NIH grants workshop

NIH Review Process and budgets

Andrew Bean, PhD

NIH Grant Components

Alexandra Thomas, PhD, Assistant Professor & Grant EducatorRush University Graduate College

IRB, Human Subjects, and Vertebrate Animal Considerations

Crista Brawley, PhD, CCRP, Vice President, Research Operations & Chief Research Administrator, ORA

NIH-funded Clinical Trial Considerations

Raj Shah, MD, Assistant Vice Provost & Medical Director Clinical Trials, RU

Pre- and Post-Award Grant Management and Submission at Rush

Kristin Moody, MBA, CRA, Associate Vice President, Basic & Translational Science Operations, ORA
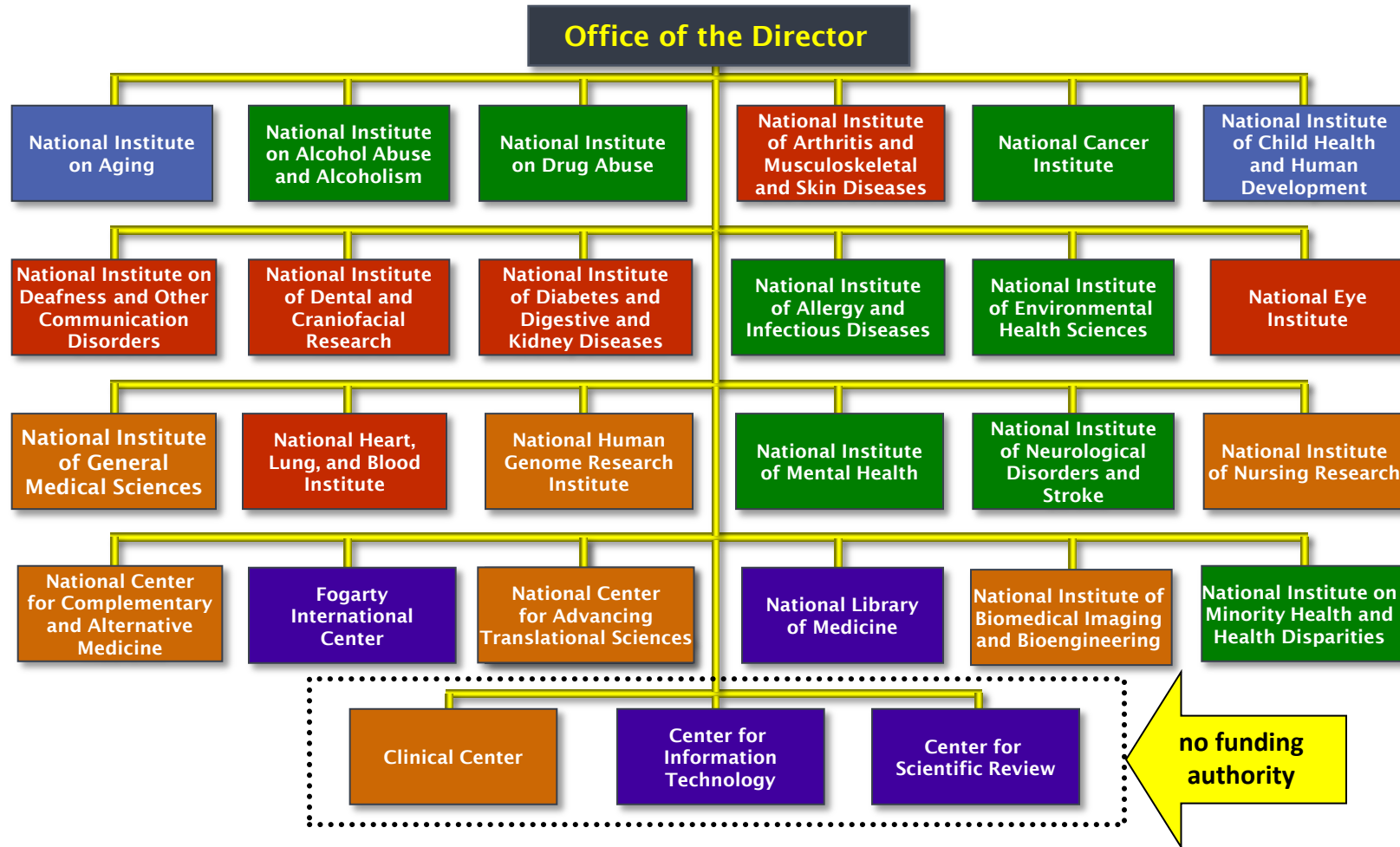
Jennifer Garcia, CRA, Director, Sponsored Programs, ORA

Andrew_J_Bean@rush.edu

National Institutes of Health Basics

- Mandate
- Branches
- CSR (Center for Scientific Review)
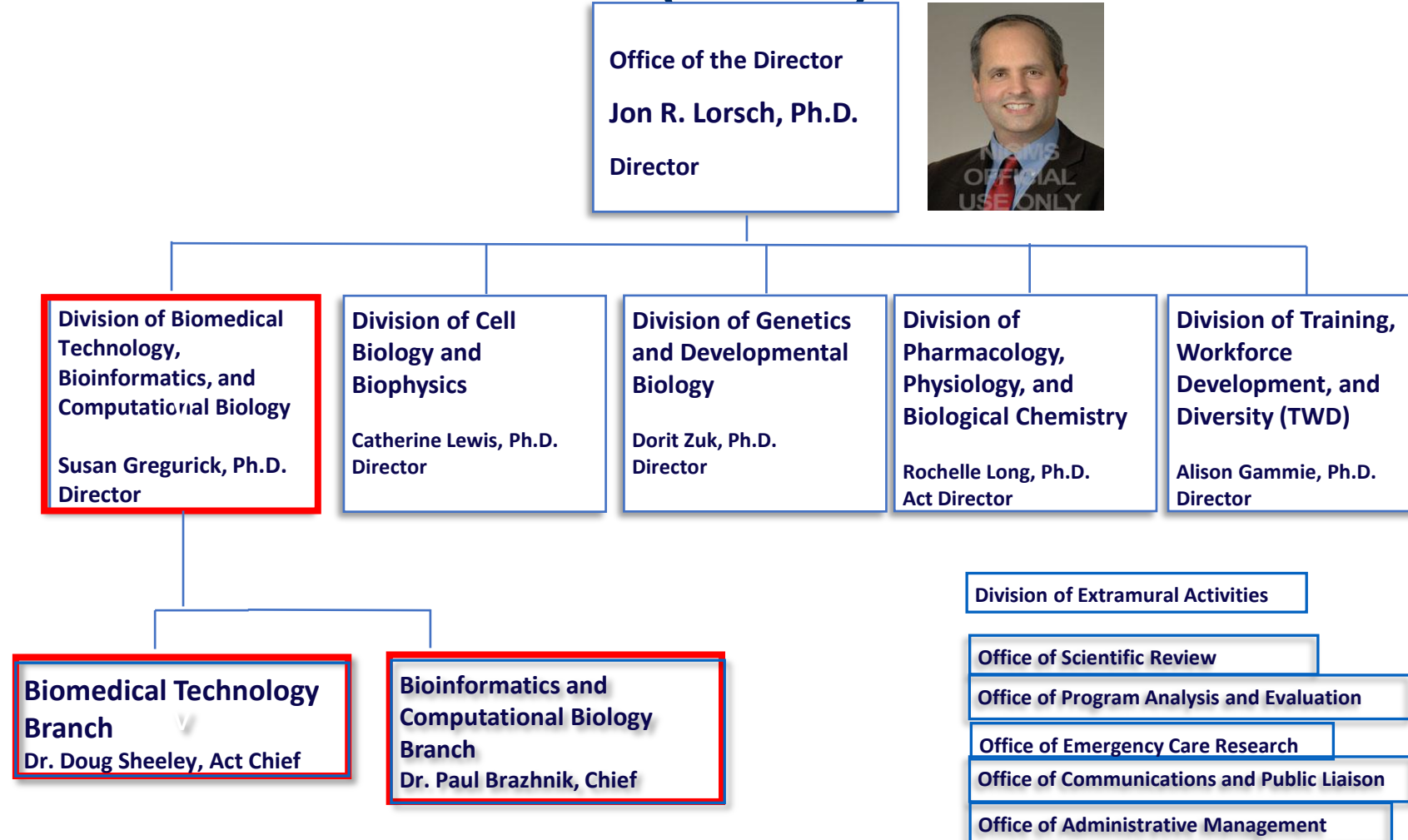- Study sections
- Council
- Funding mechanisms
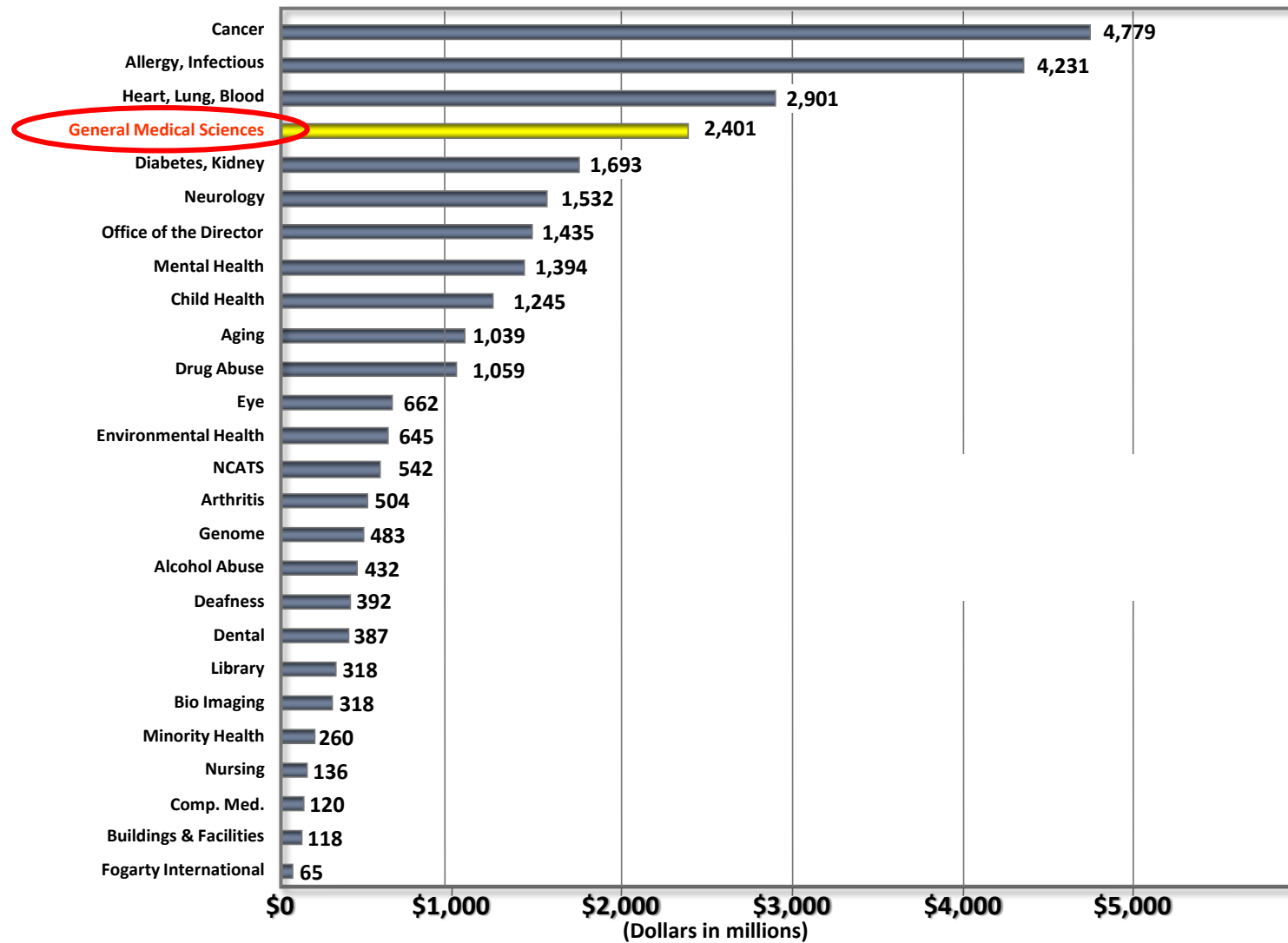
National Institutes of Health (NIH)

