDDG.....National Cooperative Drug Discovery Groups
NCI ..... National Cancer Institute
NDA..... New Drug Application
NGF..... Nerve Growth Factor
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
NMR ..... Nuclear Magnetic Resonance
NSABP..... National Surgical Adjuvant Breast and Bowel Program (Project)
NSCLC.....Non-Small Cell Lung Cancer
NSF ..... National Science Foundation
ODDES..... Office of the Deputy Director for Extramural Science
OFACP.....Office of Federal Advisory Committee Policy
OHRP..... Office of Human Research Protections
OI..... Opportunistic Infection
OLA ..... Office of Liaison Activities
ONC.....Oncology Certified Nurse
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
PCR.....Polymerase Chain Reaction
PD.....Program Director
PDGF..... Platelet Derived Growth Factor
PDQ..... Physician's Data Query
PET.....Positron Emission Tomography
PI.....Principal Investigator
PRMS.....Protocol Review and Monitoring System
PSA ..... Prostate Specific Antigen
R01 ..... Research Project Grant
RAC.....Recombinant DNA Advisory Committee
RAID..... Rapid Access to Intervention Development (program)
RAPID.....Rapid Access to Prevention Intervention Development (program)
RBC..... Red Blood Count/Cell
RFA ..... Request for Applications
RFLP..... Restriction Fragment Length Polymorphism
RNA..... Ribonucleic Acid
RPRB.....Research Programs Review Branch

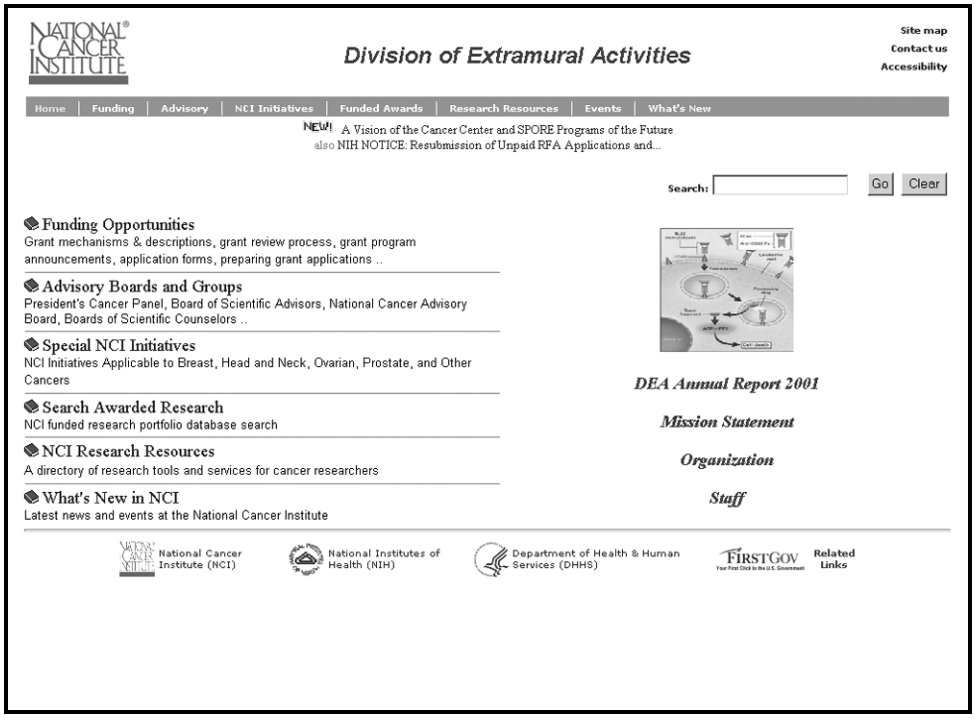
RTRB…….Resources and Training Review Branch
SBIR..... Small Business Innovative Research Program
SCLC..... Small-Cell Lung Cancer
SEER…….Surveillance, Epidemiology, and End Results Program
SEP…….Special Emphasis Panel
SERM…….Selective Estrogen Response Modifier
SIC ..... Special Interest Category
SNP…….Single Nucleotide Polymorphism
SPORE..... Specialized Program of Research Excellence
SRA…….Scientific Review Administrator
SRLB..... Special Review and Logistics Branch
SRRB ..... Special Review and Resources Branch
STTR ..... Small Business Technology Transfer Program
SV/TC…….Site Visit/Teleconference
SWOG…….Southwestern Oncology Group
TAM..... Tamoxifen
TGF……Transforming Growth Factor
TUNEL…….. Transferase-Mediated dUTP Nick End Labeling (an assay for apoptosis, or programmed cell death)
U01…….. Cooperative Agreement
U10……..Clinical Research Cooperative Agreement
U19…….. Research Program Cooperative Agreement
WHO..... World Health Organization
YAC ..... Yeast Artificial Chromosome

Appendix C. Web Sites of Interest

DEA Web Sites

http://deainfo.nci.nih.gov/index.htm

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.

