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Accelerated Peer Review *APR*

For some grant mechanisms (e.g., P01 applications) this process is used to allow applicants whose applications are close to, but not within, the deadline to submit a brief response (within a set page limit and by a set date) to the summary statement (i.e., the reviewers' comments) without having to submit an amended application at the next submission deadline.

Acceptable Proposal

A proposal judged to be complete in itself, to contain no major deficiencies, and to present sufficient evidence to indicate that the offeror is capable of satisfying the minimum requirements of the Request for Proposal (RFP) and is thus eligible for further consideration.

Accrual Basis

An accounting method whereby revenues and expenses are identified with specific periods of time, such as a month or year, and are recorded when they are earned or incurred without regard to the date of receipt or payment of cash; distinguished from cash basis.

Accrual Tables

Numbers of human subjects/patients recruited/enrolled into a research study (e.g., a clinical trial).

Acquisition Award

Contract award; the decision by the authorized contracting officer to officially award a contract to an offeror.

Acquisition Cost

The net invoice price of property or supplies including the cost of modifications, attachments, accessories, or auxiliary apparatus necessary to make the property usable for the purpose for which it was acquired.

Acquisition Plan and/or Request for Contract *AP/RFC, usually RFC/AP*

A document used to initiate an acquisition action which provides the background information necessary for the preparation of the Request for Proposal. (See Section IV, D, of the Research Contracts Branch's Orange Book).

Acquisition Process at NIH

The acquiring by contract with appropriated funds of supplies or services by and for the direct benefit or use of the Federal Government.

Activities to Promote Research Collaborations *APRC*

This is an initiative created by the Division of Cancer Biology that provides limited supplemental support to current DCB-funded investigators for meetings/workshops or grant-related research activities to establish focused scientific research collaboration in novel and promising areas related to the parent grant.

Activity Codes (Funding Mechanisms)

Activity codes are three-digit alphanumeric combinations that identify a specific category of extramural activity or mechanism of support. The NIH has more than 100 research support mechanisms. For a comprehensive list of activity codes, see:
http://grants.nih.gov/grants/funding/ac_search_results.htm.

Ad Hoc Review

Review of application(s) or contract(s) by experts selected on a temporary basis for their expertise and experience.
See Also Special Emphasis Panel

Administrative Notes (in Summary Statements)

Additional comments/concerns that may be included in Summary Statements (SS).
See Also Summary Statement

Administrative Requirements

The general business management practices that are common to the administration of all grants, such as financial accountability, reporting, equipment management, and retention of records.

Advance Agreement

Agreement negotiated before a contractor incurs a cost, specifying whether a cost is allowable. An advance agreement may be negotiated before or during a contract and must be in writing. Advance agreements may be specific to a contract, group of contracts, or all contracts of a contracting office, agency, or several agencies.

Advance Copies

In most cases, the Referral Officer will deliver these copies of applications provided by applicant(s) to the appropriate Scientific Review Administrator and Program Director.

Advance

A payment made by Treasury check or other appropriate payment mechanism to a recipient upon its request either before cash disbursements are made by the recipient or through the use of predetermined payment schedules.

Adverse Event Expedited Reporting System AdEERS

An electronic system for expedited submission of adverse event reports that is used by the NCI Clinical Trials Evaluation Program.

Adverse Events Reporting

Adverse event collection and reporting is a routine part of every clinical trial. The first step is to identify the event using the Common Toxicity Criteria (CTC). The severity of the event should then be graded using the CTC criteria. Next, determine if the adverse event is related to the medical treatment or procedure (attribution). If so, determine whether the adverse event is expected or unexpected. With this information and the adverse event reporting section in each protocol, the investigator can determine whether an adverse event should be reported to the NCI as an expedited report (AdEERS) or a routine report (CDUS or CTMS).

Affiliate

This term has the same meaning as set forth in 13 CFR Part 121 - Small Business Size Regulations, §121.103, 'What is affiliation?'

Affiliation

Who or what someone or something is associated with (e.g., a person's institutional affiliation would be the institution(s) he/she is associated with).

Allowable Cost

Those costs that are reasonable, allocable, consistently applied and not specifically prohibited by federal regulation. Cost that is reasonable, meets accepted accounting principles, is defined in the Federal Acquisition Regulation (FAR) 31, or is agreed to by the contracting parties.

Alphanumeric Combination

Used in activity codes to identify specific categories of extramural activity or mechanisms of support and also used in application identification numbers.

American Indian or Alaska Native

A person having origins in the original peoples of North, Central, or South America who maintains tribal affiliation or community.

Analysis plan(s)

Human subjects term indicating NIH requirements for analysis plans which depend on the type of research proposed. They may include monitoring to detect and address adverse effects of the research as well as the ability to detect intervention differences among different types of human subjects, for example women and minorities, ethnic or racial subgroups, and children. Requirements also differ depending on the risk and complexity of the study and the probability of finding differences in the intervention effect for participant subgroups. For grantees, renewal applications (as well as contract proposals) must include the results of such subgroup analyses.

See Also Valid Analysis

Animal Welfare

Refers to special requirements that apply to NIH grants or contracts involving the use of live vertebrate animals in research, training, experimentation, testing, and related purposes.

Appendix and Appendices

An Appendix or Appendices to a grant application may include reprints, manuscripts, figures, photographs, etc. These items may be submitted with any type of application and are usually received in limited numbers.

Applicant

The organizational entity that, at the time of award, will qualify as a Small Business Concern (SBC) and that submits a grant application for a funding agreement under the SBIR or STTR Program.

Application Interview *AI*

Also called a Reverse Site Visit. This method of review of a grant application is conducted only for amended multicomponent (e.g., Program Project) applications when they have been changed substantially by the applicant in response to comments stated in the summary statement document after review of the previous application.

Approach

The adequacy and quality of the experimental approaches, as well as the overall design, presented in a grant application. Also called "budget appropriation."

Appropriation Act

The statute that provides the authority for Federal agencies to incur obligations and to make payments out of the U.S. Treasury for specified purposes.

Approval List/Funding List

A list sent by the program office to the Grants Management Officer, showing which grant applications on the list are approved for funding and in what order.

Asian

A person having origins in the original peoples of the Far East, Southeast Asia, or the Indian subcontinent including, Cambodia, China, India, Japan, Korea, Malaysia, Pakistan, the Philippine Islands, Thailand, and Vietnam.

Assent

Agreement to participate in research by someone who is not competent to give informed consent, e.g., a child.

Assignment (of applications for review)

At the first level of assignment, applications are assigned by Referral Officers in the Center of Scientific Review (CSR) to specific Institutes/Centers (ICs) of the NIH for funding and to CSR or specific ICs for review. At the second level of assignment, applications are assigned to NIH (CSR or NCI) Scientific Review Administrators (SRAs) and NIH (NCI) Program Directors who are responsible for managing the peer review and award processes, respectively. At the third level of review, the SRAs are responsible for assignment of applications to particular peer reviewers.

Assimilation

Extent to which an individual enters a new culture and becomes a part of it. Includes both the motivation of the individual to enter the mainstream culture and the extent to which members of the mainstream culture welcome or discourage the entry and inclusion of that person in the mainstream culture.

Assistance Instrument or Assistance Award

A grant or cooperative agreement.

Assistance

The award of money, property, services, or anything of value to a recipient to accomplish a public purpose of stimulation or support authorized by a Federal statute. Assistance mechanisms such as grants and cooperative agreements are awarded in less detail than are acquisitions, such as contracts, and responsibilities for ensuring performance rest largely with a recipient or may be shared with the government.

Assurance

A certification by an applicant, normally included with the application or State plan, that it will abide by a particular requirement if awarded a Federal grant.

Autopilot Items

End-of-fiscal-year budget items that can be paid when extra money is available.

Average Programmatic Reduction

The dollar amount a grant award is reduced from the amount recommended by the scientific review group in initial peer review. This is done so institutes can maintain a sufficient number of grants in their portfolio and combat inflation of grant costs.

Awaiting Receipt of Application ARA

An official letter that is submitted electronically over a secure web site by a Program Director to signify that his/her institute or center (IC) agrees to accept the submission of a grant application (typically involving a request for greater than or equal to \$500,000 per year in direct costs) for peer review and possible funding. An ARA letter can also be used by a Program Director to inform the responsible Scientific Review Group or Administrator that an application will be submitted late (i.e., after the official deadline).

Award

The provision of funds based on an approved application and budget to provide general financial assistance to an organization or an individual to carry out an activity or program.

Awardee

Also called a Grantee. The person or persons who have submitted a grant application to the NIH and, following peer review and the decision making process, have been awarded funds by an NIH Institute or Center to conduct a specific program of research.

Awarding Agency

Any department, agency, commission, or instrumentality in the executive branch of the Federal Government that makes awards to eligible recipients.

Awarding Office

The NIH Institute or Center responsible for the award, administration, and monitoring of grant-supported activities.

Acquired Immune Deficiency Syndrome *AIDS*

A disease in which there is a severe loss of the body's cellular immunity, greatly lowering the resistance to infection and malignancy.

Accession Number

Related to electronic submission of applications, the Accession number is the Agency tracking number provided for the application after Agency validations.

Active Grant

A grant that meets the following requirements:

Today's date is between the budget start and end dates.

The grant has an eRA System (IMPAC II) application status code of "Awarded. Non-fellowships only." or "Awarded. Fellowships only."

Administrative Expenses

Expenses incurred for the support of activities relevant to the award of grants, contracts, and cooperative agreements and expenses incurred for general administration of the scientific programs and activities of the National Institutes of Health.

Application Identification Number *A/N*

The application number identifies:

type of application (1)

activity code (R01)

organization to which it is assigned (AI)

serial number assigned by the Center for Scientific Review (CSR) (183723),

suffix showing the support year for the grant (-01)

other information identifying a resubmission [previously "amendment"] (A1), supplement (S1), or a fellowship's institutional allowance. For contracts, the suffix is replaced by a modification number.

Sample Application Identification Number: 1-R01-CA164529-01A1S1

Application Viewing Window

Once an error-free application is submitted through Grants.gov to eRA, the eRA system assembles an application image and posts it in the PD/PI's Commons account. The PD/PI, any delegated Assistants, and the Signing Official (SO) have 2 business days to view the assembled application in Commons - just as a reviewer would see it. Unlike the error correction window which begins the day after the submission deadline, the application viewing window is linked to the time of submission (i.e., begins the day after the assembled application image is posted in Commons).

Within the viewing window, the SO can Reject the application and stop it from moving further in the process. After the viewing window, the application automatically moves forward for further consideration and the submission process is complete.

Assistant Role ASST

In the NIH Commons, the role designed to allow PIs to delegate certain responsibilities for data entry of grant information and upkeep of their personal profiles. The ASST does not have any other functions in the system.

Alien Registration Receipt Card

Commonly known as "Green Card," shows a person's status as a permanent resident with a right to live and work permanently in the U.S. Also called Form I-551.

American Recovery and Reinvestment Act (ARRA)

The American Recovery and Reinvestment Act of 2009 was signed into law by President Obama on February 17th, 2009. The Act includes measures to modernize our nation's infrastructure, enhance energy independence, expand educational opportunities, preserve and improve affordable health care, provide tax relief, and protect those in greatest need.

Approved Budget

The financial expenditure plan for the grant-supported project or activity, including revisions approved by NIH as well as permissible revisions made by the grantee.

Academic Research Enhancement Award AREA (R15)

This funding mechanism is designed to enhance the research environment of educational institutions that have not been traditional recipients of NIH research funds (i.e., health professional academic institutions with less than \$3 million of NIH support in total costs in four or more of the last seven years), this award provides limited funds to those institutions' faculty members to develop new research projects or expand ongoing research activities in health sciences and to encourage students to participate in the research activity. The NIH invites applications for R15 AREA grants through a standing, ongoing Program Announcement. These grants support small-scale research projects conducted by faculty in primarily baccalaureate degree-granting domestic institutions. Awards are for up to \$75,000 for direct costs (plus applicable indirect costs) for periods not to exceed 36 months. For details see: <http://grants.nih.gov/grants/funding/area.htm>

Accelerated Executive Review AER

The process that may be used by the National Cancer Institute (NCI) Scientific Program Leadership (SPL) to consider and fund applications whose priority scores are just beyond the payline.

Accrued Expenditures

The charges incurred by the recipient during a given period requiring the provision of funds for: goods and other tangible property received; services performed by employees, contractors, subrecipients, subcontractors, and other payees; and other amounts becoming owed under programs for which no current service or performance is required, such as annuities, insurance claims, and other benefit payments.

Accrued Income

The sum of earnings during a given period from services performed by the recipient and from goods and other tangible property delivered to purchasers; and amounts becoming owed to the recipient for which no current service or performance is required by the recipient

Administration for Children and Families *ACF*

The Administration for Children and Families (ACF), within the Department of Health and Human Services, is responsible for federal programs that promote the economic and social well-being of families, children, individuals, and communities.

Administrative Resource Center *ARC*

The areas the Administrative Resource Center (ARC) assist with are budget, travel, procurement and space management. The ARC manager reports to the Deputy Associate Director, Office of Management, NCI. The ARC mission statement says that the ARC is to be a recognized leader in the field of administration, providing the highest quality customer service available to our NCI programs whose ultimate goal is to find a cure for cancer. To this end, we strive to provide expert, confidential, and efficient administrative service with professionalism, integrity and compassion.

Administratively Withdrawn

Application administratively withdrawn by the funding agency

Adverse Effect

Unanticipated problem or unfavorable symptom or disease occurring during a clinical study, though not necessarily caused by the study treatment, which harms subjects or others, for example, a loss of research records, drug overdose, serious symptom, or death. Go to 45 CFR part 46, subpart A.

Adverse Event

Any unfavorable and unintended sign (including an abnormal laboratory finding), symptom or disease temporally associated with the use of a medical treatment or procedure regardless of whether it is considered related to the medical treatment or procedure.

Advisory Committee of the Director *ACD*

Provides advice and recommendations for the oversight of specific programs to the Director of an NIH Institute or Center; there is an Advisory Committee of the Director (ACD) in the NCI.

Agency for Healthcare Research and Quality *AHRQ*

This agency in the U.S. Dept. of Health and Human Services provides evidence-based information on health care outcomes; quality; and cost, use, and access. Information from the Agency for Healthcare Research and Quality's (AHRQ) research helps people make more informed decisions and improve the quality of health care services. AHRQ was formerly known as the Agency for Health Care Policy and Research.

Alcohol, Drug Abuse, and Mental Health Administration *ADAMHA*

Effective FY 1993, the service components of the Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA) became the Substance Abuse and Mental Health Services Administration (SAMHSA). The three research components of the ADAMHA - the National Institute on Alcohol Abuse and Alcoholism (NIAAA), the National Institute on Drug Abuse (NIDA), and the National Institute of Mental Health (NIMH) - became part of the NIH.

ALERT System ALERT

The Department of Health and Human Services (DHHS) Alert System is now located in the Office of Research Integrity (ORI), Office of Public Health and Science (OPHS), Office of the Secretary(OS). The system allows the NIH to identify research contract proposals that include a principal investigator who is under formal investigation. See Manual Chapter 6309-1 at <http://www1.od.nih.gov/oma/manualchapters/contracts/6309-1/>

Alterations and Renovations

Grant budget category referring to work to change the interior or other physical characteristics of an existing facility or installed equipment.

Amended Application

See Resubmission

Animal Welfare Act

The Animal Welfare Act (AWA) is intended to ensure the humane treatment of animals that are intended for research, bred for commercial sale, exhibited to the public, or commercially transported.

Animal Welfare Assurance

Document that an institution and all performance sites involving animals in research must have on file with the Office of Laboratory Animal Welfare before a PHS agency may award a grant or contract.

Animals in Research Codes

Number that a scientific review group places on a summary statement during initial peer review reflecting the application of regulations for research animals to a project; some codes indicate a concern that would result in a bar to award.

Animals in Research

Any live, vertebrate animal used for research, research training, biological testing, or related purposes. Go to the PHS Policy on Humane Care and Use of Laboratory Animals web site for information and links to legislation
See Also Office of Laboratory Animal Welfare and Animal Welfare Assurance

Anniversary Date

Based on a grant's start date, date used as the basis for funding noncompeting and competing continuation awards. NCI cannot fund these awards before the anniversary date.

Appeals Officer

Designated IC Official responsible for providing guidance to staff to help resolve issues related to appeal of review. At NCI, the DEA Director serves as the Appeal Officer as well as the Executive Secretary of the NCAB. In that capacity, he/she ensures that Board members receive all necessary documentation and that the Board considers all appeals as per NIH policy.

Application Identification Numbers

Three unique numbers identify each application: an application identification number, an accession number, and a five-part assignment number. The parts of the assignment number include: Application Type, Activity Code, Awarding Unit/ ICISerialNo.1 Suffixes1 R01 CA 12789 Yr/Other, 01/A1

Application Submission

Most competing grant programs at NIH require electronic application submission. Applicant organizations submit using Grants.gov, the federal-wide portal for finding and applying for grants. Applicants must track their application submission from Grants.gov to the eRA Commons, NIH's system for grants administration, to complete the submission process.

Application Types

Broad category of grant application, noted as the first digit on an application identification number. Type 1: New Application, Type 2: Competing continuation (renewal) application. Type 3: Supplement to current grant application. Type 4: Extension (noncompetitive) application. Type 5: Noncompeting continuation application. Type 6: Change of institute or center (new training programs) (Not used since the 1970's) application. Type 7: Change of grantee or training institution application. Type 8: Change of institute or center (noncompeting continuation) application. Type 9: Change of institute or center (competing continuation) application.

Application

A request for financial support of a project or activity submitted to NIH on specified forms and in accordance with NIH instructions.
See Also Grant Application

Applied Information Systems Branch AISB

Satisfies the information requirements of the Division and coordinates IRM activities with other relevant NCI and NIH units and provides high quality information analysis, design, development, and coordination of applications in support of Divisional business processes. Also serves as the focal point for the Division in the development, deployment and application of specialized software and data bases required for the conduct of review, referral, coding, advisory, and other extramural applications.

Association for Assessment and Accreditation of Laboratory Animal Care AAALAC

Association for Assessment and Accreditation of Laboratory Animal Care (AAALAC) is a private nonprofit organization that promotes the humane treatment of animals in science through a voluntary accreditation program. More than 640 companies, universities, hospitals, government agencies and other research institutions have earned AAALAC accreditation, demonstrating their commitment to responsible animal care and use. These institutions volunteer to participate in AAALAC's program, in addition to complying with the local, state and federal laws that regulate animal research.

Award Mechanism

Extramural research awards are divided into three main funding mechanisms: grants, cooperative agreements and contracts. A funding mechanism is the type of funded application or transaction used at the NIH. Within each funding mechanism NIH includes programs. Programs can be further refined by specific activity codes.

Award Type

NIH uses activity codes (e.g. R01, R43, etc.) to differentiate the wide variety of research-related programs we support. NIH Institutes and Centers (ICs) may vary in the way they use activity codes; not all ICs accept applications for all types of grant programs or they apply specialized eligibility criteria. Look closely at Funding Opportunity Announcements (FOAs) to determine which ICs participate and the specifics of eligibility. See *Biomedical Information Science and Technology Initiative*

Advisory Council or Board

National Advisory Council or Board, mandated by statute, that provides the second level of review for grant applications for each institute/center that awards grants. The Councils/Boards are comprised of both scientific and lay representatives. Council/Board recommendations are based on scientific merit (as judged by the initial review groups) and the relevance of the proposed study to an institute's programs and priorities. With some exceptions, grants cannot be awarded without recommendations for approval by a Council/Board. In the NCI, this council is called the National Cancer Advisory Board.

AIDS and Cancer Specimen Resource ACSR

The primary objective of the AIDS and Cancer Specimen Resource (ACSR) will be to acquire, store and equitably distribute tumor tissues, biological fluids and associated demographic data from patients with HIV-associated malignancies. In addition, the ACSR will serve and support biorepository banking activities for the AIDS Malignancy Clinical Trials Consortium.

American College of Radiology Imaging Network ACRIN

Is an international imaging cooperative group, headquartered in Philadelphia, PA with biostatistical and data management headquartered in Providence, RI at Brown University. It is sponsored by the Cancer Imaging Program (CIP), Division of Cancer Treatment and Diagnosis (DCTD), National Cancer Institute (NCI), as well as philanthropies.

Academic Public-Private Partnership Program AP4

The purpose of the Academic Public-Private Partnership Program (AP4) initiative is to provide support for the formation of new partnerships or significant expansions of existing partnerships among academia, industry, non-profit institutions, and government entities. The partnerships will conduct novel cancer therapeutic, prevention, diagnostic, and imaging intervention-directed research. The goal of the research will be to speed the translation of newly discovered cancer interventions to clinical trials.

Account Administrator AA

An individual typically in the grantee organization's central research administration office designated by a SO to facilitate the administration of NIH eRA Commons accounts. The Account Administrator (AA) can create, modify and/or remove the necessary accounts for these types: AO, AA, FSR, PI or ASST. Although the AA can create additional accounts, the AA cannot modify institutional profile (IPF) information. See Also *Association for Assessment and Accreditation of Laboratory Animal Care*

Authorized Organizational Representative AOR

The designated representative of the grantee organization in matters related to the award and administration of its NIH grants. In signing a grant application, this individual certifies that the applicant organization will comply with all applicable assurances and certifications referenced in the application. This individual's signature on the grant application further certifies that the applicant organization will be accountable both for the

appropriate use of funds awarded and for the performance of the grant-supported project or activities resulting from the application.

Account

As used by the National Institutes of Health (NIH) eRA Commons (<https://commons.era.nih.gov/>), a personal account an individual uses to log into the NIH eRA Commons which is identified by a unique combination of username and password.

Authorized Institutional Business Official

The individual, named by the applicant organization, who is authorized to act for the applicant and to assume the obligations imposed by the Federal laws, regulations, requirements, and conditions that apply to grant applications or grant awards. Also called "Institutional business official."

B

|A|B|C|D|E|F|G|H|I|J|K|L|M|N|O|P|Q|R|S|T|U|V|W|X|Y|Z|

Bar to Award

Block to an award of a grant application until concerns or special problems are resolved. If the concern is about human subjects, the study section puts a code 44 in the summary statement indicating a bar to award. For additional codes, see other human subjects inclusion codes, human subjects involvement codes, and animals in research involvement codes.

Basic, Applied, and Developmental Research Codes *B/A/D*

Codes applied to grants to characterize their thrust along this continuum from basic research to clinical deployment. Grants need not be characterized by only one code; 60% B, 40% A is an acceptable coding, for example.

Bayh-Dole Act of 1980

A Federal law that encourages universities and researchers to develop their inventions into marketable products.

Best Practices Manual

A manual of best practices presented on the NCI Intranet to guide NCI staff in their performance of activities related to review, funding, and administration of grant applications and awards. This document was created by and is maintained by the NCI Extramural Advisory Board.

Bias

Human choices or any other factors beside the treatments being tested that affect a study's results. Clinical trials use many methods to avoid bias, because biased results may not be correct.

Big SOW

Now called a Consolidated Services Contract at the NIH Suggest removing. Definition placed at Consolidated Service Contract

Bioethics

Bioethics is the philosophical study of the ethical controversies brought about by advances in biology and medicine. Bioethicists are concerned with the ethical questions that arise in the relationships among life sciences, biotechnology, medicine, politics, law, and philosophy. (From Wikipedia, the free encyclopedia, in Nov. 2010.)

Biographical Sketch or Biosketch

Curriculum vitae submitted by all applicants associated with an NIH grant application or contract proposal. Form in the PHS grant application in which the applicant states employment history, relevant publications, and ongoing and completed research support. Typically, a biosketch is limited to two printed pages.

Bioinformatics

Bioinformatics is the application of statistics and computer science to the fields of biology.

Bioinformatics involves the creation, use, and advancement of databases, algorithms, computational and statistical techniques and theories to solve formal and practical problems arising from the management and analysis of biological data. (Adapted from Wikipedia, the free encyclopedia, in Nov. 2010.)

Biological Material License *BML*

License agreement used when NIH seeks to transfer unpatented biological materials to a for-profit entity for commercial use.

Biologics License Application *BLA*

The study results submitted to the U.S. Food and Drug Administration (FDA) once clinical trials are completed.

Biomedical Research and Development Price Index *BRDPI*

The annual inflationary index for the cost of conducting biomedical research. The BRDPI was developed for the NIH to measure real annual changes in the prices of items and services required for research and development (R&D) activities.

Biostatistics

Statistical processes and methods applied to the analysis of biological phenomena.

Black or African American

Human subjects term indicating a person having origins in the black racial groups of Africa. "Haitian" or "Negro" can be used in addition to "Black" or "African American."

Block Grant

A type of mandatory grant where the recipients (normally States) have substantial authority over the type of activities to support, with minimal Federal administrative restrictions.

Board of Scientific Advisors *BSA*

A group that provides scientific advice on a wide variety of matters concerning scientific program policy, progress and future direction of the NCI's extramural research programs, and concept review of extramural program initiatives. The Board shall advise the Director and Deputy Director for Extramural Science, NCI, and the Director of each NCI Division on a wide variety of matters concerning scientific program policy, and progress and future direction of extramural research programs of each of the Divisions. The advisory activities include the evaluation of NCI awarded grants, cooperative agreements and contracts and concept review of those activities which it considers meritorious and consistent with the Institute's programs. The advisory role of the Board is scientific and does not include deliberation on matters of public policy. The members of this board are appointed to 4-year terms by the NCI Director.

Board of Scientific Counselors *BSC*

A group that advises the Directors of the Intramural Divisions of the NCI and the Director and Deputy Director, NCI, on a wide variety of matters concerning the state-of-the-science in the NCI's intramural research programs, including the scientific program policy and the progress and future direction of research programs of each Division. This includes the evaluation of performance and productivity of each Division, including the evaluation of performance and productivity of staff scientists through periodic site visits to intramural laboratories, and evaluation and advice on the course of each Division's programs. The members of this board are appointed to 4-year terms by the NCI Director.

Budget Authorization

Legislation authorizing the government to spend money on a program for several years.

Budget Caps

Limits on the total dollar amounts requested and/or awarded for specific mechanisms or types of grant applications; Also, limits on the percent increase or dollar increase in budgets of noncompeting or competing renewal grant applications.

Budget for Entire Proposed Period of Support

Sum of the budgets projected for all years of the competitive segment for an award.

Budget Period

The interval (usually 12 months) into which the grant project period is divided for funding and reporting purposes. Also called "grant budget period."

Budget

A categorical or noncategorical request for funds required to support the proposed activity.

Business/Cost Proposal Evaluation

The process of appraising an offeror's business/cost proposal to determine the reasonableness of costs proposed, and the management capabilities of the offeror to perform the required work in a timely manner.

Bioengineering Consortium *BECON*

The focus of bioengineering issues at the NIH which consists of senior-level representatives from each of the NIH Institutes, Centers, and Divisions plus representatives of other Federal Agencies concerned with biomedical research and development.

Biosketch

A Biosketch is your curriculum vitae presented in a specified NIH format. Your curriculum vita (CV) is not acceptable where a Biosketch is requested. The NIH Biosketch form is available online as a fill-in PDF file or Word document. You will upload the form through your online application.

Blinded Study

A clinical trial in which participants are unaware if they are in the experimental or control arm of the study.

Biomedical Information Science and Technology Initiative *BISTI*

A consortium of representatives from each of the NIH institutes and centers that serves as the focus of biomedical computing issues at the NIH. The mission of Biomedical Information Science and Technology Initiative (BISTI) is to make optimal use of computer science and technology to address problems in biology and medicine by fostering new basic understandings, collaborations, and transdisciplinary initiatives between the computational and biomedical sciences.

Budget Appropriation

A legislative act authorizing the expenditure of a designated amount of public funds for a specific purpose.

Best And Final Offer *BAFO*

A final proposal submitted by offerors which documents all cost and technical agreements reached following completion of negotiations with the Contracting Officer on a proposal submitted in response to a Request for Proposal (RFP).

See Final Proposal Revision

Bilateral Agreement

A general science agreement between the U.S. and a foreign country. Grant applications from institutions in countries that have been recommended for approval by the scientific review group are given special funding consideration by Council.

Biotechnology Resource Grant Program *P41*

National Institutes of Health (NIH), encourages grant applications for national Biomedical Technology Research Centers. These Centers conduct research and development on new technologies and new/improved instruments driven by the needs of basic, translational, and clinical researchers. The Centers are charged to make their technologies available, to train members of the research community in the use of the technologies, and to disseminate these technologies and the Center's experimental results broadly.

Bridge Awards (*R56*)

Provide one year of funding so investigators can continue research while reapplying for an R01 grant, or enable new investigators to gather preliminary data to improve their applications. Investigators do not apply for bridge awards but are selected from R01 grants at the payline margin. A bridge award is made as an R21 with one year of funding, which the PI can choose to spend over a two-year period. This enables the PI to submit an amended R01 application for the next receipt date while receiving interim (bridge) funding under the R21 mechanism.

Broad Agency Announcement *BAA*

The Broad Agency Announcement (BAA) is a general solicitation announcement that identifies areas of scientific interest or aims to advance science. It differs from a Request for Proposals (RFP), which specifies a service or product that the government wishes to acquire. BAAs include criteria for selecting proposals and attracting qualified offerors, who develop a statement of work and performance specifications. The BAA is a competitive procedure available for use in fulfilling the requirement for full and open competition in the acquisition process. BAA's may be used for scientific study and experimentation directed toward advancing state-of-the-art or increasing knowledge or understanding rather than focusing on a specific system or hardware solution.

Breast Cancer and Environment Research Centers *BCERC*

The Breast Cancer and the Environment Research Centers (BCERC) sponsored by the National Institute for Environmental Health Sciences (NIEHS) and the National Cancer Institute (NCI) were established to better understand how environmental factors may influence pubertal development and to enable primary breast cancer prevention strategies. In 2003, after a period of focused and thoughtful advocacy integrated with scientific consultation, BCERCs were awarded to The Fox Chase Comprehensive Cancer Center in Philadelphia, Pennsylvania; Michigan State University in East Lansing, Michigan; the University of Cincinnati, Ohio; and the University of California San Francisco Helen Diller Family Comprehensive Cancer Center.

Blood and Marrow Transplant Clinical Trials Network *BMTCTN*

Conducts large clinical trials focused on marrow and cord blood transplants

Broad Agency Agreement *BAA*

A general solicitation announcement that identifies areas of scientific interest or aims to advance science. It differs from a Request for Proposals (RFP), which specifies a service or product that the government wishes to acquire. Broad Agency Agreements (BAAs) include criteria for selecting proposals and attracting qualified offerors, who develop a statement of work and performance specifications. The BAA is a competitive procedure available for use in fulfilling the requirement for full and open competition in the acquisition process. BAA's may be used for scientific study and experimentation directed toward advancing state-of-the-art or increasing knowledge or understanding rather than focusing on a specific system or hardware solution

Breast Cancer Surveillance Consortium *BCSC*

Is an NCI-sponsored collaborative network of mammography registries with linkages to tumor registries and pathology data. The Breast Cancer Surveillance Consortium (BCSC) was established in 1994 in response to a legislative mandate from the 1992 Mammography Quality Standards Act (MQSA) to evaluate the performance of mammography in community practice and related screening and breast cancer outcomes. Several SEER investigators participate in the Consortium.

C

|A|B|C|D|E|F|G|H|I|J|K|L|M|N|O|P|Q|R|S|T|U|V|W|X|Y|Z|

Cancer Education and Career Development Program *R25T*

This is a program that was developed uniquely by the National Cancer Institute (NCI) to encourage institutions to develop training programs that are multi-departmental and/or multi-institutional and focused on preparing predoctoral and postdoctoral candidates to conduct cancer research in team settings that are highly-interdisciplinary and collaborative.

Cancer Genome Anatomy Project *CGAP*

The goal of the NCI's Cancer Genome Anatomy Project is to determine the gene expression profiles of normal, precancer, and cancer cells, leading eventually to improved detection, diagnosis, and treatment for the patient. The CGAP web site provides researchers with on-line access to all CGAP data and biological resources.

Cancer Training Branch *CTB*

The Cancer Training Branch manages the institute's research training, career development and education programs for U.S. citizens, providing guidance to the extramural biomedical research community and administration of awards. This assures continued development of well-trained investigators in the basic, clinical, population and behavioral sciences, who are prepared to address problems in cancer biology, causation, prevention and control, detection and diagnosis, treatment and rehabilitation.

Catalog of Federal Domestic Assistance *CFDA*

Catalog of Federal Domestic Assistance gives you access to a database of all Federal programs available to State and local governments (including the District of Columbia); federally-recognized Indian tribal governments; Territories (and possessions) of the United States; domestic public, quasi-public, and private profit and nonprofit organizations and institutions; specialized groups; and individuals.

Categorical Budget

Type of budget used for applications that do not follow the modular grant guidelines, requiring an itemized budget listing direct costs.

Categorical Grant

A grant having a specifically defined purpose.

Center for Information Technology *CIT*

Coordinated and manages information technology, and advance computational science.

Centers for Medicare & Medicaid Services *CMS*

The Centers for Medicare & Medicaid Services (CMS) is a federal agency within the U.S. Department of Health and Human Services. CMS runs the Medicare and Medicaid programs - two national health care programs that benefit about 75 million Americans. With the Health Resources and Services Administration, CMS runs the State Children's Health Insurance Program (SCHIP), a program that is expected to cover many of the approximately 10 million uninsured children in the United States.

Certificate of Confidentiality *COC*

Protects an investigator from being required to release research records that could be used to identify research participants in a legal proceeding.

Change of Applicant's Institution

Type 7: change of grantee institution. An investigator who is moving an active, funded research project grant to another institution must submit a revised PHS Form 398 face page, budget pages, facilities statement, and checklist for the new institution. The authorized official at the new

institution must sign the face page. In addition, PHS Form 3734 (a statement from the original grantee institution relinquishing its interest and rights to the grant) is required. This information is sent directly to the funding IC by the investigator and forwarded to OER. OER assigns the application as a Type 7, with NIR (No Initial Review) status. The application number stays the same except that the project year goes up by one if the change occurs during a project year. Changes in grantee institution that occur during the funding period of an awarded project generally do not undergo SRG review, but are handled administratively by the IC and OER.

Change of Scope or Change in Scope

A process, usually initiated by the grantee, whereby the objectives or specific aims identified in the approved grant application are significantly changed.

Change Order

A written order that a contracting officer signs, which, in effect, directs a contractor to make a change. (See FAR 43.101). A written order, signed by the Contracting Officer, which changes the specifications within the scope of the contract and is issued pursuant to the authority of the Changes Clause of the contract. The change may be effected by issuing a unilateral change order to be definitized later by supplemental agreement, or bilaterally as a supplemental agreement under the authority of the Changes clause.

Charter

An instrument in writing from the sovereign power of a state or country (here, laws of the U.S. Federal Government) granting or guaranteeing rights, franchises, or privileges; to endow with certain rights or functions by charter.