Office of the Director

National Institute on Aging	National Institute on Alcohol Abuse and Alcoholism	National Institute on Drug Abuse	National Institute of Arthritis and Musculoskeletal and Skin Diseases	National Cancer Institute	National Institute of Child Health and Human Development
National Institute on Deafness and Other Communication Disorders	National Institute of Dental and Craniofacial Research	National Institute of Diabetes and Digestive and Kidney Diseases	National Institute of Allergy and Infectious Diseases	National Institute of Environmental Health Sciences	National Eye Institute
National Institute of General Medical Sciences	National Heart, Lung, and Blood Institute	National Human Genome Research Institute	National Institute of Mental Health	National Institute of Neurological Disorders and Stroke	National Institute of Nursing Research
National Center for Complementary and Alternative Medicine	Fogarty International Center	National Center for Advancing Translational Sciences	National Library of Medicine	National Institute of Biomedical Imaging and Bioengineering	National Institute on Minority Health and Health Disparities

Clinical Center	Center for Information Technology	Center for Scientific Review

no funding authority

Different Missions, Responsibilities and Constituencies

Disease, Anatomy, Life Stage, Approach & Support

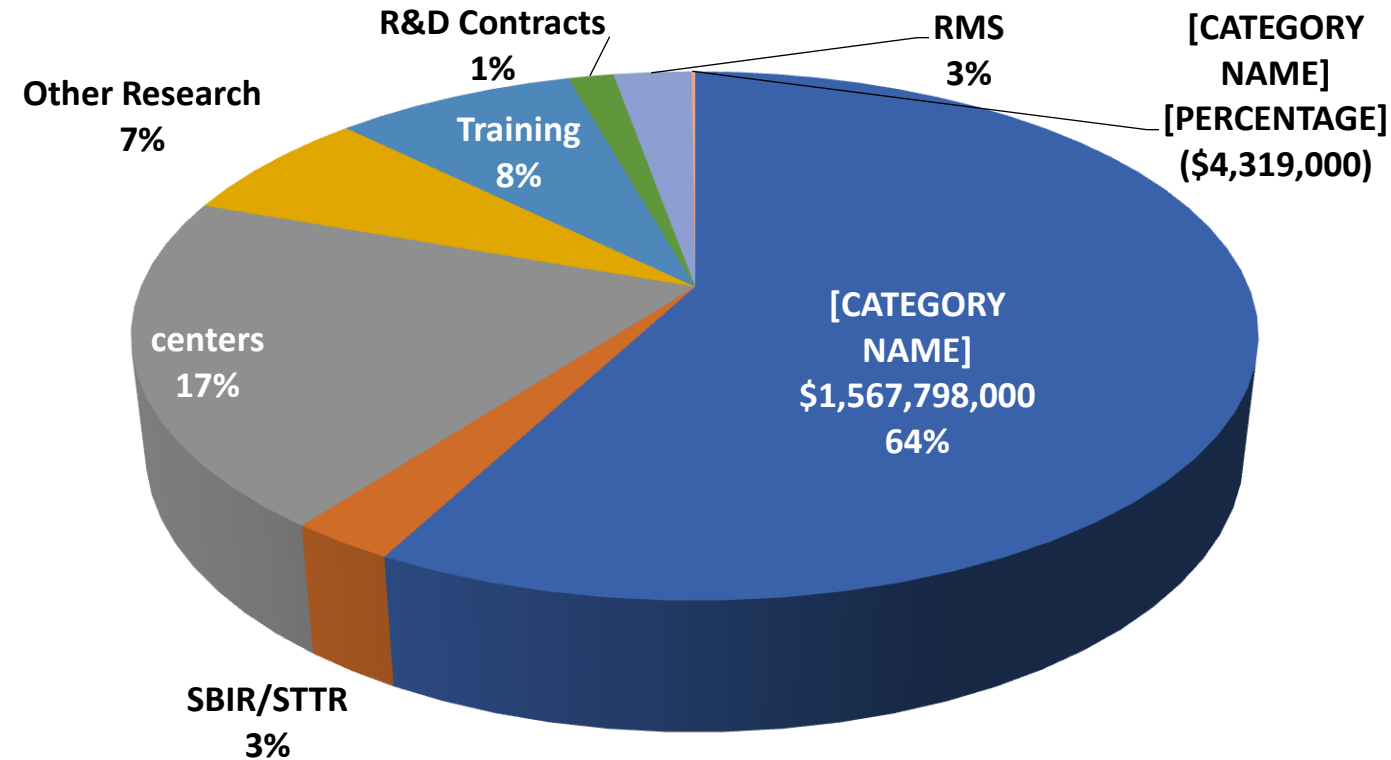# Example: National Institute of General Medical Sciences (NIGMS)

Office of the Director

Jon R. Lorsch, Ph.D.

