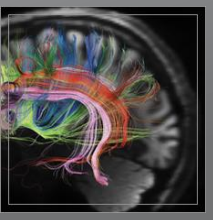



Introduction to NIH

Roberto Delgado, Jr., PhD

Kathy Etz, PhD

19 June 2018

National Institute of Mental Health

The National Institutes of Health

- *Science in pursuit of fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to extend healthy life and reduce the burdens of illness and disability*
- Comprised of 27 Institutes and Centers
- *37 Billion Dollar budget*

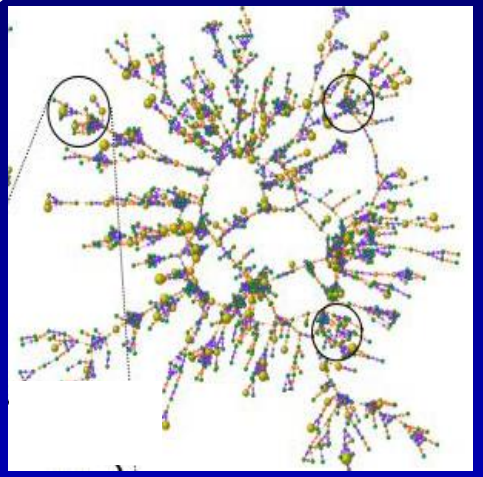
The National Institutes of Health

Source: *http://www.nih.gov/*

Society

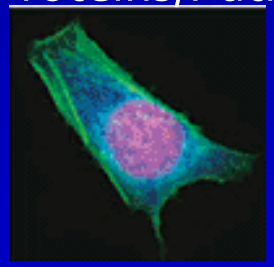
Peer/
Family

Brain

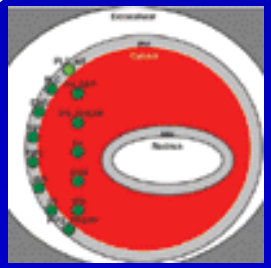


Social Networks

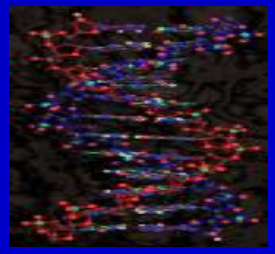
Proteins/Pathways



Individual/Behavior



Cell



Gene

Adapted from Pennisi *Science 2003*

Tribal Health Research Office

- Coordinate tribal health research-related activities across NIH and leverage resources or develop initiatives to support tribal health research
- Coordinate and support the NIH Tribal Advisory Committee
- Development and dissemination of reports on tribal health topics
- Convene trans-NIH committees, workshops, meetings and other activities related to tribal health research and scientific priorities
- Convene Tribal Consultation sessions

The National Institute on Drug Abuse

What is NIDA?

NIDA's Mission is to lead the nation in bringing the power of science to bear on drug abuse and addiction.

- support and conduct of research
- rapid and effective dissemination and use of research results

National Institute of Mental Health

What does NIH fund?

What kind of **grants** of interest to ***early career investigators*** does NIH Fund?

Research

Research Training

U.S. Department of Health & Human Services

Text Size A A A

NIH Research Portfolio Online Reporting Tools (RePORT)

Search

HOME | ABOUT RePORT | FAQs | GLOSSARY | CONTACT

QUICK LINKS | RESEARCH | ORGANIZATIONS | WORKFORCE | FUNDING | REPORTS | LINKS & DATA

Home > RePORTER > Query Form

MyRePORTER Login | Register System Health: GREE

NIH RePORTER

Version: 5.7.0

06/13/2013 Release Note: New enhancements now available.
View Release Notes for more information.

About RePORTER DATA | FAQ | ExPORTER | RePORTER Manual | RSS of Newly Added Projects

QUERY NEW | OLD QUERY | BROWSE NIH BETA

Old query form available until July 11

http://projectreporter.nih.gov/reporter.cfm

SUBMIT QUERY | CLEAR QUERY

Fiscal Year (FY): Current FY is 2013 — Active Projects SELECT

RESEARCHER AND ORGANIZATION

Principal Investigator (PI) / Project Leader: (Last Name, First Name)
Use '%' for wildcard
Enter several PI/Project Leader names

Organization: LOOKUP
Please enter at least 3 characters to use Lookup.
Contains Begins with Exact

Department: SELECT

Organization Type: SELECT

City:
Use '%' for wildcard

State: SELECT

Country: SELECT

Congressional District: SELECT

DUNS Number:

TEXT SEARCH

Text Search (*Logic*):
And
Or

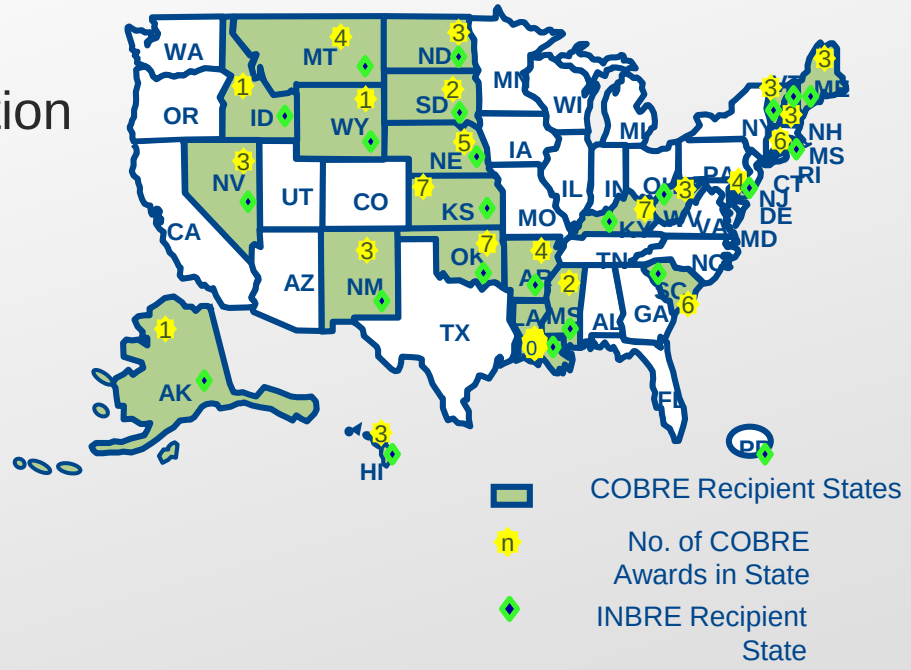
Search in
Projects
Publications
Projects & Publications

Limit Project search to
Project Title
Project Terms

Limit Publication search to
Start Year 2012
End Year 2013

Institutional Development Award

- Enhance geographical distribution of NIH research funds and increase research capacity
- Currently 23 states and Puerto Rico are IDeA eligible



Increasing Competitiveness of Investigators and Institutions in IDeA States

https://www.nigms.nih.gov/Research/DRCB/IDeA/Pages/INBRE.aspx

NIGMS Programs Supporting Research in and by the AI/AN Community

- INBRE *
  - An IDeA program that supports the development of a statewide multi-disciplinary research network of doctoral degree-granting,

undergraduate institutions and community colleges. INBRE grants work to build and increase research capacity by supporting faculty, fellows and students at participating institutions. Currently over 20 Tribal Community Colleges are networked with supported INBRE grants

* INBRE applications must represent a collaborative effort to sponsor research with undergraduate institutions, community colleges and tribal colleges and universities (TCUs)
-IDeA Networks of Biomedical Research Excellence

TCUs involved with INBREs

- Montana INBRE (at Montana State University-Bozeman)
  - Fort Belknap College
  - Chief Dull Knife College
  - Fort Belknap Tribal health Administration
  - Salish Kootenai College
  - Stone Child College
  - Fort Peck Community College
  - Little Big Horn College
  - Blackfeet Community College
- University of Nebraska Medical Center
  - Little Priest Tribal College
- University of Kansas Medical Center
  - Haskell Indian Nations University
- University of North Dakota
  - Cankdeska Cikana Community College
  - Fort Berthold Community College
  - Sitting Bull College
  - Turtle Mountain Community College
  - United Tribes Technical College
- University of Oklahoma
  - Commanche Nation College
- University of South Dakota
  - Oglala Lakota College
  - Sisseton Wahpeton College

National Institute of Mental Health

NARCH and Institutional Development Award (IDeA) Interactions

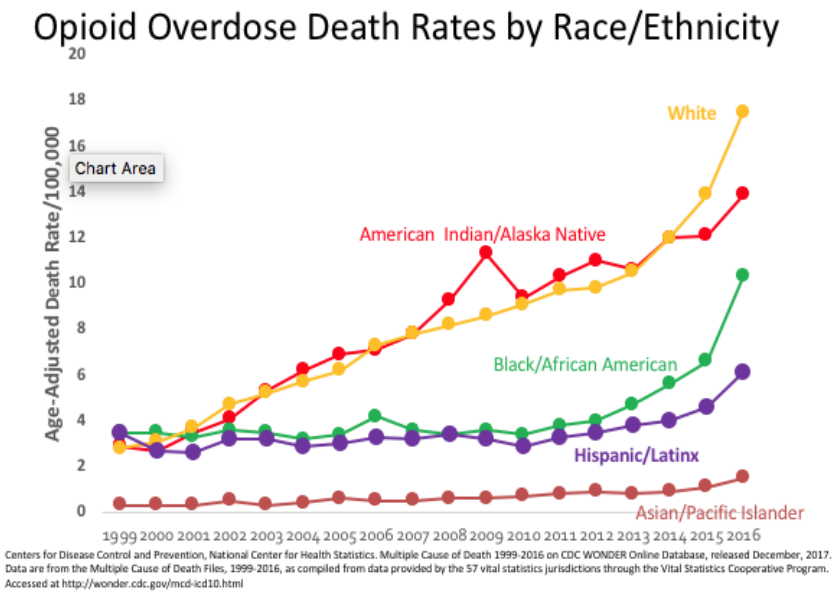
- Blackfeet Community College NARCH and Montana IDeA Network for Biomedical Research Excellence (INBRE)
- Cherokee Nation NARCH and Oklahoma IDeA Clinical and Translational Research (IDeA-CTR)
- Cankdeska Cikana NARCH and North Dakota INBRE
- South Central Foundation NARCH, Alaska Native Tribal Health Consortium NARCH and Alaska Center of Biomedical Research Excellence (COBRE) and Montana IDeA-CTR

National Institute on Drug Abuse

Responding to Opioid Use Disorders in Tribal Communities in the Context of SAMHSA Tribal Funding