Chartered Advisory Committee

Any committee formed for advisory purposes composed not wholly of federal officials. Under the Federal Advisory Committee Act, standing committees must be chartered, i.e., approved by their parent agency in collaboration with the Government Services Agency to ensure a properly balanced representation (geographical, women, minorities) and that other legal requirements are met.

Child

A human subjects term that for the purposes of Federal research funding applications and awards signifies any person under age 21.

Circular, OMB

In setting policy, the Office of Management and Budget (OMB) in the Executive Branch of the Federal government (i.e., in the Office of the President) issues government-wide policy directives, called Circulars, such as the A-76 Circular that provides the policies and procedures for competitive sourcing of Federal work. Web address: <http://www.whitehouse.gov/OMB/circulars/>.

Civil Rights

Before a grant award can be made, a domestic applicant organization must certify that it has filed with the DHHS Office for Civil Rights and Assurance of Compliance (Form HHS 690), pertaining to four non-discrimination requirements.

Clarification

As used in FAR 15.306, communication with an offeror to correct a proposal's minor irregularities. An offeror or the government may initiate a clarification, but an offeror may not revise a proposal except to correct clerical mistakes.

Clean Codes Macro

This is a word processor software tool (a macro) that is used in NCI DEA to remove codes from WORD and Word Perfect documents.

Clinical Investigator Award *K08 / CIA*

To provide the opportunity for promising medical scientists with demonstrated aptitude to develop into independent investigators, or for faculty members to pursue research aspects of categorical areas applicable to the awarding unit, and aid in filling the academic faculty gap in these shortage areas within health profession's institutions of the country.

Clinical Protocol

The formal design or plan of an experiment or research activity; specifically, the plan submitted to an IRB for review and to an agency for research support. The protocol includes a description of the research design or methodology to be employed, the eligibility requirements for prospective subjects and controls, the treatment regimen(s), and the proposed methods of analysis that will be performed on the collected data.

Clinical Research

Research conducted on human subjects or on material of human origin identifiable with the source person. Policy covers large and small-scale, exploratory, and observational studies. There are three types: 1. Patient-oriented research-mechanisms of disease, therapeutic interventions, clinical trials, development of new technologies 2. Epidemiologic and behavioral studies 3. Outcomes research and health services research - Training grants (T32) are exempt, but all projects to which trainees are assigned must comply with policies on inclusion of women and minorities.

Clinical Trial, Cancer

Research study in which people help doctors find ways to improve health and cancer care. Each study tries to answer scientific questions and to find better ways to prevent, diagnose, or treat cancer.

Clinical Trial, Phase I

A Phase I clinical trial is a test of a new intervention in 20-80 (sometimes fewer) people for an initial evaluation of its safety, e.g., to determine a safe dosage range and to identify side effects.

Clinical Trial, Phase II

A phase II clinical trial is a study of an intervention in a larger group of people, usually several hundred, to determine efficacy and to further evaluate safety.

Clinical Trial, Phase III

A phase III clinical trial is a study of the efficacy of an intervention in large groups of several hundred to several thousand human subjects by comparing it to other standard or experimental interventions, while monitoring adverse events and collecting information that will allow safe use.

Clinical Trial, Phase IV

A phase IV clinical trial is a study done after an intervention has been marketed to monitor its effectiveness in the general population, and to collect information about adverse effects associated with widespread use.

Clinical

In general, pertaining to observation and treatment of patients. Clinical research is a term applied to the study and treatment of patients.

Co-Funding or Co-Funding Agreement

An agreement by two or more awarding agencies to jointly participate in the support of an assistance award.

Code of Federal Regulations *CFR*

An annually revised codification of the general and permanent rules published in the Federal Register.

Collaborator

An individual involved with the Principal Investigator in the scientific development or execution of the project.

Commercial Evaluation License *CEL*

License agreement that grants a nonexclusive right to make and use, but not sell, a technology to evaluate its commercial potential for a limited number of months.

Commercialization

The process of developing marketable products and/or services and producing and delivering products or services for sale (whether by the originating party or by others) to Government and/or commercial markets.

Common (Commercial) Carrier

Any firm furnishing commercial transportation. This includes airplanes, trains, ships and buses.

Common Accounting Number *CAN*

A number used in Federal financial transactions to facilitate tracking through the Federal accounting system. It contains accounting, organizational, geographical, and other data elements.

Common Rule

A process whereby Federal agencies issue essentially identical regulations under the direction of OMB.

Competing Application

Application that is either new or reapplying that must undergo initial peer review.

See Also Application Types

Competing Continuation Award

An award of financial assistance which adds funds to a grant and extends one or more budget periods beyond the currently established project period.

Competition Advocate

An individual designated by the agency for the purpose of reviewing, determining the appropriateness, and approving all projects which propose other than full and open competition.

Competition in Contracting Act

Public law increasing the number of government procurements awarded competitively. See the 41 USC 253 Web site.

Competitive Proposal

Procurement that meets the following criteria: 1. Is initiated by a request for proposals. 2. Accepts submission of timely proposals by the maximum number of offerors. 3. Usually provides discussions with offerors in the competitive range. 4. Awards a contract to the offeror whose proposal is most advantageous to the government.

Competitive Range

The range of qualified offers for a competitive procurement. A contracting term denoting a group of contract proposals considered to be acceptable by the initial peer review group and that are potential candidates for an award. Also, a determination established by the Contracting Officer based on the ratings of each proposal against all evaluation criteria (e.g., technical factors, price/cost, other factors) set forth in the Request for Proposal, generally after conducting written or oral discussions with all offerors whose proposals are within a certain range; a competitive range is comprised of all the most highly rated proposals. See FAR 15.306(c)(1).

Competitive Segment

The initial project period recommended for support (usually 1 to 5 years) or each extension of the prior project resulting from the award of a competing continuation grant.

Complementary Funding

Separate funding by two or more awarding agencies of individual projects or activities that relate to each other.

Comprehensive Minority Biomedical Branch *CMBB*

This NCI office provides funds to under-represented minority individuals who are pursuing careers in the biomedical sciences that address the mission of the National Cancer Program. This office also oversees the processing of all applications for individual supplements (minority, disability, and reentry).

Comprehensive Minority Institution/Cancer Center Collaboration, Cooperative Planning Grant *U56*

Cooperative planning grant for a Minority Institution/Cancer Center Collaboration that is administered by the NCI's Minority Institution/Cancer Center Program.

Computer Retrieval of Information on Scientific Programs *CRISP*

NIH database with descriptions of awarded grants and contracts, including financial data, project abstracts, and indexing terms. Web address:
<http://crisp.cit.nih.gov/>

Concept

The earliest, planning stage of an initiative [request for applications (RFA), request for proposals (RFP), or program announcement (PA)]. Concepts are brought before the advisory Council for concept clearance. Not all concepts cleared by Council are published as initiatives depending on the availability of funds.

Concurrence

Agreement or union in action; agreement of opinion.

Conflict of Interest *COI*

Any action by a reviewer in the grant or contract review or awarding process which would affect, or could appear to affect, the reviewer's financial interest, or would cause the reviewer's impartiality in the grants process to be questioned.

Conflict-of-Interest Guidelines or Conflict-of-Interest Regulations

Regulations to ensure that government employees, scientific reviewers and other scientific review group members, NCI advisory board and council and other committee members, and others having the ability to influence funding decisions have no personal interest in the outcome.

Congressional Inquiries

A Congressional Inquiry is a correspondence from Congress which originates when an individual contacts the Congressional representative for assistance in resolving a problem. Responses to the inquiry must address each allegation or problem and the manner in which each problem was or will be resolved. For further information see DHHS Policy and Procedure Manual Section IV: General Administration, Title: Legislative and Congressional Inquiries, Reports and Presentations, dated August 1, 2002.

Consolidated Services Contracts

The Research Contracts Branch has a multiple task order contracts for Support Services. These contracts will allow any requester in the National Cancer Institute to acquire an indefinite quantity of services with delivery or performance to be scheduled by placing orders with the awarded contractors. The services include, Meeting Support, Documentation Support, Communications Support, Administrative Support, Evaluation Support, and Data Manipulation.

Consortium Agreement

Collaborative arrangement in support of a research project in which some portion of the programmatic activity is carried out through a formalized agreement between the grantee and one or more other organizations.

Consortium Contractual Arrangements

An agreement whereby a research project is carried out by the grantee and one or more other organizations that are separate legal entities. In this arrangement, the grantee contracts for the performance of a substantial and/or significant portion of the activities to be conducted under the grant. These agreements typically involve a specific percent of effort from the consortium organization's Principal Investigator and a categorical breakdown of costs, such as personnel, supplies, and other allowable expenses, including indirect costs.

Consortium Grant

A grant made to one institution in support of a research project, in which the project is carried out through a collaborative arrangement between the grantee institution and one or more participating institutions.

Constant Dollars

Dollar amounts adjusted for inflation, based on buying power in a selected base year. The BRDPI is used to determine constant dollars from current dollars.

Construction Grant C06

Construction grants support the creation of state-of-the-art cancer research laboratories and clinics for basic and applied research.

Constructive Change

During contract performance, the contracting officer or other authorized government official's oral or written act, which has the same effect as a written change order.

Consultant

An individual who provides professional advice or services on the basis of a written agreement for a fee, but is not acting as an employee. The term includes paid guest speakers.

Consumer Advocates in Research and Related Activities CARRA

The NCI created the Consumer Advocates in Research and Related Activities (CARRA) program in 2001 to encourage people affected by cancer to provide their viewpoint and ideas directly to NCI staff so that the NCI can incorporate this perspective into our programs and activities. This program is managed by the Office of Liaison Activities in the NCI Office of the Director. The goal of the program is to recruit consumer advocates to form a "ready and waiting" group of people who are available to participate in a wide range of NCI activities. CARRA members represent many different cancer types, age groups, and ethnic groups from across the Nation. In addition to participating in NCI activities, CARRA members will represent the opinions of their groups and play critical roles as two-way information links between their own communities and constituencies and the NCI.

Consumer Price Index CPI

Measurement of changes in prices of a broad range of consumer items.

Continental United States CONUS

Type of Per Diem rate.

Continuing Umbrella of Research Experiences *CURE*

This program begins with introductory science experiences at the high school level and continues progressively and selectively to the production of well-trained scientists conducting independent cancer research (<http://deainfo.nci.nih.gov/cmbs/index.htm>)

Contract Closeout

Final actions taken after a contract is completed to certify that all services and deliverables are satisfactory and complete.

Contract Modification

Written order a contracting officer signs directing the contractor to make a change. (FAR 43.101). This written order can be bilateral or unilateral.

Contract Proposal Evaluation and Source Selection

Source Selection: The selection of an offeror based on a comprehensive/comparative assessment of proposals against all evaluation criteria listed in the solicitation.

Contract Proposal

Written offer by an individual or non-federal organization to enter into a contract, usually in response to a request for proposals (RFP). It consists of a technical and a business proposal, including a description of the project and its costs, and the methods, personnel, and facilities to carry it out.

Contract

An award instrument used for the acquisition, by purchase, lease, or barter, of property or services. A mutually binding legal relationship obligating the seller (contractor) to furnish the supplies or services, and the buyer (Government) to pay for them. It includes all types of commitments that obligate the Government to an expenditure of appropriated funds, and except as otherwise authorized, are in writing. The three most common types of contracts utilized in the Research Contracts Branch (RCB) include Cost Reimbursement contracts, Fixed Price contracts, and Indefinite Delivery contracts. Part 16 of the Federal Acquisition Regulations lists all other types of contracts.

Contractor-Acquired Property

Government -titled property acquired or otherwise provided by a contractor for performing a contract. (FAR 45.101)

Control Group

In a clinical trial, the group of people that receives standard treatment for their cancer.

Cooperative Agreement

An award instrument of financial assistance where "substantial involvement" is anticipated between the awarding agency within the Department of Health and Human Services (e.g., the NIH/NCI) and the recipient during performance of the contemplated project or activity. "Substantial involvement" means that the recipient can expect Federal programmatic collaboration or participation in managing the award.

Cooperative Clinical Research - Cooperative Agreements U10

To support clinical evaluation of various methods of therapy and/or prevention in specific disease areas. These represent cooperative programs between sponsoring institutions and participating principal investigators, and are usually conducted under established protocols.

Cooperative Research And Development Agreement CRADA

A mechanism for collaboration between government and outside scientists that legally defines intellectual property rights and financial and other responsibilities. See "technology transfer" and go to the 15 USC 63 Sec. 3710 Web site.

Cost Analysis

Analysis performed by a contracting officer to determine whether an offeror's proposed costs are fair and reasonable. Go to the FAR 15.404 Web site.

Cost Estimate

Proposed expenditures necessary to accomplish the government's requirements.

Cost Overrun

When the allowable actual cost of performing a cost-reimbursement type contract is expected to exceed the total estimated cost specified in the contract.

Cost Reimbursement Contract or Cost Reimbursement

Provides for payment of allowable incurred costs, to the extent prescribed in the contract. These contracts establish an estimate of total cost for the purpose of obligating funds and establishing a ceiling that the contractor may not exceed. Under a cost reimbursement type contract, the statement of work may take one of two basic forms. The first type is the "Completion" form, which clearly specifies in the statement of work the desired end product required. The degree of effort is not measured in time allotted to the project but rather the percentage of completion. The second type is the "Term" form (also known as "Level of Effort"), which identifies the type of effort to be expended by the contractor within a given time period. Cost reimbursement can also signify a tabulation of specific types and number of staff hours to be devoted to the project which is included in the contract.

Cost Sharing (or Matching)

The value of allowable third party in-kind contributions and the allowable costs of a federally assisted project or program not borne by the Federal Government.

Cost-Plus-Fixed-Fee Contract

Cost-reimbursement contract that pays a negotiated fee fixed at the inception of a contract. The fee does not vary with actual costs but may be adjusted as a result of changes in the work performed under the contract. This contract type permits contracting for efforts that might otherwise be too risky for contractors and provides a contractor a small incentive to control costs. (FAR 16.306)

Cost-Sharing Contract

Cost-reimbursement contract in which a contractor receives no fee and is reimbursed only for an agreed-upon portion of allowable costs. (FAR 16.303)

Count

Unless noted, the total number of grants shown, excluding administrative supplements.

Countersigned

Signing of a document by more than one official, e.g., a training grant program director and the institutional business official.

Criteria for Review

Also called Review Criteria or NIH Peer Review Criteria. The standard NIH review criteria include Significance, Approach, Innovation, Investigators, and Environment. Peer reviewers must address each of these review criteria when discussing an application in an NIH review meeting and when writing their critique for a summary statement.

Critique

Written evaluation that a primary peer reviewer (and often one or more secondary reviewers) prepares before an initial review meeting and presents to a scientific review group at the meeting. It generally contains a recommendation of a priority score (or not recommended for further consideration) and addresses the requested budget, initial peer review criteria, progress made (for a competing continuation application), and responses to the critique from a previous review (for an amended application).

Cultural Competence

A set of academic and interpersonal skills that allows individuals to increase their understanding and appreciation of cultural differences and similarities within, among, and between groups. This requires a willingness and ability to draw on community-based values, traditions, and customs and to work with persons who are knowledgeable about and from the community in developing focused interventions, communications, and other supports.

Cultural Diversity

Differences in race, ethnicity, language, nationality, or religion among various groups within a community, organization, or nation. A city is said to be culturally diverse if its residents include members of different racial and/or ethnic groups.

Cultural Sensitivity

Respect for ethnic individuals and for their culture; the recognition that such individuals have cultural health beliefs and practices; the integration of those beliefs and practices in the overall treatment plan for the patient; and the ability to act on behalf of the individual to assure quality health care.

Current Dollars

Actual dollars awarded, without adjustment for inflation.

Cancer Care Outcomes Research and Surveillance Consortium *CanCORS*

Cancer Intervention and Surveillance Modeling Network *CISNET*

Citation ID

The number used when citing papers falling under the Public Access Policy on applications, proposals, or progress reports. The citation ID will be a PubMed Central Reference Number (PMCID) or an alternative when the PMCID has not been assigned yet.

Co-Investigator

An individual involved with the PI in the scientific development or execution of a project. The co-investigator (collaborator) may be employed by, or be affiliated with, the applicant/grantee organization or another organization participating in the project under a consortium agreement. A co-investigator typically devotes a specified percentage of time to the project and is considered ?key personnel.? The designation of a co-investigator, if applicable, does not affect the PI?s roles and responsibilities as specified in the NIH Grants Policy Statement (NIH GPS).

Committee Management Officer *CMO*

NIH CMO: The NIH Committee Management Officer is responsible for the oversight of all NIH Federal advisory committees under the auspices of the Federal Advisory Committee Act. The NIH CMO is responsible for directing and managing all phases of committee management policy and procedure development and dissemination to all NIH I/C staff as well as to Federal advisory committee members.

I/C CMO: Each I/C has a CMO or uses the resources of a service center to support the committee management function within the Institute or Center. The I/C CMO is responsible for developing charters for committees, preparing nomination and appointment documents for membership to committees, providing technical assistance to committee members, providing initial review of conflict of interest disclosures and other responsibilities.

Commons

See electronic Research Administration (eRA) Commons
See Electronic Research Administration

Catchment Area

The geographical area served by a medical facility and from which the majority of its patients are drawn.

Center Grants

Financial assistance awards to institutions on behalf of research leaders and groups of collaborating investigators. Center grants provide support for long-term, multidisciplinary programs of research and development.

Clinical Trial

For review of applications submitted to the NIH, a clinical trial is defined as a prospective biomedical or behavioral research study of human subjects designed to answer specific questions about biomedical or behavioral interventions (drugs, treatments, devices, or new ways of using known drugs, treatments, or devices). Clinical trials are used to determine whether new biomedical or behavioral interventions are safe, efficacious, and effective. Clinical trials of experimental drug, treatment, device, or behavioral intervention may proceed through four phases:

Phase I, Phase II, Phase III, and Phase IV. [See separate definitions below.]

Concern

In the context of research involving human subjects and/or vertebrate animals, a concern is an issue so critical that it must be resolved before funds can be awarded.

Core Director

The investigator responsible for the scientific direction and conduct of a core component of a multi-component application.

Council Round

At the NCI, there are three NCAB rounds each February, June, and September for second level review of grant applications. In addition, there is an NCAB meeting in December for intramural reviews.

Cover Letter

Letter attached to a grant application that may request a scientific review group or institute or provide other information (e.g., list of individuals in conflict, disciplines involved). For late applications, include an explanation of the delay as part of the cover letter attachment. A cover letter is required for late applications. Use the PHS 398 Cover Letter File for SF424 applications. The cover letter is for internal use only and will not be shared with peer reviewers.

CAMP Web Site *CAMP*

National Cancer Institute (NCI) Intranet site with NCI-restricted access that contains links to most, if not all, components of NCI extramural research operations.

Cancer Center Support Grant *CCSG or P30*

The Cancer Center Support Grants (CCSGs) (P30 awards) support cancer research programs on an "institutional" basis rather than by funding a multiplicity of individual research and project grants. This required a review of an institution's cancer research program in totality; the extent to which a center successfully integrates and promotes institutional cancer-related activities remains a principal criterion for success of an NCI-designated cancer center.

Cancer Diagnosis Program *CDP*

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.

Cancer Information Service *CIS*

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. <http://cis.nci.nih.gov>

Career Development Awards

Funding opportunity for scientists at various career stages to further develop their capabilities in biomedical, behavioral and clinical research. Applicants are generally required to hold a research or health-professional doctoral degree or its equivalent; in some cases, eligibility is limited to only applicants with health professional doctoral degrees. (See K Series)

Carryover or Carry over

The ability of grantees to use grant funds from one budget period (typically, one year) in the next period for grants covered by new a grant regulation, 45 CFR Part 74 (known as the expanded authorities), which applies to most R (but not R41 or 43), P, K, and T series grants. As indicated by the Notice of Award (NoA), carryover authority provides grantees permission to carry over funds unobligated at the end of a budget period to the next budget period.

Center for Scientific Review CSR

Center for Scientific Review (CSR) is the focal point at NIH for the conduct of initial peer review, the foundation of the NIH grant and award process. The Center carries out peer review of the majority of research and research training applications submitted to the NIH. In addition, the Center serves as the central receipt point for all such Public Health Service (PHS) applications and makes referrals to scientific review groups for scientific and technical merit review of applications and to funding components for potential award. To this end, the Center develops and implements innovative, flexible ways to conduct referral and review for all aspects of science.

Centers for Disease Control and Prevention CDC

The Centers for Disease Control and Prevention (CDC) provides a system of health surveillance to monitor and prevent outbreak of diseases. With the assistance of states and other partners, CDC guards against international disease transmission, maintains national health statistics and provides for immunization services and supports research into disease and injury prevention.

Change of Assignment *Form 901*

Once an application has been assigned a number and processed by Project Control Unit II, changes in council date, SRG assignment, primary and/or secondary IC assignments, application number, or withdrawal or deletion of an application typically require the preparation of a form 901. However, transfer of an application between SRGs within the same IRG generally does not require a 901. Furthermore, ICs can add and subtract themselves as dual assignees without a 901, and they also can administratively withdraw an application in a situation involving grant funding without a 901 (e.g., withdrawing an amended application, if the unamended application will be funded). Also, a 901 form is not used to make other changes in an IMPAC entry for an application (e.g., Principal Investigator's name or budget information).

Change of Grantee Institution

May be requested when the original grantee has agreed to relinquish responsibility for the grant before the expiration of the approved project period.

Change of Study Section

A change in the application assignment, from a specific study section within an IRG, to a different study section within the same IRG.

Clinical Trial Monitoring

Monitoring system set up for a clinical trial to provide an independent and objective review of the research, interim safety and efficacy data, and progress towards achieving study goals. The degree of monitoring depends on the risks involved, ranging from an independent safety monitor to an independent monitoring or safety committee to a data and safety monitoring board, the highest level (which is required by the NIH for phase III clinical trials).

Clinical Trial, Phase III

An NIH-defined phase III clinical trial is a broadly based, prospective investigation, including community and other population-based trials, usually involving several hundred or more people, to evaluate an experimental intervention in comparison with a standard or control, or to compare two or more existing treatments. Often, the aim is to provide evidence for changing policy or standard of care. It includes pharmacologic, non-pharmacologic, and behavioral interventions for disease prevention, prophylaxis, diagnosis, or therapy. Community trials and other population-based intervention trials are also included. In determining whether a study fits the NIH definition of a Phase III clinical trial, an essential consideration is trial outcome - whether it would contribute to a change in the standard of care or contribute to a change in public health policy, regardless of the number of participants in the study. This NIH definition of a Phase III clinical trial is broad and encompasses the wide range of research that NIH sponsors. It differs from the FDA definition of Phase III clinical trials, which focuses primarily on a clinical investigation of drugs, vaccines, biologics, and devices. Clinical trials of experimental drugs covered in the FDA definition proceed through four phases (21 CFR Section 312.21, 4_1_94 edition). For additional information regarding the FDA definitions of the different phases of clinical trials, check the NIH Clinical Trials Website at: <http://clinicaltrials.gov>.

Clinical Trials Cooperative Group Program

Designed to promote and support clinical trials (research studies) of new cancer treatments, explore methods of cancer prevention and early detection, and study quality-of-life and rehabilitation issues.

Clinical Terms of Award

Incorporated into the Notice of Award, the clinical terms of award specify a grantee's responsibilities and deadlines for providing documentation and approvals when starting and during a study.

Closed Session

A portion of the meeting that is closed to the public in accordance with the provisions set forth in the Federal Advisory Committee Act.

Co-Sponsorship

The joint development of a conference, seminar, symposium, educational program, public information campaign, or similar event related to the mission of the Department, by HHS and one or more non-Federal entities that share a mutual interest in the subject matter.

Collaborations: Intramural and Extramural Scientists

Extramural grant awards in which intramural scientist(s) play a substantial role must be converted to cooperative agreements.

Commerce Business Daily CBD

The Commerce Business Daily (CBD) was used as point of entry for Federal acquisitions, but it no longer exists; it has been replaced by FedBizOpps (see definition).

Commitment Base

Funds used for noncompeting (type 5 or ongoing awards), typically 70-80 percent of the dollars spent for research project grants.

Committee Management Module IMPAC II COM

The Committee Management Module manages the information associated with establishing, amending, and re-chartering committees and subcommittees and the nomination and appointment of members to these committees and subcommittees. The Committee Management Module also is used to maintain the information associated with committee meetings and meeting attendees.

Committee Management Office CMO

The Committee Management Office (CMO) supports the NCI peer review process by compensating consultants for their services on the NCI IRG subcommittees or SEPs and by reimbursing them for their travel and other expenses.

Communication Channels

The means by which a message gets from a source to a receiver. Mass media channels are more effective in making people aware of a new idea; interpersonal channels are more effective in persuading people to adopt a new idea.

Community-Based Organizations

Organizations that have their origins or basis within the community and which utilize some aspect of the community's goals, mandate, or objectives as part of their efforts.

Compassionate Use Investigational New Drug CUIND

The Federal Drug Administration (FDA) procedure for making available to a patient a non-investigational new drug, based on a physician's request. Also called "Treatment New Investigational Drug."

Competing Continuation

See Renewal

Competing Renewal

Application submitted to extend the period of support for a project whose funding would otherwise expire. Also known as Type 2.
See Competing Continuation

Comprehensive Minority Biomedical Program CMBP

Eligible applicants can apply for any RPG or non-RPG grant through the Comprehensive Minority Biomedical Program (CMBP) (also called the S06 grant mechanism).

Comprehensiveness

The National Cancer Institute (NCI) designation for a Cancer Center that demonstrates substantial expertise and focus in laboratory, clinical, and behavioral and population-based research.

Concept Review

A required review of a brief concept document outlining a proposed RFA. In the NCI, this concept review is generally done by the BSA.

Conference Grant *R13*

Institutes and Centers of the NIH provide funding for conferences to coordinate, exchange, and disseminate information related to its program interests. From the NCI perspective, these grants support recipient-sponsored and directed international, national, or regional meetings, conferences, and workshops that are of value in promoting the goals of the National Cancer Program.

Contiguous United States *CONUS*

The contiguous United States refers to the 48 adjoining U.S. states on the continent of North America that are south of Canada and north of Mexico, plus the District of Columbia.[1] The term excludes the non-contiguous states of Alaska and Hawaii, and all off-shore U.S. territories and possessions

Continuing Education Training Program *T15*

Assists professional schools and other public and nonprofit institutions to establish, expand, or improve programs of continuing professional education, especially for programs of extensive continuation, extension, or refresher education dealing with new developments in the science of technology of the profession.

Continuing Resolution *CR*

A Continuing Resolution, also known as a "CR," is a legislative act that continues funding for a program if the fiscal year ends without a new appropriation in place. A "CR" provides temporary funding at current levels or less.

Contract Specialist *CS*

An individual who is subject to the general supervision of the contracting officer and who actually carries out most of the procedural steps, as contrasted with the approvals required to be taken by the contracting officer under applicable regulations. (Also called Contract Negotiator)

Contract Transaction Types

Type 1 - New contract, Type 2 - Renewal, Type 3 - Modification, Type 4 - Letter contract, Type 5 - Continuation of an incrementally (typically, in one-year increments) funded contract, Type 6 - Task orders and subsequent modifications relating to existing ordering agreements, Type 7 - Exercise of option

Contract Under a Grant

A written agreement between a grantee and a third party to acquire routine goods and services.

Contracting Officer's Representative *COR*

This person is officially responsible for monitoring the acceptability of a contractor's performance of a contract for the NCI.
See Also Project Officer

Contracting Officer CO

Government employee authorized to execute contractual agreements on behalf of the government. The individual who is the Government's authorized agent in dealing with the contractor(s). This individual has authority to negotiate, award, and modify contracts on behalf of the Government.

Cooperative Human Tissue Network CHTN

The Cooperative Human Tissue Network (CHTN) was formed in 1987 by three organizations along with a subcontract with the Children's Cancer Group (CCG). In 1991 the Pediatric Division became an independent group and an additional adult collection center was added to the CHTN. All six organizations (Ohio State University, Children's Hospital of Columbus [Ohio], University of Alabama at Birmingham, University of Pennsylvania, University of Virginia, and Vanderbilt University) that currently comprise the CHTN have extensive experience in providing human tissues for research.

Comprehensive Partnerships to Reduce Cancer Health Disparities CPRCHD

The Comprehensive Partnerships to Reduce Cancer Health Disparities (CPRCHD), formerly known as the Minority Institution Cancer Center Partnership (MI/CCP), is a program that enables minority-serving institutions (MSIs) and NCI Cancer Centers (CCs) to train scientists from diverse backgrounds in cancer research and to effectively deliver cancer advances to racially and ethnically diverse communities.

Comprehensive Cancer Centers

A cancer research institution that is a recipient of a cancer center support grant and that also meets additional criteria for community outreach and education.

Contract Suspension

Action taken to disqualify a contractor temporarily from contracting and subcontracting.

Center for Biologics and Research, FDA CBER

Center within the Food and Drug Administration (FDA), an Agency within the Department of Health and Human Services, established to protect and enhance the public health through the regulation of biological and related products including blood, vaccines, allergenics, tissues, and cellular and gene therapies.

Coordinating Center for Clinical Trials CCCT

The Coordinating Center for Clinical Trials (CCCT) is central to NCI's efforts to accelerate the delivery of new tools into the clinic through its translational science and clinical trial enterprises.

Center of Cancer Nanotechnology Excellence CCNE

The main venue for the discovery and tool development toward the application of nanotechnology to clinical oncology.

Center Contractor Registration Database CCR

A Federal government owned and maintained database, which is being merged into a new database called System for Award Management (SAM). All organizations that receive contracts from the Federal government are required to register and maintain an active account in this

database.

Center for Drug Evaluation and Research, FDA *CDER*

Center within the Food and Drug Administration (FDA), an Agency within the Department of Health and Human Services, established to ensure that safe and effective drugs are available to improve the health of people in the United States. The Center regulates over-the-counter and prescription drugs, including biological therapeutics and generic drugs, as well as other products such as fluoride toothpaste, antiperspirants, dandruff shampoos and sunscreens.

Cancer Disparities Research Partnership Program *CDRP*

An effort to strengthen the national cancer program by developing models to reduce significant negative consequences of cancer disparities seen in certain U.S. populations. The Program supports the planning, development, and conduct of radiation oncology clinical trials in institutions that care for a disproportionate number of medically underserved, low-income, ethnic and minority populations but have not been traditionally involved in NCI-sponsored research. In addition, CDRP supports the planning, development, and implementation of nurturing partnerships between applicant institutions and committed and experienced institutions actively involved in NCI-sponsored cancer research.

Cancer Genetic Markers of Susceptibility *CGEMS*

A program developed by the NCI Division of Cancer Epidemiology and Genetics, in collaboration with extramural scientists, to identify common inherited genetic variations associated with risk for a variety of cancer types..

Center for International Blood and Marrow Transplant Research *CIMBTR*

Collaborates with the global scientific community to advance hematopoietic cell transplantation and cellular therapy research worldwide.

Cancer Nanotechnology Platforms Partnerships *CNPP*

The Cancer Nanotechnology Platform Partnerships (CNPPs) engage in directed, product-focused research that aims to translate cutting-edge science and technology into the next generation of diagnostic and therapeutic tools. These platforms serve as the core technologies for a wide array of specific applications that will ultimately benefit cancer patients.

Clinical Proteomic Technology Assessment for Cancer *CPTAC*

The Clinical Proteomic Technology Assessment for Cancer (CPTAC) network's ultimate goal is to enable all researchers conducting cancer-related protein research at different laboratories to effectively use proteomic technologies and methodologies to directly compare and analyze their work.

Cancer Research Network *CRN*

An NCI-funded initiative to support and facilitate cancer research based in non-profit integrated health care delivery settings.

Cancer Research Portfolio *CRP*

A database that contains information about research grant and contract awards made by the NCI. Provides information on the funding organization, awardee institution, the principal investigator, and a detailed abstract of the research.

Cancer Bioinformatics Grid *caBig*

A voluntary network or grid connecting individuals and institutions to enable the sharing of data and tools used for cancer research and for speeding the delivery of innovative approaches for the prevention and treatment of cancer.

Cancer Image Database *CA Image*

An annotated database of animal model and human cancer images submitted by cancer researchers.

Cancer Center *CC*

NCI-designated institutions dedicated to research in the development of more effective approaches to prevention, diagnosis, and treatment of cancer.

Clinical Cooperative Groups *CCGs*

A national network maintained by NCI consisting of a number of consortia (cooperative groups) that conduct clinical trials to identify and evaluate new anti-cancer agents or to develop new treatment strategies.

Community Clinical Oncology Program *CCOP*

A network for conducting cancer prevention and treatment clinical trials by community medical practitioners.

Center for Cancer Research *CCR*

The Center for Cancer Research (CCR), the basic and clinical intramural research program of NCI, conducts research with the goal of improving the lives of people affected by cancer and HIV/AIDS.

Common Data Elements *CDEs*

Commonly collected in all clinical studies regardless of the type of study or therapeutic area. Examples include medical history data; scores on neurological assessments; demographic information (e.g., age, race, ethnicity and educational level); and details about medications used by patients throughout a study.

Centers of Excellence in Cancer Communication Research *CECCR*

The centerpiece of NCI's Extraordinary Opportunity in Cancer Communications. The Request for Applications (RFA) used the P50 grant mechanism to invite applications for Centers that include three or more individual, hypothesis-driven research projects and a pilot or developmental research project process, cores, and plan for career development.

Cancer Family Registries *CFR*

A unique resource for investigators to use in conducting studies on the genetics and molecular epidemiology of breast and colon cancer.

Cancer Genetics Network *CGN*

Infrastructure established by NCI to support collaborative investigations into the genetic basis of cancer susceptibility, explore mechanisms to integrate this new knowledge into medical practice, and identify ways of addressing the associated psychosocial, ethical, legal, and public health issues.

Consumer Health Profiles *CHP*

Give a portrait of the intended audience segments most in need of cancer prevention and detection messages.

Cancer Imaging Program *CIP*

Program developed by NCI to promote and support: Cancer-related basic, translational and clinical research in imaging sciences and technology, and integration and application of these imaging discoveries and developments to the understanding of cancer biology and to the clinical management of cancer and cancer risk.

Central Institutional Review Board *CIRB*

The Central Institutional Review Board (CIRB) provides an innovative approach to human subject protection through a "facilitated review" process that can streamline local Institutional Review Board (IRB) reviews of adult and pediatric national multi-center cancer treatment trials.

Centers for Medicare and Medicaid Services *CMS*

A federal agency within the United States Department of Health and Human Services (DHHS) that administers the Medicare program and works in partnership with state governments to administer Medicaid, the State Children's Health Insurance Program (SCHIP), and health insurance portability standards.

Community Networks Program *CNP*

Aims to reduce cancer health disparities through community-based participatory education, training, and research among racial/ethnic minorities and underserved populations.