Director

Division of Biomedical Technology, Bioinformatics, and Computational Biology

Susan Gregurick, Ph.D.
Director

Division of Cell Biology and Biophysics

Catherine Lewis, Ph.D.
Director

Division of Genetics and Developmental Biology

Dorit Zuk, Ph.D.
Director

Division of Pharmacology, Physiology, and Biological Chemistry

Rochelle Long, Ph.D.
Act Director

Division of Training, Workforce Development, and Diversity (TWD)

Alison Gammie, Ph.D.
Director

Biomedical Technology Branch
Dr. Doug Sheeley, Act Chief

Bioinformatics and Computational Biology Branch
Dr. Paul Brazhnik, Chief

Division of Extramural Activities

Office of Scientific Review

Office of Program Analysis and Evaluation

Office of Emergency Care Research

Office of Communications and Public Liaison

Office of Administrative Management

Direct responsibility for funding research and training relevant to their mission.

Category	Dollars in millions
Cancer	4,779
Allergy, Infectious	4,231
Heart, Lung, Blood	2,901
General Medical Sciences	2,401
Diabetes, Kidney	1,693
Neurology	1,532
Office of the Director	1,435
Mental Health	1,394
Child Health	1,245
Aging	1,039
Drug Abuse	1,059
Eye	662
Environmental Health	645
NCATS	542
Arthritis	504
Genome	483
Alcohol Abuse	432
Deafness	392
Dental	387
Library	318
Bio Imaging	318
Minority Health	260
Nursing	136
Comp. Med.	120
Buildings & Facilities	118
Fogarty International	65

(Dollars in millions)

Example: National Institute of General Medical Sciences

- **To support research that increases understanding of life processes and lays the foundation for advances in disease diagnosis, treatment, and prevention.**

- **Provide leadership in training the next generation of scientists to assure the vitality and continued productivity of the research enterprise.**

R&D Contracts
1%

RMS
3%

[CATEGORY NAME]
[PERCENTAGE]
($4,319,000)

Other Research
7%

Training
8%

centers
17%

[CATEGORY NAME]
$1,567,798,000
64%

SBIR/STTR
3%

NIH Funding Mechanisms: Examples

Research

R01	**Research Project Grant**
R03	**Small Research Grant Project**
R13	**Support for Conferences and Scientific Meetings**
R15	**Academic Research Enhancement Award (AREA)**
R21	**Exploratory Development Research Grant**
R41-44	**Small Business Grant**
P01	**Program Project Grant**
P50/P41	**Research Center Grant**

Training

F30	**Individual Predoctoral Fellowship for MD/PhD**
F31	**Individual Predoctoral Fellowship to Promote Diversity**
F31	**Individual Predoctoral Fellowship**
F32	**Individual Postdoctoral Fellowship**
K99/R00	**Pathway to Independence Award**
T32	**Institutional Training Grant**

Sponsor's Institution Submits Application

Electronic Submission
GRANTS.GOV℠

National Institutes of Health
NATIONAL INSTITUTES OF HEALTH

Assign to Institute and Study Panel
center for scientific review

Applicant & Sponsor Initiate Research Idea

Conducts Research

Starts here!

FUNDING CYCLE

Study Panel

Review of Scientific Merit

Resubmission

Allocation of Funds

Take Action

Institute Director

Recommend Action

Leaders in the biological and medical sciences, education, health care, and public affairs.
Advisory Council

Evaluate Relevance

Institute
(24 with funding authority)

NCI	NIAMS	NIEHS	CIT
NEI	NIBIB	NIGMS	CSR
NHLBI	NICHD	NIMH	FIC
NHGRI	NIDCD	NIMHD	NCATS
NIA	NIDCR	NINDS	NCCAM
NIAAA	NIDDK	NINR	CC
NIAID	NIDA	NLM	OD

Your Application is . . .

- Checked for being on time, formatted correctly and complete

- Assigned to a CSR Study Section for review

- Assigned to an NIH Institute or Center for eventual funding consideration

SROs are doctoral-level scientists who manage the overall peer review of your application.

Role of the Scientific Review Officer

Designated Federal Official with overall responsibility for the review process

- Performs administrative review of applications to ensure completeness and scientific fit with study section

- Recruits and assigns reviewers based upon applications under review

- Addresses applicant questions and accepts supplemental material prior to the study section meeting

- Manages study section meetings

- Prepares summary statements

Your SRO Assigns Three Reviewers to Your Application

Review Criteria

- <u>Overall Impact</u>
  Training Grant: Assessment of the likelihood that the proposed training will enhance the candidate's potential for a productive, independent scientific career.

  Research Grant: Assessment of the scientific merit, feasibility, and likelihood of the research resulting in impactful results.

- <u>Five core score driving review criteria</u>
  - Significance
  - Investigator (including Collaborators and Consultants)
  - Innovation
  - Approach
  - Environment

Overall Impact and Each Review Criterion scored from 1-9

9-Point Scoring Scale

Impact	Score	Descriptor
High Impact	1	Exceptional
	2	Outstanding
	3	Excellent
Medium Impact	4	Very Good
	5	Good
	6	Satisfactory
Low Impact	7	Fair
	8	Marginal
	9	Poor

At the Meeting

Order of Review

- The average of the preliminary Overall Impact score from the assigned reviewers determines the review order
- Discussions start with the application with the best average preliminary Overall Impact score

Not Discussed Applications

- About half the applications will be discussed
- Applications unanimously judged by the review committee to be in the lower half are not discussed

CSR Study Sections: The Meeting

- About 60-100 applications are normally reviewed at each study section meeting.
- For the 50% that are discussed, three assigned reviewers present their impressions and scores.
- Remaining panel members participate in discussion
- Everyone on the panel provides scores.

After the Review Meeting
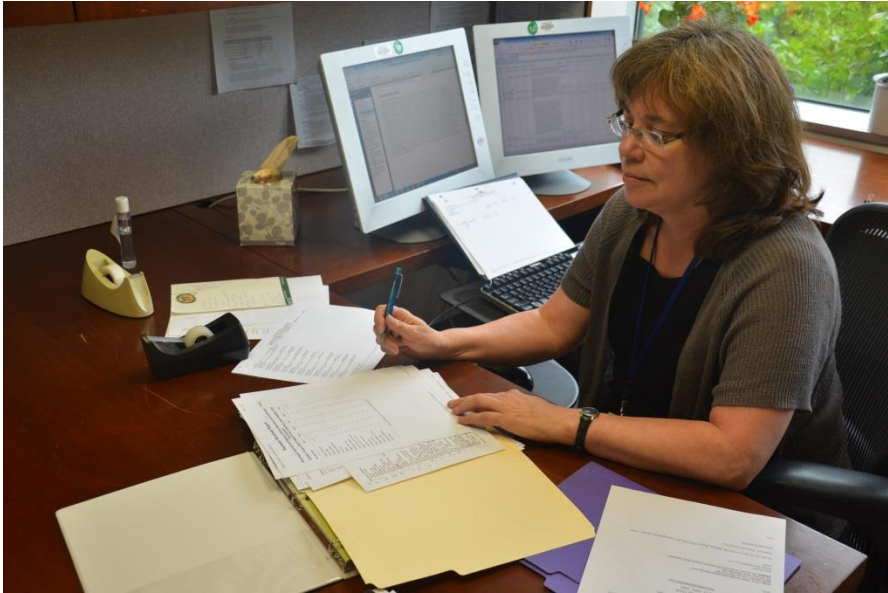
Your SRO

- Releases the scores

- Prepares summary statements

- Provides information to NIH Institutes and Centers

You should …

- Check the status of your application in eRA Commons

- Wait to contact your Program Officer until after you have received your summary statement

Check the Status of Your Application in NIH Commons

Status Information

Status →

General Grant Information		Other Relevant Documents
Status:	Scientific Review Group review pending. Refer any questions to the Scientific Review Administrator.	e-Application
Institution Name:		Additions for Review (0 documents)
School Name:		
School Category:		**Correspondence**
Division Name:	NONE	**Referral**
Department Name:		**Date** **Description**
PI Name:		
Application ID:		
Proposal Title:		
Proposal Receipt Date:	10/18/2013	
Last Status Update Date:	10/31/2013	
Current Award Notice Date:		
Application Source:	Grants.gov	
Project Period Begin Date:	08/01/2014	
Project Period End Date:	07/31/2017	
eApplication Status:	Submission Complete	
FOA:	[PA13-313] - Academic Research Enhancement Award (Parent R15)	
NIH Appl. ID:		

