Study Guide DHHS and National Institutes of Health

CPRA Exam Review Material/Study Guide

Dated 8/20/2025

Note this material is taken from the NIH Grants Policy Statement (GPS). The GPS is a great resource to learn about NIH grants and prepare for the CPRA Exam. This Study Guide attempts to extract the information from the GPS that may be pertinent to preparing for the exam.

Disclaimer Note: CPRA, Certified Pre-Award Research Administrator certification is copyrighted by the Research Administrators Certification Council (RACC). This guide and accompanying materials are intended to provide resources for those preparing to take the CPRA exam and for those just wanting to learn more about research administration. These materials are not endorsed by RACC. There is no guarantee that using these materials will help you pass the exam. Resources do not have any inside information on the content of the exam beyond what is available on the RACC website.

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1. Overview of DHHS & of NIH.

DHHS: U.S. Dept of Health & Human Services: DHHS has 12 operating divisions, including 9 agencies in the U.S. Public Health Service and three human services agencies. These divisions administer a wide variety of health and human services and conduct life-saving research for the nation, protecting and serving all Americans.

- NIH is one of 12 Public Health Service (PHS) Agencies within DHHS. Other PHS agencies include
- Centers for Disease Control & Prevention (CDC, which also includes NIOSH). part of the Public Health Service, protects the public health of the nation by providing leadership and direction in the prevention and control of diseases and other preventable conditions, and responding to public health emergencies
- Agency for Healthcare Research and Quality (AHRQ) The Agency for Healthcare Research and Quality's mission is to produce evidence to make health care safer, higher quality, more accessible, equitable, and affordable,
- Health Resources and Service Administration (HRSA) The Health Resources and Services Administration, part of the Public Health Service, provides health care to people who are geographically isolated, economically or medically vulnerable
- Food & Drug Administration (FDA) The Food and Drug Administration, part of the Public Health Service, ensures that food is safe, pure, and wholesome; human and animal drugs, biological products, and medical devices are safe and effective; and electronic products that emit radiation are safe

- Centers for Medicare and Medicaid Services (CMS) The Centers for Medicare & Medicaid Services combines the oversight of the Medicare program, the federal portion of the Medicaid program and State Children's Health Insurance Program, the Health Insurance Marketplace, and related quality assurance activities
- ARPA-H advances high-potential, high-impact biomedical and health research that cannot be readily accomplished through traditional research or commercial activity
  - ☐ Independent component of HHS within NIH, but not an Institute.
  - ☐ ARPA-H Director reports directly to HHS Secretary
  - ☐ Not grant-based; focus on Cooperative agreements, OTAs, contracts
  - ☐ High Risk/High Impact Research

National Institutes of Health (NIH)

NIH is the nation's medical research agency — making important discoveries that improve health and save lives. NIH is made up of **27 Institutes and Centers**, each with a specific research agenda, often focusing on particular diseases or body systems. Only 24 of the 27 Institutes and Centers actually award grants. NIH leadership plays an active role in shaping the agency's activities and outlook.

Originally, all of the National Institutes of Health (NIH) research was intramural, that is, performed in federal research facilities. The Intramural Research Program (IRP) is the internal research program of the National Institutes of Health (NIH). With 1,200 Principal Investigators and more than 4,000 Postdoctoral Fellows conducting basic, translational, and clinical research, the IRP is the largest biomedical research institution on earth. More than 50 buildings on NIH campuses are devoted to the research enterprise. The 240-bed research hospital is devoted to clinical research protocols. Now most of the NIH budget goes to support Extramural research.

NIH : 27 Institutes & Centers + OD - Each awarding Institute/Center (IC) has its own mission and priorities, budget and funding mechanisms **(http://www.nih.gov/icd/)**

- OD - NIH Office of the Director - The central office at NIH responsible for setting policy and planning, managing, and coordinating NIH programs and activities.
- CC - NIH Clinical Center — Est. in 1953 The NIH Clinical Center, America's research hospital, provides a versatile clinical research environment enabling the NIH mission to improve human health by investigating the pathogenesis of disease; conducting first-in-human clinical trials with an emphasis on rare diseases and diseases of high public health impact; developing state-of-the-art diagnostic, preventive, and therapeutic interventions; training the current and next generations of clinical researchers; and, ensuring that clinical research is ethical, efficient, and of high scientific quality.

- CIT - Center for Information Technology — Est. in 1964 focusing on three primary activities: conducting computational biosciences research, developing computer systems, and providing computer facilities.
- CSR - Center for Scientific Review - The Center for Scientific Review (CSR) is the portal for NIH grant applications and their review for scientific merit. CSR organizes the peer review groups or study sections that evaluate the majority (70%) of the research grant applications sent to NIH. CSR also receives all grant applications for NIH, as well as for some other components of the U.S. Department of Health and Human Services (DHHS) Since 1946, the CSR mission has remained clear and timely: to see that NIH grant applications receive fair, independent, expert, and timely reviews — free from inappropriate influences — so NIH can fund the most promising research.
- FIC - Fogarty International Center — Est. in 1968 FIC promotes and supports scientific research and training internationally to reduce disparities in global health.
- NCATS - National Center for Advancing translational Sciences — Est. in 2011 The mission of NCATS is to catalyze the generation of innovative methods and technologies that will enhance the development, testing, and implementation of diagnostics and therapeutics across a wide range of human diseases and conditions
- NCCIH - National Center for Complementary & Integrative Health — Est. in 1999 Their mission is to define, the usefulness and safety of complementary and integrative health interventions
- NCI - National Cancer Institute – Est.. 1939 NCI leads a national effort to eliminate the suffering and death due to cancer
- NEI - National Eye Institute - Est. 1968 Conducts research on blinding eye diseases, visual disorders, mechanisms of visual function, preservation of sight, and the special health problems and requirements of the blind.
- NHLBI - National Heart, Lung and Blood Institute — Est. 1948 provides research, training, and education program to promote the prevention and treatment of heart, lung, and blood diseases
- NHGRI - National Human Genome Research Institute Est.1989 led NIH's contribution to the Human Genome Project, which was successfully completed in 2003
- NIA - National Institute on Aging - Est.1974 research on the biomedical, social, and behavioral aspects of the aging process; the prevention of age-related diseases and disabilities
- NIAAA - National Institute on Alcohol Abuse & Alcoholism - Est. 1974 research focused on improving the treatment and prevention of alcoholism and alcohol-related problems
- NIAID - National Institute of Allergy and Infectious Diseases — Est. 1948
  NIAID research strives to understand, treat, and ultimately prevent the infectious, immunologic, and allergic diseases that threaten millions of human lives.
- NIAMS - National Institute of Arthritis & Musculoskeletal & Skin Diseases — Est. 1986
  NIAMS supports research into the causes, treatment, and prevention of arthritis and musculoskeletal and skin diseases,