Cancer Research Training Award *CRTA*

Program developed by NCI to provide recent college graduates who are planning to apply to graduate or professional (medical/dental/pharmacy) school an opportunity to spend one or two years performing full-time research at the NIH.

Common Scientific Outline *CSO*

A coding system used by public and private organizations in the United States, United Kingdom, and Canada to describe research projects.

Clinical Trials and Translational Research Advisory Committee *CTTRAC*

The Committee makes recommendations on the NCI-supported national clinical trials enterprise to build a strong scientific infrastructure by bringing together a broadly developed and engaged coalition of stakeholders involved in the clinical trials process. In addition, the Committee makes recommendations regarding the effectiveness of NCI's translational research management and administration program, including needs and opportunities across disease sites, patient populations, translational developmental pathways, and the range of molecular mechanisms responsible for cancer development.

Cancer Therapy Evaluation Program *CTEP*

Improve the lives of cancer patients by finding better ways to treat, control and cure cancer.

Clinical Trials Support Unit *CTSU*

A project sponsored by the National Cancer Institute (NCI) for the support of a national network of physicians to participate in NCI-sponsored cancer treatment trials, cancer prevention and control trials, and correlative science studies.

Computed Tomography *CT*

Computed tomography (CT) is a diagnostic procedure that uses special x-ray equipment to obtain cross-sectional pictures of the body. The CT computer displays these pictures as detailed images of organs, bones, and other tissues. This procedure is also called CT scanning, computerized tomography, or computerized axial tomography (CAT).

Central Contractor Registry *CCR*

The main vendor database for the U.S. Federal Government. Grant-applicant institutions need to register with the Central Contractor Registry (CCR) to apply for a grant through Grants.gov. The CCR stores organizational information, allowing Grants.gov to verify the organization's identity and to pre-fill organizational information on its grant application. Institutions must have a DUNS number to register in the CCR.

Central Contractor Registration Database (*CRR*)

Primary database for organizations and persons who do business with the federal government. Grant-applicant institutions need to register with the CCR (<http://www.ccr.gov>) to apply for a grant through <http://Grants.gov>.

Co-Funding

Funding arrangement through which two or more Institutes or Centers pay for a grant.

Competing Revision

An application that proposes a change in 1) the Federal Government's financial obligations or contingent liability from an existing obligation, or 2) any other change in the terms and conditions of the existing award. Note in general for NIH applicants, #2 would not require the submission of another application. NIH grantees use revision applications to request an increase in support in a current budget period for expansion of the project's approved scope or research protocol. Applicants must apply and undergo peer review. The previous NIH term was "competing supplemental." NOTE: The former NIH term "revision," is now "resubmission". A revision has a suffix in its application identification number; e.g., S1.

Clinical and Translational Research Operations Committee *CTROC*

An internal NCI advisory committee composed of representatives from NCI divisions, offices, and centers involved in NCI-supported clinical trials and translational research. The committee reviews and prioritizes NCI-supported clinical trials, correlative science programs, and translational research.

D

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Data and Safety Monitoring Plan *DSMP*

A Data and Safety Monitoring Plan (DSMP) for a clinical study is an outline set out in advance for the routine review and evaluation of enrollment, data, outcomes, and adverse events.

Data and Safety Monitoring *DSM*

To assure participant safety and clinical research integrity, data from clinical studies must be routinely reviewed and monitored in the context of the disease being studied and the type and risk level of the clinical study. Such review is called Data and Safety Monitoring (DSM).

Debarment

Grantees may be debarred or suspended if they are found to have seriously and willfully not complied with grant conditions or are found to have engaged in scientific misconduct.

Debriefing

A mechanism used to furnish information to unsuccessful offerors about the selection decision and the contract award. Debriefing can either be pre or post award and follow the regulations at FAR 15.505 (Preaward) or FAR 15.506 (Postaward).

Deferral

For certain mandatory grants, a temporary suspension of payment on public assistance grants by HHS pending receipt of additional information relating to allowability of a recipient's cost. For discretionary grants, the term may indicate that applications are approved but not funded or held for a later review cycle.

Deferred (for Further Information) *DF*

Refers to the delay in the review of an application by a scientific review group, usually to the next review cycle, due to insufficient information.

Demonstration Contracts

Developments in some programs lead to opportunities to demonstrate the feasibility of applying advances to solve certain health problems. Where demonstration projects seek specific goals desired by the NIH, the activities are conducted under contracts. These may include many cancer and heart control and prevention projects.

Demonstration Project

A project, supported through a grant or a cooperative agreement, generally to establish or demonstrate the feasibility of new methods or new types of services.

Department of Health and Human Services *DHHS*

Department in the executive branch of the Federal government whose primary missions are to protect the health of Americans and to provide essential human services. The NIH is one of twelve agencies in the DHHS.

Designated Federal Official *DFO*

In the NIH system for peer review of grant applications and contract proposals, a designated federal official, typically the Scientific Review Administrator, must always be present in the room whenever such peer review activities are actually occurring.

Detailed Budget for Initial Budget Period

Categorical budget not required for applications with modular budgets.

Development Contracts

These contracts are to develop substances, devices, systems or other approaches to diagnose, prevent, treat, or control disorders, including development of effective vaccines or drugs; surgical techniques or medical devices to assist or replace organ functions; and sophisticated instruments to refine laboratory or clinical procedures.

Direct Cost or Direct Costs

In grants, direct costs are costs for equipment, supplies, personnel, travel, and other expenses necessary to carry out a research project. In contracts, direct costs include any cost that can be identified specifically with a particular final cost objective. Costs identified specifically with the contract (salaries and wages, fringe benefits, materials & supplies, subcontracts, consultants, inpatient and outpatient costs for human subjects, alterations and renovations to facilities, publications and other miscellaneous expenses, costs for consortium participants, etc.) are direct costs of the contract and are to be charged directly to the contract.

Direct Operations

Funds for salary and other administrative costs.

Disaggregation

Selection of one or two research projects by an institute for funding from a multi-project (P series or U19) application, although the parent grant did not fare well enough in peer review to warrant an award.

Discretionary Grant

A grant that permits the Federal Government, according to specific authorizing legislation, to exercise judgment ("discretion") in selecting the applicant/recipient organization, through a competitive grant process. Types of activities commonly supported by discretionary grants include demonstration, research, training, service, and construction projects or programs. Discretionary grants are sometimes referred to as "project grants."

Division of Cancer Control and Population Sciences *DCCPS*

Supports research on methods of cancer prevention through grants, contracts, and in-house research.

Draft Review Report *DRR*

A preliminary compilation of reviewers' critiques that is used by Scientific Review Groups to guide the final discussion and assignment of overall priority scores to applications.

Dual Assignment

Application simultaneously assigned to two institutes, centers, or divisions. The primary institute has complete responsibility for administering and funding the application; the secondary assumes this responsibility only if the primary is unable or unwilling to support it.

Double-Blind Study

A clinical trial design in which neither the subject participants nor the study staff know which patients are receiving the experimental drug and which are receiving a placebo or another therapy.

Data and Safety Monitoring Board *DSMB*

An independent committee, composed of community representatives and clinical research experts, that reviews data while a clinical trial is in progress to ensure that participants are not exposed to undue risk. A Data and Safety Monitoring Board (DSMB) should always be established and used for an NIH-defined phase III clinical trial. A DSMB may recommend that a trial be stopped if there are safety concerns, or if the trial objectives have been achieved.

Data Sharing

Policy requiring that researchers who are requesting more than \$500,000 in direct costs in a year to include a data-sharing plan with their grant application or explain why data sharing is not possible.

Deliverable

Report or product a contractor must deliver to the government to satisfy contractual requirements. Also known as end product.

Deviation

Any exception to established regulations, policies or procedures. NIH prior approval is required for any deviation from terms or conditions stated or referenced in the Notice of Grant Award, including those in the NIH Grants Policy Statement. This includes undertaking any activities disapproved or restricted as a condition of the award.

Disallowance of Costs

A charge to a grant that the Federal awarding agency determines to be unallowable in accordance with the applicable Federal cost principles or other terms and conditions contained in the award.

Discussion, Contracts

As used in Federal Acquisitions Regulations (FAR) 15.6, any oral or written communication between the government and an offeror, other than minor clarifications, which (a) enables a contracting officer to determine whether a proposal is acceptable or (b) allows an offeror to revise a proposal.

Division Approving Official *DAO*

At the National Cancer Institute (NCI), the Division Approving Official (DAO) is usually a Division Director.

Division of Cancer Prevention *DCP*

This division of the National Cancer Institute (NCI) supports extramural research on cancer prevention through grants, contracts, and cooperative agreements.

Division of Cost Allocation *DCA*

Division of Cost Allocation (DCA) has major responsibilities for evaluating, negotiating and approving Indirect Cost (and other specialty) Rates.

Division of Extramural Activities *DEA*

The National Cancer Institute (NCI) Division of Extramural Activities (DEA) is centrally involved in all aspects of grant development and tracking, from the original conception of research and training programs for introduction in the extramural community, to the issuance of announcements of such programs, to the receipt and referral of incoming applications, to review and approval of the final award, and to follow-up after disbursement of funds. The DEA was established to: 1) provide advice and guidance to potential applicants; 2) refer incoming grant applications to appropriate programs within the NCI; 3) provide the highest quality and most effective scientific peer review and oversight of extramural research; 4) coordinate and administer advisory activities, such as the National Cancer Advisory Board and Board of Scientific Advisors, related to the various aspects of the NCI mission; 5) establish and disseminate extramural policies and procedures, such as requirements for inclusion of certain populations in research, actions for ensuring research integrity, or budgetary limitations for grant applications; 6) track the NCI research portfolio using consistent budget-linked scientific information to provide a basis for budget projections; and 7) serve as a resource for the dissemination of information about cancer.

Division of Intramural Research *DIR*

This term is not currently used in the National Cancer Institute (NCI). The two Divisions of the NCI that conduct intramural research are the Center for Cancer Research and the Division of Cancer Epidemiology and Genetics.

Division of Receipt and Referral *DRR*

The Division of Receipt and Referral (DRR) is the Division of the Center for Scientific Review (CSR) of the NIH that receives all grant applications that are submitted to the NIH. After logging in all grant applications received, the DRR refers the applications to the appropriate CSR study sections or review operations of the Institutes and Centers.

Division of Research Grants *DRG*

This term (last used in 1997) refers to the former name for the Center for Scientific Review (CSR).

Domestic Travel Voucher Code in the NIH Administrative Database System

VCH

Dual Peer Review and Process

Peer review process used by NIH. The first level of review by an initial review group provides a judgment of scientific merit. The second level of review, usually conducted by an IC's advisory council (i.e., the National Cancer Advisory Board [NCAB]), assesses the quality of the first review, sets program priorities, and makes funding recommendations.

Dual Review System

Peer review process used by NIH. The first level of review provides a judgment of scientific merit. The second level of review (usually conducted by an IC's advisory Council) assesses the quality of the first review, sets program priorities, and makes funding recommendations.

Defense Advanced Research Projects Agency *DARPA*

Agency of the U.S. Department of Defense responsible for the development of new technologies for use by the military.

Director's Consumer Liaison Group *DCLG*

A Federal Advisory Committee comprising advocate leaders, chosen for their expert understanding of the perspectives and dynamics of the cancer research community. Identifies and responds to issues and challenges facing the Institute at the request of the Director.

Division of Program Coordination, Planning, and Strategic Initiatives *DPCPSI*

The Division of Program Coordination, Planning, and Strategic Initiatives' (DPCPSI) mission includes identifying emerging scientific opportunities, rising public health challenges, and scientific knowledge gaps that merit further research. The Division plans and implements trans-NIH initiatives supported by the Common Fund and coordinates research related to AIDS, behavioral and social sciences, women's health, disease prevention, and research infrastructure.

Data Universal Numbering System *DUNS*

The Data Universal Numbering System (DUNS) number is a unique nine-digit number assigned by Dun and Bradstreet Information Services. It is recognized as the universal standard for identifying and keeping track of more than 92 million businesses worldwide. Grants.gov requires a DUNS number for registration. For applicants, the DUNS number in the application must match the DUNS number in the Institutional Profile in Commons.

Domestic Organization

A public (including a State or other governmental agency) or private non-profit or for-profit organization that is located in the United States or its territories, is subject to U.S. laws, and assumes legal and financial accountability for awarded funds and for the performance of the grant-supported activities.

E

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Earmarked Funds

A requirement by Congress that a federal agency spend a specified amount of money for a stated purpose, for example to establish a centers program or conduct a clinical trial.

Edison *iEdison*

NIH's electronic invention reporting system. Usually called iEdison.

Electronic Council Book *ECB*

NIH database system showing an application's summary statement, percentile, priority score, study section, program class code, application type, activity code, grant number, PI name, and project title; downloaded from IMPAC II. ECB also lets members of NCI's main advisory Council (NCAB) approve early awards for fundable applications with no special concerns.

Employer Identification Number *EIN (TIN)*

Also known as Taxpayer Identification Number or "TIN". This is the number required by the Internal Revenue Service (IRS) to be used by the offeror in reporting income tax and other returns. The TIN may be either a Social Security Number or an Employer Identification Number issued by the IRS.

Environment

Scientific, organizational, and administrative environment. The Environment for performance of research proposed in a grant application is a standard Review Criterion that must be addressed by peer reviewers of the application.

Essentially Equivalent Work

This term is meant to identify "scientific overlap," which occurs when (1) substantially the same research is proposed for funding in more than one proposal (contract proposal or grant application) submitted to the same Federal agency; OR (2) substantially the same research is submitted to two or more different Federal agencies for review and funding consideration; OR (3) a specific research objective and the research design for accomplishing that objective are the same or closely related in two or more proposals or awards, regardless of the funding source.

Established Investigator Award in Cancer Prevention, Control, Behavioral, and Population Research *K05*

For the support of a research scientist qualified to pursue independent research which would extend the research program of the sponsoring institution, or to direct an essential part of this research program.

Ethnic and Racial Subgroups

Human subjects terms defined by the Federal government's Office of Management and Budget (OMB) and used by the NIH to allow comparisons to national databases.

See Also Subpopulations

Ethnicity

Easily identifiable characteristic that implies a common cultural history with others possessing the same characteristic. Based on Federal reporting standards the ethnic categories required by NIH is Hispanic or Latino, which includes a person of Cuban, Mexican, Puerto Rican, South or Central American, or other Spanish culture or origin, regardless of race.

Euthanasia

An easy death or means of inducing one. Often used by scientists when referring to killing an animal that has been part of a research study.

Exceptions Meeting

Meeting at which proposed exceptions funding is considered.

Exceptions Process

Process by which potential exceptions are identified, evaluated, and approved for funding.

Exceptions

Applications funded outside an established payline or where no payline exists.

Exclusion

Refusal of entry of a patient into a clinical study because he/she exhibits clinical characteristics that match defined Exclusion Criteria and/or he/she does not exhibit clinical characteristics that match defined Inclusion Criteria.

Executive Branch

That portion of the Federal Government that serves the President of the United States. The Department of Health and Human Services, of which the National Institutes of Health is one of twelve component agencies, is part of the Executive Branch of our government.

Executive Plaza North/South *EPN/S*

6130 and 6120 Executive Boulevard, Rockville, MD, respectively; the loci of most NCI extramural staff members.

Executive Secretary

At the NIH, an Executive Secretary generally refers to the federal government employee who organizes and manages review and/or advisory committee meetings (e.g., study section meetings in the Center for Scientific Review [CSR], the Advisory Council of an Institute or Center [e.g., the National Cancer Advisory Board], or a workgroup of experts meeting to develop an initiative or to determine the current state-of-the-science in a particular area of research). In the CSR and in the review operations of the various Institutes and Centers, the Executive Secretary (now simply called a Scientific Review Administrator in most cases), with the approval of his or her supervisor, and in consultation with the Chairman of the Initial Review Group or Study Section and others, is the staff person responsible for judging the need for the specific review process (e.g., by site visit, by teleconference, or study section, etc.), determining finally the scientific disciplines to be represented, compiling names of scientists with qualifications needed for adequate scientific review, and selecting and contacting individual scientists to serve as members of a review committee.

Exemption Category 1, Human Subjects Research *E1*

Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as research on instructional strategies, or on instructional techniques, curricula, or classroom management methods.

Exemption Category 2, Human Subjects Research *E2*

Research using cognitive, diagnostic, aptitude, and achievement educational tests, surveys, interviews, or observations of public behavior, unless human subjects are identifiable and disclosure of the responses outside the research could reasonably place the subjects at risk of liability or be damaging to their financial standing, employability, or reputation.

Exemption Category 3, Human Subjects Research E3

Research using cognitive, diagnostic, aptitude, and achievement educational tests, surveys, interviews, or observations of public behavior that is not exempt if the subjects are public officials or candidates for public office or federal statutes require that the confidentiality of identifiable information will be maintained.

Exemption Category 4, Human Subjects Research E4

Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if the sources are publicly available or the information is recorded so that subjects cannot be identified.

Exemption Category 5, Human Subjects Research E5

Research and demonstration projects conducted or approved by agency heads to study public benefit or service programs; procedures for obtaining benefits or services or other changes to those programs.

Exemption Category 6, Human Subjects Research E6

Taste and food quality evaluation and consumer acceptance studies a) in wholesome foods without additives or b) in food containing a food ingredient at or below the level and use found to be safe, or agricultural chemical or environmental contaminant at or below the level deemed safe by FDA or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

Expanded Authorities EA

Grant regulation 45 CFR Part 74 gives greater autonomy to grantees, including the ability to carry over funds from one budget period to the next. Expanded authorities apply to most R (but not R41 or 43), P, K, and T series grants.

Exploratory Development Grant Applications R21

The processing of these applications is very much like that of R01s, except that this mechanism also has its own set of review guidelines.

Exploratory Grants - Cooperative Agreements U56

To support planning for new programs, expansion or modification of existing resources, and feasibility studies to explore various approaches to the development of interdisciplinary programs that offer potential solutions to problems of special significance to the mission of the NIH. These exploratory studies may lead to specialized or comprehensive centers. Substantial Federal programmatic staff involvement is intended to assist investigators during performance of the research activities, as defined in the terms and conditions of award.

Exploratory Grants P20

To support planning for new programs, expansion or modification of existing resources, and feasibility studies to explore various approaches to the development of interdisciplinary programs that offer potential solutions to problems of special significance to the mission of the NIH. These exploratory studies may lead to specialized or comprehensive centers.

Exploratory/Developmental Grants Phase II R33

To provide a second phase for support of innovative exploratory and developmental research activities initiated under the R21 mechanism. Although only R21 awardees are generally eligible to apply for R33 support, specific program initiatives may establish eligibility criteria under which applications could be accepted from applicants who demonstrate program competency equivalent to that expected under R33.

Exploratory/Developmental Grants R21

To encourage the development of new research activities in categorical program areas. (Support generally is restricted in level of support and duration.)

Extension

The extension of a project period.

Extensions for Grants Not Covered by Expanded Authorities

A request for a non-competing extension of the project period for a non-SNAP grant should be submitted to the IC GMO, in writing, at least 30 days before the project period will expire.

Extramural Awards

Funds provided by the NIH to researchers and organizations outside the NIH.

Extramural Financial Data Branch *EFDB*

A branch in the Office of the Director of the NCI that (1) plans, directs and coordinates the financial management of the Institute's grant programs and manages the information systems containing data on grants and grant applications; (2) provides advice, information and policy recommendations concerning grants funding and associated information systems technology to the Office Director and the Institute Director, the NCI Executive Committee, and senior staff of the Institute; (3) participates in the formulation of all major grant budget submissions; (4) administers systems containing data on all Institute grant obligations and makes that information available to Institute and NIH staff; (5) prepares regular and special financial reports on NCI grant and contract programs; and (6) maintains liaison with NIH and NCI offices interested in and responsible for extramural research financial data to assure that the contract and grant databases and systems that are developed and used internally and at NIH are efficient, flexible, user friendly, and allow connectivity for sharing data.

Extramural Program Management Committee *EPMC*

This advisory committee on extramural research policies and practices at the NIH is chaired by the NIH Deputy Director for Extramural Research and it has one member from an extramural division of every NIH Institute and Center. The Director of the NCI Division of Extramural Activities is the NCI representative to this NIH committee.

Extramural Scientist Administrator *ESA*

Includes Health Scientist Administrators, Medical Officers, Program Directors, Scientific Review Administrators, and other professional staff of the NIH and its component institutes and centers.

EZ Accrual Database

Also called the NIH "Population Tracking Database."

Enrollment Data

Provides race and ethnicity data for the cumulative number of human subjects enrolled in an NIH-funded clinical research study since the protocol began. This data is provided in competing continuation applications and annual progress reports.

Equipment

An article of tangible nonexpendable personal property that has a useful life of more than 1 year and an acquisition cost per unit that equals or exceeds \$5,000 or the capitalization threshold established by the organization, whichever is less.

Error

During the process of submitting a grant application electronically, applicants may receive a notification from the eRA Commons regarding errors or warnings that need to be corrected to complete the application process. NIH now allows applicants to only correct errors or warnings up until, but not after, the end of the receipt date deadline. To make any corrections, the original application submission must have been submitted on time with all appropriate registrations in place. Note: Errors stop applications from processing and must be corrected. However, warnings do not stop application submission and are corrected at the discretion of the applicant.

Expiration Date

The date signifying the end of the current budget period, after which the grantee is not authorized to obligate grant funds regardless of the ending date of the project period or "completion date."

Extramural Support Assistant *ESA*

A staff member who assists scientific review officers (SROs) in peer-review related work. Formerly called Grants Technical Assistant (GTA).

Early Notification System *ENS*

Electronic system developed to give NIH institutes and centers (ICs) the opportunity to comment on NIH request for applications (RFAs) or program announcements (PAs) before they are published.

Electronic Research Administration *eRA*

NIH's infrastructure for conducting the interactive electronic transactions necessary for the submission, receipt, referral, review, monitoring, and administration of grant applications and awards. Registration is required.

Eligibility Criteria

In clinical trials, requirements that must be met for an individual to be included in a study. These requirements help make sure that patients in a trial are similar to each other in terms of specific factors such as age, type and stage of cancer, general health, and previous treatment. When all participants meet the same eligibility criteria, it gives researchers greater confidence that results of the study are caused by the intervention being tested and not by other factors.

Employee Invention Report *EIR*

Invention report is due to NCI within 2 months after giving written disclosure to an organizational official. Go to the iEdison Web site for invention reporting.

En Bloc Concurrence

A streamlined (i.e., more rapid and efficient) process for obtaining agreement of opinion or union in action by an Advisory Council (e.g., the National Cancer Advisory Board) on one item of business (e.g., the collective decision about the Scientific Review Group recommendations for a collection of grant applications).

Extensions for Grants Awarded under Expanded Authorities

The grantee may extend the final budget period of the previously approved project period one time for a period of up to 12 months beyond the original expiration date shown in the Notice of Grant Award if: (1) no additional funds are required to be obligated by the NIH awarding office; (2) the project's originally approved scope will not change; and (3) any one of the following applies (a) additional time beyond the established expiration date is required to ensure adequate completion of the originally approved project, (b) continuity of NIH grant support is required while a competing continuation application is under review, (c) the extension is necessary to permit an orderly phase-out of a project that will not receive continued support. The grantee must notify the NIH awarding office, in writing, of the extension 10 days before the expiration date of the project period.

Extramural Advisory Board *EAB*

The National Cancer Institute (NCI) Extramural Advisory Board (EAB) provides advice to the Director, NCI, Deputy Director, NCI, and Directors of the NCI Extramural Divisions on issues affecting the extramural program of the NCI from the review, award, and management of extramural grants, contracts, and cooperative agreements, to the broader scientific issues of planning, management, and evaluation of the NCI's extramural programs. The EAB will evaluate existing and proposed policies, procedures, and guidelines for their impact on extramural operations and make recommendations on modifications or development of new policies to improve the effectiveness of extramural operations in meeting the mission of the NCI. The Board will also provide a forum for extramural staff to discuss problems and develop ideas for improving the effectiveness of interactions and communication across programs and with the extramural and intramural scientific community.

Enterprise Vocabulary Services *EVS*

NCI-based system that provides resources and services to meet NCI needs for controlled terminology, and to facilitate the standardization of terminology and information systems across the Institute and the larger biomedical community.

Early Detection/Diagnosis Research Network *EDRN*

An National Cancer Institute (NCI) initiative developed to bring together multiple institutions to help accelerate the translation of biomarker information into clinical applications and to evaluate new ways of testing cancer in its earliest stages and for cancer risk.

Equal Employment Opportunity *EEO*

Laws, policies and guidelines to ensure equal employment opportunity regardless of race, color, national origin, sex, religion, age, or handicapping condition.

Extramural Research Program *ERP*

Research supported by NIH through a grant, contract, or cooperative agreement awarded to an institution outside of NIH.

Early Stage Investigator *ESI*

Early Stage Investigators (ESIs) are New Investigators who are within 10 years of completing their terminal research degree or within 10 years of completing their medical residency at the time they apply for R01 grants.

Electronic Review *ER*

Internet-assisted method by which reviewers of contract proposals submit their critiques

Electronic Streamlined Non-Competing Award Process *eSNAP*

NIH eRA Commons module that allows Principal Investigators (PIs) and grantee institutions to electronically submit their Streamlined Noncompeting Award Process (eSNAP) type 5 progress reports. eSNAPs are due 45 days before a noncompeting award's start date. Use of eSNAP is mandatory for SNAP awards (see NOT OD-10-093).

F

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Facilities and Administrative Costs *F&A*

Also known as Indirect Costs. An award component provided to help defray costs of institutional overhead and grant administration. The amount awarded is usually derived from the "indirect-cost rate," a prearranged, negotiated percentage of the direct cost award. Separate rates are negotiated with each institution. F&A costs are associated with the general operation of an institution and the conduct of its research activities. DHHS supports the full reimbursement for F&A costs for most grant programs. Allowable F&A costs include: depreciation use allowance, facilities operations and maintenance, general administration and expenses, departmental administration, sponsored project administration, and libraries.

Fast Track (SBIR/STTR grants) Award Policy

A review option available to those small business concerns (applicant organizations) whose applications simultaneously satisfy review criteria for both Phase I and Phase II, which enhances the probability of the project's commercial success. Applications that do not meet these criteria may be redirected for review through the standard peer review procedures. Fast Track offers two major advantages: (a) Concurrent submission and peer review of both Phase I and Phase II projects and (b) Minimal or no funding gap between Phase I and Phase II.

Feasibility

The practical extent to which a project is capable of being successfully performed.

Federal Acquisition Regulations *FAR*

Laws regulating government contracting. The regulations governing the acquisition of supplies and services, used by the Executive Agencies of the Federal Government. The FAR was published as Chapter 1 of Title 48 of the Code of Federal Regulations. Its provisions are implemented and augmented by agency supplements.

Federal Advisory Committee Act *FACA*

A Federal law that regulates Federal advisory committees to ensure an appropriate balance of scientists and lay persons and minority, geographical, and racial representation.

Federal Business Opportunities *FedBizOpps*

The single point of universal electronic public access on the Internet for Government-wide Federal procurement opportunities. It replaced the Federal government's Commerce Business Daily (CBD), which no longer exists.

Federal Demonstration Partnership *FDP*

A cooperative initiative among some Federal agencies, including NIH, select organizations that receive Federal funding for research and certain professional organizations. Its efforts include a variety of demonstration projects intended to simplify and standardize Federal requirements in order to increase research productivity and reduce administrative costs.

Federal Emergency Management Agency *FEMA*

An independent agency reporting to the President and tasked with responding to, planning for, recovering from and mitigating against disaster. FEMA can trace its beginnings to the Congressional Act of 1803.

Federal Grant and Cooperative Agreement Act of 1977

The Act (31 U.S.C. 6301 et seq.) which establishes guidelines for distinguishing Federal assistance relationships from Federal procurement relationships.

Federal Premier Lodging Program *FPLP*

A Government-wide program administered by GSA; Establishes contractual relationships with lodging facilities in the 77 top federal travel locations for rooms at rates at or below per diem rates; Is for use by all federal government travelers (State government employees and cost reimbursable contractors are not covered by the program); Is required by the Federal Travel Regulation as the first consideration for official travel lodging.

Federal Register Notice *FRN*

Notices issued by federal agencies that are published in the Federal Register.

Federal Register

The Federal Register is the official daily publication for Rules, Proposed Rules, and Notices, of and by Federal agencies and organizations, as well as Executive Orders, Notices of Funding Availability (NOFAs) and other Presidential Documents.

Federal Technology Transfer Act *FTTA*

Authorizes government agencies to enter into cooperative research and development awards (CRADAs) with private companies.

Federally Funded Research and Development Center *FFRDC*

A Federally Funded Research and Development Center (FFRDC) is a unique organization that assists the United States government with scientific research and analysis, systems development, and systems acquisition. FFRDCs bring together the expertise and outlook of government, industry, and academia to solve complex technical problems that cannot be solved by any one group alone. In 1975, the National Science Foundation notified DHHS that NCI-Frederick met the criteria and was designated as a Federally Funded Research and Development Center.

Federalwide Assurance (for Protection for Human Subjects) *FWA*

Online form that every institution conducting human subjects research must file with the Office of Human Research Protections (OHRP), DHHS, showing its commitment to protect human subjects. It applies to award recipients and collaborating institutions.

Fee

In cost-reimbursement type contracts, an agreed-to amount beyond the initial cost estimate. A fee may be fixed at the outset of performance, as in a cost-plus-fixed-fee contract or may vary within a specified range, as in a cost-plus-incentive-fee contract.

Fellowships *F*

An NIH training program award where the NIH specifies the individual receiving the award. Award that provides individual grants to students and scientists at predoctoral, postdoctoral, or senior levels; to minorities and the disabled; and to postdoctoral trainees in the NCI intramural research program to develop careers in biomedical research. Fellowships comprise the F activity codes (F31, F32, F33, F35).

Final Proposal Revision *FPR*

After completion of negotiations, offerors are asked to submit a final proposal revision which documents all cost and technical agreements reached during negotiations. In other words, a final revised proposal submission prepared by the offeror in response to negotiations/discussions held with the Contracting Officer on a proposal submitted in response to a Request for Proposal (RFP).

Financial Management Plan

A policy to establish consistency in funding, it specifies levels for items such as the payline, programmatic reductions, and caps for re-competing grants.

Financial Status Report (SF-269 or 269A) *FSR*

A financial report due from a grantee by 90 days after the end of each budget period for a grant or cooperative agreement showing the status of awarded funds for that period; this report is submitted to the NCI Grants Administration Branch (GAB). The report is mandatory for continued funding of the grant.

Firm-Fixed-Price Contract *FFP*

A firm-fixed price contract provides for a price that is not subject to any adjustment on the basis of the contractor's cost experience in performing the contract. It provides maximum incentive for a contractor to control costs and perform efficiently and imposes a minimum administrative burden on the contracting parties. (FAR 16.202-1)

Fiscal Year *FY*

Federal budget year: October 1 to September 30.

Fixed-Ceiling-Price Contract

Contract type that provides for a fixed-ceiling-price with an adjustable price redetermination. Fixed-price contracts with an adjustable price may include a ceiling price, target price, or both. Unless otherwise specified, these prices can be adjusted only by clauses in a contract. (FAR 16.206-1)

Fogarty International Center *FIC*

The Fogarty International Center promotes and supports scientific research and training internationally to reduce disparities in global health.

Food and Drug Administration *FDA*

This Federal agency (which is one of twelve agencies in the DHHS) has a public health regulatory function in that it reviews clinical research in order to regulate the marketing of foods, drugs, devices, and cosmetics. The agency relies on the results of clinical trials to ensure the safety and effectiveness of new drugs and biologic agents before they can go on the market for use in humans.

For-Profit Organization

An organization, institution, corporation, or other legal entity that is organized or operated for the profit or financial benefit of its shareholders or other owners. Such organizations are also referred to as "commercial organizations."

Form PHS 398 398

Used for all new competing grant applications at the NIH.

Freedom of Information Act (of 1966) *FOIA*

Federal law that requires the wide dissemination of government documents on public request, while safeguarding proprietary information.

Freedom of Information Requests *FOIA*

Requests for information made under the above act.

Fringe Benefits

Services or benefits provided to employees. e.g., Health Insurance, Payroll Taxes, Pension Contribution, paid Absences, etc. Fringe Benefits are a form of indirect costs

Full and Open Competition

Process that permits all sources to compete for a contract. See Justification for Other than Full and Open Competition (JOFOC), and see FAR 6.000 for complete information.

Full-Time Equivalent *FTE*

The Federal government uses the figure of 1776 hours of actual work per Federal employee per year; the reduction from the maximum number of hours of work possible in a year (i.e., 52 weeks X 40 hours/week = 2080 hours) is primarily due to hours "lost" to annual leave, sick leave, and training. For contract negotiations, the Federal government generally uses the figure of 1920 hours of actual work per contractor employee per year. These figures are also used in OMB Circular A-76 competitions.

Funding Period

The period of time when Federal funding is available for obligation by the recipient of a grant or contract.

Funding Plan

Budget outline that NCI develops according to the congressional allocation for that fiscal year. It specifies standard budget items, such as the payline, selective payment amounts, bridge award pools, and caps for recompeting grants. A set of priorities for research project grants (RPGs)

Federal Institution

A Cabinet-level Department or independent Agency of the Executive Branch of the Federal Government or any component organization of such a Department or Agency.

Funding Rate

Percentage of applicants that receive funding in a fiscal year.

Fast-Track Initiative

The Fast-Track Initiative is an opportunity for small businesses to submit both Phase I and II contract proposals for concurrent peer review. It can be used by small businesses whose proposals are likely to enhance the probability of the project's commercial success. This initiative also helps minimize any funding gaps between Phases I and II.

Foreign Component

The performance of any significant element or segment of the project outside the United States either by the grantee or by a researcher employed by a foreign institution, whether or not grant funds are expended.

Fast Res Fax Form

A template fax form that is provided to all external consultants to the NIH so that they can more easily provide information to the official travel agency for the NIH (i.e., the NIH's Travel Management System, which is currently provided through a contract with Omega Travel) regarding their plans for travel on official government business (e.g., to attend an NIH grants review meeting).

Federal Cash Transaction Report (SF-269 or 269A) *FCTR*

To monitor the use and pattern of cash expenditures of federal funds.

Federal Supply Schedule *FSS*

The Federal Supply Schedule (FSS) program is also known as the General Services Administration (GSA) Schedules Program or the Multiple Award Schedule Program. The FSS program is directed and managed by GSA and provides Federal agencies with a simplified process for obtaining commercial supplies and services at prices associated with volume buying.