Kathy Etz, Ph.D.
Sarah Duffy, Ph.D.
DESPR
May 15, 2018

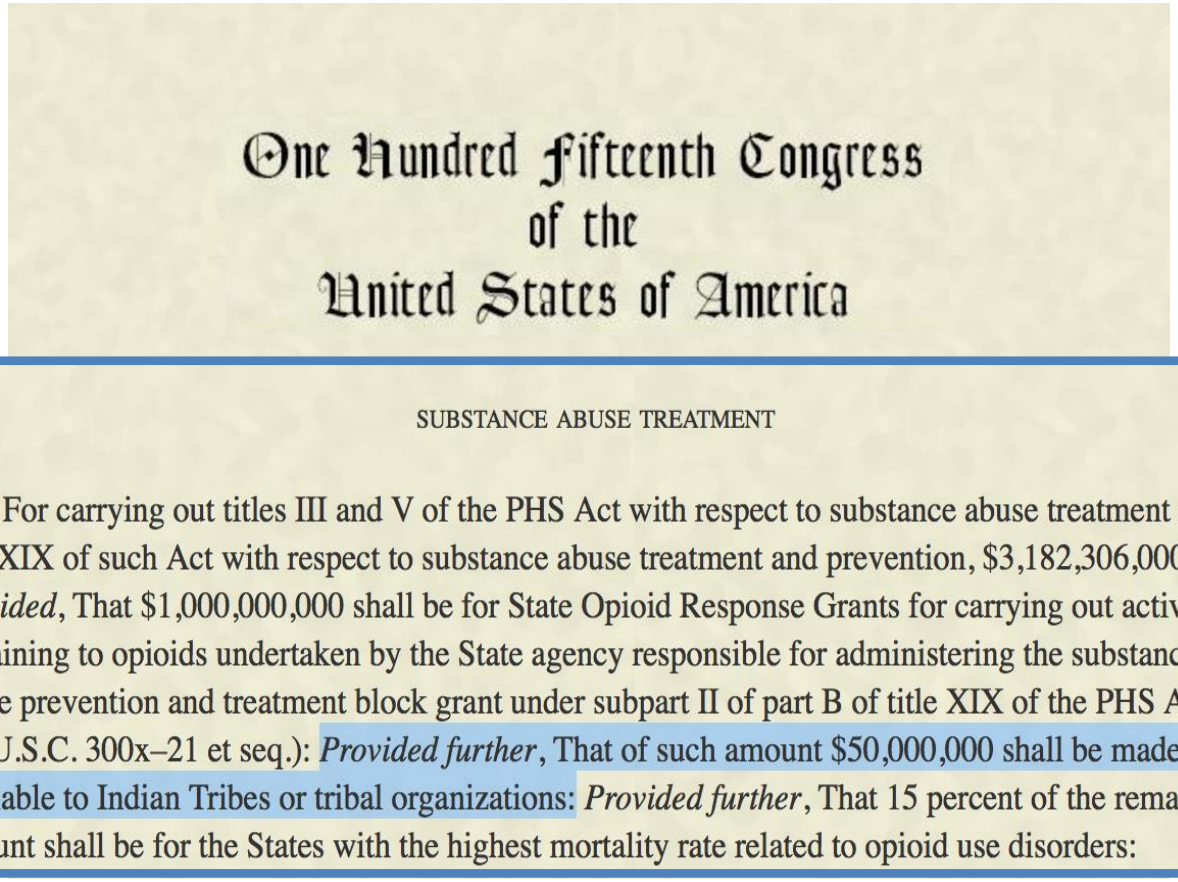
Background and Justification



- **Unique barriers exist for responding to OUD in AI/AN Communities**

  - Funding
  - No published outcome studies of MAT for AI/AN
  - Idea of substituting one drug for another
  - Culturally incongruent treatment, failing to incorporate traditional practices or drawing on strengths
  - Stigma
  - Access including distance

$50,000,000 for SAMHSA to fund Tribal response to OUD



One Hundred Fifteenth Congress
of the
United States of America

SUBSTANCE ABUSE TREATMENT

For carrying out titles III and V of the PHS Act with respect to substance abuse treatment and title XIX of such Act with respect to substance abuse treatment and prevention, $3,182,306,000: *Provided*, That $1,000,000,000 shall be for State Opioid Response Grants for carrying out activities pertaining to opioids undertaken by the State agency responsible for administering the substance abuse prevention and treatment block grant under subpart II of part B of title XIX of the PHS Act (42 U.S.C. 300x–21 et seq.): *Provided further*, That of such amount $50,000,000 shall be made available to Indian Tribes or tribal organizations: *Provided further*, That 15 percent of the remaining amount shall be for the States with the highest mortality rate related to opioid use disorders:

Research Goals

- **Assess interventions implemented with SAMHSA funding to identify the most efficacious strategies for preventing and treating OUD in tribal communities**
  - Partnerships between researchers and AI/AN communities, using community engagement and/or CBPR
  - Identify efficacious prevention strategies, including multi-pronged strategies facilitated by engagement across tribal departments
  - Identify and address barriers to appropriate treatment and hasten the availability of MAT
    - Develop and assess culturally appropriate interventions
    - Assess telehealth approaches in remote communities
    - Assess whether the use of long acting MAT (Sublocade, Vivitrol, Probuphine) helps in making MAT available to remote communities

Intervention Research to Improve Native American Health

PAR-14-260

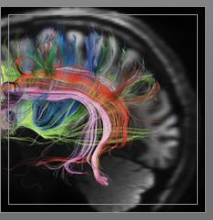
This FOA encourages exploratory developmental research to improve Native American health. Such research can include: conducting secondary analysis of existing data (possibly TEC data); merge various sources of data to answer critical research questions; conduct pilot and feasibility studies; and/or assess and validate measures that are being developed and/or adapted for use in NA communities. Possible areas of interest would include the following:

- Piloting of potential treatment interventions, both adapted, evidence-based treatments and those that build upon screening and brief interventions often included in prevention interventions;
- Analyzing existing data to develop and test models that account for differential risk, morbidity, and mortality for NA in a variety of health domains;
- Examining patterns of health services utilization and best practices to reduce health disparities;
- Conducting analyses to understand where there are critical failures of health-care systems and public health systems to provide timely and readily available health services; ascertain where making even minor, cost-effective additions would have most impact on health outcomes (e.g., case management, community care workers, social support groups, etc.);
- Developing and demonstrating programs that encourage enhanced health screenings;
- Understanding how traditional practices, beliefs, and medicine can be linked with or integrated into medical and psychological interventions to improve health services and health outcomes.

Native American Research Centers for Health (NARCH)

The NARCH initiative supports partnerships between American Indian/Alaska Native (AI/AN) tribes or tribally-based organizations and institutions that conduct intensive academic-level biomedical research. NARCH supports:

- conducting research, research training and faculty development
- opportunities for tribes and tribal organizations to build research infrastructure
- capacity building to address the health disparities prevalent in AI/AN communities and increase trust of research within the AIAN communities.




NIH Research Training and Career Development

Roberto Delgado, PhD

Program Chief, Rural Mental Health Research

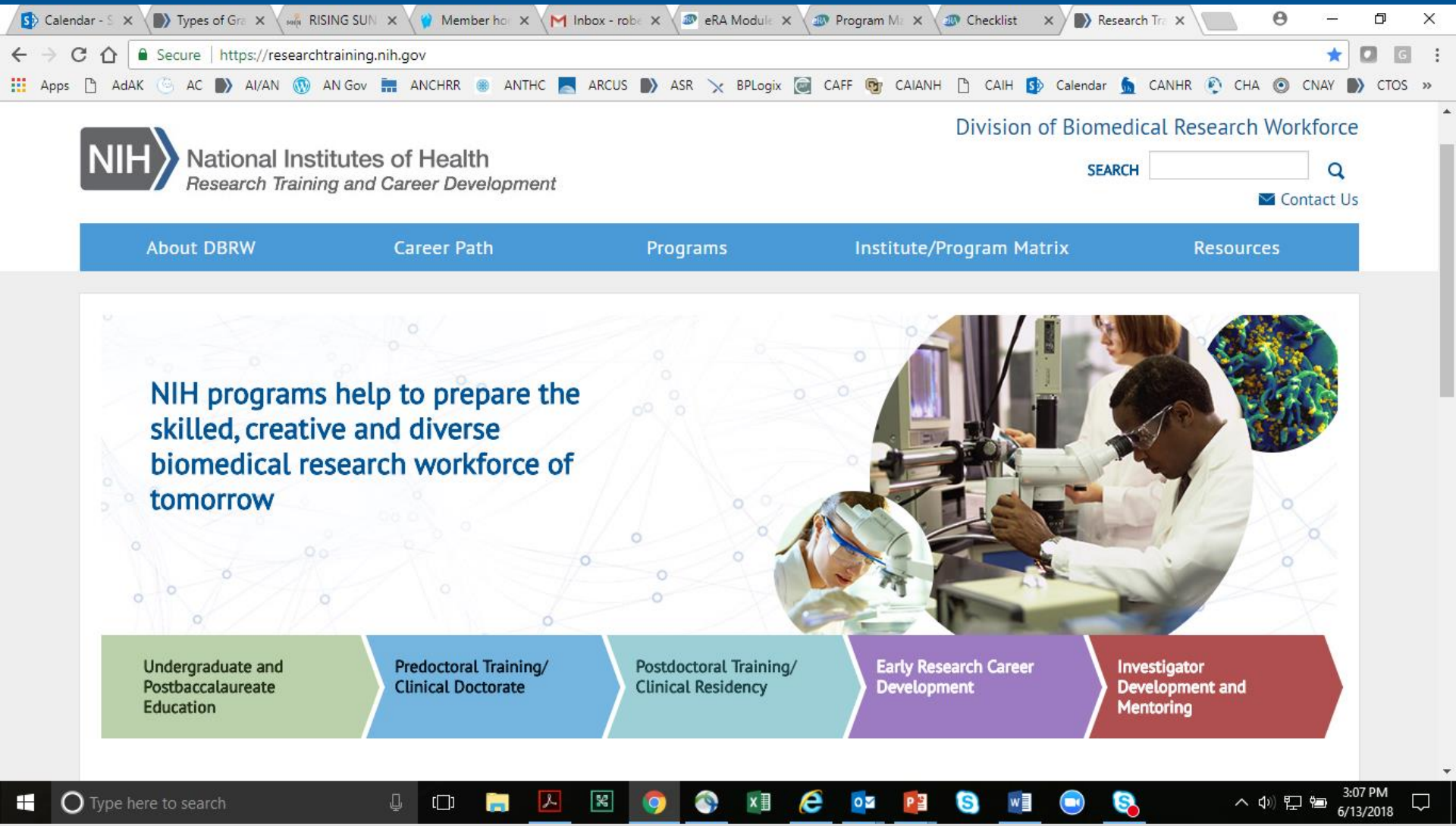
Office for Research on Disparities and Global Mental Health

National Institute of Mental Health

19 June 2018

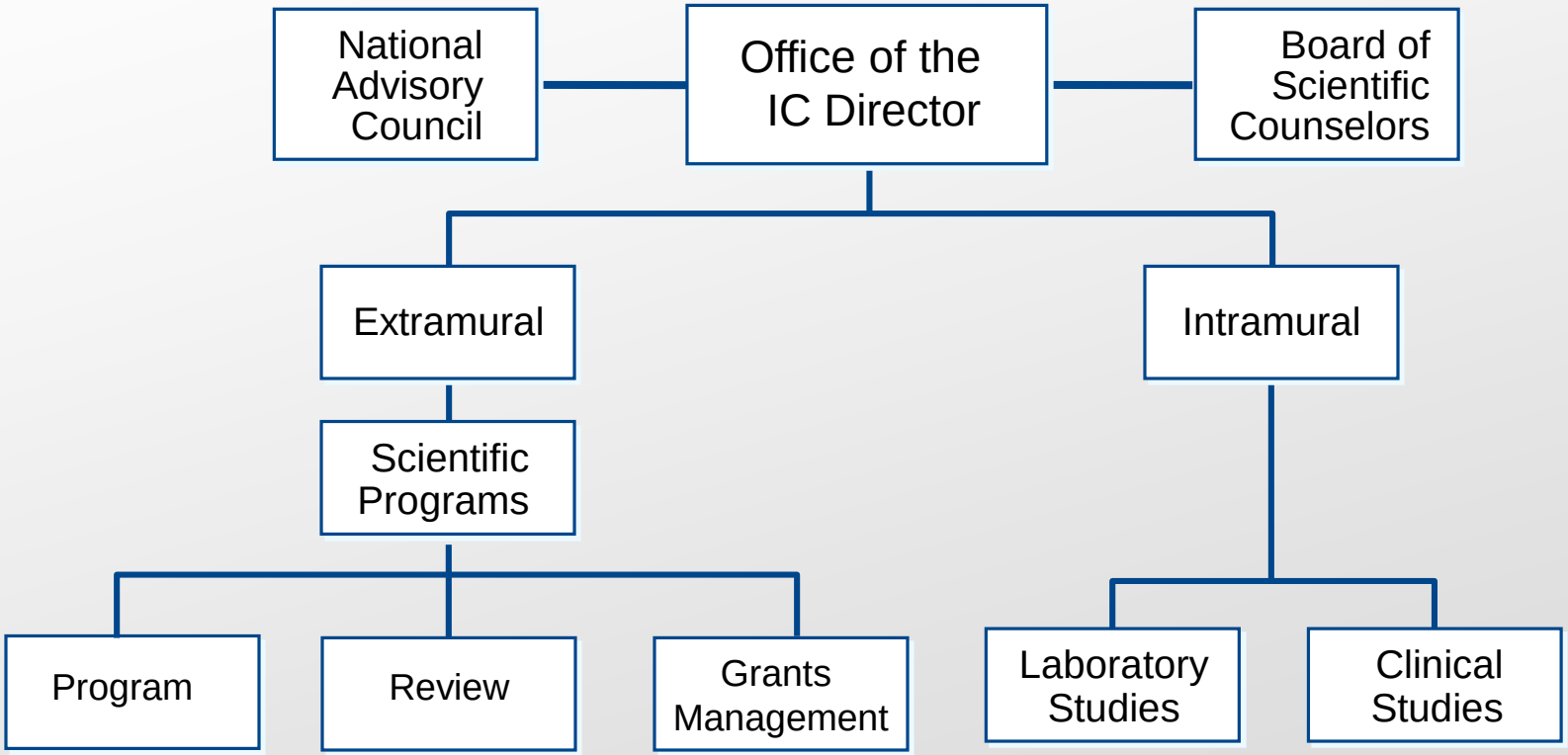
National Institute of Mental Health

https://researchtraining.nih.gov/



National Institute of Mental Health

A Typical Institute / Center



National Institute of Mental Health Staff

NIMH STAFF

Program Officer

- Oversees portfolio of grants & contracts
- Identifies scientific priorities
- Monitors research progress
- Advocates for the best science