- NIBIB - National Institute of Biomedical Imaging & Bioengineering — Est. 2000 the mission is to improve health by leading the development and accelerating the application of biomedical technologies. Integrating the physical and engineering sciences with the life sciences to advance basic research and medical care.
- NICHD - National Institute of Child Health & Human Development Est. 1962 NICHD research on fertility, pregnancy, growth, development, and medical rehabilitation
- NIDA - National Institute on Drug Abuse — Est. 1974 advances science on the causes and consequences of drug use and addiction
- NIDCD - National Institute on Deafness & Other Communication Disorders — Est. 1988 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
- NIDCR - National Institute of Dental & Craniofacial Research — Est. 1948
  NIDCR provides leadership for a national research program designed to understand, treat, and ultimately prevent the infectious and inherited craniofacial-oral-dental diseases
- NIDDK - National Institute of Diabetes & Digestive & Kidney Diseases — Est. 1950 conducts and supports research, training and dissemination of science-based information on diabetes and other endocrine and metabolic diseases; digestive diseases, nutritional disorders, and obesity; and kidney, urologic, and hematologic diseases
- NIEHS - National Institute of Environmental Health Sciences — Est. 1969 The mission of the National Institute of Environmental Health Sciences is to discover how the environment affects people in order to promote healthier lives.
- NIGMS - National Institute of General Medical Sciences — Est. 1962 supports basic research that increases understanding of biological processes and lays the foundation for advances in disease diagnosis, treatment and prevention. Investigates how living systems work at a range of levels, from molecules and cells to tissues, whole organisms and populations.
- NIMH - National Institute of Mental Health — Est. 1949 dedicated to understanding, treating, and preventing mental illnesses through basic research on the brain and behavior, and through clinical, epidemiological, and services research.
- NIMHD - National Institute on Minority Health & Health Disparities
- NINDS - National Institute of Neurological Disorders & Stroke — Est. 1950 seeks fundamental knowledge about the brain and nervous system and to use that knowledge to reduce the burden of neurological disease.
- NINR - National Institute of Nursing Research — Est. 1986 supports and conducts clinical and basic research and research training on health and illness across the lifespan to build the scientific foundation for clinical practice, prevent disease and disability, manage and eliminate symptoms caused by illness, and improve palliative and end-of-life care.
- NLM - National Library of Medicine — Est. 1956 NLM collects, organizes, and makes available biomedical science information to scientists, health professionals, and the public. The Library's

Web-based databases, include PubMed/Medline and MedlinePlus. The world's largest biomedical library, NLM maintains and makes available a vast print collection and produces electronic information resources on a wide range of topics.

PubMed comprises more than 26 million citations for biomedical literature from MEDLINE, life science journals, and online books. Requirement to submit to PubMed no later than twelve months after journal publication.

Per the *NIH Public Access Policy - The Director of the National Institutes of Health ("NIH") shall require in the current fiscal year and thereafter that all investigators funded by the NIH submit or have submitted for them to the National Library of Medicine's PubMed Central an electronic version of their final, peer-reviewed manuscripts upon acceptance for publication, to be made publicly available no later than 12 months after the official date of publication.*.

Applies to any manuscript that:

- Is peer-reviewed and
- is accepted for publication in a journal

And, arises from

- Any direct funding[4] from an NIH grant or cooperative agreement in FY 2008 or beyond or
- Any direct funding from the NIH Intramural Program
- An NIH employee

ClinicalTrials.gov is a registry and results database of publicly and privately supported clinical studies of human participants conducted around the world

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Question: How many ICs fund grants for sponsored (extramural) research?

Answer -24 + Office of the Director

Those that do not fund extramural research:

- ☐ Center for Scientific Review (CSR),
- ☐ Center for Information Technology (CIT);
- ☐ Clinical Center (can fund intramural research).

The Office of the Director funds its grants (meaning they are administered) through one of the 24 awarding institutes.

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Research Portfolio Online Reporting Tools (RePORT) In addition to carrying out its scientific mission, the NIH exemplifies and promotes the highest level of public accountability. To that end, the Research Portfolio Online Reporting Tools provides access to reports, data, and analyses of NIH research activities, including information on NIH expenditures and the results of NIH supported research. Available information:

- ☐ Federal Obligations for Health Research and Development: Obligations, by federal agency
- ☐ Grants: Competing applications, awards, success rates, and total funding, by IC, mechanism, activity code, and funding source
- ☐ NIH Success Rate Definition
- ☐ Funded Organizations
- ☐ Workforce

Federal RePORTER allows the public to search for funding information from several research funders, including NIH, USDA, NSF, NASA, EPA, HHS, DOD, VA, and more.

World RePORT is a new system that highlights world biomedical research from several major funders, and includes information on collaborations.

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The IC Extramural Team:

- **Program Official/Officer (PO**) - The NIH official responsible for the programmatic, scientific, and/or technical aspects of a grant. This person is your point of contact before you submit an application and after your application is reviewed, including funding decisions. A PO has a portfolio of grants, and has input on which applications ultimately receive funding. The PO is an applicant's point of contact for questions about:

  - appropriate topics for an application
  - programmatic interest in funding specific research
  - activity codes and mechanisms for funding (see below)
  - your score and summary statement from an application that has undergone peer review

- **Scientific Review Officer (SRO)**, formerly **Scientific Review Administrator** (SRA), is the Designated Federal Official for peer review meetings at the NIH. The SRO is the applicant's point of contact from the time you submit your application until the time of the review meeting. You can address review-related questions or concerns to your SRO, including:

  - completeness of your application and allowable post-submission materials
  - roster of attendees for the meeting at which your application will be reviewed
  - general questions about the review process and timeline

  The Scientific Review Officer (SRO) works in partnership with the scientific community to ensure that the scientific review group (study section) identifies the most meritorious science for funding by the Institutes and Centers. Identifying and Recruiting Reviewers: Possibly the most important role of the SRO is to ensure that the reviewers present at the study section meeting have all the needed expertise to evaluate the applications under review. The study section

cannot legally be held without the presence of the SRO, who is the official government representative.

- **Chief Grants Management Officer (CGMO)** - The Grants Management Officer within an awarding agency who is the principal Grants Officer in the agency.
- **Grants Management Officer (GMO)** - An NIH official responsible for the business management aspects of grants and cooperative agreements, including review, negotiation, award, and administration, and for the interpretation of grants administration policies and provisions. GMOs are delegated the authority from the CGMO to obligate NIH to the expenditure of funds and permit changes to approved projects on behalf of NIH. Each NIH IC that awards grants has one or more GMOs with responsibility for particular programs or awards
- **Grants Management Specialist (GMS)** - An NIH staff member who oversees the day-to-dayfiscal and administrative aspects of a portfolio grants and/or cooperative agreements. These activities include, but are not limited to, evaluating grant applications for administrative content and compliance with statutes, regulations, and guidelines; negotiating grants; providing consultation and technical assistance to recipients; and administering grants after award
- **Contracts Officer (CO) and Contracts Specialist (CS)** same as GMO and GMS but for contracts.