Federal Travel Regulation *FTR*

Implements statutory requirements and Executive branch policies for travel by federal civilian employees and others authorized to travel at government expense (41 CFR 300-304)

Fellowship Grants *F Grants*

Fellowship grants help ensure that a diverse pool of highly trained scientists is available in adequate numbers and in appropriate research areas to carry out the Nation's biomedical and behavioral research agenda. Fellowships are awarded as a result of national competition for research training in specified health-related areas. Certain specialized individual fellowships, such as the predoctoral fellowships (F31 and F30), postdoctoral fellowships (F32), Senior Fellowships (F33), and other institute-specific fellowship programs are provided under this authority.

Fiduciary

A legal or ethical relationship of confidence or trust between two or more parties. Fiduciaries have a duty to act prudently and solely in the interest of their beneficiaries.

Financial Conflicts of Interest

Situation in which the grantee's designated official(s) reasonably determines that an investigator's significant financial interest could directly and significantly affect the design, conduct, or reporting of the PHS-funded research.

Fiscal Linked Analysis of Research Emphasis *FLARE*

The National Cancer Institute (NCI) Funded Research Portfolio (FLARE) database contains information about research grant and contract awards made by the National Cancer Institute. It includes awards for the current and past five fiscal years. The web site provides the ability to search the database in various ways including a text search of the project abstract and a search of the Special Interest Category (SIC) and anatomic site codes assigned to the project.

Foreign Institution

An organization located in a country other than the United States and its territories that is subject to the laws of that country, regardless of the citizenship of the proposed Program Director/Principal Investigator.

Formative Evaluation

Collects information about the components of the recruitment and retention aspects of the research project. Information from this type of evaluation can be used to test messages, select communications channels, and revise the communication process.

Funding Mechanism

Extramural research awards are divided into three main funding mechanisms: grants, cooperative agreements and contracts. A funding mechanism is the type of funded application or transaction used at the NIH. Within each funding mechanism NIH includes programs. Programs

can be further refined by specific activity codes.

See Also Biomedical Information Science and Technology Initiative

Funding Opportunity Announcement FOA

- A publicly available document by which a Federal Agency makes known its intentions to award discretionary grants or cooperative agreements usually as a result of competition for funds. Funding opportunity announcements may be known as program announcements, requests for applications, notices of funding
- availability, solicitations, or other names depending on the Agency and type of program. Funding opportunity announcements can be found at Grants.gov and in the NIH Guide for Grants and Contracts.

Freedom of Information Act FOIA

Policy that requires dissemination, upon request, of Government documents while ensuring protection of proprietary and other privacy act information.

Focused Ultrasound FUS

Applies high intensity focused sonic energy to locally heat and destroy diseased or damaged tissue through ablation.

G

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General Services Administration GSA

A central management agency that sets Federal policy in such areas as Federal procurement, real property management, and information resources management

Government Charge Card Coordinator

Person designated to administer the contractor-issued government charge card program, including the processing of applications for the card and answering employee questions.

Government Printing Office GPO

Produces and distributes Federal Government information products. Web address: <http://www.access.gpo.gov/index.html>

Government Rate

The maximum permitted daily cost for hotel accommodations for travelers on official government business and government-sponsored travel.

Government-Furnished Property

Items the government possesses or acquires and makes available to a contractor; see FAR 45.101.

Grant Application Form and Instructions, PHS PHS 398

Public Health Service Form #398 that is used for most NIH grant applications.

Grant Closeout

A procedure to officially conclude a grant (within 90 days after the end of the award, if possible). NIH/NCI grants management and program staff must determine that all applicable administrative actions and all required work of the grantee have been completed. A grantee sends the grants management specialist in the Grants Administration Branch a final financial status report, status of federal cash (PSC 272), final progress report, and final invention statement (HHS 568), including any inventions reported previously for that award (see iEdison for invention reporting).

Grant Compliance Review

An evaluation by grants management staff (usually a specialist) to assess an institution's business and financial management systems to ensure that regulations and policies are being followed for an NIH grant.

Grant File

The official file of a particular grant that contains all significant documents and correspondence related to the award.

Grant Out Years

Years following the first year of funding of a competitive segment, during which the PI applies for a noncompeting continuation award.

Grant Project Period

Total period a project has been recommended for support, which may include more than one competitive segment. For example, a project period for a grant begun in 1990 can be divided into competitive segments 1990-1994, 1994-1998, 1999-2003, etc.

Grant Rebudgeting

Also just called "Rebudgeting." With the advent of modular grants, grantees no longer have to request permission from NIH for rebudgeting (formerly moving money from one budget category to another). For nonmodular grants, permission is still needed for some items.

Grant Start Date

Official date a grant award begins.

See Also Anniversary Date

Grantee

The institution (public or private, nonprofit or for-profit, educational institution, hospital, cooperation, organization, domestic or foreign agency, or other legally accountable entity) that receives a grant or cooperative agreement and assumes legal, financial, and scientific responsibility and accountability both for the awarded funds and for the performance of the grant-supported activity. In certain cases, a grantee may be an individual in the United States.

Grants Management Officer *GMO*

The NIH official who is responsible for the business management of grants and cooperative agreements, including ensuring that both the granting agency and grantees meet all requirements of laws, regulations, and policies.

Grants Management Specialist *GMS*

An NIH staff member who is the focal point for all business activities associated with the negotiation, award, and administration of a grant or cooperative agreement. He or she also interprets grant administration policy and provisions.

Grants Policy Statement, NIH *GPS* or NIH *GPS*

An NIH document that outlines policy requirements for all NIH grants. The National Institutes of Health Grants Policy Statement (NIH GPS) is intended to make available to NIH grantees, in a single document, up-to-date policy guidance that will serve as the terms and conditions of NIH awards. This document is also designed to be useful to those interested in NIH grants by providing information about NIH-its organization, its staff, and its grants process. The NIH GPS is available on-line from the NIH Home Page at <http://www.nih.gov>

Grants with Foreign Components

Grants to domestic institutions that contain substantial funds going via subcontract to a foreign institution.

Green Sheet

Grant Documentation Control Form for Competing Applications Form. A Green Sheet must be completed for every grant.

Grants.gov

An access point through which any person, business, or State, local, or Tribal government may electronically find and apply for more than 1,000 competitive grant opportunities from the 26 Federal grant-making Agencies. The Department of Health and Human Services (HHS) is the managing partner for the Federal Grants.gov initiative, one of 24 initiatives of the overall E-Government program for improving access to Government services via the Internet. Registration is required to apply.

Grant-Supported Project/Activity

Those programmatic activities specified or described in a grant application or in a subsequent submission(s) approved by an NIH Institute or Center for funding, regardless of whether Federal funding constitutes all or only a portion of the financial support necessary to carry them out.

Grant Application Guide

Instructions for completing an electronic Grant Application Package. Each Funding Opportunity Announcement has its own package and guide. Go to NIH Application Guides: <http://grants.nih.gov/grants/forms.htm>.

Gender

Human subjects term indicating a classification of research subjects into women and men. In some cases, gender cannot be accurately determined, e.g., for pooled blood samples.

General Accounting Office *GAO*

An oversight organization reporting to Congress. Go to General Accounting Office (GAO) reports. Web address: <http://www.gao.gov/>

General Clinical Research Centers *GRCs*

General Clinical Research Centers (GCRC) are approximately 75 centers nationwide that embody the GCRC Program which was established in 1960 and is funded by the National Institutes of Health through The National Center for Research Resources. The objective of the GCRC Program is to provide scientists the infrastructure necessary for the efficient and productive conduct of high quality clinical research. GCRCs strive to provide a conducive environment for studies of normal and abnormal body function and for investigations of the cause, progression, prevention, control, and cure of human disease. Use of the Centers for interdisciplinary, collaborative research and training in medical research is encouraged. GCRCs are available to investigators from all medical specialties and from the basic sciences.

Good Laboratory Practice *GLP*

Good Laboratory Practice (GLP) is a set of principles that provides a framework within which laboratory studies are planned, performed, monitored, recorded, reported, and archived to ensure the reliability of data generated within a compliant laboratory. A key feature of this is the generation of quality-control methods and data management within the cell culture laboratory.

Good Manufacturing Practice *GMP*

A system for ensuring that medicinal products are consistently produced and controlled according to the quality standards appropriate to their intended use and as required by the product specification.

Government-Owned Contractor-Operated Facilities *GOCO*

A manufacturing plant that is owned by the Government and operated under contract by a non-government, private firm.

Grant (Award)

A financial assistance mechanism between the Government (e.g., an NIH institute like the NCI) and a recipient (i.e., an approved outside institution) for approved activities. Performance responsibility rests primarily with the recipient and there is little or no Government involvement or participation in the performance of activities.

Grant Appeal

A Department of Health and Human Services (DHHS) policy that provides for an appeal by the grantee institution of post award administrative decisions made by awarding offices. There are two levels of appeal available: an informal NIH procedure and a formal DHHS procedure. The grantee must first exhaust the informal procedures before appealing to the DHHS Appeals Board; A procedure for contesting the peer review of a grant application. Synonymous with "rebuttal."

Grant Application

Application for financial assistance from a Public Health Service (PHS) agency (e.g., the NIH) to fund biomedical or behavioral research, using PHS 398 application forms and instructions.

Grant Documentation Control Firm

The Green Sheet.
See Green Sheet

Grant Review Cycle

Refers to the Center for Scientific Review's thrice yearly initial peer review cycle, from the receipt of applications to the date of the review. See [Standard Receipt Dates](http://grants.nih.gov/grants/funding/submissionschedule.htm).

Grant Type

See *Activity Codes (Funding Mechanisms)*

Grant Update Module *GUM*

An initiative that spans modules which allows for updating of grant information to apply across various modules.

Grants Management Advisory Committee *GMAC*

Serves in an advisory capacity to the NIH Deputy Director of Extramural Research (DDER) through the Extramural Program Management Committee.

Grants Reporting and Information Tracking System *GRITS*

Designed to track decisions in the IMPACII database

Grant Suspension

This action is taken by a Federal awarding agency when a grantee has materially failed to comply with the terms and conditions of a grant or for other cause. This action temporarily suspends Federal sponsorship under an award (meaning that the grantee loses the authority to use the grant funds), pending corrective action by the grantee or a decision by the NIH to terminate the award.

Genes, Environment and Health Initiative *GEI*

To support research that will lead to the understanding of genetic contributions and gene-environment interactions in common disease.

Geographic Information System *GIS*

A Geographic Information System (GIS) consists of an integrated hardware, software, and data system that can capture, manage, analyze, and visualize diverse types of geographical information. GIS systems enable researchers to examine data in unique ways so that they can more readily observe and interpret relationships, patterns, and trends in complicated data sets. The NCI is engaged in a variety of GIS-related activities and initiatives. The NCI GIS site was designed to provide a central source of information about GIS and related resources.

Government Performance Review Act *GPRA*

An act to require quarterly performance assessments of Government programs for purposes of assessing agency performance and improvement, and to establish agency performance improvement officers and the Performance Improvement Council.

Genome Wide Association Studies *GWAS*

A Genome-Wide Association Study (GWAS) is defined as a genetic association study in which the density of genetic markers and the extent of linkage disequilibrium is sufficient to capture a large proportion of the common variation in the human genome in the population under study, and the number of specimens genotyped provides sufficient power to detect variants of modest effect.

H

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Health and Human Services Acquisition Regulation *HHSAR*

Department regulations applicable to Department of Health and Human Services (DHHS) acquisition activities that implement and supplement the Federal Acquisition Regulations (FAR).

Health Disparities

Diminished health status associated with differences in culture, language, diet, nutrition, physical activity, socioeconomic and demographic status, gender, age and environmental pollutants and occupational hazards.

Health Literacy

The degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decision.

Health Promotion

The combination of educational and environmental supports for actions and conditions of living conducive to health.

High Risk/High Impact *HR/HI*

A formerly used term for a category of applications identified by a scientific review group as having a high degree of uncertainty in approach but also a high potential for impact. NIH no longer tracks how many of these applications are identified and funded.

Hispanic or Latino

A person of Cuban, Mexican, Puerto Rican, South or Central American, or other Spanish culture or origin, regardless of race. The term, "Spanish origin," can also be used.

Historically Underutilized Business Zone *HUBZone*

The relevance of HUBZone is in the domain of contract proposals and contracts.

Hold On Award

Block to the release of award funds often implemented in response to human subjects concerns raised by the study section during peer review.

Human Embryo Research

Section 513 of the FY 1998 Appropriations Act, P.L. 105-78, signed November 13, 1997, reinstates the current ban that prohibits NIH from using appropriated funds to support human embryo research.

Human Embryonic Stem Cells *HESCs*

Human embryonic stem cells are derived from human embryos that develop from eggs that have been fertilized in vitro in an in vitro fertilization clinic and then donated for research purposes with informed consent of the donors. They are not derived from eggs fertilized in a woman's body. The embryos from which human embryonic stem cells are derived are typically four or five days old and are a hollow microscopic ball of cells called the blastocyst. The blastocyst includes three structures: the trophoblast, which is the layer of cells that surrounds the blastocyst; the blastocoel, which is the hollow cavity inside the blastocyst; and the inner cell mass, which is a group of approximately 30 cells at one end of the blastocoel. Human embryonic stem cells are isolated by transferring the inner cell mass into a laboratory culture dish that contains culture medium.

Human Fetal Tissue

Any tissue derived from human embryos and fetuses.

Human Pluripotent Stem Cells *hPSCs*

Such stem cells have the ability to develop into many different cell types of the body.

Human Subjects Concern

A human subjects term that indicates any actual or potential unacceptable risk or inadequate protection against risk to human subjects.

Human Subjects

Individuals whose physiologic or behavioral characteristics and responses are the object of study in a research project. A legally defined term that indicates a living person with whom an investigator directly interacts or intervenes or obtains identifiable, private information. Regulations apply to human organs, tissues, body fluids, and recorded information from identifiable people. See 45 CRF 46.

Health Disparities Research

Basic, clinical, or behavioral research on a health disparity population (including individual members and communities of such populations), including the causes of health disparities and methods to prevent, diagnose, and treat such disparities.

Health Disparity Populations

Groups determined by the Director of the National Center on Minority Health and Health Disparities (NCMHD), in consultation with the Director of the Agency for Healthcare Research and Quality (AHRQ), in which there is significant disparity in the overall rate of disease incidence, prevalence, morbidity, mortality, or survival as compared to the health status of the general population. The following populations have been designated as health disparity populations: Blacks/African Americans, Hispanics/Latinos, Native Americans, Alaska Natives, Asian Americans, Native Hawaiians, Pacific Islanders, and the medically underserved (i.e., individuals from the Appalachian region).

Human Subjects Risk and Protection Issues

Applicants are required to address the following items in their research plan: Subjects' involvement and characteristics, sources of materials, recruitment and informed consent, potential risks, protection against risk, and benefits.

Health Omnibus Programs Extension Legislation *HOPE*

Enacted November 4, 1988 (P.L. 100-607). Added rehabilitation research to NCI's mission and further expanded NCI's information dissemination programs.

Health Scientist Administrator *HSA*

This title includes primary several job descriptions at the NIH and/or in the Public Health Service. First, an HSA can be the awarding office official who is responsible for the technical, scientific, or programmatic aspects of a grant. This official may also be referred to as the program officer or project officer. Such individuals deal with recipient organization staff to assure programmatic progress and work closely with the Grants Management Officer and the grants management staff in the overall administration of grants. Second, an HSA can be a Scientific Review Administrator who is responsible for managing the peer review of grant applications and/or contract proposals.

Hispanic-Serving Institutions *HSIs*

A Hispanic-Serving Institution (HSI) is defined as an institution of higher education that (A) is an eligible institution; and (B) has an enrollment of undergraduate full-time equivalent students that is at least 25 percent Hispanic students at the end of the award year immediately preceding the date of application (per Title V, Part A of the Higher Education Act, as Amended).

Human Subjects Code

The number that a scientific review group places on a summary statement during an initial peer review that reflects the application of human subjects regulations to a project, and the inclusion of women, children, and racial and ethnic populations. Some codes indicate a human subjects concern that would result in a bar to award.

See Also Human Subjects Involvement Codes

Human Subjects Exemption Categories

Human subjects term indicating six research categories exempt from human subjects regulation (45 CFR 46.101).

Human Subjects Involvement Codes

These codes reflect the status of human subjects involvement on summary statements of grant applications and on the grants management and program officer worksheets in IMPAC.

Historically Black Colleges and Universities *HBCU*

A Historically Black College or University (HBCU) is defined as an institution established prior to 1964 whose principal mission was, and is, the education of Black Americans, and must (1) satisfy Section 332 of the Higher Education Act of 1965, as amended (HEA); (2) be legally authorized by the State in which it is located (i) to be a junior or community college, or (ii) to provide an educational program for which it awards a bachelor's degree; and (3) be accredited or preaccredited by a nationally recognized accrediting agency or association (per Title III, Part B, Sections 321-327 of the Higher Education Act, as amended).

Howard Hughes Medical Institute *HHMI*

A non-profit philanthropic funding organization for biological and medical research and science education

Health Information National Trends Survey *HINTS*

Collects nationally representative data routinely about the American public's use of cancer-related information.

Health Insurance Portability and Accountability Act *HIPAA*

The Health Insurance Portability and Accountability Act (HIPAA) includes provisions designed to encourage electronic transactions and also requires new safeguards to protect the security and confidentiality of health information.

Health Maintenance Organization *HMO*

A type of health insurance plan that usually limits coverage to care from doctors who work for or contract with the Health Maintenance Organization (HMO).

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iEdison *iEdison*

NIH's electronic invention reporting system. Sometimes called "Edison" instead of "iEdison."

Impact Evaluation

Focuses on the long-range results of the program and subsequent changes in health status. Impact evaluations are rarely possible because they are costly, involve extended commitment, and may depend upon other strategies in addition to the recruitment and retention component of the research project.

Incidence

The rate of occurrence of new cases of a particular disease in a population being studied -- compare with "prevalence."

Incremental Funding

A mechanism in which the total work effort under a contract is to be performed over multiple time periods and funds are allotted, as they become available, to cover discernible phases or increments of performance. (See Section VII, D, of the NCI Research Contracts Branch's Orange Book).

Individuals with Disabilities

Provides funds to recruit and support scientists and students with disabilities. This program will also provide support for NIH investigators who become disabled, such as assistants or special equipment.

Informed Consent

The permission given by a person before surgery or other medical procedures. The patient, or parent or guardian, must understand the potential risks and benefits of the procedure and legally agree to accept those risks.

Infrequent Traveler

Individuals that travel less than two times per year.

Initial Peer Review Criteria

Significance - Is the topic important? Will it advance scientific knowledge? Approach - Are the hypothesis, design, and methods well developed and appropriate? Are potential problems addressed? Innovation - Does the proposal involve new ideas or methods; does it challenge existing paradigms? Investigator - Does the investigator and collaborators have the training and experience to do the work? Environment - Will the scientific environment contribute to success? Is there institutional support for the project? Does the work take advantage of existing opportunities including collaborations?

Initial Review Group *IRG*

The first level of a two-stage peer review system. Legislatively mandated panels of subject matter experts are established according to scientific discipline or medical specialty. Their primary function is the review and rating of research grant applications for scientific and technical merit. They make recommendations for the appropriate level of support and duration of award.

Initiative

A request for applications (RFA), request for proposals (RFP), or program announcement (PA) stating the Institute's interest in receiving research applications in a given area because of a programmatic need or scientific opportunity. RFAs and RFPs generally have monies set aside to fund the applications responding to them; program announcements generally do not.

Innovation

In the review of a grant application submitted to the NIH, this term refers to a required peer review criterion. In this context, "innovation" means the degree to which a project or program applies novel concepts and innovative approaches.

Institute and/or Center *IC*

Major NIH organizations; Institutes, such as NIAID and Centers, such as the Fogarty International Center.

Institutional Clinical Oncology Research Career Development Award *K12*

To support a newly trained clinician appointed by an institution for development of independent research skills and experience in a fundamental science within the framework of an interdisciplinary research and development program.

Institutional National Research Service Award with Involvement of NIH Intramural Faculty *TU2*

The cooperative agreement counterpart to the T32, this award enables institutions to provide research-training experiences for graduate students and postdoctoral scientists in specified shortage areas. In addition, these awards involve identified NIH Intramural Staff who serve as a part of the training faculty and participate in the operation of the training program.

Institutional Review Board Certification *IRB*

Documentation from your Institutional Review Board that it has approved your research protocol, consent form (if applicable), monitoring and reporting procedures, and plans for analyzing intervention differences among different types of human subjects, for example women and minorities, ethnic or racial subgroups, and children. The IRB also approves your research annually with the noncompeting grant application and

any time there are major changes in the research protocol or other procedures. The IRB must also certify its approval of the results of subset analyses in renewal applications and contract proposals.

Integrated Review Group *IRG*

A cluster of study sections in the Center for Scientific Review that are responsible for the review of grant applications in scientifically related areas. These study sections share common intellectual and human resources.

Intellectual Property

The separate and distinct types of intangible property that are referred to collectively as "intellectual property," including but not limited to: patents, trademarks, copyrights, trade secrets, SBIR technical data (as defined in this section), ideas, designs, know-how, business, technical and research methods, and other types of intangible business assets, and including all types of intangible assets either proposed or generated by an SBC as a result of its participation in the SBIR Program.

Interagency Agreement or Inter-agency Agreement

A formal agreement among government agencies to collaborate on and fund research. In the context of the NCI, an Interagency Agreement is a written arrangement between NCI and one or more Federal Agencies outside the Department of Health and Human Services (DHHS). (See Section II, C, of the Research Contracts Branch's Orange Book).

Interagency Edison *iEdison*

NIH's electronic invention reporting system.

Interim Support

This support is intended to provide minimal funding to maintain continuity in research enterprises or to obtain additional data that would allow the investigator to re-complete for renewal of a current grant.

Intra-Agency Agreement

A formal agreement among distinct components of a government agency to collaborate on and fund research. In the context of the NCI, an Intra-agency Agreement is a written arrangement between the NCI and one or more other component(s) of DHHS. (See Section II, C, of the Research Contracts Branch's Orange Book).

Intramural Research

Research conducted by government-run NIH laboratories.

Invention

Any discovery which is or may be patentable or otherwise protectable.

Investigational Commitment

Adequate research facilities and educational opportunities for pursuing cancer-related research - commitment to scientific development of applicant, and commitment to provide protected time.

Investigational New Drug Application *IND Application*

Under regulation 21 CFR 312, application filed by a drug sponsor with FDA on Form FDA 1571 to conduct clinical trials, including detailed descriptions of all trial phases, protocols, Institutional Review Board (IRB) members, and investigators. Once clinical evaluation is completed, a new drug application must be submitted to FDA to obtain approval to market the drug. Often used interchangeably with "IND."

Investigational New Drug *IND*

Status given by the U.S. Food and Drug Administration (FDA) to a new drug or biological product to be used in a clinical investigation. FDA approval to experimentally test a new drug in people under controlled circumstances. However, an investigational new drug cannot be legally marketed and sold in the United States until the FDA grants approval after concluding that it is safe and effective for appropriate use in humans.
See Also Investigational New Drug Application

Investigator-Initiated Research

Research funded as a result of an investigator, on his or her own, submitting a research application. Also known as unsolicited research. Unsolicited applications are reviewed by chartered CSR review committees.
See Also Targeted Research

Investigators

In clinical trials, an individual who actually conducts an investigation [21 CFR 312.3]. Any interventions (e.g., drugs) involved in the study are administered to subjects under the immediate direction of the investigator.

Indian Health Service *IHS*

U.S. Department of Health and Human Services agency providing healthcare to Native American and Alaskan Native peoples.

Identifier

Information linking specimens or data to individually identifiable living people or their medical information. Examples include names, social security numbers, medical record numbers, and pathology accession numbers.

Indirect Costs

Costs that are incurred by a grantee for common or joint objectives and cannot be identified specifically with a particular project or program.
See Facilities and Administrative Costs

Institutional Base Salary

The annual compensation paid by an applicant/grantee organization for an employee's appointment whether that individual's time is spent on research, teaching, patient care, or other activities. The base salary excludes any income that an individual is permitted to earn outside of duties for the applicant/grantee organization. Base salary may not be increased as a result of replacing organizational salary funds with NIH grant funds.

Internet Assisted Review *IAR*

Allows peer reviewer to submit critiques and preliminary scores for the applications that they are reviewing. Allows Peer Reviewers, scientific review officers (SROs), and extramural support assistants (ESAs) to view all critiques in preparation for a review meeting. IAR creates a preliminary summary statement body containing submitted critiques for the SRO(s) and ESA(s).

Initial Peer Review

First level of peer review by non-NIH scientific experts, called peer reviewers, who assess the scientific and technical merit of grant applications and contract proposals.

IMPACII Review Module *REV*

Information for Management, Planning, Analysis and Coordination (IMPAC) II is the second generation computer database system developed and maintained by the Office of Extramural Research for information concerning PHS extramural programs..

IMPACII *IMP2*

Information for Management, Planning, Analysis and Coordination (IMPAC) is the second generation computer database system developed and maintained by the Office of Extramural Research for information concerning PHS extramural programs.

In Vivo Cellular and Molecular Imaging Centers *ICMIC*

In Vivo Cellular and Molecular Imaging Centers (CPCPR) is one of the task forces that were created by the NCI Imaging Sciences Working Group to address pressing issues in functional tumor imaging. is charged to link the vast array of emerging physiologic markers uncovered by powerful, new techniques of molecular genetics to existing and incipient imaging modalities.

Indefinite Delivery Contract

A contract used to acquire supplies and/or services when the exact times and/or exact quantities of future deliveries are not known at the time of contract award. This type of contract is generally reserved for Non-R&D requirements. There are three types of indefinite - delivery contracts: definite quantity, requirements, and indefinite quantity.

Independent Ethics Committee *IEC*

Independent Review Boards (IRBs) or Ethics Committees (ECs) have been entrusted with the responsibility to safeguard the rights, safety, and well-being of all trial subjects.

Information for Management, Planning, Analysis, and Coordination *IMPAC*

Information for Management, Planning, Analysis, and Coordination (IMPAC) was a computer database system developed and maintained by the Office of Extramural Research for information concerning PHS extramural programs. This internal NIH database contained confidential information on applications, awards, awardees, and peer reviewers. It has been replaced by IMPAC II.

Institutional Animal Care and Use Committee *IACUC*

The Institutional Animal Care and Use Committee (IACUC) derive their authority from the law. IACUCs are mandated by the Health Research Extension Act (HREA) and the Animal Welfare Act (AWA) of 1985. The laws require that each institute that receives PHS support for activities involving vertebrate animals or is subject to the authority of the AWA must operate an animal care and use program with clear lines of authority

and responsibility. The program must include a properly constituted and functioning IACUC with procedures for self monitoring, training, veterinary care and appropriately maintained facilities.

Institutional Assurance of Protection for Human Subjects

A document filed with the Health and Human Services (HHS) Office for Human Research Protections (OHRP) formalizing the research institution's commitment to protect human subjects in its federally supported research. The OHRP has developed a new, simplified process for obtaining a Federal wide Assurance (FWA) of Protection for Human Subjects, applicable to all federal agencies. In the future, only the FWA will be accepted, although the deadline when it will replace other more limited assurances (e.g., the special project assurance for a specific research project) has been indefinitely extended.

See Also IRB certification

Institutional Assurance

A certification by an applicant, normally included with the application or State plan, indicating that the entity is in compliance with, or that it will abide by, a particular requirement if awarded a Federal grant.

Institutional Biosafety Committee *IBC*

Represents the interests of the surrounding community with respect to public health and protection of the environment, animal containment principles and biological safety.

Institutional Business Official

Person working in a research organization's business office who has signature or other authority. That person is the same as Grants.gov's Authorized Organizational Representative (AOR) and the eRA Commons' Signing Official (SO).

Institutional Development Award *IDeA*

Broadens the geographic distribution of NIH funding for biomedical and behavioral research.

Institutional Review Board

A specially constituted review body established or designated by an entity to protect the welfare of human subjects recruited to participate in biomedical or behavioral research.

Integrated Effort

"Integration of Effort" or "Program as an Integrated Effort," is a characteristic evaluated in the review of program project (P01) grant applications. When evaluating this review criterion, the following aspects of the research program are assessed by the peer reviewers: 1) evidence of coordination, inter-relationships, and synergy among the meritorious research projects and core components as related to the common theme of the program project; 2) the advantages or value added that could be realized by conducting the proposed research as a P01 rather than through separate research efforts; 3) the presence and quality of mechanisms for regular communication and coordination among investigators; 4) the mechanisms for quality control of the research (e.g., internal or external advisory boards; and 5) for competing renewal applications, evidence of productive collaborations, such as joint publications, that have resulted from the P01 award.

Intergovernmental Personnel Act Mobility Program *IPA*

Provides for the temporary assignment of personnel between the Federal Government and state and local governments, colleges and universities, Indian tribal governments, federally funded research and development centers, and other eligible organizations.

Internal Monitoring Board *IMB*

Person(s) designated by a sponsor or contract research organization to oversee an investigation. A monitor may be an employee, contractor or consultant to a sponsor. Monitor also means to oversee an investigation.

Invention Reporting

The requirement pursuant to 37 CFR part 401 that recipients of contracts, grants or cooperative agreements fully disclose any subject inventions made during the performance of work under a funding agreement in order to protect the Federal government's rights.

See Also Edison

Investigational Device Exemption *IDE*

Allows an unapproved medical device to be used for investigational purposes (21 CFR 812.1).

IRB certification

Provide ethical and regulatory oversight of research that involves human subjects.

Integrative Cancer Biology Programs *ICBPs*

The Integrative Cancer Biology Program (ICBP) is a research effort promoting the application of a systems or integrative approach to the study of cancer biology. The core of the ICBP comprises twelve Centers for Cancer Systems Biology housed at research institutions across the country. These Centers represent multidisciplinary research groups that apply state-of-the-art techniques to the understanding and management of cancer.

Investigational Drug Steering Committee (CCCT) *IDSC*

Provides the National Cancer Institute (NCI) with broad external scientific and clinical input on the design and prioritization of phase I and phase II trials with agents for which Cancer Therapy Evaluation Program (CTEP) holds an Investigational New Drug (IND) application.

International Agency for Research on Cancer *IARC*

Promotes international collaboration in cancer research. The Agency is inter-disciplinary, bringing together skills in epidemiology, laboratory sciences and biostatistics to identify the causes of cancer so that preventive measures may be adopted and the burden of disease and associated suffering reduced.

Institute or Center *IC*

The NIH organizational component responsible for a particular grant program or set of activities. NIH is made up of 27 Institutes and Centers, each with a specific research agenda, often focusing on particular diseases or body systems.

Innovative Molecular Analysis Technologies *IMAT*

Aimed at the inception, development, integration, and application of novel and emerging technologies in the support of cancer research, treatment, diagnosis, and prevention.

Institute of Medicine *IOM*

A not-for-profit, non-governmental American organization that provides national advice on issues relating to biomedical science, medicine, and health, and its mission to serve as adviser to the nation to improve health. It works outside the framework of the U.S. federal government to provide independent guidance and analysis and relies on a volunteer workforce of scientists and other experts, operating under a rigorous, formal peer-review system. The Institute provides unbiased, evidence-based, and authoritative information and advice concerning health and science policy to policy-makers, professionals, leaders in every sector of society, and the public at large.

Intellectual Property Rights *IPR*

Ideas, inventions, and creative expressions based on which there is a public willingness to bestow the status of property.

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James A. Shannon Director's Award *R55*

To provide a limited award to investigators to further develop, test, and refine research techniques; perform secondary analysis of available data sets; test the feasibility of innovative and creative approaches; and conduct other discrete projects that can demonstrate their research capabilities and lend additional weight to their already meritorious applications.

Javits-Wagner-O'Day Program *JWOD*

The Committee for Purchase from People Who are Blind or Severely Disabled.

Joint Venture

An association of persons or concerns with interests in any degree or proportion by way of contract, express or implied, consorting to engage in and carry out a single specific business venture for joint profit, for which purpose they combine their efforts, property, money, skill, or knowledge, but not on a continuing or permanent basis for conducting business generally. A joint venture is viewed as a business entity in determining power to control its management, has been assigned its own Employer Identification Number by the Internal Revenue Service, and is eligible under the SBIR Program provided that the entity created qualifies as a "SBC" as defined in this section.

Joint Federal Travel Regulations *JFTRs*

Travel policy for member of the Uniformed Services of the United States (Volume 1) and for Department of Defense civilian employees (Volume 2). The JFTR contains regulations related to per diem, travel and transportation allowances, relocation allowances, and certain other allowances.

Just in Time

A reinvention innovation in which applicants send some information to NIH only if an award is likely, streamlining the application process. Just in time is used for other support information and several items for human subjects research: certification of IRB approval, Federalwide assurance,

and a letter stating that key personnel have been trained in protecting human subjects.

Justification for Other than Full and Open Competition *JOFOC*

Documentation justifying the use of any of the seven exceptions to using full and open competition as identified in FAR Part 6. The exception, with supporting documentation, must be certified and approved at certain levels that vary according to the dollar value of the acquisition. The information that must be included in each justification is identified in FAR Part 6.

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K12 CURE Supplement *K12 CURE*

Purpose is to increase the number of medical doctors and doctorally degreed Oncology Registered Nurses from underrepresented populations who are motivated and properly trained to: 1) communicate and collaborate with basic/ behavioral research scientists in order to expedite the translation of basic/ behavioral info into patient-oriented research; 2) perform independent clinical research that develops and tests rational scientific hypotheses based on fundamental and clinical research findings with the potential for improving the medical care of cancer patients; and 3) design and test innovative clinical protocols and manage all phases (i.e., pilot/Phase I, Phase II, Phase III) of clinical trials research. The CURE supplement is not intended to provide an alternative means of supporting minority individuals who already receive support from a research grant, a research training grant, a career development award, or any other DHHS funding mechanism essentially duplicating the provisions of the CURE supplement.

Key Personnel Engaged on Project

This term is meant to identify those individuals who contribute in a substantive way to the scientific development or execution of the project, whether or not salaries are requested.

Key Personnel

Individuals who contribute in a substantive way to the scientific development or execution of a project, whether or not they receive compensation from the grant supporting that project. The principal investigator (PI) is included in this category.

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Letter Contract

Written preliminary contractual instrument that authorizes a contractor to begin immediately manufacturing supplies or performing services. See FAR 16.603-1.

Letter of Intent *LOI*

A non-binding notification submitted to NCI staff by a principal investigator indicating intent to submit an application or contract proposal.

License

Legally binding agreement that gives certain rights to a licensee, e.g., patent rights or use of materials, such as in a Biological Material License (BML) or a Material Transfer Agreement (MTA).

Limited Competition Solicitations *RFAs*

Locality Rate

Type of Per Diem rate.

Legislative Mandates

A mandatory order or requirement under statute, regulation, or by a public agency.

Levels of Authority

The National Cancer Institute (NCI) document, maintained by GAB, giving the level of approval authority required for different grant actions.