Scientific Review Officer

- Manages the review of grants & contracts
- Appoints members to review (IRGs/SEPs)
- Prepares summary statements
- Responds to questions about review at Advisory Councils

Grants Management Specialist/Officer

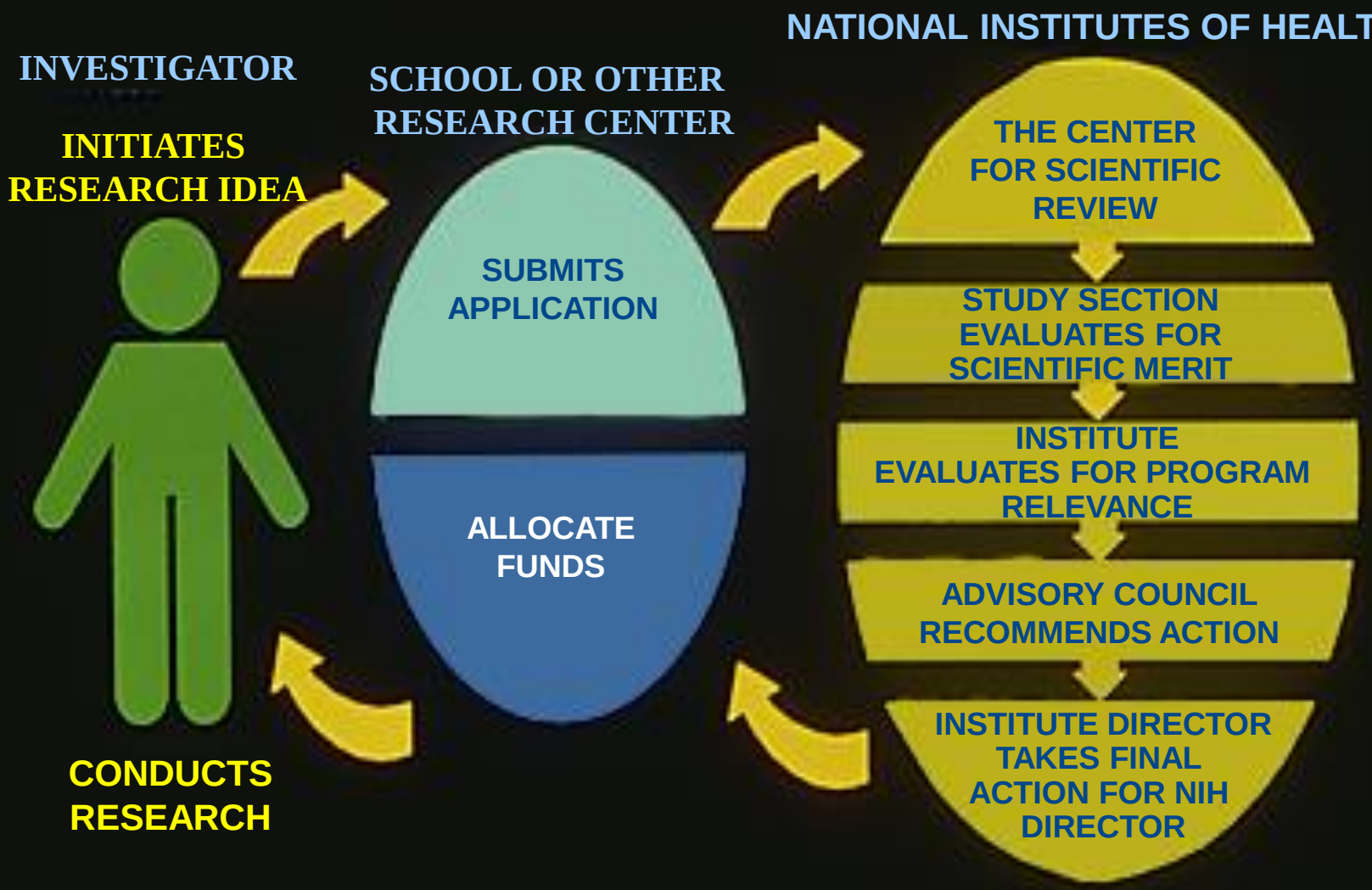
- Implements the funding process
- Monitors the budget
- Ensures compliance with Institute policies and regulations

National Institute of Mental Health

NIMH Staff

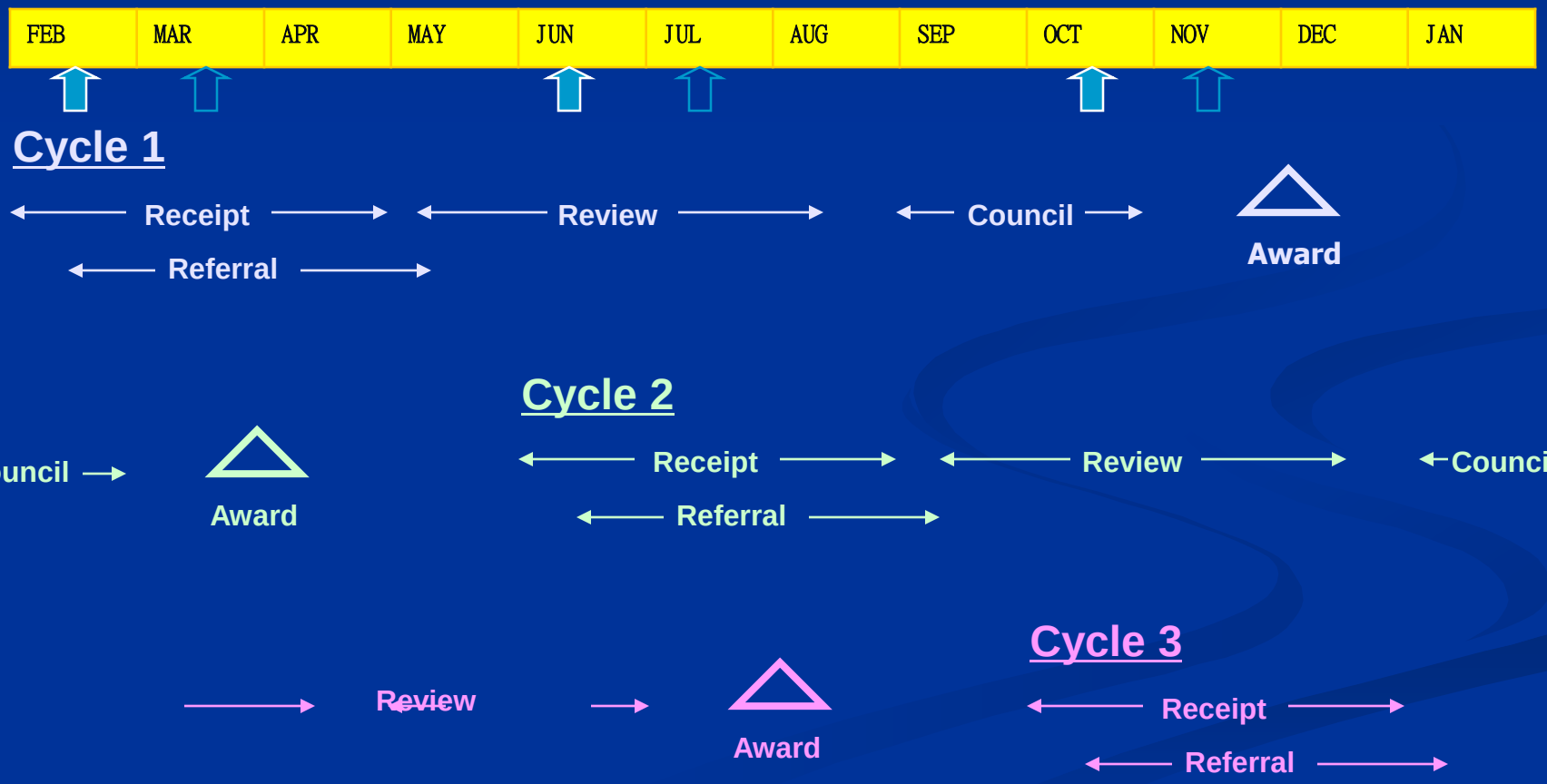
	Program Officer	Scientific Review Officer	Grants Management Specialist or Officer
Before Submitting--to discuss your research idea and for information about the application process	√		
After the application is submitted --to discuss questions pertinent to review assignment		√	
After the review--to discuss questions about the review and response to critiques	√		
At any point--for questions about the budget and administrative questions after a grant is awarded	√		√

HOW A RESEARCH GRANT IS MADE

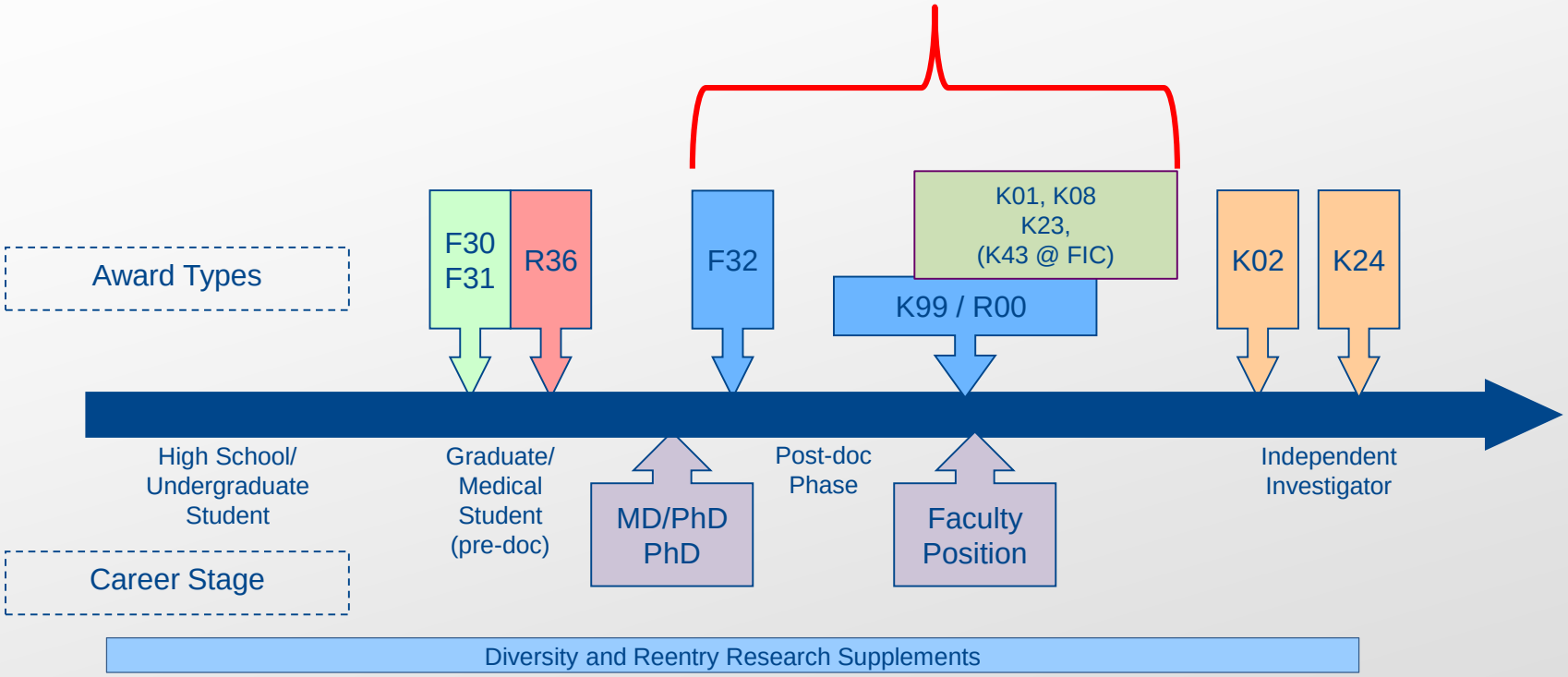


Be patient – It's a long process

There are three overlapping cycles per year:



Research Training and Career Development



What is Right for You?