NIH Offices/Resources

- **NIH Grants Policy Statement (NIHGPS)** - The NIH Grants Policy Statement (NIHGPS) makes available, in a single document, the policy requirements that serve as the terms and conditions of NIH grant awards. https://grants.nih.gov/policy/nihgps/index.htm
- **NIH Guide for Grants and Contracts** - Policy notices published in the NIH Guide for Grants and Contracts supersede information in the NIH Grants Policy Statement. Compliance with these policy updates is a term and condition of award. NIH incorporates these notices into the annual update of the NIH Grants Policy Statement. The NIH Guide for Grants and Contracts is the official publication for **NIH grant policies, guidelines and funding opportunities**. It is published daily and issues a table of contents weekly.
- **Office of Extramural Research (OER)** - OER - provides the leadership, oversight, tools and guidance needed to administer and manage NIH grants policies and operations.
    - ☐ **Office of Laboratory Animal Welfare (OLAW)** - provides guidance and interpretation of the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals (Policy), supports educational programs, and monitors compliance with the Policy by Assured institutions
    - ☐ **Office of Policy for Extramural Research Administration (OPERA)** - OPERA - provides leadership and oversight in grants management policy and compliance, intellectual property, and OMB clearances to the extramural research community and NIH extramural staff through policy development, expert guidance, analysis, outreach, and related information dissemination in order to promote effective stewardship of NIH

extramural funds in support of health research. Responsible for the **NIH Grants Policy Statement.**

- ☐ **Office of Extramural Programs (OEP)** responsible for the **NIH Guide**.

DHHS/NIH Offices

- **HHS Office of Research Integrity (ORI)** - The HHS Office of Research Integrity (ORI) has responsibility for addressing research integrity and misconduct, monitors institutional investigations of research misconduct and facilitates the responsible conduct of research through education, preventive, and regulatory activities
- **Office for Human Research Protections (OHRP)** - OHRP has regulatory responsibility for oversight of recipient compliance with the HHS Human Subjects regulations.

Types of FOA's

- ☐ Funding Opportunity Announcement (FOA) Government-wide funding opportunity announcement - A publicly available document by which the NIH 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.
- ☐ Program Announcement (PA): IC request in a particular scientific area - Program Announcement (PA): is a formal statement about a new or ongoing extramural activity or program. It may serve as a reminder of continuing interest in a research area, describe modification in an activity or program, and/or invite applications for grant support
- ☐ Request for Application (RFA): Official invitation for applications - An RFA is a formal statement that solicits grant or cooperative agreement applications in a well-defined scientific area to accomplish specific program objectives. An RFA indicates the estimated amount of funds set aside for the competition, the estimated number of awards to be made, whether cost sharing is required, and the application submission date(s). Typically RFAs have a single deadline
- ☐ Parent Announcement: For "unsolicited" applications which do not fall within the scope of targeted announcements - open for 3 years. - Parent announcements are broad funding opportunity announcements allowing applicants to submit investigator-initiated applications for specific activity codes. They are open for up to 3 years and use standard due dates. Not all NIH Institutes and Centers participate on all parent announcements.

- All NIH FOAs are published in the *NIH Guide for Grants and Contracts. They are referred to as Notice of Funding Opportunity (NOFO). Notice of Special Interest (NOSIs) that outline an funding*

interest for one or more ICs and point to a Parent Announcement or Program Announcement for actual submission are also published the *Guide*.

2. Types of NIH Funding

Research Grants (R series) R01, R03, R15, R21, R25, R56

Career Development Awards (K series) K01

Research Training & fellowship (T&F series) T32, T35, F31

Program Project /Center Grants (P series) P01, P20, P30

Cooperative Agreements (U series) U01

Small Business Grants (R41,R42,R43,R44)

Description of Various Funding Mechanisms

- **NIH Research Project Grant Program (R01)**
  - ☐ Used to support a discrete, specified, circumscribed research project
  - ☐ NIH's most commonly used grant program
  - ☐ No specific dollar limit unless specified in FOA
  - ☐ **Advance permission required for $500K or more (direct costs) in any year**. Any applicant requesting $500,000 or more in direct costs (excluding consortium F&A costs) in any one budget period is required to contact the IC PO, in writing or by telephone, as early as possible during development of the application but no later than 6 weeks before submission for prior approval. This requirement applies to a single grant application, whether a new, renewal, revision, or resubmission application, under any NIH support mechanism; This policy does not apply to applications submitted in response to RFAs or to other announcements that include specific budgetary limits. The PD/PI must include a cover letter with the application identifying the PO contacted and the IC that has agreed to accept assignment of the application
  - ☐ Generally awarded for 3 -5 years; may be renewed
  - ☐ In a given year most, but not all ICs use

- **NIH Small Grant Program (R03)**
  - ☐ Provides limited funding for a short period of time to support a variety of types of projects, including: pilot or feasibility studies, collection of preliminary data, secondary

analysis of existing data, small, self-contained research projects, development of new research technology, etc.

- ☐ Limited to two years of funding
- ☐ Direct costs up to $50,000 per year
- ☐ Not renewable
- ☐ Utilized by more than half of the NIH ICs

- **NIH Support for Conferences and Scientific Meetings (R13 and U13)**
  - ☐ Support for high quality conferences/scientific meetings that are relevant to NIH's scientific mission and to the public health
  - ☐ Requires advance permission from the funding IC; not all ICs award
  - ☐ Foreign institutions are not eligible to apply
  - ☐ Award amounts vary and limits are set by individual ICs
  - ☐ Support for up to 5 years may be possible

- **NIH Academic Research Enhancement Award (AREA) (R15)**
  - ☐ Support small research projects in the biomedical and behavioral sciences conducted by students and faculty in health professional schools and other academic components that have not been major recipients of NIH research grant funds
  - ☐ Eligibility limited (see http://grants.nih.gov/grants/funding/area.htm)
  - ☐ Direct cost limited to $300,000 over entire project period
  - ☐ Project period limited to up to 3 years; may be renewed
  - ☐ Most, but not all, ICs utilize

- **NIH Exploratory/Developmental Research Grant Award (R21, R33)**
  - ☐ Encourages new, exploratory and developmental research projects by providing support for the early stages of project development. Sometimes used for pilot and feasibility studies.
  - ☐ R21 Limited to up to two years of funding.

- ☐ Combined budget for direct costs for the two year project period usually may not exceed $275,000.
- ☐ When included as an option R33 provides a 2nd phase of support (up to three year) for the research initiated under a R21.
- ☐ Most ICs utilize.

- **SBIR and STTR Programs**

The Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs, also known as America's Seed Fund, are one of the largest sources of early-stage capital for technology commercialization in the United States. These programs allow US-owned and operated small businesses to engage in federal research and development that has a strong potential for commercialization

The NIH SBIR program funds early stage small businesses that are seeking to commercialize innovative biomedical technologies. This competitive program helps small businesses participate in federal research and development, develop life-saving technologies, and create jobs.

The NIH STTR program is similar to the NIH SBIR program, but requires that the small business formally collaborate with a research institution in Phase I and Phase II. Under SBIR, the research institution can complete up to 33 percent of the total effort for a Phase I, and up to 50 percent of the total effort for Phase II. Under STTR, the small business must perform at least 40 percent of the work and the research institution must perform at least 30 percent. The remaining 30 percent may be with the small business concern, the collaborating non-profit research institution, or additional third party/parties.

Small Business Technology Transfer (STTR) (R41/R42) Structure

- ☐ Three-phase structure
  - I - Feasibility study to establish scientific/technical merit of the proposed R/R&D efforts (generally, 6 months to 2 years; 2023 guideline up to $306,872 direct costs)
  - II - Full R/R&D efforts initiated in Phase I (generally 1 to 3 years; 2023 guideline up to $2,045,816)
  - III- Commercialization stage (cannot use STTR funds)
- ☐ Eligibility limited to U.S. small business concerns
- ☐ Requires that the small business formally collaborate with a single non-profit research institution in Phase I and Phase II.

