

How is the National Cancer Institute part of the Federal Government?

- *The Department of Health and Human Services (DHHS) is part of the Executive Branch of the United States Federal Government and is one of fourteen Presidential Cabinet Level Departments.*
- *The National Institutes of Health (NIH) is the largest of twelve agencies in the DHHS.*
- *The National Cancer Institute (NCI) is the largest of the 19 Institutes and 7 Centers that make up the NIH.*



Leadership of DHHS, NIH, and NCI

- *The Secretary of DHHS is selected by the President of the United States and is confirmed by the Congress.*
- *The Director of the NIH is also selected by the President of the United States and is confirmed by the Congress. The NIH does not currently have a Director.*
- *Since the enactment of the National Cancer Act in 1971, the Director of the NCI has been appointed by the President of the United States, and this appointment does not required confirmation by the Congress.*

Leadership of non-NCI Components of the NIH

The Directorships of the other NIH Institutes and Centers (i.e., other than that of the NCI) are filled by the NIH Director and do not require a Presidential Appointment or Congressional Approval

NCI's Bypass Budget

- *It is an annual strategic plan and budget document prepared by the National Cancer Institute (NCI)*
- *In this document of approximately one hundred pages in length, the leadership and staff of the NCI describe their vision for cancer research, the goals and progress in specific priority areas, and the plans and funding requirements for a specific fiscal year*

Why is the Bypass Budget produced each year by the NCI?

- *Each year, as mandated by the National Cancer Act of 1971, the NCI prepares this plan and budget proposal for supporting the cancer research workforce with the technologies and resources it needs, building on research successes, and ensuring that research discoveries are applied to improve human health*
- *The proposal is called the “Bypass Budget” because it is provided directly to the President of the United States in the fall of each year for use in formulating the budget request to Congress, thus “bypassing” the ordinary budget channels at the NIH and the DHHS*

Who should read the Bypass Budget?

In addition to the President and Congress, the document is intended for use by:

- NCI staff*
- The cancer research community*
- Professional organizations*
- Advisory group (e.g., NCAB) members*
- Cancer information, education, and advocacy organizations*
- Public and private policymakers whose decisions affect cancer research and care in America*

How did the NCI construct its budget request for 2003?

The budget request is divided into the following four categories:

- 2002 President's Budget for NCI (i.e., what the President asked for in the previous year);*
- 2003 Core Budget Increase Request (i.e., the funding increase that the NCI needs to support operations as in 2002, adjusted for inflation);*
- 2003 Challenge Budget Increase Request (i.e., additional funding that the NCI needs to support initiatives to improve the infrastructure for cancer research);*
- 2003 Opportunities Budget Increase Request (i.e., additional funding that the NCI needs to set scientific priorities for cancer research).*

How does the NCI spend its budget?

- *About 73% of the budget supports basic, translational, clinical, and population-based studies conducted by researchers and clinicians across the Nation through our Extramural Research Program*
- *About 16% of the budget supports the Intramural Research Program in which NCI scientists conduct cancer-related research*
- *About 3% of the budget supports our communication of the latest information to health professionals and the general public, including those with cancer*
- *About 4% of the budget supports the administration and management of NCI programs*

Where are grant applications reviewed at the NIH?

- *Institutes and Centers (ICs) generally handle the review of grants applications that have IC-specific relevance or focus, which can be related to the topic, the granting mechanism, or a request from the IC for applications on a particular area of research*
- *The Center for Scientific Review (CSR) manages the review of most of the investigator-initiated R01 grant applications, as well as the majority of R01s submitted in response to Program Announcements (PAs), most Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) applications, and most pre- and postdoctoral fellowships*

The Division of Extramural Activities (DEA) of the NCI

DEA is the operational unit for management of the review of funding mechanisms (i.e., grants and contracts) that have specific features and relevance to the mission of the NCI

Types of grant applications reviewed through NCI DEA

The funding mechanisms reviewed through NCI DEA include granting programs for support of training and career development programs, scientific conferences, Institute-specific solicitations for defined types of grant applications (i.e., Requests for Applications [RFAs] and Program Announcements [PAs]), multi-project program projects, Specialized Programs of Research Excellence (SPOREs), multi-center clinical trials, and centers for basic and clinical cancer research (i.e., cancer centers)



Review of Contract Proposals

NCI DEA is also responsible for the technical merit review of research-and-development contract proposals that have been submitted in response to published Requests for Proposals (RFPs), which may be highly specific with respect to the nature of the work to be performed and the results to be delivered

The Federal Advisory Committee Act (Public Law 92-463)

- *Congress recognizes that numerous committees, boards, commissions, councils, and similar groups are established to advise officers and agencies in the executive branch of the Federal Government*
- *These advisory groups are frequently a useful and beneficial means of furnishing expert advice, ideas, and diverse opinions to the Federal Government*
- *This law, abbreviated as FACA, sets the guidelines for the operations of such groups*

The National Cancer Advisory Board (NCAB)

The National Cancer Advisory Board is an advisory group that gains its mandate and operates through the FACA, and, as you know, the members are appointed by The President of the United States