- Where you are in your career?
  - pre-doc, post-doc, new faculty member
- Type of research interest?
  - basic, translational, clinical, services
- Types of resources you need:
  - money, time, training, etc.
- Match qualifications / eligibility

How to. . .

Select the Right Mechanism:

- Read announcements on the web
- Get advice from colleagues / mentors
- Speak with NIH Project Officers
  - *Early in the process!*

Enhancing Workforce Diversity

NIH Institutes and Centers support various diversity mechanisms in different ways – check with the IC

NIMH supports diversity mechanisms:

- Diversity Dissertation Awards (R36)
- Diversity Pre-doctoral Fellowships (F31)
- Diversity Supplements* – Undergrad to Investigator Level

* Supplements are to existing “parent” RPGs

Postdoctoral Awards

- National Research Service Awards
  - Individual Fellowships (F32)
  - Institutional Training Grants (T32)
- Diversity Supplements
- K99/R00 Pathway to Independence (PI) Award

Types of Mentored Ks

- K01 Mentored Research Scientist Development Award
- K08 Mentored Clinical Scientist Research Career Development Award
- K23 Mentored Patient-Oriented Research Career Development Award
- K99 NIH Pathway to Independence Award

Mentored Career Development Awards

Intended for those who:

- Are in initial phase of research career
- Require supervised career development beyond post-doc
- Have a goal of becoming an independent scientific investigator

Mentored Career Options

Variables Influencing Mentored Career Options

- Citizenship
  - If not U.S. citizen, eligible only for K99
- Type of terminal degree held
  - research doctorate or health professional doctorate?
- Type of research
  - Bench, pre-clinical, or patient-oriented?
- Current position
  - Post-doc or faculty?
- Prior NIH funding
  - R01 (not likely to be eligible for K)
- Read FOA carefully!

K Award Eligibility

- U.S. Citizen, Non-Citizen National, or Permanent Resident *(except K99)*
- Research Doctoral Degree (K01)
- Clinical Doctoral Degree (K01/K08/K23)
- Ineligible if current PI of PHS Career Development (K) or certain Research (R) Awards
- Ineligible if former PI of PHS Career Development (K) and Research (R) Awards (Except R03, R21, R34)…but…

Mentored Ks

Review Criteria

- Candidate
- Career Development Plan
- Research Plan
- Mentor(s), Consultants, and Collaborators
- Environment and Institutional Commitment to the Candidate

Research (R) Awards

R03 – NIH Small Research Grant

- Various projects: pilot or feasibility, preliminary data collection, secondary data analysis, small research projects, development of new technology, etc.
- Limited to two years of funding; up to $50,000 per year
- Not renewable

R21 Exploratory/Developmental Research Grant

- Early stage of project development; pilot and feasibility studies.
- Up to two years of funding; not to exceed $275,000 combined

Other Mechanisms - Supplements

- Administrative Supplements to Grants and Cooperative Agreements
  - The purpose of an administrative supplement is to provide additional funds to an active grant or cooperative agreement to pay for necessary items or activities that fall **within the scope** of that award but were unanticipated at the time that the new or competing continuation application was submitted

- Diversity Supplements
  - Funds are available for administrative supplements to improve the diversity of the research workforce by recruiting and supporting students, post-doctorates, and eligible investigators from groups that have been shown to be underrepresented in health-related research.

NI and ESI—Definitions

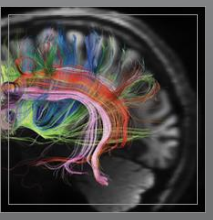
- New Investigator: individuals who have not competed successfully for *significant* NIH research grant support

- Early Stage Investigator (ESIs): are NIs who are within 10 years of receiving their terminal research degree or completing medical residency

Getting Started, Moving Forward

- Find a mentor(s) & develop a plan for your career & funding
- Find out about NIH Institute missions and programs (www.nih.gov)
- Find out about Institute and Center-specific utilization of funding mechanisms
- Contact program staff (early & often!)
- Talk with potential mentors, collaborators, & peers about ideas for your application
- Use NIH RePORTER as a resource http://projectreporter.nih.gov/reporter.cfm

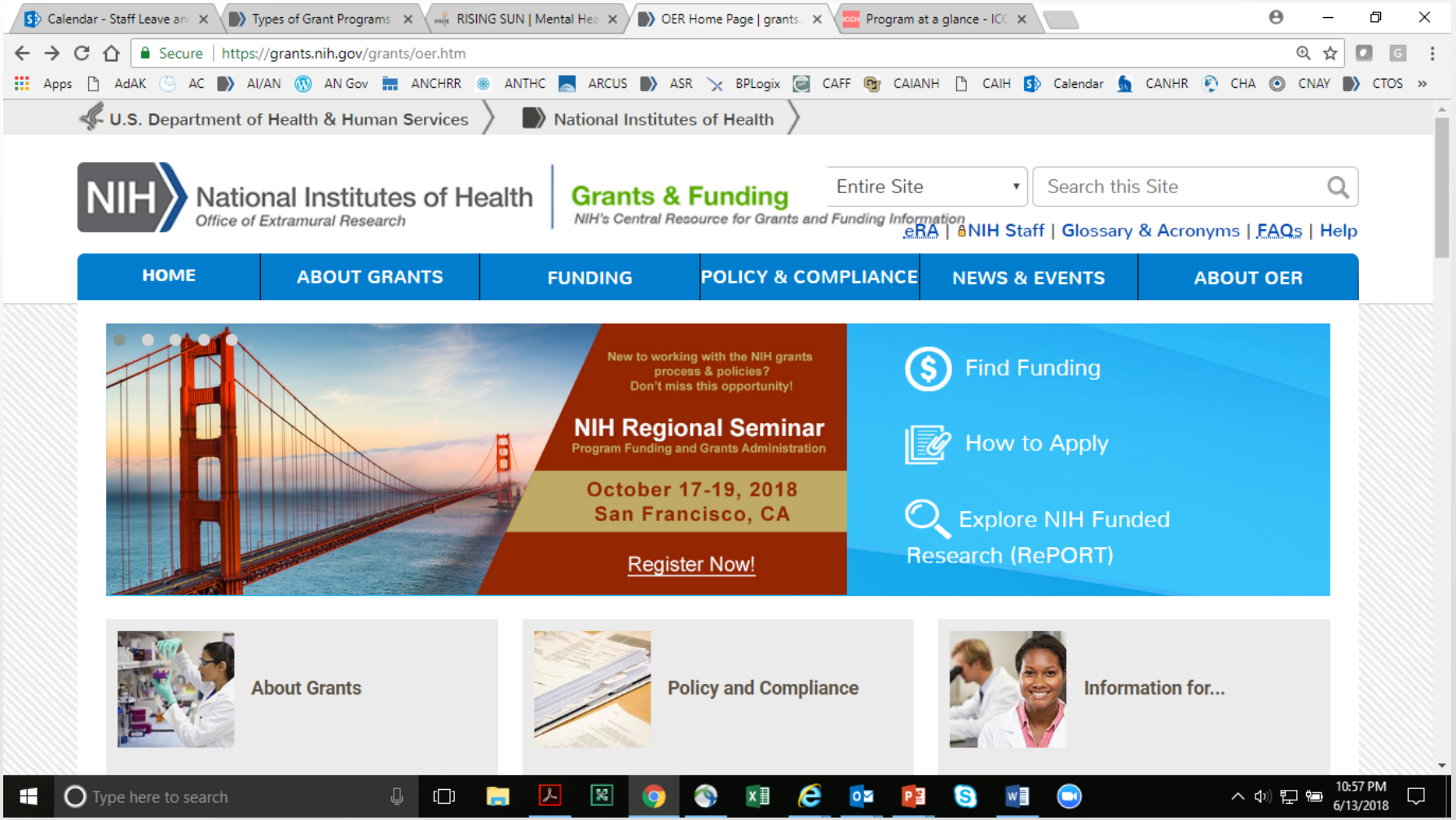
https://researchtraining.nih.gov/




NIH Guide to Grants and Contracts

National Institute of Mental Health

https://grants.nih.gov/grants/oer.htm



National Institute of Mental Health

An Iterative Process – A Team Endeavor

- Program Officer (PO)
- Collaborators experienced in NIH grant process
- Collaborators with complimentary research skills / expertise
- Engaged mentor(s)
- Community partners for conduct of study and/or eventual implementation of findings

Steps to Success…

- Find a FOA that Fits Your Research – See Criteria
- Determine Application Submission Date(s)
- Plan Within Your Organization (e.g., Office of Sponsored Research)
- Obtain Any Required Prior Approvals from NIH (e.g., Over $500K in DC)
- Know the NIH Peer Review Process & Criteria

More Steps…

- Evaluate Your Resources (feasibility of study)

- Human Subjects Requirements (see: https://humansubjects.nih.gov/)

- Rigor and Transparency Requirements in Your Application

  1) the scientific premise forming the basis of the proposed research,

  2) rigorous experimental design for robust and unbiased results,

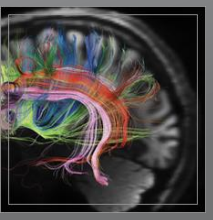
  3) consideration of relevant biological variables, and

  4) authentication of key biological and/or other resources.

Organize Your Time

- Can aims can be accomplished within the proposed time and resources?
- Do you have or need preliminary data?
- Get team feedback on draft application
- Be realistic about time to write, revise, incorporate feedback, and meet Office of Sponsored Research deadline.
- Build study timeline to accommodate unforeseen circumstances
- Submit application well ahead of the deadline (days, not hours)

https://grants.nih.gov/grants/oer.htm




Clinical Research Overview

National Institute of Mental Health

Points to Consider When Filling Out Section 3: Protection and Monitoring Plans of the NIH grant Application

Overview

We will cover points for applicants to consider when filling out Section 3: Protection and Monitoring Plans of the PHS Human Subjects and Clinical Trials Information form in the NIH grant application.

Specifically, we will give an overview of the following:

- **3.1** Protections of Human Subjects
- **3.2** Is this a multi-site study that will use the same protocol to conduct non-exempt human subjects research at more than one domestic site?
- **3.3** Data and Safety Monitoring Plan
- **3.4** Will a Data and Safety Monitoring Board be appointed for this study?
- **3.5** Overall Structure of the Study Team

- The PHS Human Subjects and Clinical Trials Information form is used to collect information on human subjects research, clinical research, and/or clinical trials, including study population characteristics, protection and monitoring plans, and a protocol synopsis.