- ☐ Project Director/Principal investigator (PD/PI) may be employed with the SBC *or* the participating non-profit research institution as long as he/she has a formal appointment with or commitment to the applicant SBC. The PD/PI must devote at least 10% effort.
- ☐ Multiple PD/PIs allowed
- ☐ All ICs utilize except FIC

☐ **Small Business Innovative Research (SBIR) (R43/R44) Structure**

- ☐ Three-phase structure
  - I - Feasibility study to establish scientific/technical merit of the proposed R/R&D efforts (generally, 6 months to 2 years; 2023 guideline up to $308,872 direct costs)
  - II - Full R/R&D efforts initiated in Phase I (generally 1 to 3 years; in 2023 up to $2,045,816 direct costs)
  - III- Commercialization stage (cannot use STTR funds)
- ☐ Eligibility limited to U.S. small business concerns
- ☐ The primary employment (>50%) of the Project Director/Principal investigator (PD/PI) must be with the small business concern.
- ☐ Multiple PD/PIs allowed.
- ☐ All ICs utilize except FIC

☐ **NIH High Priority, Short-Term Project Award (R56)**

- ☐ Will fund, for one or two years, high-priority new or competing renewal R01 applications with priority scores or percentiles that fall just outside the funding limits of participating NIH Institutes and Centers (IC). Investigators may not apply for R56 grants.

☐ **K01 is most common early career award**

- ☐ The purpose of this program is to provide support and protected time for an intensive, supervised career development experience in the biomedical, behavioral, or clinical sciences leading to research independence. Some NIH Institutes use the K01 to enhance workforce diversity, or for individuals who propose to train in a new field, or for individuals who have had a hiatus in their research career.Individual must be a U.S. citizen or non-citizen national.

☐ **K99/R00: Pathway to Independence (PI) Award**

- ☐ Provides up to five years of support consisting of two phases
- ☐ I - will provide 1-2 years of mentored support for highly promising, postdoctoral research scientists
- ☐ II - up to 3 years of independent support contingent on securing an independent research position
- ☐ Award recipients will be expected to compete successfully for independent R01 support from the NIH during the career transition award period
- ☐ Foreign institutions are not eligible to apply
- ☐ For K99/R00: PI can be a non-U.S. citizen.

- **Ruth L. Kirsch stein National Research Service Awards for Individual Fellowships (F series) and Training Grants (T series)**
  - ☐ F31 to enable promising predoctoral students with potential to develop into a productive, independent research scientists, to obtain mentored research training while conducting dissertation research.
  - ☐ T32 to enable institutions to recruit individuals selected by them for predoctoral and postdoctoral research training in specified shortage areas. The goal of this program is to prepare qualified predoctoral and/or postdoctoral trainees for careers that have a significant impact on the health-related research needs of the Nation. U.S. citizens or permanent residents enrolled in a research or clinical doctoral or postdoctoral program.
  - ☐ Stipends are determined each year by NIH
  - ☐ For K and T grants: F&A is limited to 8%
  - ☐ For F grants: Institutional Allowance (no F&A)
  - ☐ The individual to be trained must be a citizen or a noncitizen national of the United States or have been lawfully admitted for permanent residence by the time of award. Noncitizen nationals are individuals, who, although not citizens of the United States, owe permanent allegiance to the United States

- **Research Project Cooperative Agreement (U01)**
  - ☐ Supports discrete, specified, circumscribed projects to be performed by investigator(s) in an area representing their specific interests and competencies
  - ☐ Used when substantial programmatic involvement is anticipated between the awarding Institute and Center
  - ☐ Award-specific terms and conditions outlined in the FOA

- ☐ One of many types of cooperative agreements
- ☐ No specific dollar limit unless specified in FOA

■ **Research Program Project and Centers Grant (P01)**

- ☐ Support for integrated, multi-project research projects involving a number of independent investigators who share knowledge and common resources
- ☐ Each project contributes or is directly related to the common theme of the total research effort, thus forming a system of research activities and projects directed toward a well-defined research program goal
- ☐ No specific dollar limit unless specified in FOA

■ **Exploratory Grants (P20)**

- ☐ Often used to support planning activities associated with large multi-project program project grants. Always announced in an RFA

■ **Center Core Grants (P30)**

- ☐ To support shared resources and facilities for categorical research by a number of investigators from different disciplines who provide a multidisciplinary approach to a joint research effort or from the same discipline who focus on a common research problem. Always announced in an RFA
- ☐ The core grant is integrated with the center's component projects or program projects, though funded independently from them.

■ **Specialized Center (P50)**

- ☐ To support any part of the full range of research and development from very basic to clinical. Always announced in an RFA
- ☐ 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.
- ☐ Receive continuous attention from staff funding IC.
- ☐ Centers may serve as regional or national resources for special research purposes.

Clinical Trials

- A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.
- See http://grants.nih.gov/grants/glossary.htm#ClinicalTrial
- Biomedical clinical trials of an experimental drug, treatment, device, or behavioral intervention may proceed through four phases:

Clinical Trials Phases

- **Phase I:** First-time test of a new intervention in a small group (usually 20-80 persons) to determine safety. Often healthy volunteers.
- **Phase II:** Study intervention in a larger group (several hundred persons) to determine efficacy.
- **Phase III:** Study the intervention in large groups (several hundred to several thousand persons), by comparing the intervention to other standard or controlled experimental interventions.
- **NIH-Defined Phase III:** Aim is to provide scientific evidence that would support a change in health policy or standard of care.
- **Phase IV:** Study conducted after an intervention has been marketed, to monitor effectiveness and adverse effects in the general population.

Certain Clinical Trials funded by NIH are subject to the **FDAAA (Food and Drug Administration Amendments Act of 2007**) http://grants.nih.gov/ClinicalTrials_fdaaa/

- ☐ Registering the clinical trial in ClinicalTrials.gov,
- ☐ Certifications,
- ☐ Enrollment of the Human Subjects
- ☐ Reporting the data (including after the period of performance has ended)

Implementing the FDAAA Requirements: http://grants.nih.gov/ClinicalTrials_fdaaa/steps.htm

ClinicalTrials.gov

- ☐ Requires all clinical trials funded in whole or in part through NIH extramural and intramural programs to register in ClinicalTrials.gov
- ☐ Applies to all clinical trials even those that are not considered “Applicable Clinical Trials” under the FDAA.

- ■ Including behavioral interventions
- ■ Including all clinical trial phases (phase 1)

☐ Required to submit a plan for dissemination of NIH-funded clinical trial information that will address how expectations of this policy will be met as part of the application or proposal.