Summary Statement

Status History		Institute or Center Assignment		
Effective Date	**Status Message**	**Institute or Center**		**Assignment**
10/21/2013	Application entered into system			10/28/2013
		NATIONAL INSTITUTE OF NEUROLOGICAL DISORDERS AND STROKE **(Primary)**		10/21/2013
		NATIONAL INSTITUTE OF NEUROLOGICAL DISORDERS AND STROKE **(Primary)**		10/28/2013

Application Information		Study Section		Advisory Council(AC) Information
Award Document Number:	RNS088123A	Scientific Review Group:	ZRG1 MDCN-R (86)	
FSR Accepted Code:	N	Council Meeting Date(YYYY/MM):	2014/05	
Snap Indicator Code:		Meeting Date:	03/06/2014	
Impact Score:		Meeting Time:	08:00	**Meeting Date**
Percentile:		Study Roster:	View Meeting Roster	
Early Stage Investigator Eligible:				

Your Summary Statement

- Released by SRO within 30 days of
  the study section meeting.
- Scores for each of 5 review criterion
  from 3 assigned reviewers
- Critiques from 3 assigned reviewers

If your application is discussed, you also will receive:

- An overall impact/priority score and percentile ranking
- A summary of review discussion written by your SRO

eRA **Commons**
A program of the National Institutes of Health

| Home | Admin | Institution Profile | Personal Profile | Status | ASSIST | Prior Approval | RPPR | Internet Assisted Review | xTrain | xTRACT | Admin Supp | eRA Partners | Non-Research |

Welcome to the Commons

Welcome

ANDREW BEAN
ID: AJBEAN
Institution: UNIVERSITY OF TEXAS HLTH SCI CTR HOUSTON
Roles: PI IAR

eRA Service Desk

- **Hours:** Mon-Fri, 7AM-8PM EDT/EST
- **Web:** http://grants.nih.gov/support
- **Toll-free:** 866-504-9552
- **Phone:** 301-402-7469

Contact initiated outside of business hours via Web or voice mail will be returned the next business day.

ⓘ System Information Message

All systems are currently available.

Commons allows you to perform the following activities below based on the privileges associated with this profile:

- **Administration** - Allows you to assign a delegate to perform system and accounts maintenance more...

- **Institution Profile** - Enables you to view and update institution information more...

- **Personal Profile** - Allows you to update your personal information. Please periodically review your profile to ensure accuracy of information submitted more...

- **Status** - Allows you to check the status of awards and applications that have been submitted more...

- **RPPR** - Allows you to review the information needed to complete a progress report. See RPPR Information and Submitting Progress Reports.

- **xTrain** - Enables you in a Trainee or SO role to confirm the information that you have submitted for a Trainee role type more...

- **Internet Assisted Review (IAR)** - Allows reviewer to submit critiques and preliminary scores for applications they are reviewing more...

What's New

- New in RPPR
- New Service Desk System

Commons Resources

- Frequently Asked Questions
- Archived Release Notes
- Commons Login Tutorial
- Commons Support Page
- eRA Training
- User Guides
- Grantee Organization Registration
- eRA Website
- Applying Electronically

Additional Links

- eRA Contacts
- RePORT
- Grants.gov
- iEdison
- National Institutes of Health
- Public Access Policy Page
- Loan Repayment Program
- LikeThis
- Multiple Affiliations
- Commons Quick Queries

How do you decide on your budget?

- How much do you need to do your work?
    - How many Key Personnel? Salary? Expenses?
    - Do you have subcontracts? How much do they need to do their work?
- What are allowable expenses?
- What is the maximum budget listed in the RFA?
- Is the grant modular? E.g. 25K modules?
- Do you want to ask for the max budget? Why? Why not?
- What are direct and indirect costs? Which one is relevant with respect to the amount I am requesting?

END

1 Identify a funding opportunity

2 Develop a relevant research question

3 Grant writing basics

4 Write a strong research plan

5 Training plans for individual training grants

Identify a funding opportunity

Considerations

- Career stage (R vs. K vs. F)
- Early investigator status
- Amount of preliminary data

Find the right award

- Funding opportunity announcements (FOA)
- Requests for applications (RFA)
- Parent Announcements
- Program Announcements (PA)
- Notice of Special Interest (NOSI)

NIH NIH Guide for Grants and Contracts

July 02, 2021

Weekly NIH Funding Opportunities and Notices

General Notices

- Notice to Extend Eligibility for Submission of K99/R00 Pathway to Independence Award Applications (and Physician-Scientist K99/R00) due to COVIDrelated Disruptions
  (NOT-AI-21-061)
  National Institute of Allergy and Infectious Diseases

- Notice of Pre-Application Webinar for "Radiation Oncology-Biology Integration Network (ROBIN) Centers: RFA-CA-21-040"
  (NOT-CA-21-093)
  National Cancer Institute

- Notice Informing the Community of Application Form Issue with RFA-RM-21-016 NIH Directors New Innovator Award Program (DP2 Clinical Trial Optional)
  (NOT-RM-21-030)
  Office of Strategic Coordination (Common Fund)

Notice of Changes to Funding Opportunities

- Notice of Change to Award Information for RFA-AG-22-018 Leveraging Existing Large Databases and Cohorts to Better Understand the Risks and Benefits of Long-Term Osteoporosis Therapy and Drug Holiday (R01 Clinical Trial Not Allowed)
  (NOT-AG-21-030)
  National Institute on Aging

Requests for Proposal

Funding Opportunities

- Change of Recipient Organization (Type 7 Parent Clinical Trial Optional)
  (PA-21-268)
  National Institutes of Health
  John E. Fogarty International Center
  National Center for Advancing Translational Sciences
  National Center for Complementary and Integrative Health
  National Cancer Institute
  National Eye Institute
  National Human Genome Research Institute
  National Heart, Lung, and Blood Institute
  National Institute on Aging
  National Institute on Alcohol Abuse and Alcoholism
  National Institute of Allergy and Infectious Diseases
  National Institute of Arthritis and Musculoskeletal and Skin Diseases
  National Institute of Biomedical Imaging and Bioengineering
  Eunice Kennedy Shriver National Institute of Child Health and Human Devel
  National Institute on Drug Abuse
  National Institute on Deafness and Other Communication Disorders
  National Institute of Dental and Craniofacial Research
  National Institute of Diabetes and Digestive and Kidney Diseases
  National Institute of Environmental Health Sciences
  National Institute of General Medical Sciences
  National Institute of Mental Health
 National Institute on Minority Health and Health Disparities

Develop a relevant research question

Will your idea have impact?

- Has it been answered?

- Are people interested?

- Foundation for a hypothesis

- Should it be done? Can it be done?