- For a complete list of instructions on how to fill out the entire PHS Human Subjects and Clinical Trials Information portion of your application, you can go to:

  https://grants.nih.gov/grants/how-to-apply-application-guide/forms-e/general/g.500-phs-human-subjects-and-clinical-trials-information.htm

Applicant Initial Responsibilities

- Applicant must designate if human subjects are involved in the proposed research, and if so, whether the proposed activities meet the criteria for exemption.
- Applications that involve human subjects must complete Section 3: Protection and Monitoring Plans of the application.
- If it has been determined that the applicant is conducting exempt human subjects research, applicant must provide justification for how the research in the grant meets the relevant exemption category.
- Applications that are not proposing human subjects research but will use human data or biological specimens, must provide a justification for the claim of no involvement of human subjects.

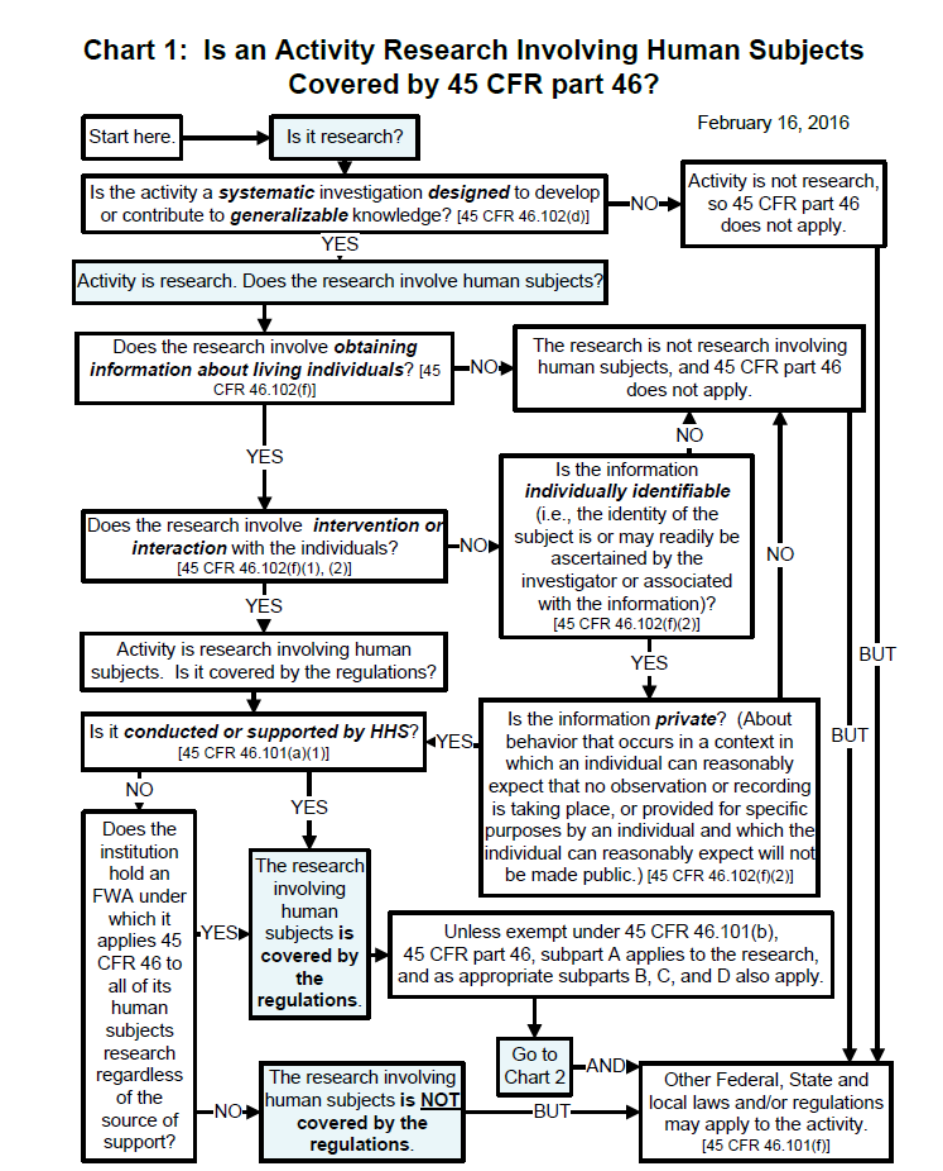
Conducting Human Subjects Research

- It can be confusing to determine what constitutes human subjects research.

- The Office for Human Research Protection (OHRP) has helpful resources. For example:
  - Human Subject Regulations Decision Charts which can be useful in determining what constitutes human subjects research and when research might be exempt from the IRB approval process (https://www.hhs.gov/ohrp/regulations-and-policy/decision-charts/index.html)

- NIH has helpful resources. For example:
  - Exempt Human Subjects Research infographic (https://humansubjects.nih.gov/sites/hs/public_files/exemption_infographic_v6_hs_internet.pdf)

Example of OHRP HS Regulations Decision Chart



Section 3: Protection and Monitoring Plans

- For any proposed nonexempt study involving human subjects, NIH requires a ***Protection of Human Subjects*** attachment that is commensurate with the risks of the study, its size, and its complexity. Official guidelines for fulfilling the requirements for human subjects use in grant applications can be found in the PHS 398 Application Kit instructions (https://grants.nih.gov/grants/funding/phs398/phs398.html).

- Keep in mind that this ***Protection of Human Subjects*** attachment is reviewed during peer review.

3.1: Protection of Human Subjects

Applicants should organize the ***Protection of Human Subjects*** attachment into four sections:

1.) The risks to human subjects

A.) Human subjects involvement, characteristics, and design (i.e., brief overview of overall study design, description of subject population(s), etc.)

B.) Study procedures, materials, and potential risks to subjects associated with each study intervention, procedure or interaction

3.1: Protection of Human Subjects

2.) The adequacy of protections against risk

A.) The informed consent and assent procedures

B.) The protections against risk

C.) Vulnerable subjects (if relevant to study)

3.1: Protection of Human Subjects

3.) The potential benefits of the proposed research to subjects and others

A.) Potential benefits of the research to research participants and others

B.) Why risks to subjects are reasonable in relation to the anticipated benefits to research participants and others

Note: Financial compensation of subjects should not be presented as a benefit of participation in research.

3.1: Protection of Human Subjects

4.) The importance of the knowledge to be gained

A.) Discuss the importance of the knowledge to be gained as a result of the proposed research.

B.) Discuss why the risks to subjects are reasonable in relation to the importance of the knowledge that reasonably may be expected to result.

3.2 Is this a multi-site study that will use the same protocol to conduct non-exempt human subjects research at more than one domestic site?

- If an investigator answers **"Yes"** to their study being a non-exempt multi-site study that will use the same protocol to conduct non-exempt human subjects research at more than one **domestic site***, then they will be required to use a single Institutional Review Board (sIRB) to conduct the ethical review required for the protection of human subjects. They are thus expected to also describe in this Protection of Human Subjects section, their single Institutional Review Board (sIRB) plan.

- See NIH's Single IRB Policy for Multi-site Research for more information (https://grants.nih.gov/policy/clinical-trials/single-irb-policy-multi-site-research.htm).

*The NIH sIRB policy applies to participating domestic sites. Foreign sites participating in NIH-funded, multi-site studies are not expected to follow this policy. (https://grants.nih.gov/policy/clinical-trials/single-irb-policy-multi-site-research.htm)

3.3 Data and Safety Monitoring Plan

- If an investigator answers **"Yes"** to all the questions in the **"Clinical Trial Questionnaire,"** then they are required by NIH grant policies to include a **"Data and Safety Monitoring Plan"** (DSMP). For human subjects research that do not meet criteria for clinical trial designation, investigators still have an option of including a DSMP (i.e., in studies that may have significant risk to participants).

  - **NIH** provides guidance for what should be included in a DSMP in the Research Instructions for NIH and Other PHS Agencies document (https://grants.nih.gov/grants/how-to-apply-application-guide/forms-e/research-forms-e.pdf)

  - **NIMH** provides additional information for what should be included in a DSMP in the Guidance for Developing a Data and Safety Monitoring Plan for Clinical Trials Sponsored by NIMH (https://www.nimh.nih.gov/funding/clinical-research/data-and-safety-monitoring-plan-writing-guidance.shtml)

3.3 Data and Safety Monitoring Plan

For any proposed clinical trial, NIH requires a data and safety monitoring plan (DSMP) that is commensurate with the risks of the trial, its size, and its complexity.

Applicants should provide a description of the DSMP, including:

- The overall framework for safety monitoring and what information will be monitored.
- The frequency of monitoring, including any plans for interim analysis and stopping rules (if applicable).
- The process by which Adverse Events (AEs), including Serious Adverse Events (SAEs) such as deaths, hospitalizations, and life threatening events and Unanticipated Problems (UPs), will be managed and reported, as required, to the IRB, the person or group responsible for monitoring, the awarding NIH IC, the NIH Office of Biotechnology Activities, and the Food and Drug Administration.

3.3 Data and Safety Monitoring Plan

- The individual(s) or group that will be responsible for trial monitoring and advising the appointing entity. Because the DSMP will depend on potential risks, complexity, and the nature of the trial, a number of options for monitoring are possible. These include, but are not limited to, monitoring by a:

  - PI and IRB: While the PI and IRB must ensure that the trial is conducted according to the approved protocol, in some cases (e.g., low risk trials, not blinded), it may be acceptable for the PI and IRB of record to also be responsible for carrying out the monitoring responsibilities of the research.

  - Independent safety monitor (ISM): an independent physician or other appropriate expert with relevant expertise who advises the grantee/contractor and the IC (as appropriate) of any safety concerns (e.g. for blinded study designs).

  - Data and Safety Monitoring Board (DSMB): an independent board of experts that may include investigators and biostatisticians not associated with the study.

3.4 Will a Data and Safety Monitoring Board be appointed for this study?

- A **Data and Safety Monitoring Board (DSMB)** is a formal, independent board of experts including investigators and biostatisticians that advise study investigators regarding the safety progression of a study. NIH requires the establishment of DSMBs for multi-site clinical trials involving interventions that entail potential risk to the participants, and generally, for all Phase III clinical trials. As necessary, a DSMB may be appropriate for Phase I and Phase II or other clinical trials if the studies are blinded (masked), employ high-risk interventions, or involve vulnerable populations (https://grants.nih.gov/grants/guide/notice-files/not98-084.html).

3.4 Will a Data and Safety Monitoring Board be appointed for this study? (Cont.)

- With NIMH grants, there are two types of DSMBs:
  - 1. External independent DSMB
  - 2.NIMH-constituted independent DSMB
- Depending on the circumstance, NIMH may assign a study to one of its NIMH-constituted DSMBs.
- If a DSMB is used, the applicant should describe the general composition of the Board without naming specific individuals.
- DSMBs members are expected to be independent from any professional or financial COI with the research project and investigators.

3.5 Overall Structure of the Study Team

- Applicants are required to fill out the **"Overall Structure of the Study Team"** attachment if they answered **"Yes"** to all questions in the **"Clinical Trials Questionnaire."**

- This question is optional for all other HS research.

- Within this attachment, applicants should provide a brief overview of the organizational structure of the study team, particularly the administrative sites, data coordinating sites, enrollment/participating sites, and any separate laboratory or testing centers.

Note: Do not include study team members' individual professional experiences (i.e., biosketch information).

Commonly Identified HS Issues During NIMH Human Research Protection Branch (HRPB) Review of Applications

- Missing or inadequate Data and Safety Monitoring Plan (DSMP)
- No mention of adverse event monitoring/reporting (should reference the NIMH Reportable Events Policy: https://www.nimh.nih.gov/funding/clinical-research/nimh-reportable-events-policy.shtml)
- No plan for “Incidental Findings”
- Insufficient Clinical Oversight (e.g., medication washouts without involvement of a licensed physician)
- If pregnancy is listed as an exclusion criterion in the study, a plan and method for evaluating pregnancy status is needed.