Loan Repayment Program *NIH*

The overall objective of the NIH Loan Repayment Programs (LRPS) is the recruitment and retention of highly qualified health professionals to careers in clinical, pediatric, health disparities, or contraception and infertility research. The five NIH extramural LRPs include the Clinical Research, Pediatric Research, Contraception & Infertility Research, Health Disparities Research, and Clinical Research for Individuals from Disadvantaged Backgrounds.

Long Island Breast Cancer Study Project *LIBCSP*

A multi-study effort to investigate whether environmental factors are responsible for breast cancer in Suffolk and Nassau counties (Long Island), NY, as well as in Schoharie County, NY, and Tolland County, CT.

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Mail Reviewers

Peer reviewers of grant applications who send in their critiques rather than participating in grant review meetings in person.

Mainstream

Used to describe the general market, but usually refers to a broad population that, in the continental United States, is primarily white and middle class.

Majority Group

A Human Subjects term indicating a white person, not of Hispanic origin; a person having origins in the original peoples of Europe, North Africa, or the Middle East.

Master Agreement Order *MAO*

A binding contract issued to the successful Master Agreement (MA) holder as a result of a competitive process held among all eligible MA holders.

Master Agreement *MA*

A mechanism used to enhance competition among prospective offerors by establishing pools of qualified sources in a particular research and development, evaluation or area of study. The intent is to establish qualified pools of sources (known as Master Agreement holders) who can respond to competitive solicitations in a short time frame.

Matching or Cost Sharing

The value of third party in-kind contributions and the portion of the costs of a federally assisted project of program not borne by the Federal Government.

Material Transfer Agreement *MTA*

A legal document that defines the conditions under which research or other materials can be transferred and used among research laboratories, usually for unpatented biological materials transferring to non-profit entities, or to for-profit entities for research purposes only.

MEDLINE

National Library of Medicine's database for scientific publications. Web address: <http://www.nlm.nih.gov/medlineplus/>

Mentor

Scientific qualifications, support for the research project, track record of research support and training, proposed mentoring role.

Mentored Patient-Oriented Research Career Development Award *K23*

To provide support for the career development of investigators who have made a commitment of focus their research endeavors on patient-oriented research. This mechanism provides support for a 3 year minimum up to 5 year period of supervised study and research for clinically trained professionals who have the potential to develop into productive, clinical investigators.

Mentored Quantitative Research Career Development Award *K25*

These are awards for independent scientists in highly technical fields of research to identify an appropriate mentor with extensive experience in cancer research and to receive the necessary training and career development required to become involved in multidisciplinary cancer research. The NCI participates in the NIH program, which uses the K25 grant mechanism and is dedicated to this goal. The announcement for this NIH program can be accessed at the following website address: <http://grants.nih.gov/grants/guide/pa-files/PA-99-087.html>

Merit Descriptor

Adjectival descriptors of the level of merit of the science proposed in an application (e.g., outstanding, excellent, very good, good, fair, etc.); less frequently used now compared with several years ago.

Method to Extend Research in Time Award *R37* or *MERIT* Award

This award is designed to provide long-term grant support to investigators whose research competence and productivity are distinctly superior and who are highly likely to continue to perform in an outstanding manner. Investigators may not apply for a MERIT award. Program staff and/or members of the cognizant National Advisory Council/Board will identify candidates for the MERIT award during the course of review of

competing R01 research grant applications prepared and submitted in accordance with regular PHS requirements. When a MERIT Award is made, the recipient will be funded for the period recommended by peer review and the NCI Executive Committee (typically 5 years) and approved by the National Cancer Advisory Board. In addition, the recipient will have the opportunity to apply administratively for up to 5 years of additional funding without submitting a new application for peer review.

Midcareer Investigator Award in Patient-Oriented Research *K24*

To provide support for clinicians to allow them protected time to devote patient-oriented research and to act as mentors for beginning clinical investigators. The target candidates are outstanding clinical scientists engaged in patient-oriented research who are within 15 years of their specialty training, who can demonstrate the need for a period of intensive research focus as a means of enhancing their clinical research careers, and who are committed to mentoring the next generation of clinical investigators in patient-oriented research.

Mileage Allowance

A fixed rate per mile allowed for operating a privately-owned vehicle when such use is authorized or approved as advantageous to the Government.

Minimal Risk

The probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or test. See the official regulations for more information at Section 46.102(i).

Minorities in Clinical Oncology Award *K08*

One of two types of Mentored Clinical Scientist Development Awards (K08s) that support the development of outstanding clinical research scientists, with this type being reserved for qualified individuals from under-represented minority groups. These awards provide specialized study for clinically trained professionals who are committed to a career in research and have the potential to develop into independent investigators. The other NCI K08 award is called the Clinical Investigator Award.

Minority Access to Research Careers *MARC, also T34*

A program to provide special research training opportunities in the biomedical sciences for students and faculty at 4-year colleges and health professional schools in which substantial student enrollments are from minority groups. MARC Undergraduate NRSA Institutional (T34) Grants enable minority institutions to make National Research Service Awards to individuals selected by them for predoctoral and postdoctoral research training in the biomedical and behavioral sciences.

Minority Biomedical Research Support *MBRS*

An instrument of the NCI's Comprehensive Minority Biomedical Program for strengthening the biomedical research and research training capability of ethnic minority institutions. The intent is to increase the involvement of minority faculty and students in biomedical research.

Minority Graduate Research Assistants *MGRA*

An instrument of the NCI's Comprehensive Minority Biomedical Program for providing support to assist minority individuals who wish to develop research capabilities in the biomedical and/or behavioral sciences.

Minority Group

A minority group is a readily identifiable subset of the US population that is distinguished by racial, ethnic, and/or cultural heritage. The following racial/ethnic minority groups are those currently identified by the Office of Management and Budget (OMB) for federal reporting: American Indian/Alaska Native; Asian, Black or African American, Hispanic/Latino, Native Hawaiian or Other Pacific Islander. The minority group (and subpopulation) to which an individual belongs is determined by self-reporting. This classification is for administrative purposes and is prevalent in the scientific and other literature and databases available for research. The purpose of investigators routinely specifying the racial ethnic population(s) under investigation is to begin to systematically obtain data on the various minority groups (and subpopulations) to fill the gaps of health research information on the populations so that the study results may be optimally applicable to all citizens so that health disparities can be reduced or eliminated. Investigators may report their findings in the research literature consistent with the purpose of the research.

Minority High School Student *MHS*

An instrument of the NCI's Comprehensive Minority Biomedical Program for providing support to minority high school students who have an interest in the biomedical or behavioral sciences.

Minority Individuals in Postdoctoral Training *MIPT*

An instrument of the NCI's Comprehensive Minority Biomedical Program for providing support for minority individuals who wish to participate as postdoctoral researchers on ongoing research projects in preparation for independent careers in the biomedical or behavioral sciences.

Minority Institution/Cancer Center Collaboration, Planning Grant *P20*

Planning grant for a Minority Institution/Cancer Center Collaboration that is administered by the NCI's Minority Institution/Cancer Center Program.

Minority Investigator Supplement *MIS*

An instrument of the NCI's Comprehensive Minority Biomedical Program for providing short-term and long-term opportunities for minority investigators to participate in ongoing research projects while further developing their own independent research potential.

Minority Supplements

An NIH program of grant supplements, begun in 1989, to support the addition of a person who is an underrepresented minority to an ongoing grant-supported project.

Minority Undergraduate Student *MUS*

An instrument of the NCI's Comprehensive Minority Biomedical Program for providing support to minority undergraduate students who have demonstrated an interest in biomedical or behavioral sciences and wish to pursue graduate-level training in these areas.

Minority-Serving Institution *MSI*

This institution is one in which students from ethnic minority groups, including African Americans, Hispanic Americans, American Indians, Alaska natives or Pacific Islanders, comprise a significant proportion of the enrollments and which has a commitment to the special encouragement of ethnic minority faculty, students, and investigators.

Misconduct in Science

Misconduct in science is defined as one or both of the following: (1) serious deviation, such as fabrication, falsification, or plagiarism, from accepted practices in carrying out research or in reporting the results of research; and/or (2) material failure to comply with Federal requirements affecting specific aspects of the conduct of research. It does not include honest error or honest differences in interpretations or judgments of data.

Modular Research Grant Application *R01*

The modular research grant procedures will affect the NIH peer review process by enabling reviewers to evaluate proposed project budgets on the basis of a general, expert estimate of the total effort and resources required to conduct the proposed research. Reviewers will recommend changes in a proposed project's budget in \$25,000 modules. NIH Institute staff will continue to make all final award decisions. R01 Research Project Grants are awarded to institutions to allow a Principal Investigator to pursue a scientific focus or objective in his or her area of interest and competence. Institutional sponsorship assures the NIH that the institution will provide facilities necessary to conduct the research and will be accountable for the grant funds. Applications are accepted for health-related research and development in all areas within the scope of the NIHs mission.

Module

A \$25,000 unit of grant award.

Monitoring

A process whereby the programmatic and business management performance aspects of a grant are reviewed by assessing information gathered from various required reports, audits, site visits and other sources.

Morbidity

A diseased state or symptom; the incidence of disease or the rate of sickness.

Multi-Project Award or Multi-Project Grant *P01, P50, U19*

Grant award that involves at least three inter-related research projects. NCI funds P01, P50, and U19 grant applications [check if others]. Multi-project grant applications may be investigator initiated or submitted in response to requests for applications (RFAs) or program announcements (PAs).

Multi-Project Grant Application *P01, P50, U19*

Grant application that involves at least three inter-related research projects. NCI funds P01, P50, and U19 grant applications [check if others]. Multi-project grant applications may be investigator initiated or submitted in response to requests for applications (RFAs) or program announcements (PAs).

Multicultural

Designed for, or pertaining to, two or more distinctive cultures.

Medical Scientist Training Program *MSTP*

The Medical Scientist Training Program (MSTP) supports the integrated medical (or equivalent professional clinical) degree and graduate research training required for the investigation of human diseases. MSTP assures highly selected trainees a choice of a wide range of pertinent graduate programs in the biological, chemical, and physical sciences which, when combined with training in medicine, lead to the M.D.-Ph.D. degree.

Model Organism

Animal, plant, or other organism used to study basic biologic processes to provide insight into other organisms.

Medically Underserved

A term that refers to individuals who lack access to primary and specialty care either because they are socioeconomically disadvantaged and may live in areas with high poverty rates or because they reside in rural areas. The term also refers to individuals who reside in geographic areas where the Index of Medical Underservice (IMU) is 62 or less. Health Resource Services Administration (HRSA) criteria designate a service area with an IMU of 62 or less as a "medically underserved area (MUA)." The IMU is a weighted score derived from four variables: the ratio of primary medical care physicians per 1,000 population, infant mortality rate, percentage of population below the federal poverty level, and percentage of the population age 65 years or over.

Minority Report

In cases when two or more member(s) of a review committee hold(s) a strong opinion dissenting from that of the majority (e.g., when the majority recommends that an application be not recommended for further consideration), a minority report should be prepared by the dissenting member(s).

Modular Application

A type of grant application in which support is requested in specified increments without the need for detailed supporting information related to separate budget categories. When modular procedures apply, they affect not only application preparation but also review, award, and administration of the application/award. Go to: <http://grants.nih.gov/grants/funding/modular/modular.htm>

Multiple Principal Investigator

Individual research awards in which more than one Principal Investigator (PI) is identified by the applicant or institution. Go to: http://grants.nih.gov/grants/multi_pi/overview.htm.

Malignancy

A term for diseases in which abnormal cells divide without control and can invade nearby tissues. Malignant cells can also spread to other parts of the body through the blood and lymph systems. Also called cancer.

Meals and Incidental Expenses *M&IE*

The Meals and Incidental Expenses (M&IE) rate is determined by the location of the traveler's TDY assignment. This is the location/destination where the traveler actually performs TDY travel. The meals portion covers expenses for breakfast, lunch, and dinner. Incidental expenses

include fees and tips to waiters, waitresses, porters, baggage carriers, bellhops, hotel maids, laundry, dry-cleaning or pressing of clothing, transportation between places of lodging/business and places where meals are taken and telephone calls necessary to reserve lodging accommodations.

Memorandum of Understanding *MOU*

A document that expresses mutual accord on an issue between two or more parties. Memoranda of understanding are generally recognized as binding, even if no legal claim could be based on the rights and obligations laid down in them. To be legally operative, a memorandum of understanding must (1) identify the contracting parties, (2) spell out the subject matter of the agreement and its objectives, (3) summarize the essential terms of the agreement, and (4) must be signed by the contracting parties. Also called letter of intent.

MERIT Award *R37*

An award mechanism that provides long-term grant support to investigators with impressive records of scientific achievement in research areas of special importance or promise.

See Method to Extend Research in Time Award

Misconduct Policy

42 CFR Parts 50 and 93 - Public Health Service Policies on Research Misconduct

Modification, Contract

A bilateral or unilateral written change to the terms of a contract.

Modular Grant

Used at NIH for grants requesting less than \$250,000, eliminates the need for budget details. Applicants request budgets in modules of \$25,000.

Web address: <http://grants.nih.gov/grants/funding/modular/modular.htm>

Mortality

The quality or state of being mortal; the whole sum or number of deaths in a given time or a given community; the proportion of deaths to population or to a specific number of the population (mortality or death rate).

Multi-Year Funding

Multi-year funded (MYF) awards are where the project period and budget period are the same and are longer than one year. A no-cost extension of an existing grant does not constitute Multi-Year Funding.

Multicomponent Application *MCA*

For the support of a broadly based, multidisciplinary, often long-term research program which has a specific major objective or a basic theme. A program project generally involves the organized efforts of relatively large groups, members of which are conducting research projects designed to elucidate the various aspects or components of this objective.

Meeting Roster *ROS*

Identifies who is serving on a review panel and clarifies the expertise represented.

Minority-Based Community Clinical Oncology Program *MBCCOP*

Launched in 1990 as part of the efforts of the Community Clinical Oncology Program (CCOP) is to deliver the best cancer care to patients, wherever they live.

Minority Biomedical Research Support Program

Minority Biomedical Research Support (MBRS) Program award 4-year colleges, M.S.- and Ph.D.-granting universities that have a historical mission focused on serving students from diverse backgrounds underrepresented in biomedical and behavioral research as defined by the National Science Foundation (i.e., African Americans, Hispanic Americans, American Indians, Alaska Natives, Native Hawaiians, U.S. Pacific Islanders and persons with disabilities) to support research by faculty members; strengthen the institutions' biomedical research capabilities; and increase the interest, skills and competitiveness of students and faculty in pursuit of biomedical research careers.

Most Efficient Organization *MEO*

This process involves identifying functions would be considered commercial and under going a process in which the government structures an in-house workforce and then compares it with any qualified commercial providers through a contract bid process.

Mouse Models of Human Cancer Consortium *MMHCC*

A collaborative program designed to derive and characterize mouse models, to generate resources and information, and to use innovative approaches in pre-clinical trials and drug intervention studies.

Magnetic Resonance Imaging *MRI*

A procedure in which radio waves and a powerful magnet linked to a computer are used to create detailed pictures of areas inside the body.

Molecular Targets Laboratory *MTL*

Provides the focus and infrastructure that enables Center for Cancer Research (CCR) investigators to pursue molecularly targeted drug discovery research by promoting an interdisciplinary, collaborative, team-oriented approach to identifying and validating potential cancer-pertinent targets.

Model Organism Sharing

Policy stating a Principal Investigator (PI) applicant must submit plans for sharing mammalian and non-mammalian eukaryotic models to comply with the NIH Policy on Sharing Model Organisms. Go to NIH's Model Organism for Biomedical Research.

Mandatory Criteria

In some Request for Proposals (RFPs), the Project Officer (PO) identifies the basic requirements that proposals must meet to execute the contract properly. These criteria are usually specific to a particular RFP and are generally outside the scope of the Technical Evaluation Criteria in each RFP.

N

|A|B|C|D|E|F|G|H|I|J|K|L|M|N|O|P|Q|R|S|T|U|V|W|X|Y|Z|

NIH Bioengineering Consortium of the NIH *BECON*

The focus of bioengineering issues at the NIH is the Bioengineering Consortium (BECON) which consists of senior-level representatives from each of the NIH institutes, centers, and divisions plus representatives of other federal agencies concerned with biomedical research and development.

National Cancer Advisory Board *NCAB*

A chartered advisory committee to the Secretary, DHHS, and the Director, NCI, composed of both scientists and lay members, which performs the final advisory review of grant applications and advises on matters of significance to the policies, missions, and goals of the NCI.

National Cancer Institute (NCI) Scholars Program *K22*

To provide an opportunity for outstanding new investigators to begin their independent research careers, first within the special environment of the National Cancer Institute and then at an institution of their choice. Specifically, this Program provides necessary resources to initiate an independent research program of 3 to 4 years at the NCI followed by an extramural funding mechanism (K22) to support their research program for 2 years at the extramural institution to which they are recruited.

National Cancer Institute (NCI) Scientific Review Group *NCI SRG*

A chartered advisory group composed primarily on non-Federal scientific experts who conduct the scientific and technical merit review (initial peer review) of grant applications and assign priority scores to meritorious applications.

National Cancer Institute (NCI) Transition Career Development Award for Underrepresented Minorities *K22*

To provide support to outstanding newly trained basic or clinical investigators to develop their independent research skills through a two phase program; an initial period involving and intramural appointment at the NIH and a final period of support at an extramural institution. The award is intended to facilitate the establishment of a record of independent research by the investigator in order to sustain or promote a successful research career.

National Cancer Institute *NCI*

The National Cancer Institute (NCI) is a component of the National Institutes of Health (NIH). The NCI, established under the National Cancer Act of 1937, 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. Over the years, legislative amendments have maintained the NCI authorities and responsibilities and added new information dissemination mandates as well as a requirement to assess the incorporation of state-of-the-art cancer treatments into clinical practice.

National Research Service Award for Individual Postdoctoral Fellows *F32 NRSA*

An NIH fellowship application and award program that is designed to provide postdoctoral research training to individuals to broaden their scientific background and extend their potential for research in specified health-related areas.

National Research Service Award for Senior Fellows *F33 NRSA*

An NIH fellowship application and award program that is designed to provide opportunities for experienced scientists to make major changes in the direction of research careers, to broaden scientific background, to acquire new research capabilities, to enlarge command of an allied research field, or to take time from regular professional responsibilities for the purpose of increasing capabilities to engage in health-related research.

National Research Service Award Institutional Research Training Grants *T32 NSRA*

An NIH fellowship application and award program that is designed to enable institutions to make National Research Service Awards to individuals selected by them for predoctoral and postdoctoral research training in specified shortage areas.

National Research Service Award *NRSA*

Awards to both individuals and institutions to provide research training in specified health-related areas.

Native Hawaiian or Other Pacific Islander

A Human Subjects term indicating a person having origins in the original peoples of Hawaii, Guam, Samoa, or other Pacific Islands.

Negotiation

Negotiations are exchanges, in either a competitive or sole source environment, between the Government and offerors, that are undertaken with the intent of allowing the offeror to revise its proposal. These negotiations may include bargaining. Bargaining includes persuasion, alteration of assumptions and positions, give-and-take, and may apply to price, schedule, technical requirements, type of contract, or other terms of a proposed contract. When negotiations are conducted in a competitive acquisition, they take place after establishment of the competitive range and are called discussions.

New Application *Type 1*

Refers to an application not previously proposed, or one that has not received prior funding.

New Drug Application *NDA*

The study results submitted to the U.S. Food and Drug Administration (FDA) once clinical trials are completed. Application by a drug sponsor to FDA to approve a new pharmaceutical for sale and marketing in the United States under regulations 21 CFR 314, based on data from animal studies and clinical trials.

New Investigator

A new investigator is an individual who has not previously competed successfully for an NIH-supported research project other than the following small or early stage research awards:

Pathway to Independence Award-Research Phase (R00)

Small Grant (R03)

Academic Research Enhancement Award (R15)

Exploratory/Developmental Grant (R21)
Clinical Trial Planning Grant (R34)
Dissertation Award (R36)
Small Business Technology Transfer Grant-Phase I (R41)
Small Business Innovation Research Grant-Phase I (R43)
Shannon Award (R55)
NIH High Priority, Short-Term Project Award (R56)

Additionally, an individual is not excluded from consideration as a ?New Investigator? if he/she has received an award from the following classes of awards:

Training-Related and Mentored Career Awards
Fellowships (F05, F30, F31, F32, F34, F37, F38)
Mentored-career awards (K01, K08, K22, K23, K25, K99-R00)
Other mentored career awards (developmental K02 as used by NINDS and the developmental K07)
Loan repayment contracts (L30, L32, L40, L50, L60)

Note: Current or past recipients of non-mentored career awards that normally require independent research support (K02, K05, K24, and K26) are not considered new investigators.

Instrumentation, Construction, Education, or Meeting Awards

G07, G08, G11, G13, G20
S10, S15
X01, X02
R25
C06, UC6
R13, U13.

NIH Guide for Grants and Contracts *NIH Guide*

An electronic publication issued by NIH on a regular (weekly) basis which includes announcements of NIH institute initiatives (e.g., Requests for Applications and Program Announcements), policy notices, and contract opportunities for services and or/products from educational and nonprofit organizations.

NIH Population Tracking Database

Also called the "EZ Accrual Database."

No Score *NS*

On the basis of evaluations of scientific merit, these applications are in the lower 50% of grant applications reviewed by an initial review group (IRG) and are not scored.

No Study Section NSS

In-house review.

No-Cost Extension

An extension of time to a project period and/or budget period to complete the work of the grant or contract under that period, without additional Federal funds or competition. For grants issued under expanded authorities, a principal investigator does not need approval from NCI to extend a project period one time for up to twelve months. An extension of a contract's period of performance requires a bilateral contract modification.

Non-RPG Grants

Examples: Construction (C06) grants, Cancer Center (P30/P20/U54) grants, Specialized Programs of Research Excellence (SPORE) (P50) grants, Cancer prevention and control grants, Training (F31-F36 & T32/T35/T36) grants such as the National Research Service Awards (NRSAs), Research Career Program Grants (K Series), Cancer Education Program (R25), Clinical Cooperative Groups (U10), Scientific Evaluation (U09), Resource Grants (R24/U24), Conference Grants (R13), Exploratory Grants/Cooperative Agreements (U56)

Noncompeting Application or Noncompeting Continuation Application *Type 5*

Those applications which will be reviewed noncompetitively, rather than through the usual competitive review process. Also, an ongoing grant whose award is contingent on a grantee's submitting a PHS 2590 progress report to the NCI as the condition of getting further support. An application for a year of continued support for a funded grant. Applications for this continued support do not undergo peer review, but are administratively reviewed by the Institute/Center (i.e., NCI) and receive an award based on prior award commitments.

See Also Streamlined Noncompeting Award Process

Noncompeting Continuation Award

A financial assistance award for a subsequent budget period within a previously approved project period for which a recipient does not have to compete with other applicants.

Noncompeting Grant Progress Report *PHS 2590*

The Public Health Service (PHS) noncompeting grant progress report is submitted to the NIH by a grantee to report progress and to continue funding for a grant's out years. The form is submitted annually, two months before the beginning of a new budget period. NIH has an electronic Streamlined Noncompeting Award Process (eSNAP or SNAP) for submitting the PHS 2590; award notices identify whether a grant is eligible for use of eSNAP.

Noncompeting Grant

An ongoing grant whose award is contingent on the completion of a progress report as the condition for the release of money for the following year.

Not Recommended for Further Consideration *NRFC*

A judgment made by a scientific review group for applications when the merit of the proposed research is not significant and substantial enough to warrant a further review, or that there are serious human subject, animal welfare, or other concerns. The study section does not recommend

funding; the application cannot be funded by an institute.

Notice of Grant Award *NGA*

Official notification to the applicant that the project is being funded by the Institute. This official award document is signed by the Grants Management Officer. It contains or references all the terms and conditions of the grant and provides the documentary basis for recording the obligation of Federal funds in the Department's accounting system.

Notification to Applicant

When the application receives an SRG assignment, a computer-generated letter is sent to the applicant and business office. This letter indicates the Assignment Number, the SRG, the SRA with address and phone number, the IC assignment with address and phone number, and the Council date. In addition, this letter states that the principal investigator should contact the SRA with any questions, concerns, or other issues that may arise before the review, and should contact the program staff in the IC with any questions after the review is completed.

NIHMS Reference Number *NIHMS ID*

The reference number assigned to a final peer-reviewed manuscript when it is submitted to the NIHMS. It can be cited on applications, proposals or reports when the PMCID has not been assigned yet.

Not Discussed

Lower 50 percent of applications in the study section—criterion and impact scores provided by assigned reviewers but no discussion at meeting.

NIH Board of Governors *BOG*

NIH Information Technology Board of Governors, which advises NIH on the overhaul of its major enterprise systems. A steering committee with strong community representation provides liaison between BOG and other groups, including the ERA Project Team, Extramural Program Management Committee, and the NIH Office of Extramural Research.

NCI Executive Committee *EC*

Abolished in late 2010. See Scientific Program Leadership.

From the 1980's to 2010 was comprised of the NCI Director, NCI Division Directors, and other scientists/managers (chosen by the Director); this group makes scientific and management policy decisions, allocates resources, establishes grant paylines, approves grant funding plans, and reviews concepts for presentation to NCI's Board of Scientific Advisors

National Center for Complimentary and Alternative Medicine *NCCAM*

National Center for Complimentary and Alternative Medicine (NCCAM) is dedicated to exploring complementary and alternative medical (CAM) practices in the context of rigorous science; training CAM researchers and disseminating authoritative information.

National Center for Research Resources *NCRR*

The National Center for Research Resources (NCRR) advances biomedical research and improves human health through research projects and shared resources that create, develop, and provide a comprehensive range of human, animal, technological, and other resources. NCRR's support is concentrated in four areas: biomedical technology, clinical research, comparative medicine, and research infrastructure. CC is the

clinical research facility of the National Institutes of Health. As a national resource, it provides the patient care, services, and environment needed to initiate and support the highest quality conduct of and training in clinical research.

National Center on Minority Health and Health Disparities *NCMHD*

The mission of National Center on Minority Health and Health Disparities (NCMHD) is to promote minority health and to lead, coordinate, support, and assess the NIH effort to reduce and ultimately eliminate health disparities. In this effort NCMHD will conduct and support basic, clinical, social, and behavioral research, promote research infrastructure and training, foster emerging programs, disseminate information, and reach out to minority and other health disparity communities.

National Eye Institute *NEI*

The National Eye Institute (NEI) conducts and supports research that helps prevent and treat eye diseases and other disorders of vision. This research leads to sight-saving treatments, reduces visual impairment and blindness, and improves the quality of life for people of all ages. NEI-supported research has advanced our knowledge of how the eye functions in health and disease.

National Heart, Lung, and Blood Institute *NHLBI*

The National Heart, Lung, and Blood Institute (NHLBI) provides leadership for a national program in diseases of the heart, blood vessels, lung, and blood; blood resources; and sleep disorders. Since October 1997, the NHLBI has also had administrative responsibility for the NIH Woman's Health Initiative. The Institute plans, conducts, fosters, and supports an integrated and coordinated program of basic research, clinical investigations and trials, observational studies, and demonstration and education projects

National Human Genome Research Institute *NHGRI*

National Human Genome Research Institute (NHGRI) supports the NIH component of the Human Genome Project, a worldwide research effort designed to analyze the structure of human DNA and determine the location of the estimated 30,000 to 40,000 human genes. The NHGRI Intramural Research Program develops and implements technology for understanding, diagnosing, and treating genetic diseases.

National Institute for Nursing Research *NINR*

National Institute for Nursing Research (NINR) supports clinical and basic research to establish a scientific basis for the care of individuals across the life span from the management of patients during illness and recovery to the reduction of risks for disease and disability; the promotion of healthy lifestyles; the promotion of quality of life in those with chronic illness; and the care for individuals at the end of life. This research may also include families within a community context, and it also focuses on the special needs of at-risk and under-served populations, with an emphasis on health disparities.

National Institute of Allergy and Infectious Diseases *NIAID*

National Institute of Allergy and Infectious Diseases (NIAID) research strives to understand, treat, and ultimately prevent the myriad infectious, immunologic, and allergic diseases that threaten millions of human lives.

National Institute of Arthritis and Musculoskeletal and Skin Diseases *NIAMS*

National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) supports research into the causes, treatment, and prevention of arthritis and musculoskeletal and skin diseases, the training of basic and clinical scientists to carry out this research, and the dissemination of information on research progress in these diseases

National Institute of Biomedical Imaging and Bioengineering *NIBIB*

National Institute of Biomedical Imaging and Bioengineering (NIBIB) improves health by promoting fundamental discoveries, design and development, and translation and assessment of technological capabilities in biomedical imaging and bioengineering, enabled by relevant areas of information science, physics, chemistry, mathematics, materials science, and computer sciences.

National Institute of Child Health and Human Development *NICHD*

National Institute of Child Health and Human Development (NICHD) research on fertility, pregnancy, growth, development, and medical rehabilitation strives to ensure that every child is born healthy and wanted and grows up free from disease and disability.

National Institute of Deafness and Other Communication Disorders *NIDCD*

National Institute of Deafness and Other Communication Disorders (NIDCD) conducts and supports biomedical research and research training on normal mechanisms as well as diseases and disorders of hearing, balance, smell, taste, voice, speech, and language that affect 46 million Americans.

National Institute of Dental and Craniofacial Research *NIDCR*

National Institute of Dental and Craniofacial Research (NIDCR) provides leadership for a national research program designed to understand, treat, and ultimately prevent the infectious and inherited craniofacial-oral-dental diseases and disorders that compromise millions of human lives.

National Institute of Diabetes and Digestive and Kidney Diseases *NIDDK*

National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) conducts and supports basic and applied research and provides leadership for a national program in diabetes, endocrinology, and metabolic diseases; digestive diseases and nutrition; and kidney, urologic, and hematologic diseases. Several of these diseases are among the leading causes of disability and death; all seriously affect the quality of life of those who have them.

National Institute of Environmental Health Sciences *NIEHS*

National Institute of Environmental Health Sciences (NIEHS) reduces the burden of human illness and dysfunction from environmental causes by, defining how environmental exposures, genetic susceptibility, and age interact to affect an individual's health.

National Institute of General Medical Sciences *NIGMS*

National Institute of General Medical Sciences (NIGMS) supports basic biomedical research that is not targeted to specific diseases. NIGMS funds studies on genes, proteins, and cells, as well as on fundamental processes like communication within and between cells, how our bodies use energy, and how we respond to medicines. The results of this research increase our understanding of life and lay the foundation for advances in disease diagnosis, treatment, and prevention. NIGMS also supports research training programs that produce the next generation of biomedical scientists, and it has special programs to encourage underrepresented minorities to pursue biomedical research careers.

National Institute of Mental Health *NIMH*

National Institute of Mental Health (NIMH) provides national leadership dedicated to understanding, treating, and preventing mental illnesses through basic research on the brain and behavior, and through clinical, epidemiological, and services research.

National Institute of Neurological Disorders and Stroke *NINDS*

The mission of the National Institute of Neurological Disorders and Stroke (NINDS) is to reduce the burden of neurological diseases; a burden borne by every age group, every segment of society, and people all over the world. To accomplish this goal the NINDS supports and conducts research, both basic and clinical, on the normal and diseased nervous system, fosters the training of investigators in the basic and clinical neurosciences, and seeks better understanding, diagnosis, treatment, and prevention of neurological disorders.

National Institute on Aging *NIA*

National Institute on Aging (NIA) leads a national program of research on the biomedical, social, and behavioral aspects of the aging process; the prevention of age-related diseases and disabilities; and the promotion of a better quality of life for all older Americans.

National Institute on Alcohol Abuse and Alcoholism *NIAAA*

National Institute on Alcohol Abuse and Alcoholism (NIAAA) conducts research focused on improving the treatment and prevention of alcoholism and alcohol-related problems to reduce the enormous health, social, and economic consequences of this disease.

National Institute on Drug Abuse *NIDA*

National Institute on Drug Abuse (NIDA) leads the nation in bringing the power of science to bear on drug abuse and addiction through support and conduct of research across a broad range of disciplines and rapid and effective dissemination of results of that research to improve drug abuse and addiction prevention, treatment, and policy.

National Institutes of Health *NIH*

A Federal agency, whose mission is to improve the health of the people of the United States. NIH is part of the Public Health System (PHS), which is part of the U.S. Department of Health and Human Services (DHHS). Comprised of 27 separate components, mainly Institutes and Centers, NIH has in excess of 75 buildings on more than 300 acres in Bethesda, Maryland. From a total of about \$300 in 1887, NIH has been appropriated nearly \$23.4 billion for 2002.

National Institutes of Health, Office of the Director *NIH/OD*

The central office at NIH, and is responsible for setting policy for NIH and for planning, managing, and coordinating the programs and activities of all the NIH components.

See Office of the Director

National Library of Medicine *NLM*

National Library of Medicine (NLM) collects, organizes, and makes available biomedical science information to investigators, educators, and practitioners and carries out programs designed to strengthen medical library services in the United States. Its electronic data bases, including MEDLINE and MEDLINEplus are used extensively throughout the world by both health professionals and the public.

NED System *NED*

A meta-directory that enables application programs staff to easily find information about the people who work at NIH.

NIH Academic Research Enhancement Awards *AREA or R15*

Supports small-scale research projects in the biomedical and behavioral sciences conducted by faculty and students at educational institutions that have not been major recipients of NIH research grant funds.

See Academic Research Enhancement Award

NIH Policy Announcements

Internal correspondence from the NIH Office of Extramural Research to Institute/Center Directors and all Extramural Staff that announces a new policy or update to an existing policy.

NIH Post-Review Certification Form

Certifies that Non-Federal and Federal Reviewers did not participate in an evaluation of any application or proposal in relation to which they were in conflict under applicable government ethics standards.

Not Present *NP*

NotPresent (NP) is noted on the vote sheet for a study section or special emphasis panel review group when a reviewer is not present for the review of a grant application; please note that this term is not used if the reviewer is absent because of a conflict-of-interest (in such cases, "CF" is noted instead).

NCI Community Cancer Centers Program *NCCCP*

A public-private partnership of the National Cancer Institute (NCI) and a network of community hospital-based cancer centers from around the United States working to support cancer research and enhance the quality of cancer care at the nation's community hospitals.

Nanotechnology Characterization Laboratory *NCL*

The Nanotechnology Characterization Laboratory (NCL), which is currently located at the Frederick National Laboratory for Cancer Research, performs and standardizes the pre-clinical characterization of nanomaterials intended for cancer therapeutics and diagnostics developed by researchers from academia, government, and industry.

National Advisory Council *NAC*

Each Institute of the National Institutes of Health maintains a national advisory council composed of both scientists and lay individuals which has two general functions: (1) to advise the Institute on policy and procedures affecting the extramural research programs and (2) to provide a second level of review for all grant and cooperative agreement applications considered by the Institute for funding.