Find the right home for your grant

- Target the right Institute/Center

- RePORTER Matchmaker

- Talk to Program Officer

- Review study sections

- Scrutinize FOAs
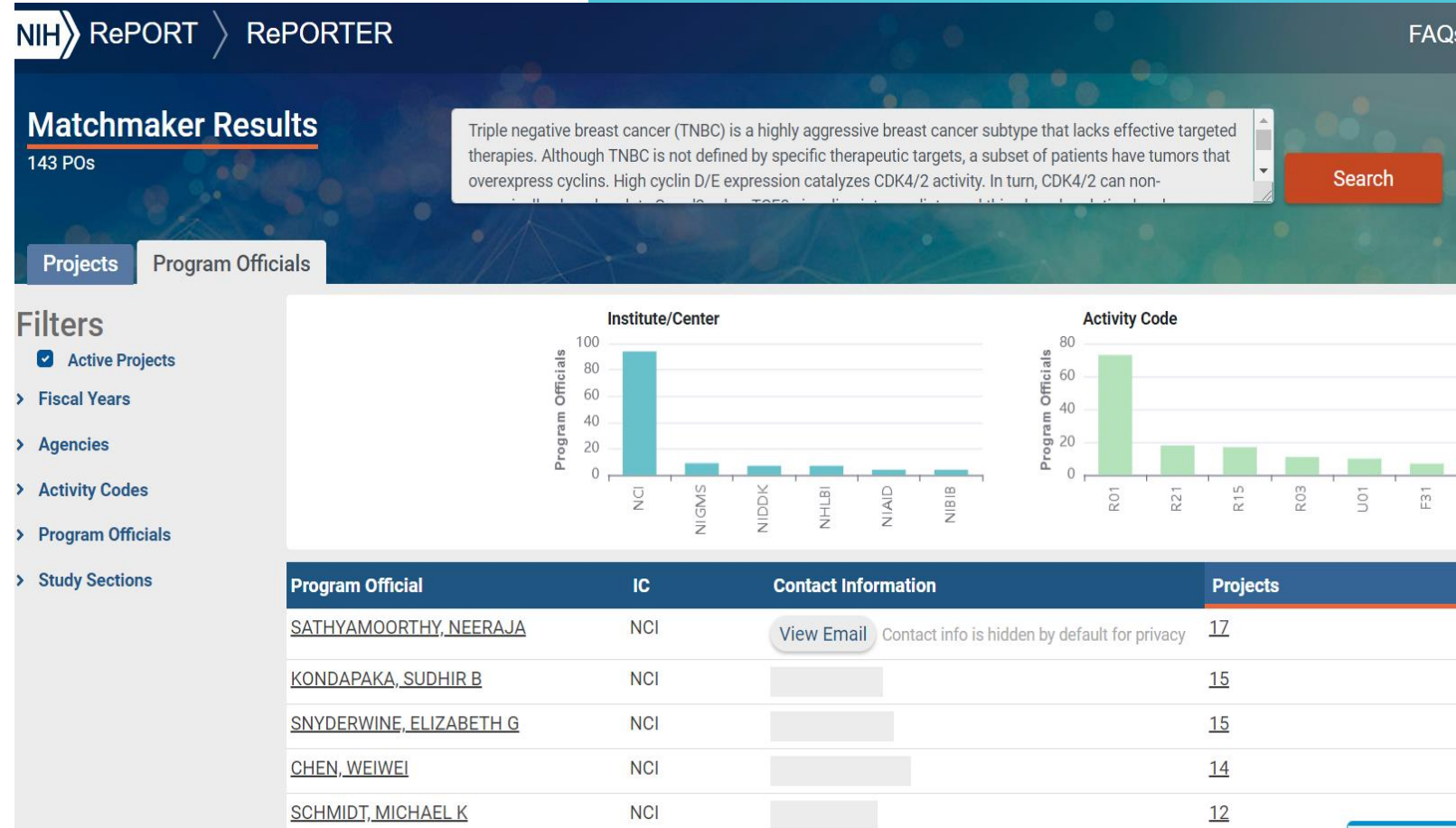
Time to Write – Grant Writing Basics

Write for success

- Start early (and submit early!)
- Writing strategy – make time
- Follow instructions and guidelines

    https://grants.nih.gov/grants/how-to-apply-application-guide.html

- Clear, succinct, active voice
- Be explicit
- Write to review criteria
- Know your audience
- Realistic timeline
- **Get feedback**
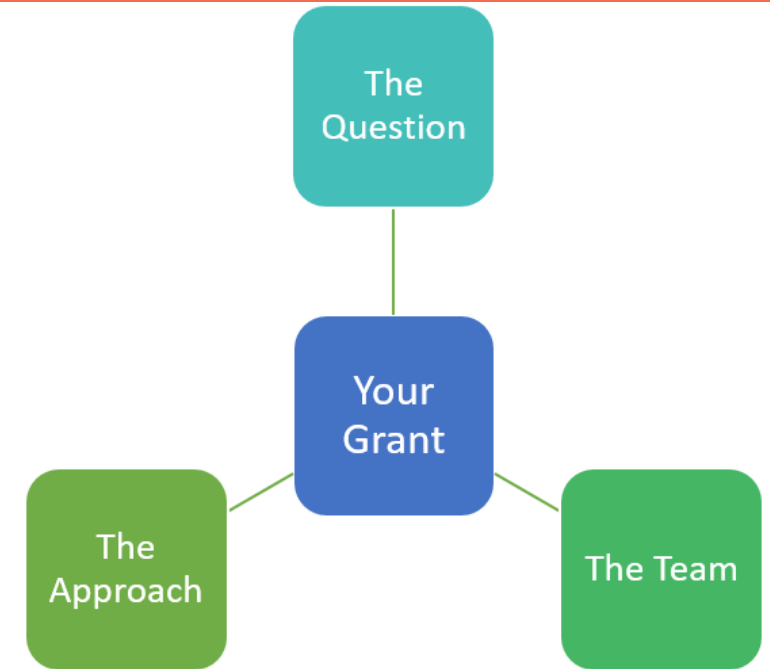
Write a strong research plan

SPECIFIC AIMS

- One page summary of research plan

- Simple, easy to follow story, narrow focus as you go

- Highlight question, importance, gap in knowledge, feasibility

- Logical, testable, focused hypothesis

- Independent aims

- Aims express *how* and *why*: "to do X, we will do Y"

- Key expected outcomes and how they will impact the field

Tips

- White space

- Use bold, underline, italics to highlight key points

- Effortless comprehension

- Even if hypothesis and aims fail, still get information

Opening Sentence

Current knowledge

Gap in knowledge

Need and consequence

Long-term goal

Objective

Hypothesis

Reasoning

Rationale

Specific aims

Expected outcomes

Positive impact

Adapted from *The Grant Application Writer's Workbook: National Institutes of Health Version* by John D. Robertson, Stephen W. Russell, and David C. Morrison. May 2020 edition.

Write a strong research plan

RESEARCH STRATEGY

Significance

- Positive impact of your research

- What is the problem and gap?

- How will your research fill this gap?

- Why is *this* work necessary?

- What would be the positive impact of achieving your aims?

- Subsections

  - Importance of Problem to be Addressed – evidence for the need of your work

  - Rigor of Prior Research – foundation and feasibility of your project

  - Significance of Expected Research Contributions – tangible benefits of your work

People vector created by pch.vector

Write a strong research plan

RESEARCH STRATEGY

Innovation

- A new way of addressing a problem

- Describe current status quo

- Explain why and how your work will change things

Business vector created by vectorjuice

Write a strong research plan

RESEARCH STRATEGY

Approach

- How you will test your hypothesis and achieve your aims
- For each aim:
  - Introduction – overview of aim
  - Research Design – narrative of project design
  - Expected Outcomes – return on investment
  - Potential Problems and Alternative Strategies – what could go wrong and how would you fix it
- Timeline
- Future Directions

Aim	Description	Year 1	Year 2	Year 3	Year 4	Year 5
1A.1	Murine *in vitro* over-expression	→→→				
1A.2	*In vivo* over-expression – effects on mitochondrial morphology and function	→→→	→→			
1A.3	Murine *in vivo* over-expression		→→→	→→→		
1A.4	Disease model in KO mice			→→→	→→→→	→
1B.1	Analysis in human patient serum		→→→	→→→	→→→	→→→
1B.2	Over-expression in human macrophages		→→→	→→→	→→→	→→→
1B.3	Mitochondrial function in human monocytes		→→	→→→	→→→	→→→
2.1 2.2 2.3	Treatment effects on: target gene expression, disease progression, metabolic phenotypes	→→→	→→→	→→→		
2.4	Treatment effects on vascular function				→→→→	→→→
2.5	Treatment effects on metabolites	→→→	→→→			
3.1	*In vitro* treatment of murine macrophages with experimental nanoparticles	→→→				
3.2	*In vivo* treatment of disease with experimental nanoparticles	→→→	→→→			
3.3	*In vitro* treatment of primary human monocytes with experimental nanoparticles		→→→	→→→	→→→	→→→

https://blog.cellsignal.com/grant-writing-part-4-additional-details
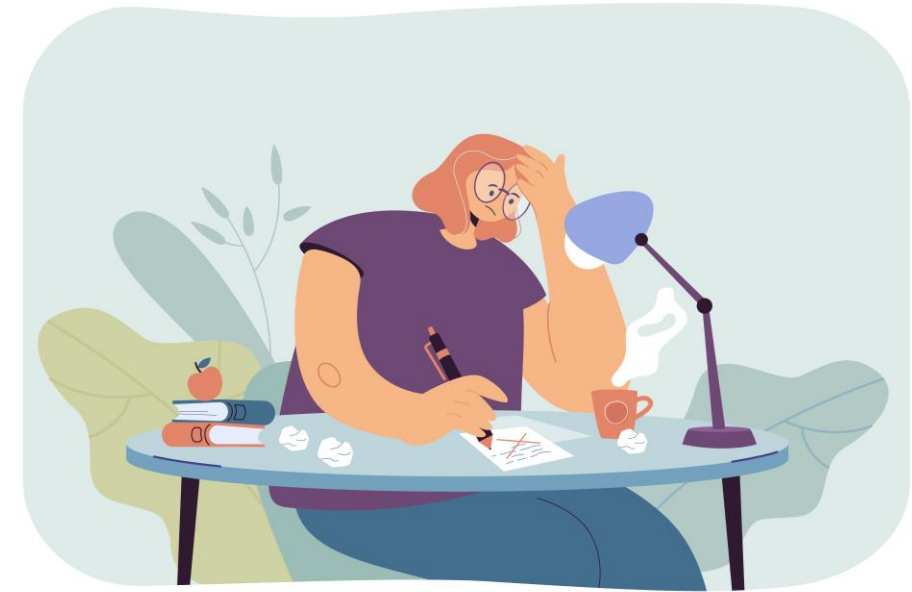
RUSH