Operational Aspects to Consider When Writing Your Grant Application

Overview

- Inclusion of Women, Minorities and Children in Clinical Research
- Operational Components to Consider When Writing Your Grant
  - Study Population
  - Study Procedures
  - Data – Confidentiality and Quality Assurance
  - Regulatory Considerations
  - Reportable Events

Inclusion of Women, Minorities and Children in Clinical Research

- **Inclusion of Women and Minorities as Participants in Research Involving Human Subjects**
  - The NIH is mandated by the **Public Health Service Act sec. 492B, 42 U.S.C. sec. 289a-2** _ to ensure the inclusion of women and minority groups in clinical research.
  - Ensure that individuals are included in clinical research in a manner that is appropriate to the scientific question under study.
- **NIH Inclusion Across the Lifespan in Research Involving Human Subjects**
  - The purpose is to ensure individuals are included in clinical research in a manner appropriate to the scientific question under study so that the knowledge gained from NIH-funded research is applicable to all those affected by the researched diseases/conditions.
  - The ***Inclusion Across the Lifespan policy*** applies to all grant applications submitted **on or after January 25, 2019**. Until then, ongoing research and grant applications/proposals are subject to the ***Inclusion of Children in Clinical Research Policy***.

https://grants.nih.gov/grants/funding/women_min/women_min.htm

https://grants.nih.gov/grants/funding/lifespan/lifespan.htm

Inclusion Section in the Grant Application

- **Inclusion of Women and Minorities**
  - Describe the planned distribution of subjects by sex/gender, race, and ethnicity.
  - Describe the rationale for selection of sex/gender, racial, and ethnic group members in terms of the scientific objectives and proposed study design. The description may include, but is not limited to, information on the population characteristics of the disease or condition under study.
  - Describe proposed outreach programs for recruiting sex/gender, racial, and ethnic group members.
  - Inclusion and Excluded Groups: Provide a reason for limiting inclusion of any group by sex/gender, race, and/or ethnicity. In general, the cost of recruiting certain groups and/or geographic location alone are not acceptable reasons for exclusion of particular groups.

Inclusion Section in the Grant Application

- Inclusion of Children
  - Children are expected to be included in all NIH-defined clinical research unless there are scientific or ethical reasons not to include them. Discuss whether children (as a whole or a subset of individuals under 18) will be included or excluded. If children will be included, include a rationale for selecting a specific age range of children, if relevant. If children will be excluded, provide a rationale for exclusion.
  - Include a description of the expertise of the investigative team for working with children of the ages included, of the appropriateness of the available facilities to accommodate the children, and the inclusion of a sufficient number of children to contribute to a meaningful analysis relative to the purpose of the study.
- A table indicating **targeted/planned** enrollment figures for the above categories (women, children and minorities) must also be included.

Operational Components to Consider When Writing your Grant Application

- Writing grants involves spending a lot of time explaining how your scientific idea is valid, novel, feasible and worthwhile.

- Thinking about operations means thinking about how to turn your ideas into procedures in your study that will allow you to:

  Find and recruit the ***population*** you need, ask them to participate in the ***assessments / interventions*** you are proposing and allow you to ***measure the outcomes*** you would like to assess.

Identifying your study population

- **WHO** are you collecting data from in the study?
  - E.g., volunteers, patients, providers/clinicians, peers, family members/ caregivers

- **WHAT** kind of data are you collecting from these individuals?

  This will help you establish who may be a research participant.
  - Parent providing information about their child. Parent might not be considered a research participant.
  - Parent providing information about their own mental health. Parent would likely be considered a research participant.
  - A provider is being trained with a new treatment technique and their level of proficiency in the technique and the acceptability of the technique is being evaluated. Provider would likely be considered a research participant.

Population in your research study

- **WHERE** will you find the research participants?
  - How many sites are participating in the study?
  - Are they patients who attend a clinic/hospital? Is it a community sample from a school, or neighborhood?
  - Are any researchers in the local area studying the same population?
    - Will your recruitment be affected if several studies in your area are recruiting the same population?
- **HOW** will you recruit your population?
  - Approach potential participants while they are in the waiting room at a clinic/hospital?
  - Ask clinicians/providers to refer individuals to the study?
  - Advertisements- Mailouts, flyers in local community, digital marketing via Twitter/Instagram

Population in your research study

- **WHAT** are the inclusion/exclusion criteria for **EACH GROUP** of participants?
  - Are the criteria feasible (Is it likely you will find participants that meet them all? Are they too narrow? Are they too broad?)
  - Will the criteria prevent you from obtaining your planned sample size? (e.g., will it be unlikely to find enough individuals who meet all of your criteria.)

- **HOW** will you measure each one of the criteria?
  - *"Major Depressive Disorder":* Will you assess via SCID? Or rely on current medical records for recent diagnosis?
  - *"IQ >80":* Will you perform an IQ test? vs. use a proxy measures? Which?
  - *"Absence of neurological conditions"* – How and who will evaluate this? Will it be based on parent report vs. a medical screen?

Study Procedures

- Procedures for **EACH GROUP** of participants
  - **HOW LONG** will a participant be in the study? (Is it longitudinal?)
  - **WHAT** procedures/interventions are being completed? Might there be incidental findings? What will you do in those instances?
  - **HOW MANY** procedures? Are any invasive? How long will they take?
  - **WHO** completes the procedures with the participant?
    - Are they blinded? Are there procedures to brake the blind if need be?
    - Do they need a particular type of training? How often do they need training?
  - **WHERE** are procedures being performed
    - Assessment on the phone vs. in person at the site. Is the location accessible?
    - More than one site? How will you ensure all staff are following the same procedure?
  - **WHEN** – within what window of time do you have to complete the procedures?
    - E.g., participants have to complete follow-up assessments every 3 months – the window of time to collect the data is **3 months +/- 1 week** from prior assessment

Study Procedures: Pharmacological Procedures

- Is there a medication washout?
  - **WHO** directs it/monitors it?
- Is there medication titration schedule?
  - **WHO** directs it/monitors it?
- **WHO** can write prescriptions for study drug?
- Compounding of the study drug
  - **WHERE** is it being compounded (On site hospital/clinic pharmacy? Your lab? Off site facility?)
  - **WHO** is compounding the study drug? Are their specific regulations that must be followed? Do the individuals have the licensures to compound study drug?
- **WHAT** happens to participants after the study ends?
- **WHO** continues treatment? Will study drug continue to be available after study ends?
- Are there any stopping rules for the study?

Study Procedures: Risks and other considerations

- **WHAT** are the risks associated to participating in the study for **EACH GROUP**?
  - E.g., loss of confidentiality, reports of distress, etc.
- **WHAT** procedures will you put in place to mitigate these risks?
  - E.g., Allowing breaks between assessments, referrals to care, etc.
- **WHAT** are the reporting requirements for the study?
  - E.g., elder abuse, child abuse, suicidal ideation, etc.
- Are there specific instances that might lead to study discontinuation?

Data – Confidentiality and Quality Assurance

- **WHERE** and **HOW** are you recording data?
  - Paper, video/audio, electronic data capture (EDC) system
- **HOW** are you protecting confidentiality?
- **WHERE** are you storing it? Lock and key? Secure/Encrypted Server?
- **HOW** are you checking for errors? **WHAT** kind of data quality procedures are in place? (e.g., double entry, algorithms to identify out of range values, etc.)
  - Is there an audit trail system to track who has entered/edited data?
- **WHO** has access to data?
  - Is there protected health information? Who is allowed to access it?
  - What happens to paper files – **HOW LONG** will they be stored?
    - All NIH grants: Retain for 3 years after the final report is submitted to the NIH (NIH Grants Policy 8.4.2). If FDA regulated, check FDA policies.
    - If institutional policy is more conservative than the regulations above (requires longer retention timelines), follow institutional policy.

Regulatory Considerations

- **WHO** are the regulatory bodies involved?
  - Institutional Review Board (IRB), Ethical Bodies, Ministry of Health, Institutions/Universities, Data Safety Monitoring Boards (DSMB)

- **HOW** will you track all the regulatory documents and approvals relevant to your study?
  - Versions and dates on all documents
  - Document to track dates of approvals (of all relevant regulatory bodies) e.g., initial submission, amendments and required continuing reviews, etc.
  - Establish procedures to ensure all staff is using the most recently approved version of a document – and that all regulatory bodies have the same version at any point in time.

Things to consider regarding Consent/Assent

Familiarize yourself with your IRB/institutional requirements as well as other regulatory bodies in your country/state.

- **WHERE** will you consent participants?
  - In the field, home, office, on the phone (Is it private?, Do you have to travel with consent forms?)
- **HOW** will you consent participants (oral vs. written)?
- **WHO** is qualified to consent participants? Do they need training?
- Do you need a witness?
- Do you need to evaluate capacity to consent? How will you evaluate this?
- Do you need to collect assent?
  - Is there any information that you are not allowed to share with parents/guardians or are you required to share with parents/guardians? Are there specific circumstances when this would occur?

Reportable Events Assessment and Reporting

- **WHAT** is an Adverse Event (AE), Serious Adverse Event (SAE), and an Unanticipated Problem? – Define these in your protocol and discuss which you might expect in your study.
  - E.g., http://www.hhs.gov/ohrp/policy/advevntguid.html#AA
  - https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=312.32
- **HOW** will you assess AEs/SAEs (e.g., with a questionnaire)?
- **HOW OFTEN** will you assess for AEs/SAEs?
- **WHO** will assess the reportable event and do they have the proper training to do so?
  - **WHAT** is the expectedness/relatedness determination?
  - Is there any necessary follow-up for the reportable event?
- **HOW** and **WHERE** will these be recorded and reviewed? By whom?

Reportable Events Assessment and Reporting

- **WHAT** is a Protocol Violation and Protocol Deviation? - Define what they are and the procedures to evaluate and report these in your protocol.
  - E.g., https://www.hhs.gov/ohrp/sachrp-committee/recommendations/2012-march-30-letter-attachment-c/index.html

- **WHAT** are your institutional policies, NIH/Government policies (FDA), DSMB (if applicable) policies, on tracking and reporting AEs/SAEs and protocol noncompliance?
  - **HOW** often (business days vs. calendar days) do you need to report them? To whom?
  - https://www.nimh.nih.gov/funding/clinical-research/nimh-reportable-events-policy.shtml

Helpful Resources

- NIH Research Involving Human Subjects: https://humansubjects.nih.gov/
- NIH Grants Policy Statement: https://grants.nih.gov/grants/policy/nihgps/HTML5/section_4/4.1_public_policy_requirements_and_objectives.htm#Human3
- International Conference on Harmonization (ICH) Good Clinical Practices (GCP): http://www.ich.org/products/guidelines.html
- FDA Regulations: http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/ucm155713.htm#FDARegulations
- NIMH Clinical Research Policies: http://www.nimh.nih.gov/funding/clinical-research/index.shtml
- Office for Human Research Protections (OHRP): http://www.hhs.gov/ohrp/humansubjects/index.html
- GCP training course: https://gcplearningcenter.niaid.nih.gov/Pages/default.aspx
- Human Subjects Protections Training: https://humansubjects.nih.gov/resources

References

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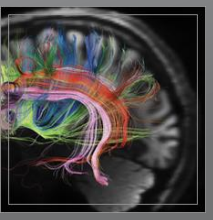
- https://grants.nih.gov/grants/peer/guidelines_general/Guidelines_for_the_Review_of_the_Human_Subjects.pdf
- https://grants.nih.gov/policy/clinical-trials/single-irb-policy-multi-site-research.htm
- https://grants.nih.gov/grants/how-to-apply-application-guide/forms-e/general/g.500-phs-human-subjects-and-clinical-trials-information.htm#3.1
- https://grants.nih.gov/grants/funding/phs398/phs398.html




NIH Peer Review Process

National Institute of Mental Health

The Life of a Research Grant: Dual Review System

First Level of Review

Scientific Review Group (SRG)

- Provides initial scientific merit review of Grant Applications
- Rates applications and makes recommendations for appropriate level of support and duration of award

Second Level of Review

Council

- Assesses SRG review of grant applications
- Makes recommendations to Institute staff on funding
- Evaluates program priorities and relevance
- Advises on policy

National Institute of Mental Health

Typical Timeline for a New Research Grant Application (R01)