3. Pre-Award

New and Early Stage Investigators

- ■ ***New Investigator.*** PD/PI is considered a New Investigator if they have not previously competed successfully as PD/PI for a substantial independent research award. For example, a PD/PI who has previously received a competing NIH R01 research grant is no longer considered a New Investigator. An investigator who previously received an R03 is still considered a New Investigator
- ■ ***Early Stage Investigator (ESI).*** An ESI is a New Investigator who is within 10 years of completing his/her terminal research degree or is within 10 years of completing medical residency (or the equivalent).
- ■ The NIH intends to support New Investigators at success rates comparable to those for established investigators submitting new application for R01 support. NIH New Investigator policies are limited to applications for traditional research project grant (R01) support.
- ■ To determine New Investigator and Early Stage Investigator status, NIH relies on the data entered by the individual in their eRA Commons Profile, therefore it is important that PD/PIs verify the accuracy of their personal profiles. Particularly key for ESIs are the terminal research degree and end date of residency data fields.

Submitting an application to NIH

eRA Commons

- ■ is an online interface where grant applicants, recipients and agency staff are able to conduct their research business.
- ■ applicants use Grants.gov to apply for grants; the eRA Commons retrieves the application or proposal information from Grants.gov
- ■ Following application submission, the eRA Commons becomes the primary site for accessing grant information

While applicants must Grants.gov to apply for NIH grants, the eRA Commons retrieves the application or proposal information from Grants.gov, compiles it into a consistent application format and then makes it available to applicants and NIH staff for electronic research administration purposes. Following application submission, the eRA Commons becomes the primary site for

accessing grant information such as Institute/Center assignments, review outcomes, Summary Statements, and Notices of Award. The eRA Commons also provides electronic business processes such as Internet Assisted Review, submission of Just-In-Time material, submission of electronic SNAP progress reports (eSNAP), submission of Financial Reports (FSRs/FFRs), submission of notification of extensions without funds, and sub-mission of Closeout documents

Submission System & Interface for Submission Tracking (ASSIST)

NIH's ASSIST System is used for the electronic preparation and submission of applications through Grants.gov to NIH. ASSIST provides many features to improve data quality, including: pre-population of organization and PD/PI data, pre- submission validation of many agency business rules and the generation of data summaries in the application image used for review.

Advantages of using ASSIST / Key features of ASSIST

- Allows Collaboration of multiple users
- Personnel data is pre-populated from eRA Commons user profiles
- Validates Grants.gov and NIH business rules before submission
- Provides preview of entire NIH application image before submission
- Generates table of contents, headers & footers
- Tracks Grants.gov and eRA Commons submission status

Required Forms for Competing Applications

The SF424 (R&R) form set, combined with PHS 398 components, is used for electronic sub-mission.

- ☐ SF424 (R&R) Form (cover form)
- ☐ Project/Performance Site Location(s)
- ☐ Research and Related Other Project Information
- ☐ Research and Related Senior/Key Person Profile
- ☐ Research & Related OR Modular Budget
- ☐ R & R Subaward Budget Attachment(s) Form
- ☐ PHS 398 Cover Page Supplement
- ☐ PHS 398 Research Plan or Training Program Plan
- ☐ PHS 398 Checklist
- ☐ PHS 398 Cover Letter
- ☐ PHS 398 Planned Enrollment Form, Inclusion Enrollment Report
- ☐ PHS Career Development Award Supplemental Form

Financial Conflict of Interest

CFR 42 Part 50 (2011 Final Rule, NOT-OD-11-109) requires that each institution maintain an appropriate written policy on conflict of interest that complies with the subpart and informs each investigator of that policy and their reporting responsibilities (this is how an institution signifies compliance with this regulation).

The Institution must require each Investigator to disclose their (and their spouse and dependent children) domestic and foreign SFIs that are related to their Institutional responsibilities to the Institution's designated official(s).

Investigators must disclose all foreign financial interests (which includes income from seminars, lectures, or teaching engagements, income from service on advisory committees or review panels, and reimbursed or sponsored travel) received from any foreign entity, including foreign Institutions of higher education and foreign governments (which includes local, provincial, or equivalent governments of another country) when such income meets the threshold for disclosure (e.g., income in excess of $5,000). Institutions are strongly encouraged to review their FCOI policy and make any necessary changes to ensure Investigators fully understand their disclosure responsibilities.

The Institution must enter into a formal written agreement, signed and agreed to by the recipient and each consortium participant and/or subrecipient. The agreement must establish whether the FCOI policy of the recipient Institution or that of the subrecipient will apply to subrecipient Investigators and in either case, the agreement must include required significant financial interest disclosure, review, and FCOI reporting timelines to ensure compliance with the FCOI regulations.

- ☐ All FCOI must be disclosed before a PHS proposal can be submitted (sub recipients, consultants, and collaborators must disclose, as well).
- ☐ Prior to expenditure of any NIH funds under a new award (supplemental, or incremental funding, too), an institution must report to NIH the existence of any conflicting financial interest and assure that the interest has been managed, reduced or eliminated in accordance with the regulations.
- ☐ Conflict must be reported within 60 days of identification
- ☐ Institutional FCOI Officer submits an FCOI report via eRA Commons
- ☐ All investigators on the PI's project team must complete Conflict of Interest training prior to conducting any research with NIH funds (including new team members added during project period).
- ■ "Investigator means the project director/principal investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research (Co-PIs, post docs, graduate students, etc.)
- ■ Consultants may or may not qualify as "investigators" depending on their role.
- ■ Service providers are not considered "investigators."

Definitions/Terminology

- **Project period** - The total time for which Federal support of a project has been programmatically approved as shown in the Notice of Award (NoA), however, it does not constitute a commitment by the Federal government to fund the entire period.
- **Budget** - The financial plan for the project or program
- **Budget period** - The intervals of time (usually 12 months each) into which a project period is divided
- **Carryover** - Unobligated Federal funds remaining at the end of any budget period that, with the approval of the GMO or under an automatic authority, may be carried forward to another budget period
- **Payment Management System** - HHS centralized grants payment system operated by the Payment Management Service

Developing the NIH Budget

- The Institution's Authorized Organizational Representative (AOR) or Designee must approve all budgets submitted to the NIH.
- Two main types of NIH budgets
  - ☐ R&R Detailed Budget
  - ☐ Modular Budget

Think of your budget as the financial expression of your Research Plan: what resources will you need to carry out your Plan?

Modular Budget Format

- The program announcement or funding mechanism may allow the budgets to be submitted in the modular budget format.
- Modular budgets are for proposals under $250,000 (direct costs) per year, excluding subcontract F&A.
- The direct costs in each year must be in increments of $25,000. F&A costs for subcontracts are not included in determining the direct cost modular amount or the total cost amount requested.
- Modular budget form requires only bottom line total direct and indirect and does not require detailed category information.
- Requires Budget Justification showing details about what the personnel are doing on the project.

- Additional budget justifications are required for the following:
  - ☐ If total direct costs increase or decrease from year to year
  - ☐ A consortium justification for all subcontractors in the budget

Budget with Subcontract as you see it internally

Subtotal of your Institution's direct costs	=	$85,000
Subcontractor's direct costs	=	$15,000
Subcontractor's indirect costs	=	$2,500
= Your Total Direct Costs	=	$102,500
+ Your Institution's indirect costs	=	$54,129
= Your Total Costs	=	$156,629

Budget with Subcontract as shown on Modular Budget Form

Your Institution's share of direct costs	=	$85,000
Subcontractor's share of direct costs	=	$15,000
Total Direct Costs less Consortium F&A	=	$100,000
Your Institution's indirect costs	=	$54,129
Subcontractor's indirect costs	=	$2,500
Total Indirect Costs	=	$56,629
Total Costs (Total Funds Requested)	=	$156,629

Consortiums

Consortium agreement - A formalized agreement whereby a research project is carried out by the recipient and one or more other organizations that are separate legal entities. These agreements typically involve a specific level of effort from the consortium organization's PD/PI and a categorical breakdown of costs, such as personnel, supplies, and other allowable expenses, including F&A costs. The relationship between the recipient and the collaborating organizations is considered a subaward relationship.