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.

http://deainfo.nci.nih.gov/advisory/bsa/bsa_program/bsaprgr.htm
Program Review Group reports.

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

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.

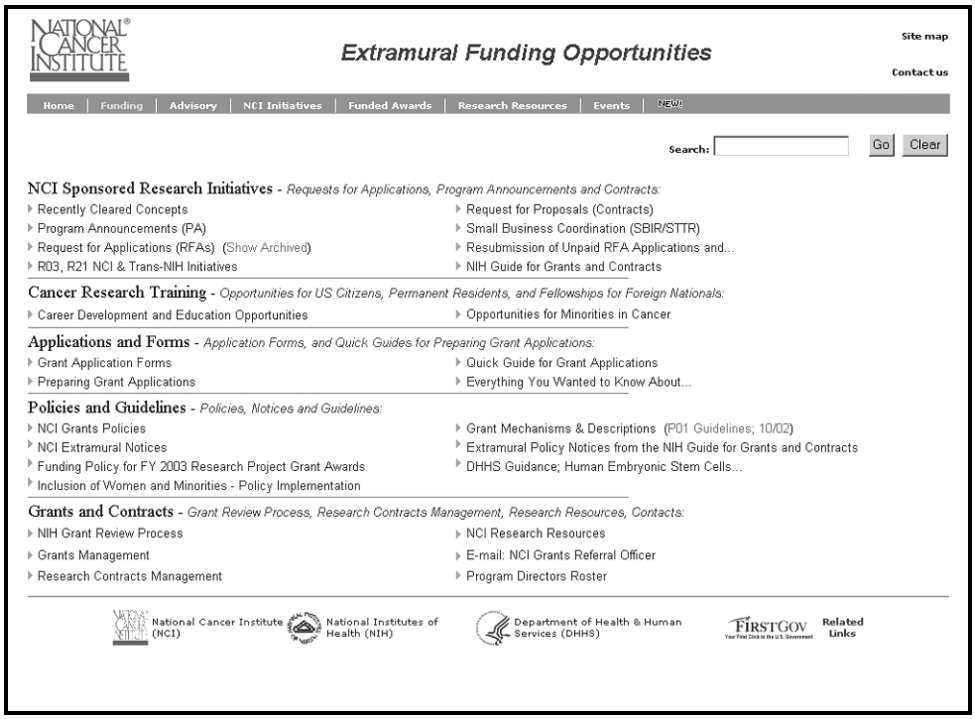
http://deainfo.nci.nih.gov/advisory/pog/progress/index.htm
Function and organization of Progress Review Groups; PRG reports and meeting schedules; members of PRGs.

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://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://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://deainfo.nci.nih.gov/extra/pa/all_pa.htm

Active PAs, with links to detailed descriptions.

http://deainfo.nci.nih.gov/extra/rfa/index.htm

Active RFAs, with links to detailed descriptions.

http://deainfo.nci.nih.gov/flash/awards.htm

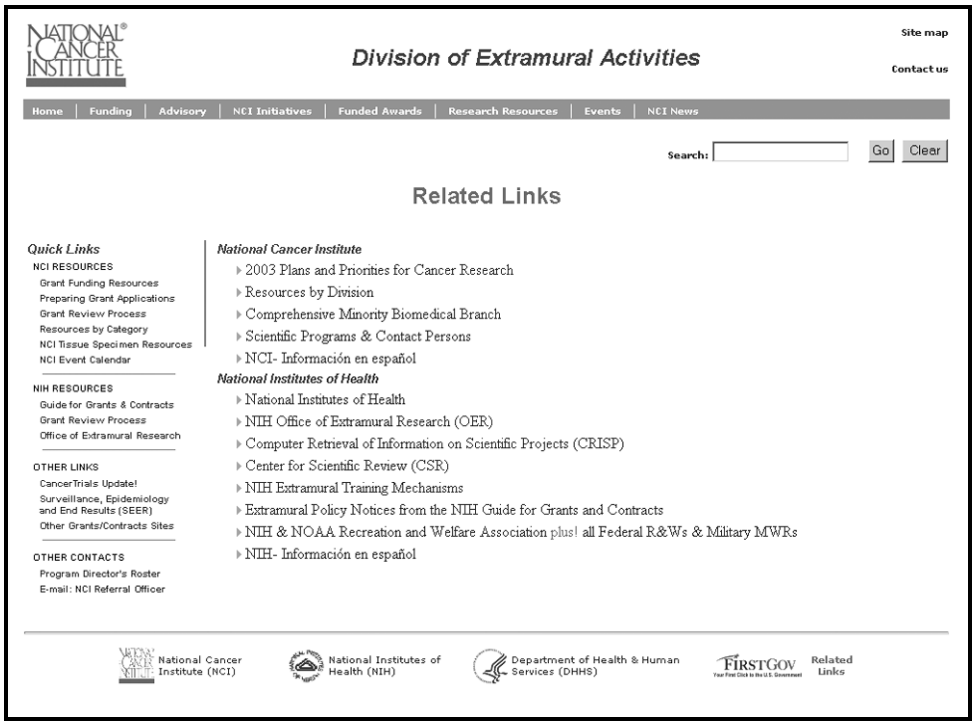
Grants Guidelines and Descriptions (descriptions of NCI funding mechanisms, with links to Program Announcements, RFAs, guidelines, and supplemental materials).

http://deais.nci.nih.gov/Query/QueryForm

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.