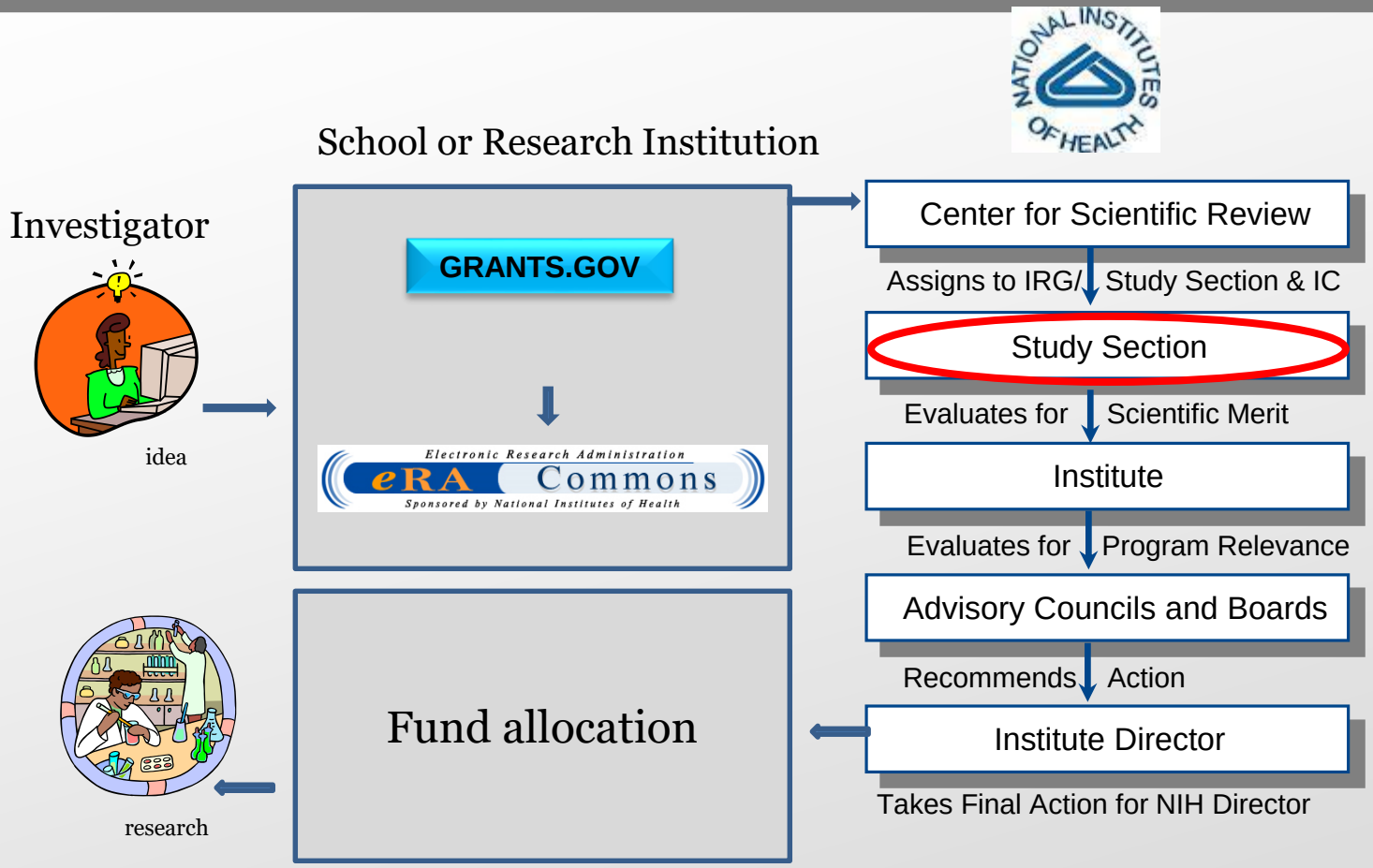
There are three overlapping cycles per year

	Cycle 1	Cycle 2	Cycle 3
Submit in	February	June	October
Review in	May/June	Sept/Oct	Jan/Feb
Council in	Sept/Oct	Jan/Feb	May/June
Earliest award in	December	April	July

After Submission

- Use the eRA Commons to follow your application
  - Find details about:
    - Review Assignment / Roster
    - Date of Review
    - Scientific Review Officer
    - Program Assignment

- All rosters available at https://public.era.nih.gov/pubroster/


School or Research Institution
Investigator
idea
GRANTS.GOV
Electronic Research Administration
eRA Commons
Sponsored by National Institutes of Health
research
Fund allocation
Center for Scientific Review
Assigns to IRG/ Study Section & IC
Study Section
Evaluates for Scientific Merit
Institute
Evaluates for Program Relevance
Advisory Councils and Boards
Recommends Action
Institute Director
Takes Final Action for NIH Director

Scientific Review Groups

- Each review group has, on average, 10-25 members who are primarily from academia.
- Review groups may meet in person, on the telephone, with video assistance, or sometimes even electronically
- As many as 100 applications are reviewed by each standing review group.

National Institute of Mental Health

Review Criteria

- IMPACT
  - Significance
  - Investigator
  - Innovation
  - Approach
  - Environment
  - Human Subjects & W/M/C Inclusion OR
  - Vertebrate Animals
- Budget & Other Considerations

Scoring Guide

Overall Impact:
The likelihood for a project to exert a sustained, powerful influence on research field(s) involved

Overall Impact	High	Medium	Low
Score	1 2 3	4 5 6	7 8 9

Evaluating Overall Impact:
Consider the 5 criteria: significance, investigator, innovation, approach, environment (weighted based on reviewer's judgment) and other score influences (e.g. human subjects)

e.g. Applications are addressing a problem of high importance/interest in the field. May have some or no technical weaknesses.

e.g. Applications may be addressing a problem of high importance in the field, but weaknesses in the criteria bring down the overall impact to medium.

e.g. Applications may be addressing a problem of moderate importance in the field, with some or no technical weaknesses

e.g. Applications may be addressing a problem of moderate/high importance in the field, but weaknesses in the criteria bring down the overall impact to low.

e.g. Applications may be addressing a problem of low or no importance in the field, with some or no technical weaknesses.

5 is a good medium-impact application, and the entire scale (1-9) should always be considered.

The Review Meeting

Review groups may:

- Discuss an application
- Elect not to discuss an application if it is “not competitive”

  - Typically “bottom half” of applications in a meeting

- Defer an application for more information

Post-Review Meeting

- Scores are released (generally within 24-72 hours)
- Reviewers have several days to edit their critiques / criterion scores
  - Ensure that language matches criteria and overall score
  - Add any additional strengths and weaknesses from the discussion
- SRO
  - Writes resume and summary of discussion of discussed applications
  - Edits critiques
- Releases Summary Statement (within 6 weeks)
  - Applicant, Program Officer, Council

How an idea becomes a grant

School or Research institution

Idea

GRANTS.GO

Electronic Research Administration eRA Commons Sponsored by National Institutes of Health

Investigator

Research

Fund Allocation

Center for Scientific Review

Assigns to IRG/Study Section & IC

Study Section

Evaluates for Scientific Merit

Institute

Evaluates for Program Relevance

Advisory Councils and Boards

Recommends Action

Institute Director

Takes Final Action for NIH Director

NIH National Institute of Mental Health

NIH National Institute of Mental Health

Responding to Summary Statement

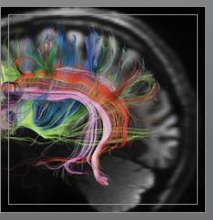
- Interpreting the Summary Statement
  - Priority Score and Percentile
  - Human Subjects protection and Inclusion Codes
  - Resume and Critiques
  - Budget and Administrative Notes
  - Program Contact Information
- Collecting and Incorporating Feedback
- Responding to the Critiques

Responding to Summary Statement

- Interpreting the Summary Statement
- Collecting and Incorporating Feedback
  - Wait for the summary statement to be available on your Commons account
  - Regulate your emotion!
  - Develop a list of Issues/Concerns and draft tentative response to each
  - Consult your colleagues and mentors for feedback
  - Contact your Program Officer:
    - Email an outline of issues/responses; Suggest times for a call
    - Collect Guidance on:
      - Institute Interest
      - Interpretation of Reviewer comments
      - Methodological strategies
      - Grantsmanship

Responding to Summary Statement

- Interpreting the Summary Statement
- Collecting and Incorporating Feedback
- Responding to the Critiques
  - Address weaknesses/concerns; consider:
    - Rebuttal with clarification
    - Modifications
  - For potentially fundable applications:
    - Response should be detailed (no page limit) and stand as an addendum to the application
    - HS/Inclusion concerns require separate, careful consideration
  - Seek feedback review from Mentor/Collaborators and Program Officer

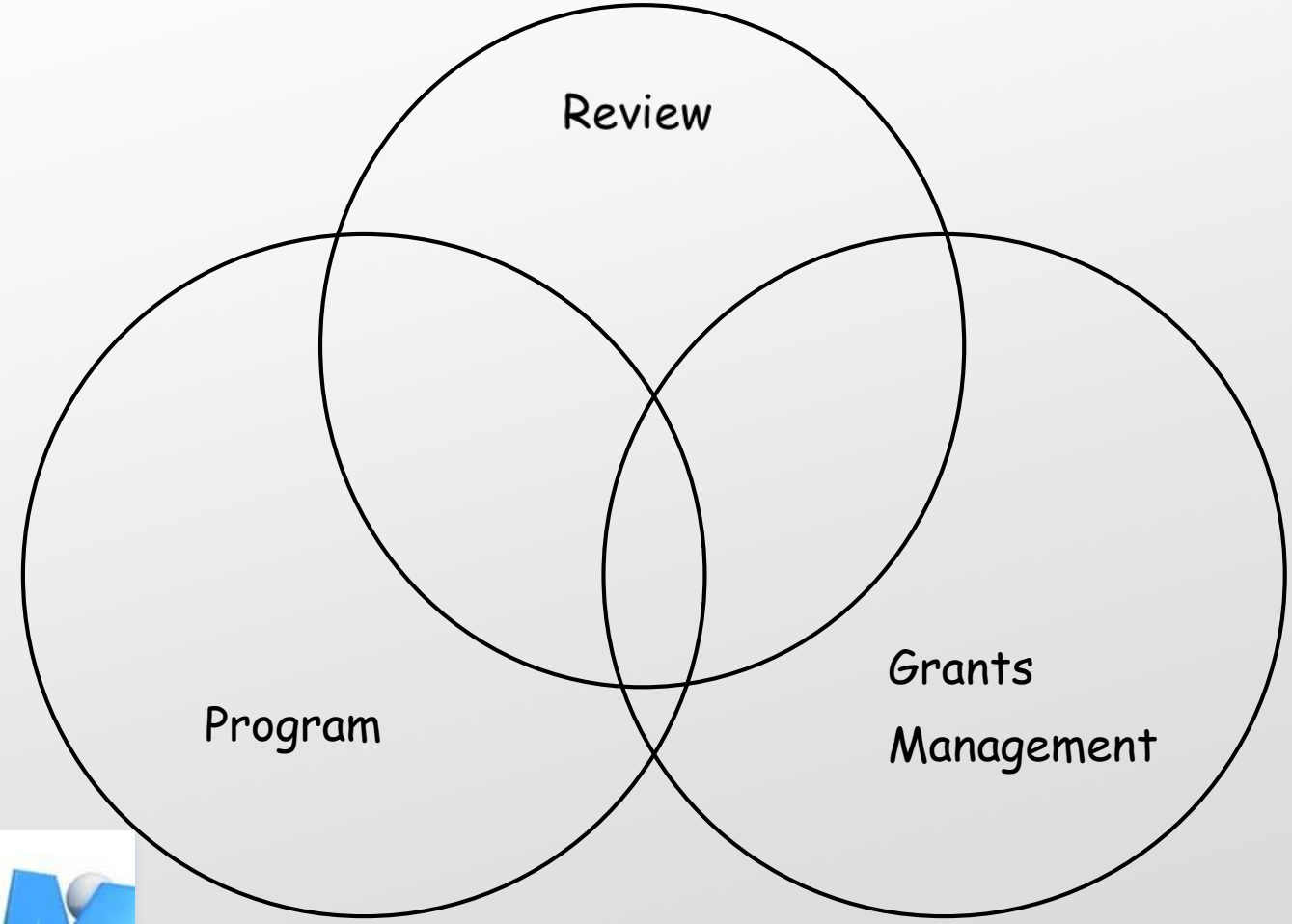



GRANTS ADMINISTRATION

National Institute of Mental Health

National Institutes of Health

THE NIH EXTRAMURAL TEAM



PROGRAM OFFICER

Responsible for the scientific, programmatic and/or technical aspects of grants

- Important initial contact for PIs
- Initiates and encourages interest in scientific area of importance to match that of Institute's mission
- Is familiar with the peer review process
- Discusses review issues with applicant
- Ascertains programmatic and mission relevance of applications
- Prepares funding recommendations
- Reviews annual progress of grants