Write a strong research plan

RESEARCH STRATEGY

Tips

- Reference primary literature

- Critically discuss citations

- Each figure should make one point

- Figure legends and titles

- Cohesive style

- Lead the reviewer through data and figures

- Emphasize the impact on public health

- Feasibility

- Quality of science

Business vector created by pch.vector

The importance of a training plan

Fellowships (F) and Career Development (K) Awards

- Express why the grant is necessary for your training and career advancement

- Highlight mentorship

- Training goals

- Training plan matches research plan

- Letters of reference

- Review FOA and correct grant guide

- Review criteria

People vector created by pch.vector

Additional Components
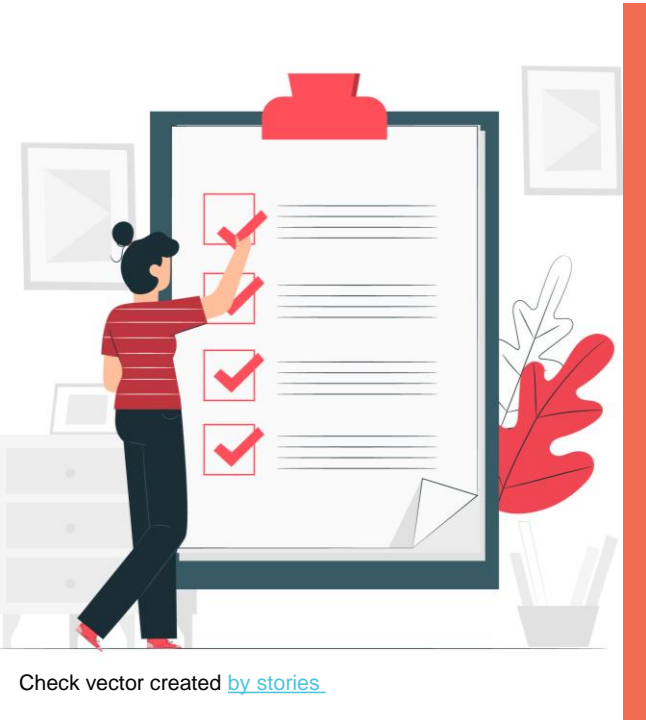
Title

Project Summary

Project Narrative

References Cited

Facilities and Other Resources

Equipment

Biosketch

Budget

Vertebrate Animals, Human Subjects, Select Agents

Check vector created by stories

Thank you.

Alexandra_L_Thomas@rush.edu

Human subjects research, IRB and Vertebrate Animal Research *(NIH)*

Crista Brawley, Ph.D. CCRP
The Office of Research Affairs
VP, Research Operations &
Chief Research Administrator

**If you have a question or comment, please unmute yourself and speak up! If you feel more comfortable typing a question into the chat, that is fine too. I will answer the chat questions at the end.

What is considered human subjects research?

NIH Definition : a human subject is "a living individual about whom an investigator (whether professional or student) is conducting research that:

- Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or
- Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens."

- *[45 CFR Part 46](#) defines a human subject as a living person about whom an investigator obtains either 1) data through intervening or interacting with the person or 2) identifiable, private information.*
- In general if you're using <u>coded</u> private information, data, or specimens, NIH will consider your research to involve human subjects unless it meets ***<u>both</u>*** of the following conditions:
  - You are not collecting samples by interacting or intervening with *living* people (meaning all subjects are deceased).
  - None of the investigators or collaborators listed in the application can identify the subjects through coded private information or specimens (e.g., an investigator's access to identity is prohibited by a written agreement).

  **If any investigator involved in the research can determine a subject's identity or has access to identifiers, the research is considered to involve human subjects and human subjects requirements apply.

- If your research meets the definition of human subjects research by NIH, when applying for an NIH grant, check "yes" for human subjects on the application face page.

 YES

**If you are not sure if your project meets the definition, please ask!

- Need to include in your NIH application:

-PHS human subject and clinical trials information where a study record must be created for each study (group by study population or same protocol use); may indicate delayed onset

1. *Basic information*

2. *Study population characteristics*

3. <u>Protection of Human Subjects and Monitoring plans:</u> *<u>(Protection of human subjects attachment)</u>*

As required by federal regulations (45 CFR 46) and NIH policy, applications that propose to involve human subjects must address:

1. the risk to subjects

2. the adequacy of protections against risk

3. potential benefits of the research to subjects and others

4. the importance of the knowledge to be gained

5. for clinical trials, data and safety monitoring plan and a data and safety monitoring board for Phase III trials

1. Risks to Human Subjects

Does the application adequately describe Human Subjects Involvement, Characteristics, and Design, Sources of Materials, and Potential Risk, including:

– description and justification for the proposed involvement of human subjects

– characteristics of subject population (number, age range, and health status)

– inclusion/exclusion criteria

– rationale for involvement of vulnerable populations (e.g. fetuses, pregnant women, children, prisoners, institutionalized individuals, or others)

– role of collaborating sites where research will be performed

– description and justification of research procedures (including dosage, frequency, etc of intervention)

– description of what research material, data, and information will be collected – access to personally identifiable information collected and retained

– management and protection of materials and information

– all potential risks to subjects (physical, psychological, financial, legal, or other) including likelihood and seriousness

– any alternative treatments or procedures

2. Adequacy of Protection Against Risks

Does the application adequately describe <u>Recruitment and Informed Consent</u> and Protections Against Risk, including:

- how subjects will be recruited and by whom
- description of informed consent, parental permission and assent, how will cognitive ability be assessed (LAR)
- waiver for any elements of consent
- how risks described previously, including privacy and confidentiality, will be minimized
- *additional protections for vulnerable populations*
- ensuring necessary medical/professional intervention for adverse events

**Do not submit your ICF document with the application

***If research includes vulnerable populations (children, pregnant women, prisoners, fetuses, neonates) clearly describe the risk level and additional protections taken

3. Potential Benefits of the Proposed Research to Human Subjects and Others

Does the application adequately describe how potential risks to subjects appear reasonable in relation to anticipated benefits?

- Discuss the potential benefits of the research to research participants and others.

-Discuss why the risks to subjects are reasonable in relation to the anticipated benefits to research participants and others.

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

4. Importance of the Knowledge to be Gained

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

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

- Need to include in your NIH application:

-PHS human subject and clinical trials information where a study record must be created for each study (group by study population or same protocol use); may indicate delayed onset

1. *Basic information*
2. *Study population characteristics*
3. <u>*Protection of Human Subjects and Monitoring plans:* *(Protection of human subjects attachment)*</u>
4. *Protocol synopsis*
5. *Clinical Trial attachments (10 max)*

Submit for IRB approval via the Rush Research Portal.
rrp.rush.edu

Training requirements:

- citiprogram.org
  - Collaborative Institutional Education Initiative
  - All individuals identified as research personnel on a study must complete human subjects protection (HSP) training, and NIH requires good clinical practice (GCP) certification.
  - Training documentation will need to be provided to NIH upon JIT.
- Friday onboarding (webex starting at 10am)
  - Human subjects compliance training
  - Rush Research Portal (RRP) introduction & navigation
- Your Rush account is activated to utilize the RRP to create master projects, create/submit grant proposals, and prepare/submit IRB applications

*Of note, you may have access to the RRP for COI disclosure, but without the appropriate training, you will not be able to utilize the other pieces of the RRP.

**Once you obtain federal funding, you may be required to take more training based on the funding agencies requirements (Rush policy CC-RC-0004: Training and Education Policy).

I did my training, what now?

Submit for IRB approval via the Rush Research Portal.
rrp.rush.edu

- What kind of human subjects study am I submitting?
  - Exempt
  - Expedited
  - Full Board

Exempt studies

Some studies might be considered human subjects research, but might be considered exempt from certain IRB requirements, such as annual renewals.

-submit a full IRB application in the RRP for an Exempt study.

Exempt Study Qualification

If any of the items below apply to this study, the study may qualify for EXEMPT review status under federal regulations. However, it will be up to the IRB to make the final determination.