NATIONAL CANCER INSTITUTE
Division of Extramural Activities
Site map
Contact us
Home | Funding | Advisory | NCI Initiatives | Funded Awards | Research Resources | Events | NCI News
Search: Go Clear
Related Links
Quick Links
NCI RESOURCES
Grant Funding Resources
Preparing Grant Applications
Grant Review Process
Resources by Category
NCI Tissue Specimen Resources
NCI Event Calendar
NIH RESOURCES
Guide for Grants & Contracts
Grant Review Process
Office of Extramural Research
OTHER LINKS
CancerTrials Update!
Surveillance, Epidemiology and End Results (SEER)
Other Grants/Contracts Sites
OTHER CONTACTS
Program Director's Roster
E-mail: NCI Referral Officer
National Cancer Institute
2003 Plans and Priorities for Cancer Research
Resources by Division
Comprehensive Minority Biomedical Branch
Scientific Programs & Contact Persons
NCI- Información en español
National Institutes of Health
National Institutes of Health
NIH Office of Extramural Research (OER)
Computer Retrieval of Information on Scientific Projects (CRISP)
Center for Scientific Review (CSR)
NIH Extramural Training Mechanisms
Extramural Policy Notices from the NIH Guide for Grants and Contracts
NIH & NOAA Recreation and Welfare Association plus! all Federal R&Ws & Military MWRs
NIH- Información en español
National Cancer Institute (NCI)
National Institutes of Health (NIH)
Department of Health & Human Services (DHHS)
FIRSTGOV
Related Links

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://newscenter.cancer.gov/
NCI's Web site for the press, managed by the NCI Office of Communications; contains news and information on cancer research and NCI programs and resources.

http://cri.nci.nih.gov/2subtier_e.cfm
Descriptions of NCI research initiatives.

http://researchportfolio.cancer.gov
Information on approximately 9,000 active research projects, including grants, contracts, and clinical trials. Can be browsed by program, topic, disease site, or geographic location.

http://resresources.nci.nih.gov/
Links to a variety of cancer-related information and resources for scientists.

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://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://www-cdp.ims.nci.nih.gov/about.html
The Cancer Diagnosis Program (CDP) stimulates and supports the development of tools to aid in the clinical management of cancer patients; focuses on informative characterization of tumor cells; supports technological development; assures access to research specimens; and facilitates the translation of new technology and better understanding of cancer biology to the clinic.

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

http://otir.nci.nih.gov/ir/index.html
The OTIR Industrial Relations site aims to educate companies about opportunities for collaboration with the NCI.

http://otir.nci.nih.gov/otir/

NCI's Office of Technology and Industrial Relations. 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://otir.nci.nih.gov/tech/index.html

The OTIR Technology site is designed to inform technology developers about relevant NCI initiatives, funding mechanisms, and current opportunities.

http://liaison.cancer.gov/CARRA

NCI's Consumer Advocates in Research and Related Activities (CARRA) program encourages people affected by cancer to provide their viewpoints and ideas directly to NCI staff so that the NCI can incorporate their perspective into its programs and activities. This 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.nci.nih.gov/cgi-bin/sb_internal

The NCI 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://cancernet.nci.nih.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://www.nci.nih.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://www1.od.nih.gov/cmo
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 Office of Extramural Research.

http://grants.nih.gov/grants/index.cfm
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://www.training.nih.gov/handbook/acronyms.html
Definitions of NIH acronyms.

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

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 150Kbps LAN or 56Kbps dial-up bandwidth).

General Government-Related Web Sites

http://firstgov.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://policyworks.gov

The Office of Governmentwide Policy (OGP) consolidates all of the General Services Administration's governmentwide policymaking activities within one central office. Contains links to resources on the management of Federal advisory committees and on travel management.

Notes

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U.S. DEPARTMENT OF HEALTH
AND HUMAN SERVICES
Public Health Service
National Institutes of Health

April 2004

WELCOME TO THE

NIH ELECTRONIC FORMS USERS' GROUP

HOME PAGE

Start by selecting the software you are using.

- **FileMaker Pro - Version 4.0**
- **JetForm FormFlow - Version 1.1 Filler**
- **Microsoft Word**
- **PDF Forms - Adobe Acrobat Reader**
- **Other Web Sites for Forms**

- **Also - NIH Letterhead - in Microsoft Word, PDF, and Word X for Mac**

Search | General information | Thank you

Your comments are important to us. Please send them via e-mail to: EATERJ@od.nih.gov