SCIENTIFIC REVIEW OFFICER

Performs administrative & technical review of applications

- Recruits and selects reviewers
- Manages study sections and project site visits
- Prepares summary statements
- Provides any requested information about study section requirements

GRANTS MANAGEMENT OFFICER

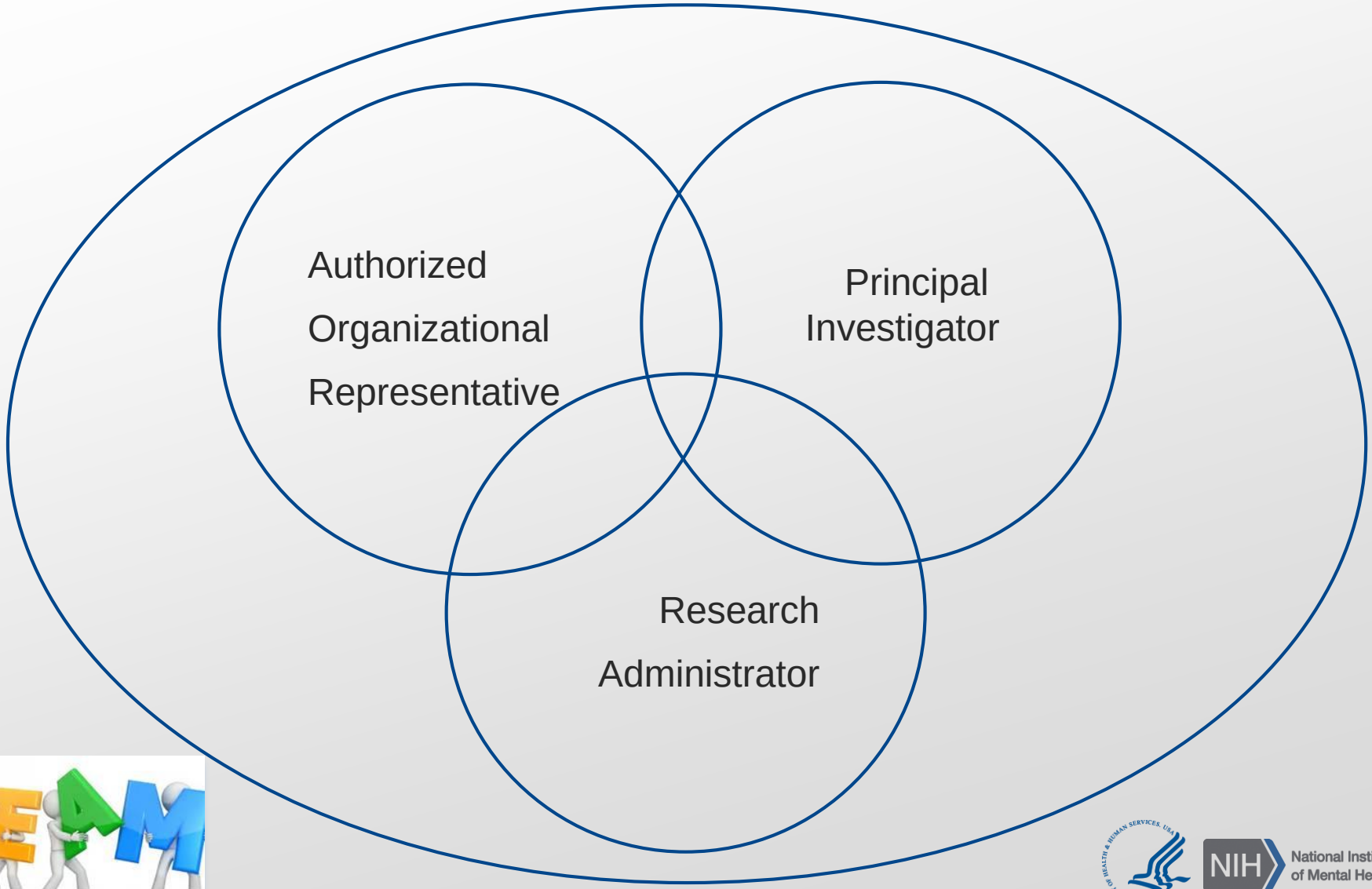
- Monitors a grant's administrative and fiscal aspects
- Assures compliance with Federal laws and NIH administrative policies and procedures
- Is the NIH official authorized to obligate the NIH to the expenditure of funds or to change funding amounts, budget/project period dates, or other terms and conditions of a grant award
- Responsible for maintaining official grant files

GRANTS MANAGEMENT SPECIALIST

Acts as an agent of the GMO

- Assures compliance with Federal laws and NIH policies and procedures
- Analyzes grant applications prior to award
- Prepares award for GMO release
- Provides technical assistance, interprets NIH policies and Institute procedures
- Reviews and responds to grantee prior approval requests
- Assures documentation of official grant files

RECIPIENT INSTITUTION TEAM



NIH National Institute of Mental Health

THE RECIPIENT INSTITUTION

- Award made to institution
- Legally responsible for proper conduct and execution of the project
- Provides fiscal management of the project
- Oversight on allocation decisions
- Assures compliance with Federal laws and regulations, and NIH policies and procedures

AUTHORIZED ORGANIZATIONAL REPRESENTIVE (AOR)

- Designated representative of the grantee organization
- Accountable for information presented in grant application, signs all official correspondence.
- Assures compliance with Federal laws and regulations, and NIH policies and procedures.

PRINCIPAL INVESTIGATOR

- Designated by grantee institution
- Responsible for scientific and technical aspects of application
- Assures compliance with Federal laws and regulations, and NIH policies and procedures - maintains contact with Grants Management Specialist
- Assures scientific compliance - maintains contact with Program Officer

PRINCiPAL INVESTIGATOR

Should work with designated officials within recipient organization to:

- Create/maintain necessary technical and administrative documentation
- Prepare justifications
- Comply with organizational and Federal requirements
- Acknowledge Federal support in publications

RESEARCH ADMINISTRATOR

- Acts as a local agent of the Authorized Organizational Rep. and/or PI
- Is a counterpart to the Grants Specialist
- Provides essential grant-related support
- Cannot assume responsibilities assigned to the Authorized Organizational Official or the PI

BUDGET COSTS

BUDGET COSTS

- Must be allowable, allocable, reasonable and consistently treated
- Must conform to any PA/RFA limitation
- Graduate student costs awarded at zero-level postdoc
- Appropriation dictates salary cap

CONSORTIUM/SUB AWARDS

The grantee has primary responsibility for the costs incurred and work performed under a subaward.

- Must have a written agreement outlining all requirements including the applicable terms and conditions of the award and details on how and when reimbursement is provided.

APPLICATIONS WITH CONSORTIUM F&A COSTS

When requesting consortium F&A costs:

- applicants should separate these costs when determining if a budget exceeds a direct cost limit

Consortia F&A costs do not count against direct cost caps

http://grants.nih.gov/grants/guide/notice-files/NOT-OD-05-004.html

F&A (INDIRECT COSTS)

The calculation of F&A must be calculated on allowable expenses. Allowable expenses for foreign organization is:

“to support the costs of compliance with NIH requirements”

F&A FOR FOREIGN

- From the NIH Grants Policy Statement:
  - NIH will not support the acquisition of, or provide for depreciation on, any capital expenditures, or support the normal, general operations of foreign and international organizations

F&A FOR FOREIGN

- Examples of allowable expenses from the NIH Grants Policy Statement:
  - protection of human subjects (including the required education in the protection of human research participants),
  - animal welfare,
  - invention reporting,
  - financial conflict of interest and
  - research misconduct.

GRANTS MANAGEMENT REVIEW AND NEGOTIATION OF AWARDS

BUDGET REVIEW

- Budget Justification
- Salary Cap
- Legislative mandates
- Consortia costs
- Indirect costs
- Escalation
- Conformance to applicable cost principles
- IRG Budget Recommendations

REQUIRED JUST-IN-TIME (JIT) INFORMATION

- Other Support
- Animal assurance and IACUC approval
- Human Subjects FWA assurance and IRB approval
- Education in the protection
    - of human subjects for all
    - key personnel involved in
    - human subject research

https://grants.nih.gov/grants/guide/notice-files/NOT-OD-12-101.html

OTHER SUPPORT - OVERLAP

Scientific:

- Substantially the same research is proposed in more than one application submitted to two or more different funding sources

Budgetary:

- Duplicate or equivalent budgetary items requested in an application are already funded or provided for by another source.

Commitment:

- Any key personnel who have a time commitment exceeding 100 percent or 12 person-months

WHAT SLOWS DOWN THE AWARD PROCESS….

- Lack of or Slow Response to Inquiries
- Delays Sending JIT Info
  - Missing AWA or FWA for applicable consortium sites
  - IRB & IACUC approvals/updates
  - Certification of Education on Human Subjects
  - Other Support issues
- Budgets with inadequate justification
- Missing information for Key Personnel
- Institutional closeout compliance

THE NOTICE OF AWARD

(NoA)

INFORMATION FOUND IN THE NoA?

Legally Binding Document

- Identifies grantee and PI
- Establishes funding level
- Establishes period of support
- Sets forth terms and conditions
- NIH Contact Information
  - Program Director
  - Grants Management Specialist

STANDARD TERMS AND CONDITIONS

- Acknowledgement of NIH Grant Support
- NIH Public Access Policy – PubMed Central (PMCID)
- Financial Conflict of Interest
- Federal Funding Accountability and Transparency Act (FFATA)
- Includes the terms and conditions of the NIH Grants Policy Statement (NIH GPS) by reference.

GRANT SPECIFIC TERMS AND CONDITIONS

- Included or excluded from carryover as appropriate
- Streamlined Noncompeting Award Process (SNAP)
- Federal Demonstration Partnership (FDP) Institution noted
- Disposition of Program Income

Section IV-Special Terms & Conditions
IC Specific Terms and Conditions

Cooperative Agreement terms

- Should be identical to those published in the request for applications (RFA); specify collaborative responsibilities

Restrictive terms

- May specify required action on the part of grantee for restriction to be lifted

Information Items

- Budget and effort adjustments
- Change of grantee institution terms
- Post award actions resulting from prior approval requests

GRANTEE ACCEPTANCE

- Recipients indicate acceptance of the terms and conditions of the award by drawing down funds from the Payment Management System (PMS)

- If there are concerns about the terms and conditions of award resolve them prior to drawing down funds

RESOURCES

- NIH Policy and Compliance
  https://grants.nih.gov/policy/index.htm
- NIH Grants Policy Statement
  https://grants.nih.gov/policy/nihgps/index.htm
- Notices of NIH Policy Changes
  https://grants.nih.gov/policy/notices.htm
- Grants Process Overview
  https://grants.nih.gov/grants/grants_process.htm
- Information for Researchers
  https://grants.nih.gov/grants/information-for-research.htm
- Information for Research Administrators
  https://grants.nih.gov/grants/information-for-research-administrators.htm

RESOURCES

- Information for Foreign Grants
  https://grants.nih.gov/grants/foreign/index.htm
- Financial Conflict of Interest
  https://grants.nih.gov/grants/policy/coi/index.htm
- Public Access Policy https://publicaccess.nih.gov/
- Welcome Wagon: Information for new Recipient Organizations
  https://grants.nih.gov/grants/funding/welcomewagon.htm