National Aeronautics and Space Administration *NASA*

National Aeronautics and Space Administration (NASA) is an executive branch agency of the United States government, responsible for the nation's civilian space program and aeronautics and aerospace research.

National Bio-Specimen Network *NBN*

Provides a key infrastructure to harness the potential of new technologies for cancer research, while ensuring that the privacy interests of biospecimen donors are preserved. It creates a comprehensive framework for sharing and comparing research results through a robust, flexible, scalable, and secure bioinformatics system that supports the collection, processing, storage, annotation, and distribution of biospecimens and data using standard operating procedures based on best practices. This combination of characteristics is vital to fully support emerging scientific opportunities to accelerate progress in prevention, diagnosis, and treatment of cancer.

National Cancer for Biotechnology Information *NCBI*

The National Center for Biotechnology Information (NCBI) creates automated systems for storing and analyzing knowledge about molecular biology, biochemistry, and genetics; facilitates the use of such databases and software by the research and medical community; coordinates efforts to gather biotechnology information both nationally and internationally; and performs research into advanced methods of computer-based information processing for analyzing the structure and function of biologically important molecules.

National Cooperative Drug Discovery Groups *NCDDGs*

Supports broad, innovative, multi-disciplinary approaches to the discovery of new, synthetic or natural-source derived anticancer drugs.

National Cancer Policy Board *NCPB*

From 1997 to 2005, the National Cancer Policy Board (NCPB) addressed broad policy issues that affect cancer in the United States and recommended ways to advance U.S. efforts against cancer. The Board brought together leaders from the cancer community to identify and conduct studies and other activities that contributed to cancer research, prevention, treatment, and public awareness. On May 1, 2005, the Institute of Medicine established the National Cancer Policy Forum to succeed the Board.

National Health Interview Survey *NHIS*

Designed by the Center for Disease Control and Prevention (CDC) National Center for Health Statistics (NCHS), the National Health Information Survey (NHIS) is a cross-sectional household interview survey to secure accurate and current statistical information on the amount, distribution, and effects of illness and disability in the United States and the services rendered for or because of such conditions. The NHIS covers the civilian non-institutionalized population residing in the United States at the time of the interview. Survey results have been instrumental in providing data to track health status, health care access, and progress toward achieving national health objectives.

NIH Guide for Grants and Contracts (weekly web publication) *NIH GUIDE*

The official publication for NIH's medical and behavioral research grants policies, guidelines and funding opportunities. Go to <http://grants.nih.gov/grants/guide/index.html> Funding Opportunities and Notices.

National Quality Forum *NQF*

A nonprofit, nonpartisan, public service organization that reviews, endorses, and recommends use of standardized healthcare performance measures, also called quality measures, to evaluate how well healthcare services are being delivered.

National Surgical Adjuvant Breast and Bowel Project *NSABP*

A clinical trials cooperative group that focuses on breast and colorectal cancer.

National Science Foundation *NSF*

An independent U.S. government agency responsible for promoting science and engineering through research programs and education projects.

Network for Translational Research: Optical Imaging *NTROI*

The purpose of the network is the development, optimization, and validation of imaging methods and protocols for rapid translation to clinical environments. Optimization and validation are accomplished through consensus processes.

NIH Common Fund *RM*

Enacted into law by Congress through the 2006 NIH Reform Act to support cross-cutting, trans-NIH programs that require participation by at least two NIH Institutes or Centers (ICs) or would otherwise benefit from strategic planning and coordination. The requirements for the Common Fund encourage collaboration across the ICs while providing the NIH with flexibility to determine priorities for Common Fund support.

NIH Director's Pioneer Award

The NIH Director's Pioneer Award supports individual scientists of exceptional creativity who propose pioneering approaches to major challenges in biomedical and behavioral research. The term pioneering is used to describe highly innovative potentially transformative approaches having the potential to produce an unusually high impact, and the term award is used to mean a grant for conducting research, rather than a reward for past achievements. Biomedical and behavioral research is defined broadly in this announcement as encompassing scientific investigations in the biological, behavioral, clinical, social, physical, chemical, computational, engineering, and mathematical sciences.

NIH Manuscript Submission System *NIHMS*

NIH Manuscript Submission System (NIHMS) is a system developed by NIH, and allows users to deposit and manage manuscripts.

National Cancer Policy Forum

The National Cancer Policy Forum provides a continuous focus on cancer policy at the Institute of Medicine (IOM). The objectives of the Forum are to identify emerging high priority policy issues in the nation's effort to combat cancer and to examine those issues through convening activities that promote discussion about potential opportunities for action. The IOM established the Forum, effective May 1, 2005, to succeed the National Cancer Policy Board (1997-2005).

NCI Frederick Advisory Committee

The NCI Frederick Advisory Committee (NFAC) provides advice to the Director, NCI and the Associate Director, Frederick National Laboratory for Cancer Research (FNLCR) on the optimal use of the Laboratory to meet the most urgent needs of the Institute. In addition, the NFAC reviews the state of research at the FNLCR and makes recommendations for the best use of its capabilities and infrastructure.

NCI Subcommittee A

Provides advice and recommendations on the scientific and technical merit of applications for Cancer Centers (P30).

NCI Subcommittee F

Provides advice and recommendations on the scientific and technical merit of applications for Institutional Training and Education (R25, T32, K12).

NCI Subcommittee I

Provides advice and recommendations on the scientific and technical merit of applications for Transition to Independence (K01, K22, K25, K99)

NCI Subcommittee J

Provides advice and recommendations on the scientific and technical merit of applications for Career Development (K07, K08, K05, K23).

NIH General Policy Notice

Public correspondence from the NIH Office of Extramural Research to the extramural research community that announces a new policy or updated to an existing policy.

O

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Obligation

Data based on NIH funds that have been awarded by an NIH Institute/Center.

Oconus

Outside conterminous United States.

Offeror

A contracting term denoting a respondent to a Request for Proposals (RFP).

Office for Protection from Research Risks *OPRR*

Now it is the Office of Human Research Protections (OHRP).

Office of Behavioral and Social Sciences Research *OBSSR*

Mission is to stimulate behavioral and social sciences research throughout NIH and to integrate these areas of research more fully into others of the NIH health research enterprise, thereby improving our understanding, treatment and prevention.

Office of Extramural Research *OER*

(1) Acts on behalf of the NIH Director to provide guidance to the research institutes on the development and management of extramural (grant, cooperative agreement, and contract) research and training programs; (2) advises the NIH Director and staff on issues relating to extramural research activities; and (3) oversees the protection of human subjects and the proper care and use of laboratory animals on behalf of the entire U.S. Public Health Service.

Office of Financial Management *OFM*

The Office of Financial Management (OFM) advises the NIH Director and staff and provides leadership and direction for NIH financial management activities; develops policies and instructions for budget preparation and presentation and administers allocation of funds and

manages a system of fund and budgetary controls.

Office of Government wide Policy *OGP*

Consolidates all of the General Services Administration's government wide policymaking activities within one central office. Contains links to resources on the management of Federal advisory committees and on travel management.<http://policyworks.gov>

Office of Human Research Protections *OHRP*

The office within the National Institutes of Health, an agency of the Public Health Service, Department of Health and Human Services, responsible for implementing DHHS regulations (45 CFR Part 46) governing research involving human subjects.

Office of Intramural Research *OIR*

The Office of Intramural Research (OIR) is responsible for oversight and coordination of intramural research, training, and technology transfer conducted within the laboratories and clinics of the National Institutes of Health (NIH).

Office of Laboratory Animal Welfare *OLAW*

The Office of Laboratory Animal Welfare (OLAW, formerly Office for Protection from Research Risks, Division of Animal Welfare) at the National Institutes of Health, has responsibility for the general administration and coordination of animal welfare Policy on behalf of the PHS, provides specific guidance, instruction, and materials to institutions that must comply with the Policy.

Office of Management Analysis, NCI *OMA, NCI*

The Office of Management Analysis is the principal staff resource in the NCI for management analysis. The OMA provides several administrative related products and services in the area of business analysis and policy. They conduct management studies of NCI programs and processes through manpower analysis, workload distribution, organization and lines of authority. They Interpret regulations and policies affecting the National Cancer Institute.

Office of Management Assessment and Internal Control *OMAIC*

This organization handles allegations of fraud or financial mismanagement of NIH research funding. Allegations in this area involve using research funds for unauthorized purposes and/or the submission of false expenditure claims.

Office of Policy for Extramural Research Administration *OPERA*

OPERA is part of NIH OD OER and its staff members provide assistance to NIH staff, applicants, grantees and the public regarding the laws, regulations, policies, and procedures pertinent to the administration of NIH grants. OPERA also receives all documentation relating to extramural inventions made with assistance from NIH research grants or research and development contracts. In addition, OPERA conducts activities that extend, improve, and/or maintain system capabilities to satisfy the information requirements associated with NIH extramural activities.

Office of Referral, Review, and Program Coordination *ORRPC*

This office within the NCI Division of Extramural Activities (DEA) contains four functional branches (PCRB, RTRB, RPRB, and SRLB) and is headed by a DEA Associate Director. Three branches deal with the peer review of institute-specific funding mechanisms (i.e., grant applications, e.g., for cancer centers, program projects, training, etc., and contract proposals) and one branch deals with the referral of grant applications and

the coordination of programmatic research initiatives (i.e., the development and issuance of Requests for Applications and Program Announcements).

Office of Research Integrity *ORI*

The Office of Research Integrity (ORI) promotes integrity in biomedical and behavioral research supported by the Public Health Service (PHS) at about 4,000 institutions worldwide. ORI monitors institutional investigations of research misconduct and facilitates the responsible conduct of research through educational, preventive, and regulatory activities. Organizationally, ORI is located in the Office of Public Health and Science (OPHS) within the Office of the Secretary of Health and Human Services (OS).

Office of Research on Minority Health *ORMH*

Leads the federal effort at NIH in stimulating new research ideas for improving the health status of minority Americans. The Office promotes programs aimed at increasing the participation of underrepresented minorities in all aspects of biomedical and behavioral research.

Office of Research on Women's Health *ORWH*

Serves as a focal point for women's health research at NIH. ORWH promotes, stimulates and supports efforts to improve the health of women through biomedical and behavioral research. ORWH works in partnership with the NIH ICs to ensure that women's health research is part of the scientific framework at NIH and throughout the scientific community.

Office of Special Populations Research *OSPR*

Shares the goals of the Office of Research on Minority Health and works with NCI program staff to support these goals through the grants issued by NCI.

Office of Technology and Industrial Relations *OTIR*

The National Cancer Institute's (NCI) Office of Technology and Industrial Relations (OTIR) works to accelerate the pace of cancer research and the translation of research results into new therapies, diagnostics, and preventive agents. Located in NCI's Office of the Director, OTIR encourages new technology development and promotes collaborations between NCI and the private sector.

Office of Technology Transfer *OTT*

NIH office that manages the NIH invention portfolio and oversees NIH technology transfer.

Office of the Director *OD*

The Office of the Director is the central office at NIH for its 27 Institutes and Centers. The OD is responsible for setting policy for NIH and for planning, managing, and coordinating the programs and activities of all the NIH components.

Office of the Inspector General *OIG*

The Office of Inspector General, as mandated by Public Law 95-452 (as amended), is to protect the integrity of Department of Health and Human Services (HHS) programs, as well as the health and welfare of the beneficiaries of those programs. The OIG has a responsibility to report both to the Secretary and to the Congress program and management problems and recommendations to correct them. The OIG's duties are carried out through a nationwide network of audits, investigations, inspections and other mission-related functions performed by OIG

components.

Office of Tropical Medicine and International Research *OTMIR*

In 1984 The Office of Tropical Medicine and International Research (OTMIR) was established to coordinate NIAID's intramural and extramural research activities in tropical medicine and other international research. OTMIR worked with other Federal agencies and international organizations active in these areas. In 1995 the Office of Tropical Medicine and International Research (OTMIR) was transferred to the Division of Microbiology and Infectious Diseases, and abolished.

Oncological Sciences *ONC*

The Center for Scientific Review (CSR) Integrated Review Group (IRG) for review of cancer research-related grant applications.

Oncologist

A doctor who specializes in treating cancer.

Oncology

The study and treatment of cancer.

One-Shot Funding

Funding that carries no future-year commitments.

Option

A unilateral right by which the Government, for a specified time, may elect to purchase additional supplies or services called for by the contract, or may elect to extend the term of the contract.

Organization

Institution having scientific responsibility for applications for NIH support.

Other Research Grants

Research grants not classified as research projects or research centers.

Other Research

A budget category that includes K, R13, R18, R24, and U24 awards.

Other Support

All financial resources - federal, non-federal, commercial, or institutional - that support a PI's research, including research grants, cooperative agreements, contracts, and institutional awards. Training awards, prizes, or gifts are no longer included.

Outcome Evaluation

Provides descriptive information on the project and can be used to document short-term results. Task-focused results describe the output of the activities (i.e., number of participants recruited as a result of a talk show in a local television station). Short-term results describe the immediate effects of the strategies on the target population (i.e., percentage of the target group that is participating in one of the research protocols).

Outlays or Expenditures

The charges made to the Federally-sponsored project or program.

Outreach Strategies

These are outreach efforts by investigators and their staff to appropriately recruit and retain populations of interest into research studies. Such efforts should represent a thoughtful and culturally sensitive plan of outreach and generally include involvement of other individuals and organizations relevant to the populations and communities of interest, e.g. family, religious organizations, community leaders and informal gatekeepers, and public and private institutions and organizations. The objective is to establish appropriate lines of communication and cooperation to build mutual trust and cooperation such that both the study and the participants benefit from the collaboration.

Outside Activities

For government employees, this term refers to activities or employment that he/she participates in outside of work that may have some bearing on his/her official duties as a government employee. To determine conflicts of interest for such activities, NIH employees should/must consult with the Ethics Office of his/her NIH Institute or Center, and, whenever required to do so, file and obtain a waiver before undertaking permitted outside activities.

Outside Opinion

In the NIH peer review system, this term refers to a situation in which a written expert opinion on a grant application is obtained from an appropriate (non-conflicted) consultant by a Scientific Review Administrator and provided to the members of a grants review panel.

Outstanding Investigator Grant *R35*

This NIH grant mechanism has been phased out (completely by the end of FY2001; check).

Overlap of Support

Other support duplicating research or budgetary items already funded by an NIH grant. Overlap also occurs when any project-supported personnel has time commitments exceeding 12 person months.

Official Duty Activities

Activities performed by an employee as part of, or an extension of, regular official responsibilities. This discussion refers to official duty activities with an outside organization. The Standards of Ethical Conduct for Employees of the Executive Branch (at 5 CFR 2635) provide the basic guidelines for official duty activities, and the NIH sets the policy for implementing the guidelines at the NIH. An employee may participate in such activities only with advance approval as indicated below. For questions about specific activities, contact your IC's Deputy Ethics Counselor or Ethics Coordinator.

Office of Grants Administration OGA

The Office of Grants Administration (OGA) manages all NCI business-related activities associated with the negotiation, award, and administration of grants and cooperative agreements.

Office of Dietary Supplements ODS

Supports research and disseminates research results in the area of dietary supplements. Office of Dietary Supplements (ODS) also advises other agencies about the results on the use of dietary supplements.

Office of Laboratory Animal Welfare and Animal Welfare Assurance

NIH office overseeing compliance with the [PHS Policy on Humane Care and Use of Laboratory Animals](http://grants.nih.gov/grants/olaw/references/phspol.htm). Go to [OLAW](http://grants.nih.gov/grants/olaw/olaw.htm) and [PHS Policy Tutorial](http://grants.nih.gov/grants/olaw/tutorial/index.htm).

Office of Management and Budget OMB

The Office of Management and Budget (OMB) is the Office in the Executive Branch of the Federal Government that assists the President of the United States in the preparation of the Federal Budget each fiscal year. The OMB also evaluates agency programs and policies, and sets funding priorities. In setting policy, the OMB issues government-wide policy directives, called Circulars, such as the A-76 Circular that provides the policies and procedures for competitive sourcing of Federal work. Web address: <http://www.whitehouse.gov/OMB/circulars/>.

OMB Circulars (Office of Management and Budget Circulars) OMB Circulars

Instructions or information issued by the Office of Management and Budget (OMB) to Federal agencies. These are expected to have a continuing effect of two years or more. Circulars are identified by the letter "A" and a number. When an instruction needs to be revised, the pertinent Circular will be re-issued with the same number and a new date. When the subject matter of a Circular is of such a nature as to require frequent changes in order to keep it current, revised pages may be re-issued in lieu of re-issuing the entire set of instructions in a Circular. These changes will be promulgated as a part of or attached to transmittal memorandums which will be numbered chronologically and identified by the Circular number.

Omnibus Solicitation

See Parent Announcement

Office of Federal Advisory Committee Policy (formerly NIH/CMO) OFACP

Develops policy and to provide guidance and resources to the public, advisory committee members, the Congress, the President, and those managing Federal advisory committees at the NIH, HHS, and other Federal agencies. 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://www1.od.nih.gov/cmo>

Office of Government Ethics OGE

Fosters high ethical standards for executive branch employees and strengthen the public's confidence that the Government's business is conducted with impartiality and integrity.

Office of Personnel Management *OPM*

Provides human resources, leadership, and support to Federal agencies.

Office of Research on Minority Health (NIH) *ORMH*

Dedicated to improving the health of racial and ethnic minority populations through the development of health policies and programs that will help eliminate health disparities.

Office of Research on Women's Health (NIH) *ORWH*

Dedicated specifically to women's health to promote women's health and sex differences research within and beyond the NIH scientific community.

Office of Science and Technology Policy *OSTP*

The Office of Science and Technology Policy (OSTP) advises the President and others within the Executive Office of the President on the effects of science and technology on domestic and international affairs. In addition, OSTP leads interagency efforts to develop and implement sound science and technology policies and budgets, and to work with the private sector, state and local governments, the science and higher education communities, and other nations toward this end.

On-Time Submission

For an application to be on time, all registrations must be completed prior to initial submission. Submission must be accepted by Grants.gov with a timestamp on or before 5:00 p.m. local time of submitting organization on submission deadline date. Additionally, errors or warnings must be corrected within the two-business day error correction window.

P

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Patent

A property right awarded by the Government whereby the Government grants the right to exclude others from making, using or selling the invention for a period of years.

Patient-Oriented Research *POR*

Research conducted with human subjects (or on material of human origin such as tissues, specimens and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects and/or obtains readily identifiable private information. Excluded from this definition are in vitro studies that utilize human tissues that cannot be linked to a living individual. Patient-oriented research includes: (a) mechanisms of human disease; (b) therapeutic interventions; (c) clinical trials; and (d) development of new technologies.

Payback or Payback Service

Time and effort that T32 trainees and fellows must repay the government. During the first year, trainees owe one month of payback for every month of support; then they start paying back one month for every month worked.

Payline

A percentile-based funding cutoff point determined at the beginning of the fiscal year by balancing the projected number of applications coming to an Institute with the amount of funds available.

Payment Management System *PMS*

The Division of Payment Management operates the Payment Management System (PMS). PMS was developed to establish a central point with the capability of paying most Federal Assistance grants, contracts, and block grants. The main purpose of this system is to serve as a fiscal intermediary between awarding agencies and the recipients of grants and contracts, with particular emphasis on: (1) expediting the flow of cash between the Federal Government and recipients; (2) transmitting recipient disbursement data back to the awarding agencies; and (3) managing cash advances to recipients.

Peer Review Criteria

The criteria for review of a grant application or contract proposal. The standard five NIH peer review criteria are; Significance, Approach, Innovation, Investigators, and Environment; these criteria are not pre-weighted. Different or additional criteria can be used depending on the grant or contract mechanism or announcement.

Peer Review

A system for evaluating grant applications, cooperative agreements, and contract proposals that uses reviewers who are the professional equals of the applicant. For contracts, peer review is a Federal legislative requirement (42 USC 289) for all research and development projects funded by the NIH. All biomedical and behavioral R&D contract projects require technical peer review and approval of both project concepts and proposals before contracts may be awarded, regardless of whether they originate from extramural or intramural program requirements. Technical peer review of R&D contract project concepts identifies the basic purpose, scope, and objectives of the projects and establishes relevance, priority, and need of projects to accomplish NIH program objectives. Technical peer review of R&D contract proposals provides objective evaluation of technical aspects and acceptability or nonacceptability of specific proposals based on the requirements stated in the Request for Proposal, and helps to achieve program goals by identifying the best technically qualified offerors. For peer review of grant applications.

See Also Dual Review System

Peer Reviewer

A scientist, usually from academia but increasingly from industry and other places of research, who comes to NIH to review grant applications or contract proposals. This includes the scientific review group chairperson, who leads the other peer reviewers in discussions of the scientific merit of the applications or proposals.

Per Diem

The amount of money that will be allowed and paid to cover the food and lodging expenses of an employee or consultant working on official business for the United States Federal Government at a distance of at least 50 miles away from his/her home; specific amounts are set annually for specific locations throughout the United States and the world.

Percentile Rank

A ranking that represents the relative position of each priority score among the scores assigned by a scientific review group at its last three meetings. The range is from .1 to 99.9; the lower the numerical value of the percentile score, the better.

Percentile Score

A score that represents the relative position or rank of each priority score among the scores assigned by that particular study section at its last three meetings. The range is from .1 to 99.9; the lower the numerical value of the percentile score, the better.

Percentile

Represents the relative position or rank of each priority score (along a 100.0 percentile band, with a range of 0.1 to 99.9) among the scores assigned by a particular study section.

Performance Report

A recipient report which contains for each grant information on the comparison of actual accomplishments to objectives established for the period. In addition, where the output of the project can be quantified, a computation of the cost per unit of output may be required.

Performance Site

The NIH/NCI-recognized institution at which NIH/NCI-funded research has occurred, is occurring, or will occur.

Period of Performance for a Contract

The time interval required to complete work defined in a statement of work (SOW). A period of performance can be revised only through an agreement between a contractor and a contracting officer, who must issue a formal modification to a contract.

Permanent Member

An individual who has been appointed to serve on a chartered review committee (e.g., a study section managed by the Center for Scientific Review or a parent subcommittee managed by the NCI Division of Extramural Activities) for a defined tour of duty (typically, 4 years).

Phase Out Support

Such support may be provided to grantee(s) and their institution(s) following a recommendation by Institute program staff and approval from the NCI Executive Committee for grants and cooperative agreements that will not be renewed.

Phased Innovation Award and the Phased Technology Award *R21 & R33, respectively*

NCI staff developed these award to foster the translation of emerging technologies from pilot research-to-research development, speeding the adoption of near-term technological opportunities. The R21 award is an initial short-term award that allows the grantee(s) to test and prove the feasibility and validity of a new/innovative technologic approach to a problem in cancer research and the R33 award is a larger, longer-term award that is approved (or disapproved) by Institute staff after assessing how well the R21 grantee(s) or new R33 applicants have achieved specific milestones. Notices about the availability of these awards are published in the NIH Guide.

Phases

Clinical research that involves the testing of a new drug in an orderly series of steps.

PHS 398

Standard Public Health Service application for all competing research grants and cooperative agreements.

Physician Data Query *PDQ*

This is NCI's comprehensive cancer database. It contains peer-reviewed summaries on cancer treatment, screening, prevention, genetics, and supportive care; a registry of approximately 1,800 open and 12,000 closed cancer clinical trials from around the world; and directories of physicians, professionals who provide genetics services, and organizations that provide cancer care.

Pink Sheet

This term is a common (but historic) term that continues to be used by the applicant community to refer to the summary statement, which is the official NIH record of the peer review of a grant application.

Placebo

A tablet, capsule, or injection that looks like the drug or other substance being tested but contains no drug or active agent.

Planning Grants for NCI Cancer Research Centers *P20*

Grants to support the planning and development of cancer research-focused program that are awarded for the purpose of assisting institutions and associated investigators to better compete for NCI cancer center support (P30) grants.

Policy of Humane Care and Use of Laboratory Animals

It is the Policy of the Public Health Service (PHS) to require institutions to establish and maintain proper measures to ensure the appropriate care and use of all animals involved in research, research training, and biological testing activities (hereinafter referred to as activities) conducted or supported by the PHS. The PHS endorses the "U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training" developed by the Interagency Research Animal Committee. This Policy is intended to implement and supplement those Principles. No PHS support for an activity involving animals will be provided to an individual unless that individual is affiliated with or sponsored by an institution which can and does assume responsibility for compliance with this Policy.

Post-Baccalaureate and Post Masters Degree Students *MPBM*

Provides support to minority post-baccalaureate and post masters degree graduates who intend to engage in health-related research while applying for graduate or medical school.

Preapplication

A statement in summary form of the intent of the applicant to request funds. It is used to determine the applicant's eligibility and how well the project can compete with other applications and eliminate proposals for which there is little or no chance for funding.

Predoctoral Fellowship--Minority Students *F31*

To provide predoctoral minority students with supervised research training in specified health and health-related areas leading toward the research degree (e.g., Ph.D.).

Predoctoral Fellowship--Students with Disabilities *F31*

To provide predoctoral students with disabilities with supervised research training in specified health and health-related areas leading toward the research degree (e.g., Ph.D.).

Predoctoral Individual National Research Service Award *F31 NRSA*

To provide predoctoral individuals with supervised research training in specified health and health-related areas leading toward the research degree (e.g., Ph.D.).

President's Budget

The annual budget request submitted to Congress by the U.S. President. The process begins with NCI's budget request, which, as part of the NIH budget request, is modified by the Office of Management and Budget. Since enactment of the National Cancer Act of 1971, the NCI submits a separate Bypass Budget document directly to the President.

President's Cancer Panel *PCP*

Monitors the development and execution of the activities of the National Cancer Program.

Presidential Early Career Award for Scientific Excellence

The Presidential Award established by former President Bill Clinton in 1996 is the highest honor given by the U.S. government to scientists and engineers early in their independent research careers. Eight federal departments and agencies which fund scientific and engineering research nominate investigators for the award from among their research grant recipients who are considered most meritorious and who have no more than five years of independent research experience.

Prevention Trials

Test new approaches, such as medicines, vitamins, minerals, or other supplements that doctors believe may lower the risk of a certain type of cancer.

Primary Peer Reviewer

A peer reviewer who reads a grant application thoroughly, writes a critique of it before an initial peer review meeting, and then presents it to the scientific (initial) review group for discussion.

See Also Peer Reviewer

Principal Investigator *PI*

The one person designated by, and responsible to, the applicant/awardee institution or contractor organization for the scientific and administrative direction and proper conduct of all aspects of the grant application, grant award, or contract award.

Also known as Program Director or Project Director.

Prior Approval for Contracts

See Also Prior Approval for Contracts

Prior Approval for Grants

Written approval that a principal investigator must get from an NIH institute's grants management officer to change a project or budget after an award is made.

See Also Prior Approval for Grants

Prior Approval

The written permission provided by the authorized granting official from the DHHS awarding office before the recipient may undertake certain activities (such as performance or modification of an activity), expend funds, or exceed a certain dollar level.

See Also Prior Approval for Grants

Priority Score

An average of the individual ratings given by voting members of the scientific review group. Ratings range from 1.0 (outstanding) to 5.0 (acceptable), reflecting a judgment of scientific merit.

Privacy Act

A Federal law that protects against needless collection or release of personal data.

Privately Owned Vehicle *POV*

A privately-owned automobile, aircraft, or motorcycle used by the traveler other than on a "for hire" or rental basis.

Process Evaluation

Documents the degree of implementation of the recruitment and retention activities. It describes how many items, of what materials, are provided to whom, by whom, and when and whether they responded. This type of evaluation may look at the origin of the research project, the methods used, the target population, program personnel/staff, and cost.

Program Announcement *PA*

An announcement by an NIH institute or center requesting applications in the stated scientific areas. Generally, money is not set aside to pay for them. The announcement invites applications and provides such information as eligibility and evaluation criteria, funding preferences/priorities, how to obtain application kits, and the submission deadline.

Program as an Integrated Effort

The coordination, interrelationships and synergy among the meritorious research projects and core components as related to the common theme of the program project. Also called "Integrated Effort" or "Integration of Effort," which are a characteristic evaluated in the review of program project (P01) grant applications. When evaluating this review criterion, the following aspects of the research program are assessed by the peer reviewers: 1) evidence of coordination, inter-relationships, and synergy among the meritorious research projects and core components as related to the common theme of the program project; 2) the advantages or value added that could be realized by conducting the proposed

research as a P01 rather than through separate research efforts; 3) the presence and quality of mechanisms for regular communication and coordination among investigators; 4) the mechanisms for quality control of the research (e.g., internal or external advisory boards; and 5) for competing renewal applications, evidence of productive collaborations, such as joint publications, that have resulted from the P01 award.

Program Balance

The need to balance an institute's support of research in all its programmatic areas with its high-quality applications eligible for funding.

Program Class Code

IMPAC II designator signifying a scientific program and program officer.

Program Director *PD*

The NCI Health Scientist Administrator (HSA) responsible for the development of initiatives and for the scientific management of research programs sponsored by the NCI. This person serves as the focal point for all science-related activities associated with the negotiation, award, and administration of grants. Program Directors work closely with scientific review administrators and grants management staff to resolve issues.

Program Income

Gross income earned by a grantee that is directly generated by the grant supported project or activity or earned as a result of the award.

Program Officer Approval of Competing Application *PACA*

Documentation in the official grant file of a program director's (or officer's or official's) evaluation of the scientific aspects of a research project, other support to identify possible overlap, and other factors that may affect a grant's funding level.

Program Officer *PO*

Exactly equivalent to Program Director (which is the term used in the NCI) or Program Official; Program Officer and Program Official are used in some other NIH Institutes and Centers. This person is an Institute staff member who is responsible for overseeing and monitoring a scientific program and progress of grants in his or her portfolio. Program Officers work closely with grants management staff to resolve issues.

Program Officers and Project Officers Forum *POPOF*

NIH committee of program staff that discusses extramural program and policy issues. It has at least one voting member from each NIH institute.

Program Project Grant *PPG or P01*

An assistance grant or award used by the NIH and by the recipient grantee(s) or awardee(s) and institution(s) for the support of broadly based, multidisciplinary, often long-term, research program which has a specific major objective or a basic theme. A program project generally involves the organized efforts of relatively large groups, members of which are conducting research projects designed to elucidate the various aspects or components of their objectives. Awarded on behalf of a principal investigator, a P01 grant can support projects and shared resources. A program project funded by the NCI must contain at least three related projects, and can contain one or more cores (i.e., support facilities), each of which must support at least two projects. Each research project is usually under the leadership of an established investigator. The grant can provide support for certain basic resources used by the groups in the program, including clinical components, the sharing of which facilitates the total research effort. A program project is directed toward a range of problems having a central focus, in contrast to the usually narrower thrust of the

traditional research project. Each project supported through this mechanism should contribute or be directly related to the common theme of the total research effort.

See Also Program Project Application

Program Support Assistant *PSA*

Also called Grants Technical Assistant. This person generally works with one or more Scientific Review Administrators to support the NIH peer review process.

Program

A coherent assembly of plans, project activities, and supporting resources contained within an administrative framework, whose purpose is to implement an organization's mission or some specific program-related aspect of that mission. For purpose of this policy statement, "program" refers to those NIH programs that carry out their mission through the award of grants or cooperative agreements to other organizations.

Programmatic Reduction

The dollar amount a grant award is reduced from the amount recommended by the study section (scientific review group). This is done so institutes can maintain a sufficient number of grants in their portfolio and to combat inflation of grant costs.

Progress Report

A report which contains for each grant or contract information on the comparison of actual accomplishments to objectives established for the period. In addition, where the output of the project can be quantified, a computation of the cost per unit of output may be required.

Progress Review Groups *PRGs*

Panels consisting of 20 to 30 prominent members of the scientific, medical, and advocacy communities that assess the state of the science for a single type of cancer or a group of closely related cancers and make recommendations for future research.

Project Control

Notifies the applicant organization of the application number and the assigned study section, study section address, and SRA name and phone number.

Project Costs

The total allowable cost incurred by a recipient (and the value of the in-kind contributions made by third parties) in accomplishing the objectives of the award during the project period.

Project Director, Contracts

A qualified individual designated by the contractors organization to direct the project or program being supported by the contract. This individual has primary responsibility for guiding and/or performing the work as described in the contract work statement.

Project Officer

The individual representing the Government for the purpose of technical monitoring of the contract. The Project Officer may also be considered to be the Institute staff member who coordinates the substantive aspects of a contract from planning the request for proposal to oversight. However, the project officer has no authority to obligate the Government or change the terms of the contract. This authority resides with the Contracting Officer.

Project Period

The total time for which support of a project has been recommended (usually no more than 5 years), consisting of one or more budget periods.
See Also Grant Project Period

Prompt Payment Act

Law that ensures companies transacting business with the government are paid on time. Government must pay within 30 days from the date a contractor submits an invoice or must pay interest. (FAR 32.9)

Proposal

Written offer by an individual or non-Federal organization to enter into a contract, usually in response to a request for proposals (RFP). It consists of a technical and a business proposal, including a description of the project and its costs, and the methods, personnel, and facilities to carry it out.

Protection of Children

The Pro-Children Act of 1994 requires the prohibition of smoking in indoor facilities (or in some cases portions of facilities) used routinely or regularly for the provision of health care, day care, early childhood development, education, or library services to persons under 18, if the services are funded by applicable Federal funds, either directly or through State or local governments. [check this out!!!]

Protection of Human Subjects

Required of all research activities in which human subjects are involved.

Protest

Interested party's written objection to an agency's contract solicitation, proposed award, or award. See FAR 33.101.

Protocol Review and Monitoring System *PRMS*

A process used at cancer centers for performing in-house review and monitoring of the scientific merit of clinical protocols prior to their activation and use with patients.

Protocol

The detailed plan for conducting a clinical trial. It states the trial's rationale, purpose, drug or vaccine dosages, length of study, routes of administration, who may participate, and other aspects of trial design (including a description of research and data analysis methods).

Prototype

A model of something to be further developed, which includes designs, protocols, questionnaires, software, and devices.

Public Health Service *PHS*

A component of the United States Department of Health and Human Services (DHHS). The NIH is the largest agency within the DHHS and within the Public Health Service.

PubMed

A searchable database of reports of research published in scientific and biomedical journals that is maintained by the National Library of Medicine at the NIH.

Parent Announcement

NIH-wide funding opportunity announcement enabling applicants to submit an electronic investigator-initiated grant application for a single grant mechanism, e.g., Research Project Grant (Parent R01). In the NIH Guide, view Parent Announcements for Unsolicited or Investigator-Initiated Applications.

Person Months

Measurement of a person's effort in academic, summer, or calendar months a year. Used on NIH applications and other forms instead of percent effort.

Phase IIB Competing Renewal

An application requiring competitive peer review and Institute/Center action to continue beyond the SBIR/STTR Phase II award.

PHS Policy on Humane Care and Use of Laboratory Animals

Term and condition of all PHS awards involving live, vertebrate animals.