Applicants are expected to detail their proposed collaborations as part of the grant application. If the application is approved as submitted, no further approval is required unless, during performance, the recipient plans to undertake additional or alternative collaborations that would constitute a change in the scope of the approved project

The following information must be provided to NIH as part of a competing application that proposes consortium arrangements:

- Include all proposed performance sites; those of the applicant organization and the consortium participant(s); and
- Non-modular grant applications must include complete detailed budgets for each consortium participant. Modular grant applications must include an estimate of consortium total costs (direct costs plus F&A costs) each year as part of the budget narrative justification

The signature (or electronic equivalent) of the AOR/SO on the application signifies that the applicant organization and all proposed consortium participants understand and agree with the following statement:

"The appropriate programmatic and administrative personnel of each organization involved in this grant application are aware of the NIH consortium agreement policy and are prepared to establish the necessary inter-organizational agreement(s) consistent with that policy."

- Parties must choose a lead institution and all others will be subcontracts
- All subcontractors will need to attach their budgets in the lead institution application (unless using modular format)
- NIH does not include consortium indirect costs in the lead institution's direct costs

Salary Cap

- Currently set by Congress at **$221,900** (as of January 29, 2024) set at the Federal Executive Level II salary cap, which changes almost every year. The following calculation example uses the FY23 salary cap of $212,100.
- The percentage of effort charged on NIH salary cap cannot be based on a salary more than the cap.
- All salary percentages above the cap must be shown as internal cost share – this is not reported to NIH
- NOT-OD-23-056 provides example calculations

NOT-OD-23-056: Guidance on Salary Limitation for Grants and Cooperative Agreements FY 2023 (nih.gov)

The following are examples of Salary Application Requests, Salary Cap Calculations and Adjustments:

For all examples:

- the Institutional Full-Time base salary (FTS) is $240,000
- the requested Fringe Benefits rate is 25% of the direct salary
- the (F&A) indirect cost rate is 45%
- the salary cap for grant awards/contracts issued on or after January 1, 2023, is $212,100

- ***Example 1. Individual with Full-Time Appointment***
- **Research effort requested in application/proposal – 12 months (50% effort)**

a.	Individual's institutional base salary for a FULL-TIME calendar year appointment	$ 240,000.00	*(FTS)*
b.	Direct Salary with research effort (50%)	$ 120,000.00	*(a x .50)*
c.	Fringe Benefits requested at 25% of salary	$ 30,000.00	*(b x .25)*
d.	SUBTOTAL	$ 150,000.00	*(b + c)*
e.	Requested F&A (indirect) costs at 45% of subtotal	$ 67,500.00	*(d x .45)*
f.	Total amount to be requested	$ 217,500.00	*(d + e)*

The salary cap for the above individual will be calculated as follows:

g.	Salary Cap – FY 2023	$ 212,100.00	
h.	Salary Cap with research effort (50%)	$ 106,050.00	*(g x .50)*
i.	Fringe Benefits calculated at 25% of allowable salary	$ 26,512.50	*(h x .25)*
j.	SUBTOTAL	$ 132,562.50	*(h + i)*
k.	Associated F&A (indirect) costs at 45% of subtotal	$ 59,653.13	*(j x .45)*
l.	Total amount to be awarded due to salary limitation	$ 192,215.63	*(j + k)*

Therefore, the amount of reduction due to federal salary limitation is:

m.	Total adjustment	$ (25,284.37)	*(l - f)*

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Example 2. Individual with Half-Time Appointment

Research effort requested in application/proposal – 6 months (30% effort)

a.	Individual's institutional base salary for a HALF-TIME calendar year appointment	$ 120,000.00	(FTS x (6/12))
b.	Direct Salary with research effort (30%)	$ 36,000.00	*(a x .30)*
c.	Fringe Benefit Requested at 25% of salary	$ 9,000.00	*(b x .25)*
d.	SUBTOTAL	$ 45,000.00	*(b + c)*
e.	Requested F&A (indirect) costs at 45% of subtotal	$ 20,250.00	*(d x .45)*
f.	Total amount requested	$ 65,250.00	*(d + e)*

The salary cap for the above individual will be calculated as follows:

g.	Salary Cap – FY 2023	$ 212,100.00	
h.	Salary Cap – FY 2023 (6-month rate)	$ 106,050.00	*(g x (6/12))*

i.	Salary Cap with Research effort (30%)	$ 31,815.00	*(h x .30)*
j.	Fringe Benefits calculated at 25% of allowable salary	$ 7,953.75	*(i x .25)*
k.	SUBTOTAL	$ 39,768.75	*(i + j)*
l.	Associated F&A (indirect) costs at 45% of subtotal	$ 17,895.94	*(k x .45)*
m.	Total amount to be awarded due to salary limitation	$ 57,664.69	*(k + l)*

Therefore, the amount of reduction due to federal salary limitation is:

n.	Total Adjustment	$ (7,585.31)	*(m-f)*

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Example 3. Individual with a Nine-Month Appointment

Research effort requested in application/proposal – 9 months (30% effort)

a.	Individual's institutional base salary for a nine-month calendar year appointment	$ 180,000.00	(FTS x (9/12))
b.	Direct salary requested	$ 54,000.00	*(a x .30)*
c.	Fringe Benefit Requested at 25% of salary	$ 13,500.00	*(b x .25)*
d.	SUBTOTAL	$ 67,500.00	*(b + c)*
e.	Requested F&A (indirect) costs at 45% of subtotal	$ 30,375.00	*(d x .45)*
f.	Total amount requested	$ 97,875.00	*(d + e)*

The salary cap for the above individual will be calculated as follows:

g.	Salary Cap – FY 2023	$ 212,100.00	
h.	Salary Cap – FY 2023 (9-month rate)	$ 159,075.00	*(g x (9/12))*
i.	Salary Cap with Research effort (30%)	$ 47,722.50	*(h x .30)*
j.	Fringe Benefits calculated at 25% of allowable salary	$ 11,930.63	*(i x .25)*
k.	SUBTOTAL	$ 59,653.13	*(i + j)*
l.	Associated F&A (indirect) costs at 45% of subtotal	$ 26,843.91	*(k x .45)*
m.	Total amount to be awarded due to salary limitation	$ 86,497.04	*(k + l)*

Therefore, the amount of reduction due to federal salary limitation is:

n.	Total Adjustment	$ (11,377.96)	*(m-f)*

Graduate Student Compensation

The maximum amount NIH will award for the support of a graduate student on a research grant or a cooperative agreement is tied to the National Research Service Award (NRSA) zero-level stipend in effect at the time the grant award is issued on the Federal award date.