4.1

	Question Text	Part Number
☐	This research will be conducted in established or commonly accepted educational settings, involving normal educational practices, such as research on regular and special education instructional strategies, or research on the effectiveness of instructional techniques, curricula, or classroom management methods.	45CFR46.101(b)(1)
☐	This research involves the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior. Information obtained is recorded in such a manner that human subjects cannot be identified, directly or through identifiers linked to the subjects; and any disclosure of the human subjects' responses outside the research does not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.	45CFR46.101(b)(2)
☐	This research involves the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior where the human subjects are elected or appointed public officials or candidates for public office. Research is exempt from federal statutes which require without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.	45CFR46.101(b)(3)
☐	This research involves the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are either publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.	45CFR46.101(b)(4)
☐	This is a research or demonstration project, which is conducted by or subject to the approval of Department or Agency heads, and which are designed to study, evaluate, or otherwise examine public benefit or service programs, procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures,or possible changes in methods or levels of payment for benefits or services under those programs.	45CFR46.101(b)(5)
☐	This research involves taste and food quality evaluation and consumer acceptance studies, where wholesome foods without additives are consumed or if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.	45CFR46.101(b)(6)
☐	None of these categories apply to this study, therefore it is not exempt.	

- When we refer to human subjects research for NIH, we are referring to nonexempt research. *The six human subjects exemptions rarely apply to NIH because almost all research supported by NIH is either human subjects or not human subjects.*

**Usually collaborate with the program manager to determine if exemption is valid for the research (justification process; typically can only get exemption category 4 to apply; need to submit enrollment plan).

Expedited Studies

- "Expedited review" means that one person, such as an IRB Chair, will review and approve the study rather than a fully convened IRB committee.

- The study <u>must</u> be minimal risk.

- A retrospective review is an example of an expeditable study.

- Submit a full IRB application in the Portal for an expedited study.

- **The IRB Chair or delegate decides if a study is really qualified to be expedited or not. The Chair/delegate may decide the study needs a full board review.

Full Board studies:

- More than minimal risk: must be reviewed by a full convened IRB committee

- Requires a full IRB application to be submitted via the RRP

- Typically, requires continuing review at least every 12 months

- Rush has 2 IRB Boards that meet once a week (every Monday and every Wednesday)

  - At least 5 members [where a scientist, a nonscientist, community representation, and a nonaffiliated member are represented]

Who to contact in the IRB Office:

RUSH

John Cobb
IRB Director

Jelke 601
Phone: 312-942-6855
Email: John_T_Cobb@rush.edu

Gia Hayes
IRB Manager

Jelke 601
Phone: 312-942-6693
Email: Gia_Hayes@rush.edu

Not sure where to start, or have a question

Tony DeMarco
Research Portal Expert

Jelke 601
Phone: 312-942-5097
Email: Antonio_S_Demarco@rush.edu

Rush Research Portal (RRP) navigation or access questions

Vertebrate Animal Research (NIH)

-Animals with a backbone
-Animals obtained or euthanized
for tissue harvest
-Generation of custom antibodies

What investigators need to know about the use of animals:

- Principal Investigators must ensure compliance with Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals (Policy) *[https://olaw.nih.gov/policies-laws/phs-policy.htm]*

  when using live vertebrate animals (and the animal welfare act).

- To receive an NIH award, you must have IACUC approval, and your institution must have an Animal Welfare Assurance approved by the NIH Office of Laboratory Animal Welfare (OLAW).

- Rush's animal facilities are also AAALAC accredited. (Association and Assessment for Accreditation of Laboratory Animal Care International)

Investigator Responsibilities (NIH):

Investigators are accountable for the protection of the research animals in their care from the earliest stages of planning until a study is completed, including:

1. Describing proposed use of animals in grant applications
2. Obtaining IACUC approval prior to using animals and prior to implementing significant changes
3. Ensuring research is conducted according to the protocol
4. Complying with institutional policies and procedures
5. Addressing significant changes to the use of animals in progress reports
6. Addressing changes in the use of animals that may be a potential change in scope, including changes in and at performance the site.

Vertebrate Animal Section-NIH

If the proposed work involves live vertebrate animals, federal policy requires applicants to address the criteria noted below. This includes work involving animals obtained or euthanized for tissue harvest and generation of custom antibodies.

1. Description of Procedures (Vertebrate Animals Section)

-Provide a concise description (whole VAS should not exceed 1-2 pages) of the proposed procedures to be used that involve live vertebrate animals in the work outlined in the Research Strategy section.

-Identify the species, strains, ages, sex, and total number of animals by species to be used in the proposed work. **If dogs or cats are proposed, provide the source of the animals.

2. Justifications (Vertebrate Animals Section)

-Provide justification that the species are appropriate for the proposed research.

-Explain why the research goals cannot be accomplished using an alternative model (e.g., computational, human, invertebrate, in vitro).

3. Minimization of Pain and Distress (Vertebrate Animals Section)

-Describe the interventions including analgesia, anesthesia, sedation, palliative care, and humane endpoints to minimize discomfort, distress, pain, and injury.

4. Method of Euthanasia (Cover Page Supplement / PHS Fellowship Supplemental Form)

-Provide a justification for methods of euthanasia that are not consistent with the American Veterinary Medical Association (AVMA) Guidelines for the Euthanasia of Animals.

** If answer is "No" to the question "Is method consistent with AVMA guidelines?", describe the method and provide scientific justification in the text field provided.

Important:

- Remember IACUC approval is allowed at JIT; so it is probably a good idea to consult with Jeff Oswald, DVM and his CRC team during your grant preparation time to ensure feasibility and validity of the project.

- Make sure your planned use of animals doesn't have limits/rules set by NIH (chimpanzees, dogs, cats).

Important:

- *If you must use animals, here are some ideas to limit animal use and discomfort:*
  - Limit animal involvement by using the <u>minimum number</u> required to obtain valid results.
  - Use non-animal methods, such as mathematical models, computer simulation, or *in vitro* biological systems.
  - Avoid or minimize animal discomfort, distress, and pain as is consistent with sound scientific practices.
  - Use appropriate sedation, analgesia, or anesthesia when your procedures will cause more than momentary pain or distress. Do not perform surgical or other painful procedures on non-anesthetized animals.
  - Select the lowest phylogenetic species appropriate for the experiment if animals are necessary.

How Your IACUC Is Structured

- IACUC must have at least five members, including people with the following backgrounds:
  - A <u>veterinarian</u> with experience in laboratory animal science and medicine, who has direct or delegated authority and responsibility for activities involving animals at the institution.
  - A <u>practicing scientist</u> experienced in research with animals.
  - A person whose primary concerns are in a <u>nonscientific area</u>, e.g., an ethicist, lawyer, or member of the clergy.
  - A person not affiliated with the institution who represents <u>community</u> interests and who is not a laboratory animal user.
  - Other IACUC members are usually faculty members and fellow researchers who are familiar with the issues you are facing and can serve as resources to help you prepare the best possible application.
  - ***We use eRAM which is an electronic system to manage our IACUC and our animal ordering and tracking.

Who to contact in the CRC:

RUSH

Jeff Oswald, DVM
Veterinarian

Cohn 2nd floor
Phone: *312-942-6576*
Email: *Jeffrey_P_Oswald@rush.edu*

Tony Davis
CRC Assistant Director

Cohn 2nd floor
Phone: *312-563-3372*
Email: *Anthony_D_Davis@rush.edu*

> Not sure where to start, or have a question

Danita Schaal
IACUC Coordinator

Cohn 2nd floor
Phone: *312-942-6576*
Email: *Danita_M_Schaal@rush.edu*

> eRAM navigation or access questions

Thank you!