Project Number

Commonly referred to as the application number or grant number, depending upon its processing status. This unique identification number for the grant is composed of the type code, activity code, Institute code, serial number, support year, and/or suffix code.

Public Access Policy

The NIH policy designed to ensure that the public has access to the published results of NIH-funded research (go to <http://publicaccess.nih.gov/> for more information).

PubMed ID Number *PMID*

The unique number assigned to a PubMed citation for an article published in a journal. This number does NOT indicate compliance with the Public Access Policy.

Phase 0 Clinical Trial

A Phase 0 (zero) clinical trial is designed to study the pharmacodynamic and pharmacokinetic properties of a drug. In a Phase 0 trial, a limited number of doses, and much lower doses of the drug are administered, therefore there is less risk to the participant.

Placebo-Controlled Study

A method of investigation of drugs in which an inactive substance (placebo) is given to one group of patients, while the drug being tested is given to another group.

Project

A research component of a larger multicomponent application (e.g., P01), with a separate detailed budget.

Project Leader

The person responsible for the scientific direction and conduct of an individual research project within a multi-component application.

Peer Review Appeal

Procedure for contesting an initial peer review of a grant application. Synonymous with "Rebuttal."

Paperwork Reduction Act

A United States federal law enacted in 1980 designed to reduce the total amount of paperwork burden the federal government imposes private businesses and citizens.

Patent License Agreement *PLA*

Commercial use license for patented and patent-pending technologies; Patent License Agreements (PLA)s are either nonexclusive or exclusive and define royalties to be paid.

Paylist

A list of grant applications sorted in rank order or priority score

Performance-Based Service Contracting *PBSC*

Performance-based service contracting (PBSC) emphasizes that all aspects of an acquisition be structured around the purpose of the work to be performed as opposed to the manner in which the work is to be performed or broad, imprecise statements of work which preclude an objective assessment of contractor performance. It is designed to ensure that contractors are given freedom to determine how to meet the Government's performance objectives, that appropriate performance quality levels are achieved, and that payment is made only for services that meet these levels.

PHS 2590

Public Health Service (PHS) noncompeting application to continue a grant, used to report progress. Also see SNAP and go to the 2590 on the Web.

Pre-(F31) and Post-Doctoral Fellowship (F32 & F33) Applications

When processing these fellowship applications at least three reference letters must be included. None of these letters can be from the sponsors. The original letters are sent to the appropriate Institutes(s), and the copies are destroyed after the study section meeting. These letters are found in the back of the duplicated copies. The important point is that in these cases reviewers should get a duplicated copy and not an original.

Procurement of the Government, Generally via a Contract

The acquisition of property or services for the direct benefit or use of the government, generally via a contract.

Program Announcement Inactivation

Deactivates a program announcement (PA) that has achieved its objectives.

Program Announcement with Specific Referral PAR

A Program Announcement with Specific Referral (PAR) specifies that applications will automatically be referred to an NIH Institute or Center (IC) for review; in the NCI, this means the NCI Division of Extramural Activities (DEA). In issuing the PAR, members of the program staff may want to consider establishing a single receipt date and convening a special panel to review applications submitted in response to this kind of request for applications. As with other aspects of the initiative, these features must be approved by the relevant NCI official. Specific funds are not set-aside by the ICs for PARs.

Program Announcements with Set-Aside Funds PAS

A Program Announcement with Set-Aside Funds (PAS) indicates that funds will be set aside to support research proposed in response to the announcement. The availability of a special fund to support the initiative signals NCI's interest in the research area to the scientific community.

Program Coordination and Referral Branch PCRB

The Program Coordination and Referral Branch (PCRB) is a branch within the Office of Referral, Review, and Program Coordination of the NCI Division of Extramural Activities. The staff of this branch coordinate the development and publication of NCI program concepts (e.g., Requests for Applications and Program Announcements) and the receipt, referral, and assignment of all grant applications.

Program Project Application P01

An award activity for the support of a research program that has a well-defined central theme, research focus, or objective. Program projects must have at least three interrelated, well thought-out subprojects along with (but not required) core resources necessary to support these projects at all times. It is expected that interrelationship and synergism among component research projects will often be multidisciplinary in nature, and will result in greater scientific contributions than if each subproject were supported individually
See Program Project Grant

Proof of Concept

A feasibility study demonstrating the viability of an idea.

Program Advisory Committee *PAC*

Appointed regular members of these standing NIH committees generally have a four-year commitment involving two or three meetings a year. They are nominated by the Executive Secretary of the committee and appointed by the Director, NIH, the Director, NCI, or the Secretary, HHS.

Program for the Assessment of Clinical Cancer Tests *PACCT*

The Program for the Assessment of Clinical Cancer Tests (PACCT) ensures the translation of new knowledge about cancer and new technologies to clinical practice, and develops more informative laboratory tools to help maximize the impact of cancer treatments.

Pediatric Brain Tumor Consortium *PBTC*

A network of medical centers that will evaluate promising treatments for children with brain malignancies. The consortium is intended to speed the development of innovative, technically challenging therapies.

Prostate Cancer Outcomes Study *PCOS*

The Prostate Cancer Outcomes Study (PCOS) investigates how prostate cancer and its treatments affect the quality of life of men with the disease.

Physicians Data Query *PDQ*

An NCI database that contains the latest information about cancer treatment, screening, prevention, genetics, supportive care, complementary and alternative medicine, and clinical trials.

Positron Emission Tomography *PET*

A procedure in which a small amount of radioactive glucose (sugar) is injected into a vein, and a scanner is used to make detailed, computerized pictures of areas inside the body where the glucose is taken up. Because cancer cells often take up more glucose than normal cells, the pictures can be used to find cancer cells in the body.

Patient Navigation Research Network *PNRP*

Aims to develop innovative patient navigation interventions to reduce or eliminate cancer health disparities and test their efficacy and cost-effectiveness.

Peer Review Oversight Group *PROG*

Advise and make recommendations to the Deputy Director for Extramural Research, NIH, and the Director, NIH, on the development and implementation of policies pertaining to the monitoring of, coordination of, and evaluation of peer review conducted at the NIH, to ensure that the review processes keep pace with current advances in research and that the peer reviewer expertise is appropriate for the needs of science.

Patient-Reported Outcomes Measurement Information System *PROMIS*

A publicly available Web-based resource that can be used to measure key health symptoms and health-related quality of life (HRQOL) domains such as pain, fatigue, depression, and physical function.

Physician Scientist Award *PSA*

For support to a newly trained clinician appointed by an institution for development of independent research skills and experience in a fundamental science within the framework of an interdisciplinary research and development program.

PubMed Central *PMC*

PubMed Central (PMC) is the NIH digital archive of full-text, peer-reviewed journal papers. These papers are indexed with a PMCID, a series of numbers preceded by PMC. PMC content is publicly accessible and integrated with other databases (go to <http://www.pubmedcentral.nih.gov/>).

PubMed Central Reference Number *PMCID*

The reference number assigned to an article or manuscript archived in PubMed Central. The PMCID is the number that must be cited on applications, proposals or reports as part of compliance with the Public Access Policy.

See Citation ID

Q

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Quality of Life Trials (Support Care Trials)

These clinical trials explore ways to improve comfort and quality of life for cancer patients.

Quorum

the number of members of an organized body of persons (as in a board of advisors such as the National Cancer Advisory Board) that when duly assembled is legally competent to transact business in the absence of the other members; typically, a specified number of members (as an absolute majority) in the absence of which an organized body cannot act legally.

Quality of Life *QOL*

The amount of happiness and balance in an individual's life.

Quality Cancer Care Committee *QCCC*

The Quality of Cancer Care Committee (QCCC) is a trans-governmental agency committee with members from HHS and other federal departments. The QCCC was created in 2000, on the principle that decisions about cancer services by the federal government should be consistent with the best scientific evidence available regarding quality outcomes.

Quality of Care *QOC*

The degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge.

R

|A|B|C|D|E|F|G|H||J|K|L|M|N|O|P|Q|R|S|T|U|V|W|X|Y|Z|

Racial and Ethnic Categories

Human subjects terms that are defined by the Office of Management and Budget Directive No. 15 and used by NIH to allow comparisons to national databases.

See Also Subpopulations

Randomization

A method used to prevent bias in research. People are assigned by chance to receive experimental treatment(s), standard treatment(s), or no treatment/placebo.

Randomized Trial

A study in which participants are randomly (i.e., by chance) assigned to one or two or more treatment arms or regimen of a clinical trial. Occasionally placebos are utilized. Randomization minimizes the differences among groups by equally distributing people with particular characteristics among all the trial arms.

Rapid Access to Intervention Development *RAID*

The Rapid Access to Intervention Development (RAID) program facilitates translation to the clinic of novel, scientifically meritorious therapeutic interventions originating in the academic community. See http://dtp.nci.nih.gov/docs/raid/raid_index.html

Rapid Access to NCI Discovery Resources *RAND*

This program assists academic and nonprofit investigators in the discovery stage of anticancer drug research. R-A-N-D can assist in the discovery of small molecules, biologics, or natural products through such mechanisms as the development of high-throughput screening assays, computer modeling, recombinant target protein production and characterization, and chemical library generation.

Reader

Peer reviewer who serves as a backup for a primary peer reviewer and secondary peer reviewer. A reader reads a grant application thoroughly before an initial peer review meeting, but does not necessarily prepare a written critique.

Rebudgeting

Also called "Grant Rebudgeting." With the advent of modular grants, grantees no longer have to request permission from NIH for rebudgeting (formerly moving money from one budget category to another). For nonmodular grants, permission is still required for some items.

Rebuttal

A procedure for contesting the peer review of a grant application. Synonymous with "Appeal."

Receipt Date

The date that grant applications are due for submission (to any NIH Institute or Center) at the NIH Center for Scientific Review (CSR).

Investigator-initiated applications have three receipt dates, which for the majority of applications are February 1, June 1, and October 1; see the CSR Web site for the standard receipt dates according to the type of funding mechanism (i.e., grant application). Grant applications and contract

proposals that are submitted in response to an initiative (e.g., a Request for Applications or a Requests for Proposals, respectively) from an NIH Institute or Center are listed as an initiative announcement in the NIH Guide for Grants and Contracts [check] and FedBizOpps, respectively.

Recipient

The entity receiving financial assistance directly, in the form of a grant or cooperative agreement, from a Federal agency to carry out a project or program. Although grant funding and benefits may be limited to a particular site or component of a larger entity, the entire legal entity that received the award is legally responsible for carrying out a program or project, even if the grant award document refers only to the particular site or component.

Recommended

A designation given by a study section advising that an application be funded. The application gets a priority score and summary statement. Roughly the top half of applications being reviewed are recommended for funding.

Recompeting

A grant whose term (e.g., four years) is over and for which the applicant is again seeking NIH support. Such applications are designated to be type 2 applications.

The designation of such grant applications as renewal or competing continuation applications has been discontinued and has been replaced by renewal applications.

Reentry into Biomedical and Behavioral Research Careers

Supports full-time or part-time work for individuals with high potential to reenter an active research career after taking time off to care for children or parents or to attend to other family responsibilities.

Renewal

A contract extension of six months or more which also increases the estimated cost of the contract and is intended as a continuation of work with the incumbent contractor.

Request for Assignment(s) Changes 901

When it is issued, a computer-generated letter is sent to the principal investigator with information on the change.

Request for Contract/Acquisition Plan *RFC/AP*; *sometimes AP/RFC*

A document used to initiate an acquisition action which provides the background information necessary for the preparation of the Request for Proposal. (See Section IV, D, of the Research Contracts Branch's Orange Book).

Request for Contract/Acquisition Plan/Contract Revision *RFC/AP/CR*

A document used to initiate new actions (modifications) taken after the initial contract award. (See Section VII, A, of the Research Contracts Branch's Orange Book).

Requirements Contract

Contract that provides for purchasing supplies or services during the contract period, with deliveries scheduled by placing orders with the contractor. (FAR 16.503)

Research Analysis and Evaluation Branch *RAEB*

This branch within the NCI's Division of Extramural Activities serves as the Institute's officially designated centralized source of scientific information and science-based budget information on NCI-supported research projects. This branch analyzes and classifies the science content of all Institute-supported projects as well as that of unfunded applications submitted to the Institute. RAEB also prepares analyses comparing the distribution of funds among research areas, which serve as a basis for budget projections.

Research and Development Contract *R&D*

A funding mechanism by which the NIH procures specific services. These are negotiated contracts which may be funded from intramural or extramural accounts. Excluded are inter/intra-agency agreements (Y01 and Y02), resource and support contracts (N02), and station support contracts (N03).

Research and Development Support Contracts

NIH Programs occasionally identify requirements for certain types of resources or services integral to the conduct of current research and development activities. When ICD program specific requirements can well be defined in advance, contracts may be awarded for research services, e.g., data processing, drug testing, or toxicology screening and research resources, e.g., collection and distribution of materials needed to conduct biomedical research and development, or maintaining and operating special equipment or facilities for access by a number of investigators.

Research and Development *R&D*

All research activities, both basic and applied, and all development activities that are supported at universities and other institutions. "Research" is the systematic study directed toward fuller scientific knowledge or understanding of the subject studied. "Development" is the systematic use of knowledge and understanding gained from research directed toward the production of useful materials, devices, systems, or methods, including design and development of prototypes and processes.

Research Center Grant

Activity supporting shared resources for a multidisciplinary research group of investigators focused on a common research topic;

Research Centers

Grants that support multidisciplinary, long-term research and development programs at research centers. Research centers usually have a clinical orientation and include all P activities (excluding NLM for all years and NINR for FY 1986) that are not included in research projects (R); M01 activities; selected U activities (U41, U42, U54); R07 and G12.

Research Contracts Branch *RCB*

The Research Contracts Branch (RCB) participates in the planning, review, award and management of all National Cancer Institute (NCI) contracts and simplified acquisitions. In addition, RCB acts as a service center for contract actions and purchasing required by the National Institute of Neurological Disorders and Strokes (NINDS) and the National Center for Complementary and Alternative Medicine (NCCAM).

Research Demonstration and Dissemination Projects *R18*

To provide support designed to develop, test, and evaluate health service activities, and to foster the application of existing knowledge for the control of categorical diseases.

Research Development Support

Items such as tuition, fees, books, research expenses, travel, statistical and computational services, etc.

Research Facilities Construction Grants *C06*

To provide matching Federal funds, up to 75%, for construction or major remodeling to create new research facilities. In addition to basic research laboratories, this may include, under certain circumstances, animal facilities and/or limited clinical facilities where they are an integral part of an overall research effort.

Research Grants *R01*

Extramural awards made for Other Research Grants, Research Centers, Research Projects, and SBIR/STTRs.

Research Institution

A United States research organization that is:

- A nonprofit college or university OR
- A nonprofit research institution, including nonprofit medical and surgical hospitals. (A "nonprofit institution" is defined as an organization that is owned and operated exclusively for scientific or educational purposes, no part of the net earnings of which inures to the benefit of any private shareholder or individual.) OR
- A contractor-operated, federally funded research and development center, as identified by the National Science Foundation in accordance with the Government-wide Federal Acquisition Regulation issued in accordance with section 35(c)(1) of the Office of Federal Procurement Policy Act (or any successor legislation thereto). (Laboratories staffed by Federal employees do not meet the definition of "research institution" for purposes of the STTR program.)

Research Portfolio

The cohort of grants supported by a given NIH organization and administered by an Institute or Center Program Officer (or Program Official or Program Director).

Research Program - Cooperative Agreements *U19*

To support a research program of multiple projects directed toward a specific major objective, basic theme or program goal, requiring a broadly based, multidisciplinary and often long-term approach.

Research Program Project *P01*

For the support of broadly based, multidisciplinary, often long-term, research program which has a specific major objective or a basic theme. A program project generally involves the organized efforts of relatively large groups, members of which are conducting research projects designed

to elucidate the various aspects or components of their objectives. Each research project is usually under the leadership of an established investigator. The grant can provide support for certain basic resources used by the groups in the program, including clinical components, the sharing of which facilitates the total research effort. A program project is directed toward a range of problems having a central focus, in contrast to the usually narrower thrust of the traditional research project. Each project supported through this mechanism should contribute or be directly related to the common theme of the total research effort.

See Also Program Project Application

Research Project U01

To support a discrete, specified, circumscribed project to be performed by the named investigator(s) in an area representing his specific interest and competencies.

Research Scientist Development Award - Research & Training K01

For support of a scientist, committed to research, in need of both advanced research training and additional experience.

Research Supplements for People with Disabilities

Monies that add funds to an existing grant to support graduate students, postdoctoral fellows, and faculty with disabilities.

Research Supplements for Reentry into a Research Career

Monies that add funds to an existing grant to support scientists who have taken time off to care for children or parents, or to attend to other family responsibilities.

Research Supplements for Underrepresented Minorities RSUM

Monies that add funds to an existing grant to support underrepresented minority investigators and students.

Resetting a Grant Start Date

Shortening a grant's budget period by giving it a new anniversary date, generally to avoid having too many awards start at the end of a fiscal year. Resetting a grant's start date may affect when a grantee would submit a reapplying application.

Resubmission

Sending NIH an application for initial peer review after it has been reviewed by a study section, but not funded and then revised and resubmitted by the applicant one or more times. Each resubmission is given a code, e.g., A1. NIH limits applicants to one resubmission of a particular application.

Resume

The summary of the assessment of the scientific merit of an application for research or other funding from the NIH; the Resume appears at the front of an NIH summary statement. Also, in a different context, a summary of a person's background, education, experience, and achievements that is submitted with a job application.

Review Policy Committee *RPC*

NIH committee of senior peer review administrative staff that advises NIH on extramural review issues. It has one voting member from each Institute or Center (including several from the NIH Center for Scientific Review).

Revised Application

The correct term at the NIH is "Amended Application." An amended or revised application is one that has been officially resubmitted to the NIH after having been revised in response to prior review(s) of its scientific merit by an NIH peer review group as summarized in a summary statement.

See Also Amended Application

Real Property

Land, including land improvements, structures, and appurtenances, but not movable machinery and equipment.

Research

A systematic, intensive study intended to increase knowledge or understanding of the subject studied, a systematic study specifically directed toward applying new knowledge to meet a recognized need, or a systematic application of knowledge to the production of useful materials, devices, and systems or methods, including design, development, and improvement of prototypes and new processes to meet specific requirements.

See Research and Development

Research Misconduct

Fabrication, falsification, or plagiarism in proposing, performing, or reporting research, or in reporting research results. Fabrication is making up data or results and recording or reporting them. Falsification is manipulating research materials, equipment, or processes, or changing or omitting data or results such that research is not accurately represented in the research record. Plagiarism is the appropriation of another person's ideas, results, processes, or words without giving appropriate credit. The term does not include honest error or honest differences of opinion.

Ruth L. Kirschstein National Research Service Awards (NRSA)

Awards to both individuals and institutions to provide research training in specified healthrelated areas.

R01 Application or Grant or Award *R01*

An individual, investigator-initiated research project application or grant.

R84 Application or Grant or Award *R84*

In the instances when these applications are reviewed by CSR study sections, they are processed in the same manner as the other applications. DHHS policies concerning assurances of protection of human subjects involved in research also apply to R84s. Pertinent background information may be obtained from the Fogarty International Center.

Rapid Access to Preventive Intervention Development *RAPID*

The goal of this program is the expeditious movement of novel molecules and concepts from the laboratory to the clinic for clinical trials of efficacy. Rapid Access to Preventive Intervention Development (RAPID) will assist investigators who submit successful requests by providing any (or all) of the preclinical and phase 1 clinical developmental requirements for phase 2 clinical efficacy trials. These include, for example, preclinical pharmacology, toxicology, and efficacy studies; bulk supply, GMP manufacturing and formulation; and regulatory and IND support and phase 1 clinical studies. Suitable types of agents for RAPID may range from single chemical or biological entities to defined complex mixtures with the potential to prevent, reverse, or delay carcinogenesis.

Re-Review of Application

The original application, without additional materials or modifications, will be re-reviewed by the same or a different SRG. Typically associated with a letter of appeal of the initial review of the application.

Receipt, Referral, and Assignment of Applications

The routing of applications arriving at NIH. The referral section of CSR is the central receipt point for competing applications. CSR referral officers assign each application to an institute and refer it to a scientific review group, notifying applicants of these assignments by mail. Alternatively, NIH encourages applicants to self assign. For more information, scroll down after clicking on Requesting Assignment for Your Application.

Recommended Levels of Future Support

Funding level recommended for each future year approved by the scientific review group, subject to availability of funds and scientific progress.

Referral Guidelines

Referral guidelines are an organizations internal guidance, specific advice provided by NIH program or grants management staff, or instructions found in the various application guides.

Referral Officer *RO*

Assigns applications to one primary and one or more secondary Institutes or Centers.

Renewal Application *Type 2*

A renewal application is used when previous years of funding for the project have elapsed and the applicant is competing for additional years of funding to continue the original project. (Type 2)

Request for Applications (Grants)

The official statement that invites grant or cooperative agreement applications to accomplish a specific program purpose. Request for Applications (RFA)s indicate the amount of funds set aside for the competition and generally identify a single application receipt date.

Request for Proposals (Contracts) *RFPs*

The Governments invitation to prospective offerors to submit a proposal based on the terms and conditions set forth in the Request for Proposals (RFP). The RFP is also called the Solicitation. An RFP is also considered to be an Initiative sponsored by an NIH IC that requests

proposals for a contract to meet a specific need, such as the development of an animal model. RFPs have a single proposal receipt date and are published in the FedBizOpps and NIH Guide for Grants and Contracts.

Research Centers in Minority Institutions *RCMI*

Leads scientific research to improve minority health and eliminate health disparities.

Research Enhancement Award Programs *REAP*

Supports small-scale research projects in the biomedical and behavioral sciences conducted by faculty and students at educational institutions that have not been major recipients of NIH research grant funds.

Research Integrity

The use of honest and verifiable methods in proposing, performing, and evaluating research. Reporting research results with particular attention to adherence to rules, regulations, guidelines, and following commonly accepted professional codes or norms.

Research Plan

The main part of an NIH grant application describing the objectives and importance of a principal investigator's proposed research and how the research will be conducted. Typically, the Research Plan comprises the following sections: Specific Aims; Research Strategy; and Other applicable sections, such as human subjects, animals in research, and select agents.

Research Project Grant *RPG*

Awards given in response to investigator-initiated applications for research funds. Most grants issued by NCI are Research Project Grants (RPGs). Expenditures for these grants constitute 45-50% of the NCI budget. Examples: Traditional (R01), New Investigator (*R01), Program Projects (P01), MERIT Awards (R37), RFAs (R01, U01), Cooperative Agreements (U01 not responsive to RFA), Shannon Awards (R55), Small Grants (R03), Exploratory/Developmental Grants (R21/R33), SBIR/STTR Grants (R43/R44 & R41/R42)

Resource-Related Research Projects, and Cooperative Agreements *R24 U24*

These grants are used by the NIH and the extramural community to support research projects that will enhance the capability of resources to serve biomedical research.

Responsible Conduct of Research (RCR)

Responsible conduct of research is defined as the practice of scientific investigation with integrity. It involves the awareness and application of established professional norms and ethical principles in the performance of all activities related to scientific research. NIH requires that all trainees, fellows, participants, and scholars receiving support through any NIH training, career development award (individual or institutional), research education grant, and dissertation research grant must receive instruction in responsible conduct of research. Applications for such mechanisms must include a plan for instruction in responsible conduct of research.

Review Panel

Evaluates the scientific and technical merit of grant applications.

Resource Sharing Plan

It is NIH policy that the results and accomplishments of the activities that it funds should be made available to the public. Program Directors/Principal Investigators (PD/PIs) and grantee organizations are expected to make the results and accomplishments of their activities available to the research community and to the public at large. PD/PIs must submit a plan for sharing unique research resources (i.e., Research Resources/Tools, Research Data, Model Organisms, and Genome Wide Association Studies) in the application.

Research Condition and Disease Categorization RCDC

A computerized reporting process the National Institutes of Health (NIH) is using at the end of each fiscal year to categorize its funding in medical research beginning with fiscal year 2008 (FY 2008) RCDC reports NIH funding in 233 research, condition, and disease categories.

Research Advocate

A person chosen to serve on a Scientific Review Group (IRG) or Special Emphasis Panel (SEP) as a public member. This person is allowed to serve based on his/her experience and knowledge of a disease, health status, or public health problem, and provide their viewpoint based upon their experiences as disease survivors or from having been affected by others with disease. In NCI, the Consumer Advocates in Research and Related Activities (CARRA) program coordinates consumer involvement in research activities such as peer review and advisory committees.

Revision

Application to add funds to a grant to expand its scope or meet needs of a research protocol. Applicants must apply and undergo peer review. Formerly called competing supplement; the former term revision is now resubmission.

Research Strategy

Part of the Research Plan of an NIH grant application describing the importance and innovation potential of a principal investigator's proposed research and how it will be conducted. The Research Strategy comprises these sections: Significance, Innovation, Approach (Preliminary Studies for new applications; Progress Report for renewal or revision applications).

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Salary Limitation

Is a legislative provision which changes annually in accordance with the appropriation. The Salary Rate Limitation stipulates that no appropriated funds for the NIH and the Substance Abuse and Mental Health Services Administration shall be used to pay the salary of an individual, through grant, cooperative agreement, or contract, at a specific rate ceiling established for Executive Schedule rates of pay in the HHS appropriation.

Scientific Communication and Evaluation Contracts

To fulfill the NIH mission to improve the health of the people of the United States, research results must be interpreted and communicated to those who use the information. Although results of individual experiments are usually reported in scientific journals, conferences and workshops may also be valuable for analyzing the significance of new findings and for developing a scientific consensus. The NIH awards contracts for conferences and workshops considered scientifically necessary and relevant to ICD objectives.

Scientific Initiative Management System *SIMS*

NIH database that integrates the creation and approval of concepts for subsequent development as a Request For Applications (RFA), Request For Proposals (RFP), or Program Announcement (PA), and the scheduling and tracking of initiatives by fiscal year.

Scientific Merit

Numerical rating assigned to an application by peer review, reflecting the perceived overall quality of an application.

Scientific Review and Resources Branch *SRRB*

This title is no longer used. The Scientific Review and Resources Branch of the Office of Referral, Review, and Program Coordination in the NCI Division of Extramural Activities was renamed the Special Review and Logistics Branch in 2002. Among other review-related activities, the staff members of this branch plan, manage, and assist in the scientific merit review of special grant and cooperative agreement applications (which are generally received from applicants in response to Requests for Applications and Program Announcements from the NCI).

Scientific Review Group *SRG*

A chartered committee or special emphasis panel that performs the first level of peer review; now generally called a scientific review group (also known as a study section). Formerly called initial review group; a.k.a. study section. In the context of contract proposals, the SRG is a group of experts qualified by training and experience in particular scientific or technical fields to give expert advice on the scientific and technical merits of Research and Development (R&D) contract projects; also known as Technical Evaluation Panel.

Scientifically Acceptable or Unacceptable

A determination based on whether proposed gender or minority representation conforms with NIH guidelines pertinent to the scientific purpose and type of study. A determination of unacceptable by the review panel bars the funding of an application or proposal until NIH staff resolve the issue. In addition, the definition changes if the research is a clinical trial as opposed to merely being clinical research.

Scope or Scope of Research

In the context of an NIH grant award, scope signifies the scientific parameters of a funded research project. A grantee cannot change the scope of a project on his or her own because doing so would significantly alter the project that the Council (i.e., the National Cancer Advisory Board) approved for funding.

Scored

In the Center for Scientific Review (CSR) peer review process, applications that are judged by a study section to be competitive, i.e., generally in the upper half of the applications reviewed. These applications are assigned a priority score and forwarded to the appropriate Institute/Center for the second level of review.

Screening Trials

Test the best way to find cancer, especially in its early stages.

Sealed Bidding

The method of awarding contracts through the public opening of bids and awarding to the lowest responsible, responsive bidder based on detailed specifications.

Second-Level Peer Review

Peer review to make funding recommendations to the NCI or other NIH Institute or Center. Generally conducted by an institute's advisory council (i.e., the National Cancer Advisory Board), second-level peer review results in funding recommendations to the NCI Director based on program priorities and balance, and policy issues; it does not involve a reassessment of the science.

Secondary Peer Reviewer

Peer reviewer who serves as a backup for a primary peer reviewer. Both read a grant application thoroughly before an initial peer review meeting to lend their expertise to the group discussion. The secondary peer reviewer almost always writes a critique.

See Also Reader

Selective Pay

The funding of a small number of programmatically important applications at the margin of the payline as recommended by an Institute's or Center's Council or Advisory Board (e.g., the National Cancer Advisory Board).

Set Aside 8 (a)

Section 8(a) of the Small Business Act established a program to foster the competitive viability of firms owned by individuals who are socially and economically disadvantaged, and to expand their participation in federal acquisition. Under this program, the NIH prescribes set-asides for certain requirements for socially or economically disadvantaged firms eligible under the 8(a) program. Participation is limited to these 8(a) firms, and NIH awards are made as contracts to the Small Business Administration, which issues subcontracts to the 8(a) firms. Peer review processes and source selection procedures are utilized to determine the contractor(s) to whom the award(s) should be made. If responses from 8(a) firms are considered inadequate, the NIH advertises the requirement for open competition or as a small business set aside.

Set Aside

Money taken out of the Federal budget for a specific purpose, for example, to fund a congressionally-mandated program. In the context of contracts, a Set Aside signifies the restricting of certain acquisitions to response by a specific group of sources. Small Business, Small Disadvantaged Business, and Historically Underutilized Business Zone (HUBZone) are examples of set-aside programs.

Sex Discrimination

Discrimination based on gender.

Sex/ Gender

The term gender refers to the classification of research subjects into either or both of two categories: women and men. Sex refers to biological sex, either male or female. For inclusion purposes, biological sex should be used, either male or female.

Shell

The GTA/PSA prepares the "shell" (outline) for the SS, inserts critiques, removes word processor codes, and formats the document.

Significance

The significance of the program overall and its potential to advance scientific knowledge in the field.

Significant Difference

In the context of biomedical research, a significant difference is a difference that is of clinical or public health importance, based on substantial scientific data. This definition differs from the commonly used statistically significant difference, which refers to the event that, for a given set of data, the statistical test for a difference between the effects in two groups achieves statistical significance. Statistical significance depends upon the amount of information in the data set. With a very large amount of information, one could find a statistically significant, but clinically small difference that is of very little clinical importance. Conversely, with less information one could find a large difference of potential importance that is not statistically significant.

Site of Intervention

A specific location used to establish contact with or gain access to subjects within the neighborhood or community in which they reside.

Examples include schools, work sites, beauty shops, barber shops, ethnic grocery stores, small group meetings in peoples homes, community clinics, hospitals, and day-care centers.

Site Visit Review Panel

An advisory group of scientific experts typically including representatives of an Scientific Review Group (SRG) subcommittee plus ad hoc members who recruited and brought together in person to review a grant application at the applicant institution.

Skip Process

Process for denying support to an application within the payline.

Small Business Administration SBA

In the Small Business Act of July 30, 1953, Congress created the Small Business Administration, whose function was to "aid, counsel, assist and protect, insofar as is possible, the interests of small business concerns." The charter also stipulated that the SBA would ensure small businesses a "fair proportion" of government contracts and sales of surplus property.

Small Business Concern

A business, including it's affiliates, that is independently owned and operated, is not dominant in the field of operation, and qualifies under the Small Business Administrations Criteria, such as a number of employees and average annual receipts.

Small Business Innovation Research Grants - Phase I U43 SBIR

The NIH and the extramural community use U43 SBIR grants to support projects, limited in time and amount, to establish the technical merit and feasibility of R&D ideas that may ultimately lead to commercial products or services.

Small Business Innovation Research Grants - Phase II *U44 SBIR*

The NIH and the extramural community use U44 SBIR grants to support in-depth development of R&D ideas whose feasibility have been established in Phase I that are likely to result in commercial products or services. SBIR Phase II Grants are considered "Fast Track" and do not require National Council Review.

Small Business Innovation Research Program *SBIR Program*

A government-wide program that promotes technology transfer by helping investigators form partnerships between the private and public sectors.

Small Business Innovative Research Contract *SBIR Contract*

Type of contract that fosters technological innovation by small businesses. Eligibility is limited to for-profit businesses with 500 or fewer employees. For more on SBIR, see the small business grants section of the Council News toolbox.

Small Business Set-Asides

It is the policy of the Federal Government to place a fair proportion of its requirements with small and small disadvantaged business concerns. The purpose of small business set-asides is to award certain acquisitions exclusively to small business concerns. Contracting officers are required to set-aside an individual acquisition or class of acquisitions where there is a reasonable expectation that offers will be obtained from at least two responsible small business concerns. When the NIH is not certain whether there is adequate expertise in the small business community to justify a set-aside, a notice is published in the FedBizOpps, requesting statements of capabilities from small businesses. An adequate response by small businesses may then result in a set-aside for the acquisition. When a suitable number of qualified small business firms cannot be found, the requirement is then subject to open competition.

Small Business Technology Transfer Grants - Phase I *R41 STTR*

To support cooperative R&D projects between small business concerns and research institutions, limited in time and amount, to establish the technical merit and feasibility of ideas that have potential for commercialization.

Small Business Technology Transfer Grants - Phase II *R42 STTR*

To support in-depth development of cooperative R&D projects between small business concerns and research institutions, limited in time and amount, whose feasibility has been established in Phase I and that have potential for commercial product(s) or service(s).

Small Business Technology Transfer Program *STTR*

A government-wide program that promotes technology transfer by helping investigators form partnerships between the private and public sectors. It differs from SBIR in being somewhat less restrictive in the level of activity permitted for academic institutions.

Small Disadvantaged Business Concern

Small business that is at least 51 percent unconditionally owned or has at least 51 percent of its stock unconditionally owned and is managed by one or more people who are both socially and economically disadvantaged. (FAR 19.001)

Small Research Grant Applications R03

This mechanism is designed to provide research support specifically limited in time and amount for studies in categorical program areas. The applications are processed just like R01s.

Small Research Grants R03

Small grants provide research support, specifically limited in time and amount, for activities such as pilot projects, testing of new techniques, or feasibility studies of innovative, high-risk research, which would provide a basis for more extended research. Small grants provide flexibility for initiating studies that are generally for preliminary short-term projects and are nonrenewable.

Socially and Economically Disadvantaged Individual

A member of any of the following groups:

- Black Americans
- Hispanic Americans
- Native Americans
- Asian Pacific Americans
- Subcontinent Asian Americans
- Other groups designated from time to time by SBA to be socially disadvantaged;
- or any other individual found to be socially and economically disadvantaged by SBA pursuant to Section 8(a) of the Small Business Act, 15 U.S.C. 637(a).

Socially and Economically Disadvantaged Small Business Concern

See 13 CFR Part 124 --8(A) Business Development/Small Disadvantaged Business Status Determinations, §§124.103 ("Who is socially disadvantaged?") and 124.104 ("Who is economically disadvantaged?")