Important FACA Guidelines for the NCAB

- *Meetings shall be open to the public, except for certain sessions that are permissible by law to be closed to the public*
- *Notices of meetings shall be published in the Federal Register*
- *Interested and authorized persons shall be permitted to attend and present information to the NCAB*
- *Minutes of meetings are taken and the accuracy of all minutes shall be certified to by the chairperson of the NCAB*
- *There shall always be designated an officer or employee of the Federal Government to attend and moderate each meeting of the NCAB*

Loci of Review of Applications

- *All grant applications submitted to the NIH are received by the Center for Scientific Review (CSR). Referral Officers in CSR then refer (i.e., distribute) the grant applications either to review groups managed within CSR or to the review operations of other appropriate Institutes and/or Centers (ICs) of the NIH (e.g., NCI DEA)*
- *CSR review groups and the IC review units follow the same standard NIH review policies and both utilize Scientific Review Groups (which are chartered committees comprised of “permanent” and ad hoc members that meet three times per year) and Special Emphasis Panels (which are convened for specific one-time meetings and are made up of ad hoc experts)*

Balance of review of cancer-related research between CSR and NCI DEA

- *Although the CSR typically reviews about three times as many cancer research-related grant applications as the NCI DEA each year, the total dollar amounts related to NCI grant awards associated with the applications reviewed by CSR and NCI DEA are close to parity*
- *These proportions are primarily the result of the overall difference in the types of grant mechanisms reviewed by the CSR and NCI DEA. For example, the average annual cost of an individual R01 award was approximately \$300,000 in the year 2000, whereas the average costs of program project and cancer center awards in the same year were approximately \$1,600,000 and \$2,800,000, respectively*

Review of Cancer-Related Research at the NIH and NCI

- *In summary, the review activities of the NIH CSR and the NCI DEA complement each other*
- *Together, these two organizations provide expert reviews (as free of bias as conceivably possible) for the full range of cancer research-related grant applications, cooperative agreements, and contract proposals submitted to the NIH and the NCI*

Definition of a Special Government Employee

- *A Special Government Employee is an officer or employee in the executive branch of the Federal Government who is appointed to perform temporary duties, with or without compensation, for a period not to exceed 130 days during any period of 365 consecutive days*
- *As a Member of the NCAB, you are a Special Government Employee*

Ethics Rules for Advisory Committee Members

All DHHS Advisory Committee Members appointed as Special Government Employees are required by Federal Law to file a complete financial disclosure report when first appointed, and they must update the information on that report before each meeting throughout the term of their appointment

Ethics Rules for Advisory Committee Members (continued)

*During the term of their appointments,
Special Government Employees must be
aware of relevant criminal conflict of
interest statutes and they must follow
defined standards of ethical conduct*

Funding of Foreign Grant Applications and of Domestic Applications with Substantial Foreign Components

All scored grant applications from foreign institutions, international organizations, and domestic institutions with substantial foreign components must be listed in the Board Books for presentation at the NCAB meetings

Foreign Grant Applications and Domestic Applications with Substantial Foreign Components (continued)

- *Grant applications submitted from foreign or international organizations may not be funded unless approved by the NCAB*
- *Grant awards to domestic institutions that contain substantial foreign components do not require special NCAB concurrence, except when special considerations (e.g., unusually large budget for the foreign component, potential controversy, or other extenuating factors) are involved*
- *Foreign institutions are excluded from receiving awards for funding of certain grant mechanisms (e.g., program project grants, cancer center core grants, resource grants, institutional National Research Service Awards)*

Orientation Book for New NCAB Members

- *Information about the DHHS, the PHS, the NIH, and the NCI, and their relationships*
- *The Mission of the NCI*
- *Activities led by the NCI*
- *Organizational charts for the NCI and its component divisions*
- *Advisory Groups and their roles*
- *Federal Laws and Ethics Rules for NCAB Members*
- *Legislation as related to the NCI*
- *NCI Budget Information*
- *Grants Submission and Review Process*
- *Internet (Web) Addresses for Electronic Access to the above information and more*

Limits on Increases in Budgets for Competing Renewal Grants

- *The National Cancer Institute cannot sustain a viable number of grant awards if the average costs of grants rise faster than the NCI budget*
- *Applicants who are submitting Type 2 competitive renewal R01 (single project) and P01 (program project) applications are now instructed that the requested budgets cannot exceed a 20% increase above the budgets in the prior funding period*
- *This cap is used as one way of maximizing the numbers of grants that are awarded and of ensuring that budget shortfalls do not occur*

Reasons for the Closed NCAB Session

What is the NCAB Electronic Council Book?

How do I use the NCAB Electronic Council Book?

Expedited Concurrence

Surveillance of the NCI Research Portfolio

Breadth of Cancer-Related Research Supported by the NCI



Global View of Direction

Appeals of the Review and Scoring of Applications

Exceptions and Funding Decisions

Delegations of Authority for the NCAB

Applications with Problems Related to the Inclusion of Women, Minorities, and/or Children

Applications with Problems Related to the Study of Human Subjects

Applications with Problems Related to Animal Welfare

Problems with Applications Related to Biohazards

The NCI Executive Committee



The President's Cancer Panel



The Board of Scientific Advisors of the NCI



The Board of Scientific Counselors of the NCI