The compensation of graduate students supported by research grants must be reasonable. The amount provided for compensation includes salary or wages, fringe benefits, and tuition remission. These guidelines apply to graduate students at the recipient institution who are supported by NIH research grants and cooperative agreements and not to individuals supported by NRSA training grants and fellowships.

Institutions may continue to rebudget funds to charge more than the awarded amount provided that OMB cost principles requiring reasonable compensation are observed. In general, graduate student compensation will not be considered reasonable if in excess of the amount paid to a first-year postdoctoral scientist at the same institution performing comparable work.

NIH Budget Justification

- To describe and explain the amounts in your budget categories.
- The Justification should cover all budget years of the project (and not just the first year).
- List names and roles of personnel, their expected level of effort each budget period, and their compensation.
- Describe projected Equipment purchases, Travel (where, when, why, for how much).
- Justify any significant increase or decrease from year to year.
- A separate justification is required for Subaward/Consortium budgets.

Additional Documents Required

Policy for Data Management and Sharing (DMS Policy)

The NIH Policy for Data Management and Sharing (DMS Policy) applies to all research, funded or con-ducted in whole or in part by NIH, that results in the generation of scientific data. This includes research funded or conducted by extramural grants or other funding agreements regardless of NIH funding level or funding mechanism. The DMS Policy does not apply to research and other activities that do not generate scientific data, including training, infrastructure development, and non-research activities.

Applicants must submit a DMS Plan in each competitive grant application, and outline DMS costs in the appropriate cost categories in the budget.

DMS Plans should be updated by researchers and reviewed by the NIH ICO during regular reporting intervals or sooner.

Under the NIH DMS Policy, NIH expects researchers will maximize the appropriate sharing of scientific data. Shared scientific data must be made accessible as soon as possible, and no later than the time of an associated publication, or the end of performance period, whichever comes first. Once approved, the DMS Plan will become a Term and Condition of the NOA, and failure to comply may result in an enforcement action, including additional special terms and conditions or termination of the award,

Data Management and Sharing Cost

Costs associated with data management and data sharing are subject to Federal cost principles for the reimbursement of actual costs that are allowable, allocable, reasonable, and consistently treated.

Application Deadlines

- Applications are due by 5 pm local time of the applicant organizations. FOAs may have specific deadlines or point to standard deadlines. Different grant mechanisms (e.g., R01 and R21) have different standard deadlines. Deadlines for resubmissions and renewals for some mechanisms (e.g. R01) will differ than those for new applications. Application due the next business day if deadline date falls on a weekend or holiday

See https://grants.nih.gov/grants/how-to-apply-application-guide/due-dates-and-submission-policies/due-dates.htm

Peer Review Process

- First level of review – Scientific Review Group (SRG)
  - ☐ Composed primarily of non-federal scientists who have expertise in relevant scientific disciplines and research areas
  - ☐ Receive access to grant applications ~ 6 weeks prior to peer review meeting
  - ☐ Prepare a written critique of each proposal based on review criteria and judgment of merit
  - ☐ Assign a numerical score to each review criterion
  - ☐ Make recommendations concerning the scientific and technical merit of applications under review in the form of final written comments and numerical scores
  - ☐ Make recommendations concerning protections for human subjects, welfare of vertebrate animals, and other areas as applicable for the application
  - ☐ Make recommendations concerning appropriateness of budget requests

- Scored Review Criteria
  - ☐ **Significance** – Does the project address an important problem?
  - ☐ **Investigator(s)** – Are the PD/PIs, collaborators, and other researchers well suited to the project?
  - ☐ **Innovation** – Does the application challenge and seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions?
  - ☐ **Approach** – Are the overall strategy, methodology, budget and analyses sufficient and well-reasoned and appropriate to accomplish the specific aims of the project?
  - ☐ **Environment** – Does the PD/PI have suitable and sufficient facilities, equipment and institutional support to carry out the research plan?

- Additional Review Criteria – reviewers will evaluate the following but will not give separate scores for these items:
  - ☐ Protections for Human Subjects
  - ☐ Inclusion of Women, Minorities, and Children
  - ☐ Vertebrate Animals
  - ☐ Biohazards
  - ☐ Resubmission
  - ☐ Renewal
  - ☐ Revision
  - ☐ Select Agents
  - ☐ Resource Sharing Plans
  - ☐ Budget and Period Support
  - ☐ Applications from Foreign Organizations have an extra review step:

Reviewers assess whether the expertise or resources required for this project are available in the U.S.

- Second level of review – Institute and Center (IC) National Advisory Councils or Boards
  - ☐ Composed of both scientific and non-scientific members chosen for their expertise, interest, or activity in matters related to health and disease chosen by the respective IC, approved by DHHS, and in some cases appointed by the President of the United States

- ☐ NIH program staff members examine applications, their overall impact/priority scores, percentile rankings and their summary
- ☐ Program staff provide a grant-funding plan to the Advisory Board/Council
- ☐ The Advisory Board/Council also considers the IC's goals and needs and advises the IC director. The Council concurs with the review. It does not make funding decisions.
- ☐ The IC director makes final funding decisions based on staff and Advisory Council/Board advice

Source - http://grants.nih.gov/grants/peer_review_process.htm

4. The Award

After Proposal Submission

- **Just In Time (JIT)** – Mechanism used by NIH to request more timely information prior to making the final award decision. These procedures allow certain elements of an application to be submitted later in the application process, after review when the application is under consideration for funding. The standard application elements include the following:
  - ☐ other support information (both active and pending) for senior/key personnel;
  - ☐ certification of IRB approval of the project's proposed use of human subjects;
  - ☐ verification of IACUC approval of the project's proposed use of live vertebrate animals;
  - ☐ and evidence of compliance with the education in the protection of human research participants requirement.

  Other support - Includes all financial resources, whether Federal, non-Federal, commercial or organizational, available in direct support of an individual's research endeavors, including, but not limited to, research grants, cooperative agreements, contracts, or organizational awards. Other support does not include training awards, prizes, or gifts.
- **IRB** or **IACUC** approval dates if project includes human or animal subjects
- **Human Subject Education** Information (documentation of HS protections training)

JIT Review

- Sufficient levels of effort are committed
- No scientific, budgetary, or commitment overlap.
  - ☐ Scientific overlap occurs when (1) substantially the same research is proposed in more than one application or is submitted to two or more funding sources for review and funding consideration or (2) a specific research objective and the research design for

accomplishing the objective are the same or closely related in two or more applications or awards, regardless of the funding source.

- ☐ Budgetary overlap occurs budgetary items are requested but already are provided by another source.
- ☐ Commitment overlap occurs when an individual's time commitment exceeds 100 percent.

Overlap, whether scientific, budgetary, or commitment of an individual's effort greater than 100 percent, is not permitted. Any overlap will be resolved by the IC with the applicant and the PD/PI at the time of award.

- Only funds necessary to the approved project are included in the award

Award Notification

NIH notifies the recipient organization via e-mail when an award has been issued. On the Federal award date, the NoA is made available to recipient officials and corresponding PD/PIs in the eRA Commons through the Status module. The eRA Commons is the official repository for the NoA document.

For most grants, NIH uses the project period system of funding. Under this system, projects are programmatically approved for support in their entirety but are funded in annual increments called budget periods (competitive segment). The initial NoA provides funds for the project during the first budget period. Budget periods usually are 12 months long.