Sole Source Acquisition

Contracting process to acquire goods or services after soliciting and negotiating with only one source.

See Also Sole Source Award

Sole Source Award

A new award, neither urgent nor unsolicited, which is not competed.

See Also Sole Source Acquisition

Solicitation

Solicited Research

See Targeted Research

Source Selection Document

The document used to obtain management approval of the Contracting Officers selection of the proposed contractor. (See Section VI of the Research Contracts Branch's Orange Book).

Source Selection

A contracting term denoting the review process by which a contractor is selected. The selection of an offeror based on a comprehensive/comparative assessment of proposals against all evaluation criteria listed in the solicitation.

Sources Sought

A published synopsis for the purpose of determining interest in a given acquisition. It requests interested parties to submit capability statements which may be evaluated to determine the ability to perform.

Special Conveyance

Commercially rented transportation of any type (i.e., automobiles, planes, boats, etc.). Special conveyances shall be used only when it is NOT advantageous to the Government to use: common carriers, Government-leased vehicles, and privately-owned conveyances.

Special Emphasis Panel *SEP*

An advisory group of scientific experts drawn from a large pool of reviewers and chartered for the specific review or collection of reviews by a blanket chartering mechanism. (Formerly known as Scientific Review Committees or SRCs.)

Special Programs of Research Excellence *SPORE*

An NIH/NCI funding mechanism that is designed to support diverse research approaches to the problems of cancers of specific types or origins (e.g., of a specific organ like breast or prostate), incorporating all applicable disciplines and resources.

Special Review and Logistics Branch *SRLB*

In 2002, Special Review and Logistics Branch of the Office of Referral, Review, and Program Coordination in the NCI Division of Extramural Activities was renamed from its previous name, the Scientific Review and Resources Branch. Among other review-related activities, the staff members of this branch plan, manage, and assist in the scientific merit review of special grant and cooperative agreement applications (which are generally received from applicants in response to Requests for Applications and Program Announcements from the NCI).

Specialized Center Grants *P50*

To support any part of the full range of research and development from very basic to clinical; may involve ancillary supportive activities such as protracted patient care necessary to the primary research or R & D effort. The spectrum of activities comprise a multidisciplinary attack on a specific disease entity or biomedical problem area. Their grants differ from program project grants in that they are usually developed in response to an announcement of the programmatic needs to an Institute or Division and subsequently receive continuous attention from staff. Centers may also serve as regional or national resources for special research purposes. Also Specialized Programs of Research Excellence (SPOREs) See Specialized Programs of Research Excellence (SPORE) web site.

Specialized Center-Cooperative Agreements *U54*

To support any part of the full range of research and development from very basic to clinical; may involve ancillary supportive activities such as protracted patient care necessary to the primary research or R&D effort. The spectrum of activities comprises a multidisciplinary attack on a specific disease entity or biomedical problem area. These differ from program project in that they are usually developed in response to an announcement of the programmatic needs of an Institute or Division and subsequently receive continuous attention from its staff. Centers may also serve as regional or national resources for special research purposes, with funding component staff helping to identify appropriate priority

needs.

Specific Aims

Key section of a grant application, listing concisely the major goals for the project period.

Standard Treatment

The best treatment currently known for a cancer, based on results of past research.

Statement Of Work SOW

In a contract proposal, the detailed description of the work to be performed under the contract. In other words, the portion of the solicitation/contract that states the technical procedures, objectives, and requirements of the acquisition/contract.

Stipend

Student financial support, the level of which is determined by NIH, provided on training grants and fellowships for living expenses.

Streamlined Noncompeting Award Process SNAP

Under SNAP, the Grants Management Officer (GMO) negotiates the direct costs for the entire competitive segment at the time of the competing award. This one-time negotiation eliminates the need for annual budget submissions and negotiations, simplifies the review of continuation applications, and reduces the complexity of monitoring grants.

Student Educational Employment Program SEEP

Created for the purpose of consolidating 13 student employment programs (e.g., stay-in-school, "P" and "Q" and Cooperative Education and Federal Junior Fellowships programs).

Study Section

A panel of experts established according to scientific disciplines or current research areas for the primary purpose of evaluating the scientific and technical merit of grant applications. Also called Scientific Review Groups (SRGs).

Subcontract

An agreement between a prime contractor of an original contract and a third party to provide a specified part of the work or materials required in the original contract.

Subpopulations

A human subjects term that is used for the purpose of indicating that a racial/ethnic group can be further defined as groups (subpopulations) which are delimited by geographic origins, national origins, and/or cultural differences. It is recognized that there are different ways of defining and reporting racial and ethnic subpopulation data. The subpopulation to which an individual is assigned depends on self-reporting.

Substantial Foreign Component

Under a grant to a domestic institution, the performance of any significant element or segment of the project outside of the United States, either by the grantee or by a researcher employed by a foreign institution, with or without grant funds.

Substantial Involvement

National Cancer Institute (NCI) staff will make both intellectual and practical contributions to the research.

Success Rate Base

The basis for computing the RPG success rate. It includes the total number of competing applications reviewed (the number of applications subjected to a streamlined review process). Also known as Rate Base.

Success Rate

Roughly, the number of applications funded by an institute divided by the number of applications referred to it that were reviewed (applications resubmitted during the fiscal year are counted only once).

Summary of Negotiation

A complete written record of all actions leading to award of a contract. It records the history of the acquisition and explains and supports the rationale, judgment, and authorities for all decisions and actions.

Summary Statement Top SS Top

All of the administrative information contained in the summary statement "top."

Summary Statement SS

An official document showing the outcome of initial peer review, containing priority score and percentile, codes for various areas of concern (e.g., human subject research), and recommended budget.

Supplemental Agreement

A modification of an existing contract which is accomplished by the mutual action (signature) of both parties. A supplemental agreement is also called a bilateral modification.

Supplemental Award

The award of additional funds to: (1) support new or additional activities which are not identified in the current grant or which significantly expand the project's scope beyond the purpose(s) for which the current grant was awarded; (2) support an expansion of the grant approved activities; or (3) provide for an increase in costs due to unforeseen circumstances.

Supplies

All personal property excluding equipment, intangible property, debt instruments, and inventions of a contractor conceived or first actually reduced to practice in the performance of work under a funding agreement.

Surveillance, Epidemiology, and End Results *SEER*

A cancer registry mandated under the National Cancer Act of 1971 to operate and maintain a population-based cancer reporting systems, periodically reporting estimates of cancer incidence and mortality in the U.S.

Synergy

Joint work; to work together; combined or cooperative energy or force.

System Issue

Most system issues are technical problems with federal systems used for electronic submission of grant applications (Grants.gov or eRA Commons) that keep an applicant from successfully submitting their grant application on time. Please note: Problems with computer systems at the applicant organization are not considered system issues nor is a failure to complete any required registration by the submission deadline. System issues must be reported to the eRA Helpdesk on or before the deadline and will be investigated on a case by case basis.

Signing Official *SO*

A Signing Official (SO) has institutional authority to legally bind the institution in grants administration matters. The individual fulfilling this role may have any number of titles in the grantee organization. The label, "Signing Official," is used in conjunction with the NIH eRA Commons. The SO can register the institution, and create and modify the institutional profile and user accounts. The SO also can view all grants within the institution, including status and award information. An SO can create additional SO accounts as well as accounts with any other role or combination of roles. For most institutions, the Signing Official (SO) is located in its Office of Sponsored Research or equivalent.

Significant Rebudgeting

A threshold reached when expenditures in a single direct cost budget category deviate (increase or decrease) from the categorical commitment level established for the budget period by more than 25 percent of the total costs awarded. Significant re-budgeting is one indicator of change in scope.

Select Pay

The funding of a small number of programmatically important applications at the margin of the payline as recommended by Council.

Scientific Review Officer *SRO*

The Scientific Review Officer (SRO) is the NIH official who serves as the Designated Federal Official and has legal responsibility for managing the peer review meeting, the procedures for evaluating the applications assigned to the Scientific Review Group and the determinations of conflicts of interest, as noted in 42 CFR 52(h).

See Scientific Review Administrator

Scientific Overlap

Overlap of support occurs when substantially similar research is proposed in more than one concurrent PHS grant application.

Salary Cap

A legislatively-mandated provision limiting the direct salary (also known as salary or institutional base salary, but excluding any fringe benefits and F&A costs) for individuals working on NIH grants, cooperative agreement awards, and extramural research and development contracts.

See Salary Limitation

Select Agent

Biological agent or toxin listed in 42 CFR Part 73, 7 CFR Part 331 and 9 CFR Part 121, or the HHS and USDA Select Agents and Toxins List (<http://www.selectagents.gov/>).

Small Business

A business independently owned and operated; has its principal place of business in the United States and is organized for profit; is at least 51 percent owned, or in the case of a publicly owned business, at least 51 percent of its voting stock is owned by U.S. citizens or lawfully admitted permanent resident aliens; has, including its affiliates, not more than 500 employees.

Specialized Center

Center grant (P50) to support any part of the full range of research and development from very basic to clinical for a multidisciplinary research group of investigators focused on a common research topic. Applications may include individual projects, shared resources, training components, and developmental funds.

Subcontract Under a Grant

A written agreement between a grantee and a third party to acquire routine goods and services.

Special Actions Subcommittee "Black Book"

A summary of the Board's business and informational items for consideration in a particular council round.

Special Actions Subcommittee

The purpose of this subcommittee is to review any grant brought up for discussion by the Board for any particular reason by an NCI staff member. Staff recommendations submitted to the subcommittee are those foreign grants not meeting the priority criteria or a grant with an extraordinary situation requiring Board advice, approval, or clarification. Other grants which maybe be brought to the attention of the subcommittee are those in which a Program Director disagrees with the initial review of a grant and seeks to have it referred to a different review group, deferred for a site visit, etc., and any grant that has biohazard, animal welfare, or human subject concerns. Actions taken by the staff on each grant are presented to the subcommittee for their information.

Supplement, Competing

See Revision

Shared Resource Core

A budgeted component of a multi-project application that provides essential facilities or services to two or more of the proposed research projects.

Salary Cap Adjustments

Adjustments made by NIH when an individual's institutional salary exceeds the current salary limitation. NIH grant/contract awards for applications/proposals that request direct salaries of individuals in excess of the applicable RATE per year will be adjusted in accordance with the legislative salary limitation and will include a notification such as the following: None of the funds in this award shall be used to pay the salary of an individual at a rate in excess of the applicable salary cap.

Sanctions by NIH

NIH may impose sanctions on institutions that fail to comply with the terms and conditions of award, including confirmed instances of research misconduct. Such sanctions may include, but are not limited to, corrective actions, removal of authorities, and/or delay or withholding of future awards to the project or program.

Scientific Review Administrator SRA

A federal scientist who presides over a scientific review group and is responsible for coordinating and reporting the review of each application assigned to it. The Scientific Review Administrator (SRA) serves as an intermediary between the applicant and reviewers and prepares summary statements for all applications reviewed. In the context of contract proposals, the SRA is the NIH official who has the responsibility to ensure that Research and Development (R&D)/In Support of R&D contract proposals receive a competent, thorough and fair peer review by the Scientific Review Group (SRG). The SRA organizes and provides scientific/technical support to an SRG, and is responsible for the documentation/contents of the SRG minutes, including votes on acceptability or unacceptability and scoring of the proposals, and other recommendations, to the Project Officer and Contracting Officer.

Scientific Review and Evaluation Award SREA

Scientific Review and Evaluation Award (SREA) is a payment made to a Scientific Review Group (SRG) reviewer. SREA funds are used to reimburse travel, lodging, per diem and honoraria for review group members. Also refers to the process by which the award is generated.

Scientific Review Specialist SRS

The contractor equivalent of a Scientific Review Administrator (SRA) at one company that is under contract to the NCI.

Single-Case Deviation

An exception to NIH policy involving a single grant or multiple grants that responded to the same request for applications.

Site Visit, Grant Applications SV

A optional part of the peer review process that involves a visit of the Scientific Review Group with the NCI Scientific Review Administrator and Program Director with an applicant (and co-applicants) at the applicant institution. An on-site review as such is used to evaluate and determine that applicants capability of performing the research proposed in the grant application. Site visit reviews are only performed for certain grant mechanisms (typically, for larger, multi-component applications, such as those for cancer center support grants and program projects).

Small Business Administration Procurement Center Representative SBA/PCR

The Small Business Administration Procurement Center Representative (SBA/PCR) is responsible for reviewing all new acquisition projects for suitability for set aside programs. The SBA/PCR also furnishes advice and guidance to all concerned parties regarding set aside programs and potential sources.

Small Business Innovation Research Fast Track

An Small Business Innovation Research (SBIR) award that allows concurrent submission and review of phase I and phase II applications to reduce a potential funding gap between the end of phase I and the start of phase II.

Subcommittee on Special Actions

The purpose of the subcommittee on special actions is to review any grant brought up for discussion by the Board for any particular reason by an NCI staff member. Staff recommendations submitted to the subcommittee are those foreign grants not meeting the priority criteria or a grant with an extraordinary situation requiring Board advice, approval, or clarification. Other grants which maybe be brought to the attention of the subcommittee are those in which a Program Director disagrees with the initial review of a grant and seeks to have it referred to a different review group, deferred for a site visit, etc., and any grant that has biohazard, animal welfare, or human subject concerns. Actions taken by the staff on each grant are presented to the subcommittee for their information.

Special Initiatives

Identifies scientific areas that require focused attention and manages and facilitates multi-Institute and trans-Institute activities to address those needs.

Special Interest Category *SIC*

Reporting categories for NCI research projects that describe the major areas of study or scientific disciplines that are of stated or growing interest to decision makers at the National Institutes of Health, the Department of Health and Human Services, Congress, or the public.

Sponsoring Institution

An organization that initiates but does not conduct a clinical study, usually a drug or device manufacturer or the research institution that developed a drug. Sponsors distribute investigational new drugs or investigational medical devices to principal investigators and ensure compliance with regulations, for example, obtaining Federal Drug Administration (FDA) approval to conduct a clinical trial and reporting results to the FDA.

Stages of Cancer

The extent of a cancer and whether the disease has spread from the original site to other parts of the body. Numbers with or without letters are used to define cancer stages (e.g., Stage IIb).

Standard Operating Procedure *SOP*

Spell out roles and actions for initiatives, grants, contracts, review, and Council activities.

Statement of Appointment Form *PHS 2271*

This form is to be used to appoint individuals as trainees to institutional Ruth L. Kirschstein-National Service Research Award (Kirschstein-NRSA) programs (e.g., T32, T34, T35) and applicable non-NRSA institutional research training programs (e.g., T15). It can also be used to document the appointment of scholars to institutional career development awards (e.g., K12) and individual participants to research education awards (e.g., R25).

Statistically Significant Difference

This term refers to the event that, for a given set of data, the statistical test for a difference between the effects in two groups achieves statistical significance. Statistical significance depends upon the amount of information in the data set. With a very large amount of information, one could find a statistically significant, but clinically small difference that is of very little clinical importance. Conversely, with less information one could find a large difference of potential importance that is not statistically significant.

Statistics

The practice or science of collecting and analyzing numerical data in large quantities.

Status of an Application

Allows Principal Investigators to review the current status of all their grant applications and review detailed information associated with their grants. Institution Officials (i.e., Signing Official (SO) or Administrative Official (AO) associated with the institution] can see a summary view of grant applications, review the Notice of Grant Award, and access the Progress Report face page.

Stewardship of Federal Funds

NIH and its recipient institutions share responsibility for compliance and oversight to ensure good stewardship of Federal funds. The relationship between NIH and its grantees is predicated on trust. Grantees are expected to properly administer sponsored activities and comply with applicable regulations and policies.

Streamlined Review

In the peer review process, applications not considered by the Scientific Review Group as high impact are "streamlined" and designated Not Discussed. Streamlined applications are not discussed at the review meeting and will not be assigned a numerical overall impact/priority score, but the applicants do receive the reviewers critiques. Streamlined applications will receive criterion scores from the assigned reviewers in addition to the reviewers critiques to help applicants assess whether or not they should submit a resubmission application.

Submission

The majority of competing applications now require electronic application submission. The Funding Opportunity Announcement (FOA) to which you are applying will identify whether you must submit electronically or use paper submission. Note that paper submissions require use of the PHS 398 application form, while electronic submission requires the SF424 (R&R) application. Make sure to read instructions in the Funding Opportunity Announcement and the application guide to determine submission requirements.

Subprojects

Part of a multi-component grant application that may include a scientific investigation, the provision of a service or resource, or a combination of activities and receives a specific review assignment and assessment (score and/or descriptor). Most commonly, subprojects are part of the P and U mechanisms.

Supplement

See Revision

Sweep/Release

The process of releasing the scores entered in Peer Review for a particular peer review meeting.

Synopsis, Acquisitions

A brief description of an intended acquisition which provides enough information necessary to allow prospective offerors to keep abreast of acquisition opportunities. The Synopsis is published in the FedBizOpp and the NIH guide, if applicable. Additionally, an Award Synopsis is done to inform interested parties on the result of an acquisition.

Substance Abuse and Mental Health Services Administration *SAMHSA*

The Substance Abuse and Mental Health Services Administration (SAMHSA) works to improve the quality and availability of substance abuse prevention, alcohol and drug addiction treatment, and mental health services.

Small Animal Imaging Resource Projects *SAIRP*

Small Animal Imaging Resource Program (SAIRP) grants support shared imaging research resources to be used by cancer investigators and support research related to small animal imaging technology.

Small Business Innovation Research *SBIR*

A program designed to support small business concerns conducting innovative research/research & development with potential for commercialization. For the computation of success rates, SBIR awards are not included in the count of RPGs. Go to [Small Business Funding Opportunities](http://grants.nih.gov/grants/funding/sbir.htm).

Special Government Employee *SGE*

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.

Special Population Networks *SPNs*

Created to disseminate accurate information to special populations, define research questions, develop research grants, and send them to the NCI/NIH and the Centers for Disease Control and Prevention (CDC) to generate more research on special populations.

Specialized Program of Research Excellence *SPORE*

Involve both basic and clinical/applied scientists and support projects that will result in new and diverse approaches to the prevention, early detection, diagnosis and treatment of human cancers.

Small Business Technology Transfer *STTR*

A program designed to support cooperative research/research & development with potential for commercialization, through a formal cooperative effort between a small business and a U.S. research institution. For the computation of success rates, STTR awards are not included in the count of RPGs. Go to <http://grants.nih.gov/grants/funding/sbir.htm> Small Business Funding Opportunities

Scientific Program Leadership, NCI SPL

Committee of the Institute includes the Director, Deputy Directors, Division Directors, and other senior scientific staff. The Scientific Program Leadership (SPL) meets on a regular basis to discuss various matters of NCI policy, including but not limited to review and approval of RFA and research and development contract concepts before review by the BSA; review of program announcements; development of funding plans; grant payment by exceptions, etc.

Supplement, Administrative

Funds added to a grant without peer review to pay for items within the scope of an award but unforeseen when a grant application was submitted.

Second Level Review

Review generally conducted by institute's Advisory Council or the National Cancer Advisory Board that results in funding recommendations to the NCI Director. Second-level review looks at program priorities and balance and a lack of barriers to funding such as unresolved human subjects issues. It does not reassess the science.

Subcommittee

Subcommittee means a group generally not subject to the FACA, that reports to an advisory committee and not directly to a Federal officer or agency, whether or not its members are drawn in whole or in part from the parent advisory committee. All subcommittee advice and/or recommendations from national advisory councils, program advisory committees, and boards of scientific counselors must be deliberated by the full committee prior to action by NIH officials unless the subcommittee has statutory authority to report directly to a Federal official.

Single Component Application

T

|A|B|C|D|E|F|G|H|I|J|K|L|M|N|O|P|Q|R|S|T|U|V|W|X|Y|Z|

Targeted Research

Research funded as a result of an institute set aside of dollars for a specific scientific area. Institutes solicit applications using research initiatives (RFAs for grants, RFPs for contracts). Targeted research applications are reviewed by chartered peer review committees within institutes. Also called "Solicited Research."

See Also Investigator-Initiated Research

Task Order

An order for services placed against an established contract or with Government sources.

Technical Evaluation Criteria (Contracts)

The technical evaluation criteria serve as the standard against which all proposals are evaluated. Prospective offerors rely upon the evaluation criteria in the solicitation in developing proposals, and must be assured that the evaluation is conducted in accordance with those criteria; therefore, the criteria must be consistent with the statement of work .

Technical Proposal Evaluation

The process used to measure a technical proposal against the technical evaluation criteria which are included in the RFP and are used for rating the proposals. NIH staff responsible for accomplishing these evaluations should ensure that reviews are performed in such a manner to provide for the most competent advice to guide official decisions on selection and award of contractors as prescribed by acquisition regulations. Evaluators should seek to avoid actual or apparent conflicts of interest, to maintain confidentiality of information, and to obtain compliance with procurement integrity requirements. (See Section VI of the Research Contracts Branch's Orange Book).

Technology Transfer

Sharing the knowledge and facilities among Federal laboratories, government, industry, universities, institutes, foundations, and others to make Federally-generated scientific and technological advances accessible to private industry and state and local governments.

Temporary Duty *TDY*

Authorized temporary assignment away from your official permanent duty station to which you will return upon completion of assignment.

Temporary Members

Individuals who serve on an NIH review committee (either a study section chartered by the Center for Scientific Review or a standing committee chartered by the review operations of an institute or center), on an ad hoc basis (i.e., on a temporary, not officially appointed, basis).

Termination for Convenience, Contracts

Government contract termination that does not hold a contractor at fault, usually done if it's in the government's best interest. Non-profits and educational entities can be terminated for convenience but not for default. (FAR 49)

Termination for Default

Government contract termination that holds a contractor at fault because the contractor has failed to make progress or comply with the provisions of the contract. This action is only appropriate in cost-plus-fixed-fee and fixed-price contracts. (FAR 49)

Terms and Conditions of Award

All legal requirements imposed on a grant or contract by NIH, whether based on statute, regulation, policy, or other document referenced in a grant or contract award, or specified in a Notice of (Grant) Award (NoA).

The NoA may include both standard and special conditions that are considered necessary to attain the grant's objectives, facilitate post award administration of the grant, conserve grant funds, or otherwise protect the Federal Government's interests.

Third-Party In-Kind Contribution

The value of non-cash contributions directly benefiting a grant-supported project or program that are provided by non-Federal third parties to the recipient, the subrecipient, or a cost-type contractor under the grant or subgrant without charge.

Total Direct Cost *TDC*

All costs associated with a project exclusive of indirect costs

Track Record

The history of accomplishment (publications, funding, etc.) of an investigator.

Traditional Research Project Grant Application or Award *R01*

An R01 award supports discrete, specified, circumscribed projects to be performed by named investigators in areas representing their specific interest(s) and competencies.

Training Awards

Awards designed to support the research training of scientists for careers in the biomedical and behavioral sciences, as well as help professional schools to establish, expand, or improve programs of continuing professional education. Training awards consist of institutional training grants (T) and individual fellowships (F).

Training Grants *T32*

T or F series grants. NIH Research Training Opportunities Web address: <http://grants.nih.gov/training/>

Transdisciplinary Sciences

These include training and career development for those disciplines that are normally regarded as outside of traditional behavioral and biomedical cancer research and/or training and career development in those areas of cancer research that will require individuals to conduct their research within highly inter-disciplinary, collaborative team settings.

Translational Research

The bridge between basic research findings and application of new treatments in the clinic. This research determines the biological basis for observations made in individuals with cancer or in populations at risk for cancer.

Travel Management Center *TMC*

A travel agency, under contract with GSA, that is responsible for making arrangements for official Government travel (currently, Omega Travel provides this service under contract to the NIH). All travel arrangements for official travel should be made through a TMC and travelers should have the 800 number for the TMC in the event a problem or emergency arises.

Treatment Group

The group that receives the new treatment being tested during a study.

Treatment Trials

Test new treatments like a new cancer drug, new approaches to surgery or radiation therapy, new combinations of treatments, or new methods such as gene therapy.

Targeted/Planned Enrollment Data

Provides race and ethnicity data for projected number of human subject participants to be enrolled in an NIH-funded clinical research study. The data is provided in competing applications and annual progress reports.

Targeted Planned/Enrollment Data

Provides race and ethnicity data for projected number of human subject participants to be enrolled in an NIH-funded clinical research study. The data is provided in competing applications and annual progress reports.

Temporary Member

A special reviewer invited to serve on a study section/SRG when NIH staff determine there is a need for additional expertise.

Total Project Costs

The total allowable costs (direct costs and facilities and administrative costs) incurred by the grantee to carry out a grant-supported project or activity. Total project costs include costs charged to the NIH grant and costs borne by the grantee to satisfy a matching or cost-sharing requirement.

Technical Evaluation Panel

A group of government and non government experts qualified by training and experience in particular scientific or technical fields who will be responsible for providing expert advice on the scientific and technical merits of contract proposals

See Scientific Review Group

Technology Transfer Branch (NCI) TTB

Technology Transfer Branch (TTB) provides a complete array of services to support the National Cancer Institute's technology development activities. To ensure that these activities comport with Federal statutes, regulations and the policies of the National Institutes of Health, a large part of TTB's responsibilities includes the day-to-day negotiations of transactional agreements between the NCI and outside parties, including universities, pharmaceutical and biotechnology companies.

Termination of Support

Permanent withdrawal by NIH of a grantee's authority to obligate previously awarded grant funds before that authority would otherwise expire, including the voluntary relinquishment of that authority by the grantee.

Termination of a Grant

Permanent withdrawal of a grantee's authority to obligate grant funds, pending either corrective action by the grantee, as specified by NIH, or a decision by the NIH to terminate the award.

Transdisciplinary Tobacco Use Research Centers *TTURC*

Facilitate a transdisciplinary approach to the full spectrum of basic and applied research on tobacco use to reduce the disease burden of tobacco use.

Treatment Investigational New Drug

Food and Drug Administration (FDA) procedure for making a investigational new drug available to patients with life threatening diseases outside of a clinical trial.

See Also Compassionate Use Investigational New Drug

Triage

The assigning of priority order to projects on the basis of where funds and other resources can be best used, are most needed, or are most likely to achieve success.

See Streamlined Review

The Cancer Genome Atlas *TCGA*

A comprehensive and coordinated effort to accelerate our understanding of the molecular basis of cancer through the application of genome analysis technologies, including large-scale genome sequencing.

Tissue Array Research Program *TARP*

The development and distribution of multitumor tissue microarray slides and related technologies to cancer research investigators.

Transdisciplinary Research on Energetics and Cancer *TREC*

A major scientific research effort studying obesity and cancer, funded by the National Cancer Institute (NCI).

Translational Research Working Group *TRWG*

Conducts a discussion with the broader cancer research community and develop recommendations about how the National Cancer Institute (NCI) can best organize its investment to further "translational research."

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U Grants

Cooperative agreements

Unacceptable Proposal

A proposal judged to contain deficiencies which are so material as to preclude any possibility of upgrading to a competitive level except through major revisions and additions which would be tantamount to the submission of another proposal.

Unallowable Cost

A cost determined to be unallowable in accordance with the applicable Federal cost principles or other terms and conditions contained in a grant or contract award.

Underrepresented Minorities

Includes supplements for high school students, undergraduate students, graduate research assistants, postdoctoral training, and minority investigators.

Underserved

Individuals or groups who lack access to health services information relative to the national average. The underserved population may include residents of rural, remote or inner-city areas; members of certain racial and ethnic groups; socioeconomically disadvantaged persons; or people with disabilities.

Uniform Resource Locator *URL*

An internet web site address

United States

The 50 states, the territories and possessions of the Federal Government, the Commonwealth of Puerto Rico, the District of Columbia, the Republic of the Marshall Islands, the Federated States of Micronesia, and the Republic of Palau.

Unobligated Balance

Funds not used by the completion of a project period. Grantees must report unobligated balances over 25 percent of total costs to the grants management specialist. For grants under expanded authorities, carryover of unobligated funds from one budget period to another within an approved project period is generally allowable without prior approval.

Unscored *UN*

A designation given by a study section indicating that it judges an application to be in the bottom half of applications. In the Center for Scientific Review peer review process, applications that are judged by a study section to be noncompetitive, that is generally in the lower half of the applications being reviewed and therefore unlikely to be funded. These applications are not given a priority score, although they are reviewed (generally only by the assigned reviewers without a full discussion in front of the assembled review panel) and applicants receive a summary statement.

Unsolicited Grant Application

A grant application that is submitted by an investigator of his or her own volition and not in response to a Request for Applications or a Program Announcement issued by an NIH Institute or Center.

Unsolicited Proposal

Written proposal submitted to an agency of the Federal government by a prospective offeror or contractor in order to obtain a contract with the government that is not in response to a formal or informal request (i.e., without prior formal or informal solicitation) from a procuring activity. (See FAR 15.602).

Unsolicited Research

Research funded as a result of an investigator's submitting a research application on his or her own, i.e., not in response to a program announcement or request for application. Also referred to as investigator-initiated research.

Underrepresented Group

Group underrepresented in biomedical research, such as people with disabilities, people from disadvantaged backgrounds, and racial and ethnic groups such as blacks or African Americans, Hispanics or Latinos, American Indians or Alaskan Natives, and Native Hawaiians and other Pacific Islanders.

Unconventional Innovations Program *UIP*

To spur development of daring technologic improvements in cancer treatment and detection in the 21st century.

V

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Virtual Meeting

In the context of the NIH/NCI peer review system, this term refers to the conduct of a review meeting with use of teleconferencing, videoconferencing, netconferencing, and/or other communication methods in order to bring together the peer reviewers and sometimes even the applicants for the discussion of one or more grant applications.

Valid Analysis

The term "valid analysis" means an unbiased assessment. Such an assessment will, on average, yield the correct estimate of the difference in outcomes between two groups of subjects. Valid analysis can and should be conducted for both small and large studies. A valid analysis does not need to have a high statistical power for detecting a stated effect. The principal requirements for ensuring a valid analysis of the question of interest are:

- allocation of study participants of both sexes/genders (males and females) and from different racial/ethnic groups to the intervention and control groups by an unbiased process such as randomization,
- unbiased evaluation of the outcome(s) of study participants, and
- use of unbiased statistical analyses and proper methods of inference to estimate and compare the intervention effects among the gender and racial/ethnic groups.

Value Added

Value-added sources provide some additional information over and above bibliographic details.

Vertebrate Animals

The Public Health Services Policy on Humane Care and Use of Laboratory Animals (PHS Policy) applies to the use of live, vertebrate animals in any activity supported by the NIH or other PHS agency. Vertebrate animals include traditional laboratory animals, farm animals, wildlife, and aquatic animals. Animal use encompasses research, teaching, or testing. Generation of custom antibodies is considered an activity involving vertebrate animals. A concise, complete description of the proposed procedures must be included in the Vertebrate Animal Section (VAS). While additional details may be included in the Research Strategy, a coherent, albeit brief, description of the proposed use of the animals must be provided within the VAS. The description must include sufficient detail to allow evaluation of the procedures. Examples of the types of procedures that may be described include blood collection, surgical procedures, administration of substances, tumor induction and post-irradiation procedures. In describing the animals, investigators must provide the following information for each species or strain: Species, Strain, Ages, Sex, and Number of animals to be used.

Veterans Administration VA

Provides patient care and federal benefits to veterans and their dependents.

Voter Matrix

Comprised of the application number, Principal Investigator name, and scores of all review members from a specified review panel. The priority scores are calculated from the reviewer vote sheets. The high, low, and average scores are calculated for each individual reviewer and for each application.

W

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Warren Grant Magnuson Clinical Center *CC or Clinical Center or Building 10*

The older part of the NIH research hospital on the main NIH campus in Bethesda, MD.

White

A person having origins in any of the original peoples of Europe, the Middle East, or North Africa. Previously, such a person was typically called a Caucasian.

Withholding of Support

A decision by NIH not to make a noncompeting continuation award within the current competitive segment.

Women-Owned Small Business Concern

A small business concern that is at least 51% owned by a woman or women who also control and operate it. "Control" in this context means exercising the power to make policy decisions. "Operate" in this context means being actively involved in the day-to-day management.

Work Copies

These are received for each application before duplicated copies arrive from the Print Shop.

World Health Organization *WHO*

The World Health Organization, the United Nations specialized agency for health, was established on 7 April 1948. WHO's objective, as set out in its Constitution, is the attainment by all peoples of the highest possible level of health. Health is defined in WHO's Constitution as a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity.

World Travel Service *WTS*

A commercial/private travel agency that provides travel reservation and ticketing services to NIH employees who are traveling on official government business.

Work Group

A review panel that reports to a parent committee. Work groups commonly review multicomponent applications such as P30s. The group's draft review report is provided to the SRG, where final merit scoring is made.

Waiver

A waiver is a written mechanism used to resolve an actual conflict of interest (COI). Also referred to as a deviation. In unusual circumstances, a deviation from established NIH policy regarding COI or appearance of COI for non-Federal reviewers, or the selection of Federal employees to serve as reviewers or the assignment of particular review responsibilities to a Federal employee, is warranted in order to facilitate the review of applications and maintain the fairness, timeliness, competitiveness, and impartiality of the review process. A request for a policy deviation (waiver) must be approved by the NIH Deputy Director for Extramural Research (DDER) in advance of the review meeting.

Withdrawal of Approval

Failure to comply with provisions of the Policy may result in restriction or withdrawal of approval of an Assurance and other actions initiated by funding agencies.

Withholding of All or Part of a Continuation Award

Withholding of support is a decision not to make a non-competing continuation award within the current competitive segment. Support may be withheld for one or more of the following reasons: adequate federal funds are not available to support project, a grantee failed to show satisfactory progress in achieving the objectives of the project, a grantee failed to meet the terms and conditions of a previous award, or for whatever reason, continued funding would not be in the best interests of the Federal government. If NIH denies (withholds) a non-competing continuation award because the grantee failed to comply with the terms and conditions of a previous award, the grantee may appeal that determination.

Women and Minorities (Inclusion as Research Subjects)

The NIH is mandated by law (NIH Revitalization Act of 1993, PL103-43) to ensure the inclusion of women and minority groups in clinical research. The goal is to ensure that individuals are included in clinical research in a manner that is appropriate to the scientific question under study.

Workgroup

Chartered Federal advisory committees may create working groups to provide recommendations, gather information, or provide assistance on a specific, limited project. They are temporary in nature. NIH working groups are generally not subject to the FACA under GSA Regulation, 41

CFR Part 102-3, Parts 102-3.25 and 102-3.35, if they meet the "subcommittee" definition provided in the current Rule.

Y

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Yellow Jacket Copies

This term refers to the yellow-jacketed folder containing the original single-sided copy of a grant application as well as any communications to the NIH that were submitted by the applicant; this folder is assembled in the Center for Scientific Review (CSR) and sent to the accepting Insitute or Center after CSR staff have receive and logged in the application.