The NoA that documents approval of a project period that extends beyond the budget period for which funds are provided (including anticipated levels of future support) expresses NIH's intention to provide continued financial support for the project. The amounts shown for subsequent years represent projections of future funding levels based on the information available at the time of the initial award. Such projected levels of future support are contingent on satisfactory progress, the availability of funds, and the continued best interests of the Federal government. They are not guarantees by NIH that the project will be funded or will be funded at those levels and create no legal obligation to provide funding beyond the ending date of the current budget period as shown in the NoA.

Recipients are required to submit an annual progress report as a prerequisite to NIH approval and funding of each subsequent budget period (non-competing continuation award) within an approved project period. In the case of multiyear funded grants where all the funds are provided at the time of the initial award, recipients are also required to submit and annual progress report.

Types of Applications

- **New (Type 1)** Initial request for support of a project that has not yet been funded

- **Resubmission application**

A resubmission is an unfunded application that has been modified following initial review and resubmitted for consideration. Applicants must make significant changes to the application and can only resubmit once the summary statement is available. Applicants must apply and undergo peer review. The previous NIH term was "revision." A resubmission has a suffix in its application identification number, e.g., A1.

NIH will accept a new (A0) application following an unsuccessful resubmission (A1) application. The subsequent new application need not demonstrate substantial changes in scientific direction compared to previously reviewed submissions, and must not contain an introduction to respond to the critiques from the previous review.

NIH policy allows a thirty-seven month window for one resubmission (A1) following the submission of a new, renewal, or revision application (A0 application). The initial submission of a new, renewal or revision application constitutes the starting point for the thirty-seven month policy. After thirty-seven months, NIH views a submission as a new application, regardless of whether an unsuccessful resubmission (A1) was submitted during the thirty-seven month time period.

- **Renewal (Type 2**)

  - ☐ Initial request for additional funding for a period subsequent to that provided by a current award. Renewal applications compete for funding with all other peer reviewed applications and must be developed as fully as though the applicant is applying for the first time. (Previously referred to as “competing continuation.”)

- **Competing Revision (Type 3**)

  - ☐ Initial request for (or the award of) additional funds during a current project period to support new or additional activities that are not identified in the current award. This request reflects an expansion of the scope of the grant-approved activities. Competitive revisions require peer review. (Competing revision replaces the previous NIH term, "competing supplement.")

- **Extension (Type 4**)

  - ☐ Request for additional years of support beyond the years previously awarded. (Used only for select programs.)

- **Non-Competing Continuation** (**Type 5**)

  - ☐ Request or award for a subsequent budget period within a previously approved project for which a recipient does not have to compete with other applications. Requires the submission of an annual Research Performance Progress Report (RPPR) and request for funding of a non-competing continuation award for the 2nd or subsequent budget period within an approved competitive segment.

- **Change of Organization Status (Successor-in-Interest) (Type 6)**
  - ☐ Process whereby the rights to and obligations under an NIH grant(s) are acquired incidental to the transfer of all of the assets of the grantee or the transfer of that part of the assets involved in the performance of the grant(s). May result from legislative or other legal action, such as a merger or other corporate change.
- **Change of Grantee or Training Institution (Type 7**)
  - ☐ Transfer of the legal and administrative responsibility for a grant-supported project or activity from one legal entity to another before the completion date of the approved project period (competitive segment).
- **Change of sponsoring IC within NIH for non-competing continuation** (**Type 8**)
- **Change of sponsoring IC within NIH for competing renewal** (**Type 9**)

NIH's Responsible Conduct of Research (RCR) Training Requirement

- During each career stage, and at a frequency of no less than once every four years.
- Affects certain types of awards (F, K, R25, R36, T)
- Applies to all trainees, fellows, students and post docs who work on these projects
- ***Must incorporate formal & informal training and mentoring (including face-to-face)***

List of Topics

a. conflict of interest – personal, professional, and financial – **and conflict of commitment, in allocating time, effort, or other research resources**
b. policies regarding human subjects, live vertebrate animal subjects in research, and safe laboratory practices
c. mentor/mentee responsibilities and relationships
d. **safe research environments (e.g., those that promote inclusion and are free of sexual, racial, ethnic, disability and other forms of discriminatory harassment)**
e. collaborative research, including collaborations with industry and **investigators and institutions in other countries**
f. peer review, **including the responsibility for maintaining confidentiality and security in peer review**
g. data acquisition **and analysis;** laboratory tools (**e.g., tools for analyzing data and creating or working with digital images); recordkeeping practices, including methods such as electronic laboratory notebooks**
h. **secure and ethical data use; data confidentiality**, management, sharing, and ownership
i. research misconduct and policies for handling misconduct

j. responsible authorship and publication
k. the scientist as a responsible member of society, contemporary ethical issues in biomedical research, and the environmental and societal impacts of scientific research

The Notice of Award (NoA)

- Legally binding contract between NIH and your institution. Includes the Following:
  - ☐ Identifies PI, Project and Award Number
  - ☐ Establishes funding level
  - ☐ Establishes period of support
  - ☐ **Budget Period v. Project Period**
  - ☐ Sets forth terms and conditions
  - ☐ Reporting requirements
  - ☐ NIH Contact Information Programmatic verses Financial
    - Program Official - Programmatic (technical side)
    - Grants Management Specialist - Financial (contractual side)

Project Number Breakdown

1 T32 GM129176-01

5 R01 CA198421-03S1

Type of Application

(1 = new competing; 5 = non-competing continuation)

3-character Funding Mechanism / Activity Code

2-letter IC code

Up to 6-digit Award No

Year (budget period) If grant has transferred, year may not reflect actual year of the grant

Suffix (Supplement, Amendment)

5. Miscellaneous

Pre-Award Cost

- Grantee may, as its own risk and without NIH prior approval, incur obligations and expenditures to cover costs up to 90 days before the beginning date of the initial budget period of a new or competing continuation award if such costs

- ☐ Are necessary to conduct the project
- ☐ Would be allowable under the grant, if awarded, without NIH prior approval.

Travel including International Travel

- ☐ Consistent with the organization's established travel policy (per diem, mileage, etc.).
- ☐ International travel does not need prior NIH approval even if not listed in proposal budget.
- ☐ US to Canada (vice versa) is not considered international travel by NIH. Check your institutional policy to see how they define it.
- ☐ Comply with the Fly America Act.
- ☐ Short term visas (if required) are not allowable expenses to be charged to a grant, even under UG.

Subcontract (Subaward) = Consortium

Splitting the funding among Co-Investigators

- ☐ Multiple PI grants are allowed where several PIs are considered key personnel on the project. Require a leadership plan.
- ☐ Single PI grants can have several Co-Investigators on the project either at the same institution or other institutions (consortiums).

International Applicants

In general, foreign organizations and international organizations, including public or private non-profit or for-profit organizations, are eligible to apply for research project grants, but are not eligible to submit a modular grant application. International organizations are treated as foreign organizations for the purpose of eligibility. If the Funding Opportunity Announcement (FOA) allows foreign organizations to apply, international organizations may apply. F&A Costs under grants to foreign and international organizations will be funded at a fixed rate of 8 percent of modified total direct costs.