Questions?
Crista Brawley, Ph.D., CCRP
312.942.7276
crista_brawley@rush.edu

KEY DECISION QUESTIONS

1 Does the research to date suggest that a clinical trial is necessary AND ethically and practically possible?

2 Does this Funding Opportunity Application even offer a clinical trial option?

3 Did I inadvertently propose a clinical trial when I was not intending to do so?

4 If I really want to do a clinical trial, what additional things do I have to consider in the application?

Do I Need to Do a Clinical Trial

Evidence-Based Medicine Pyramid
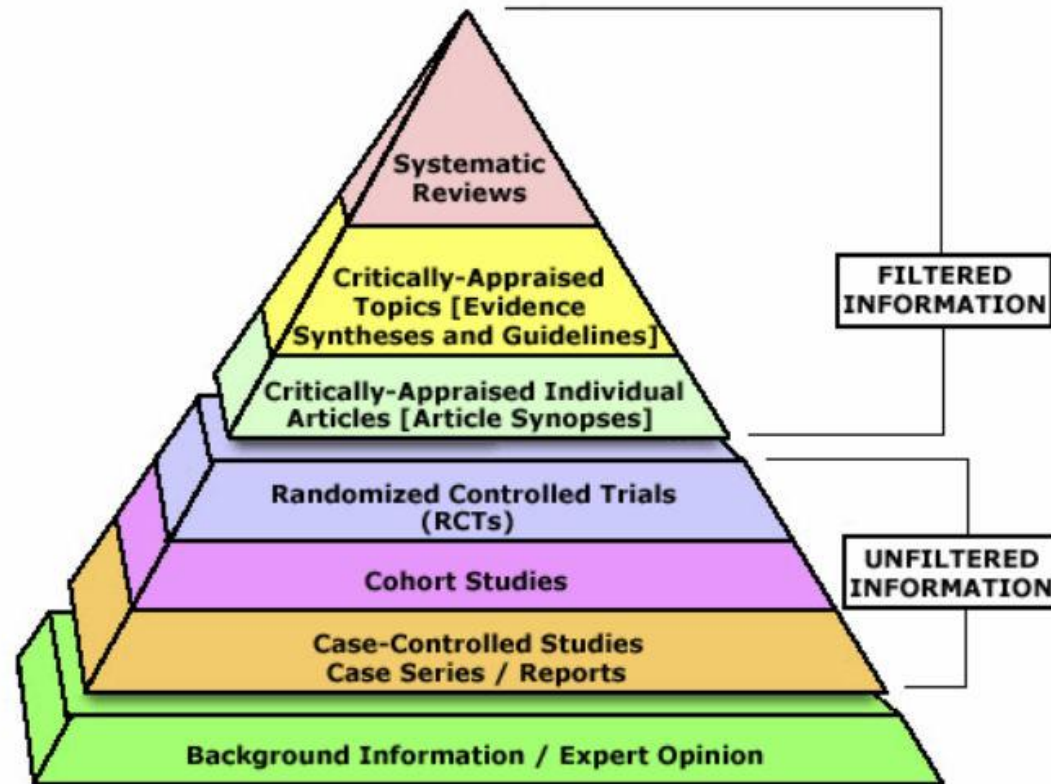
The pyramid was produced by HLWIKI
Canada: http://hlwiki.slais.ubc.ca/index.php/File:EBMpyramid.gif

Clinical Equipoise

Clinical equipoise occurs "if there is genuine uncertainty within the expert medical community — not necessarily on the part of the individual investigator — about the preferred treatment."

Theoretical equipoise: requires evidence on behalf of the alternative treatments to be exactly balanced and thus yields a very fragile epistemic threshold for favoring one treatment over the other.

Freedman, B. (1987) 'Equipoise and the ethics of clinical research'. *The New England Journal of Medicine*, 317, (3):141–145.

Funding Opportunity Application for Clinical Trials

NIH FOA Policy for Clinical Trials

Purpose

For due dates on or after January 25, 2018, NIH requires all applications involving one or more clinical trials to be submitted through a Funding Opportunity Announcement (FOA) specifically designed for clinical trials. The purpose of this policy is to improve our ability to identify proposed clinical trials, ensure that key pieces of trial-specific information are submitted with each application, and uniformly apply trial-specific review criteria.

Policy Implementation

Remember that NIH supports many types of clinical trials (mechanistic, exploratory/developmental, pilot/feasibility, pragmatic, behavioral, and others), so be sure to read your FOA carefully for specific instructions and considerations.

It is also recommended that applicants check the online version of their FOA within 8 weeks of the due date to ensure it is still appropriate for their application.

FOAs that accept clinical trials have specific review criteria to ensure that reviewers appropriately consider clinical trial-related information
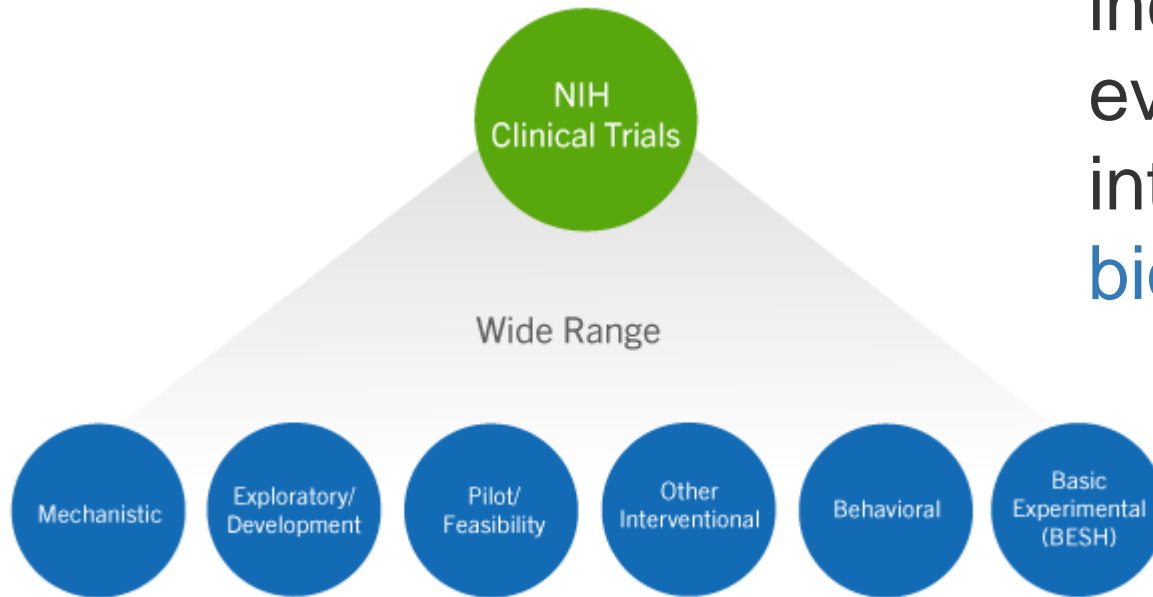
FOA Designations for Clinical Trials

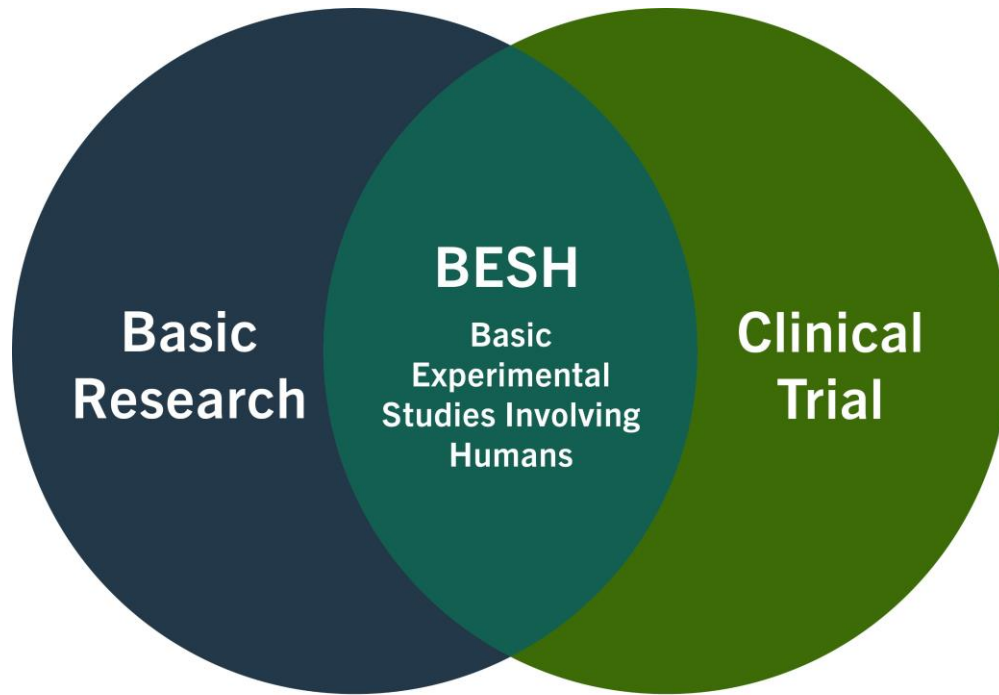|	
Clinical Trial Not Allowed	Only accepts applications that do not propose clinical trial(s)
Clinical Trial Required	Only accepts applications that propose clinical trial(s)
Clinical Trial Optional	Accepts applications that either propose or do not propose clinical trial(s)
Basic Experimental Studies with Humans (BESH) Required	Only accepts applications that propose clinical trial(s) that also meet the definition of basic research

Did I Inadvertently Design a Clinical Trial

NIH Definition of a Clinical Trial

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.

NIH Clinical Trials

Wide Range

Mechanistic   Exploratory/ Development   Pilot/ Feasibility   Other Interventional   Behavioral   Basic Experimental (BESH)

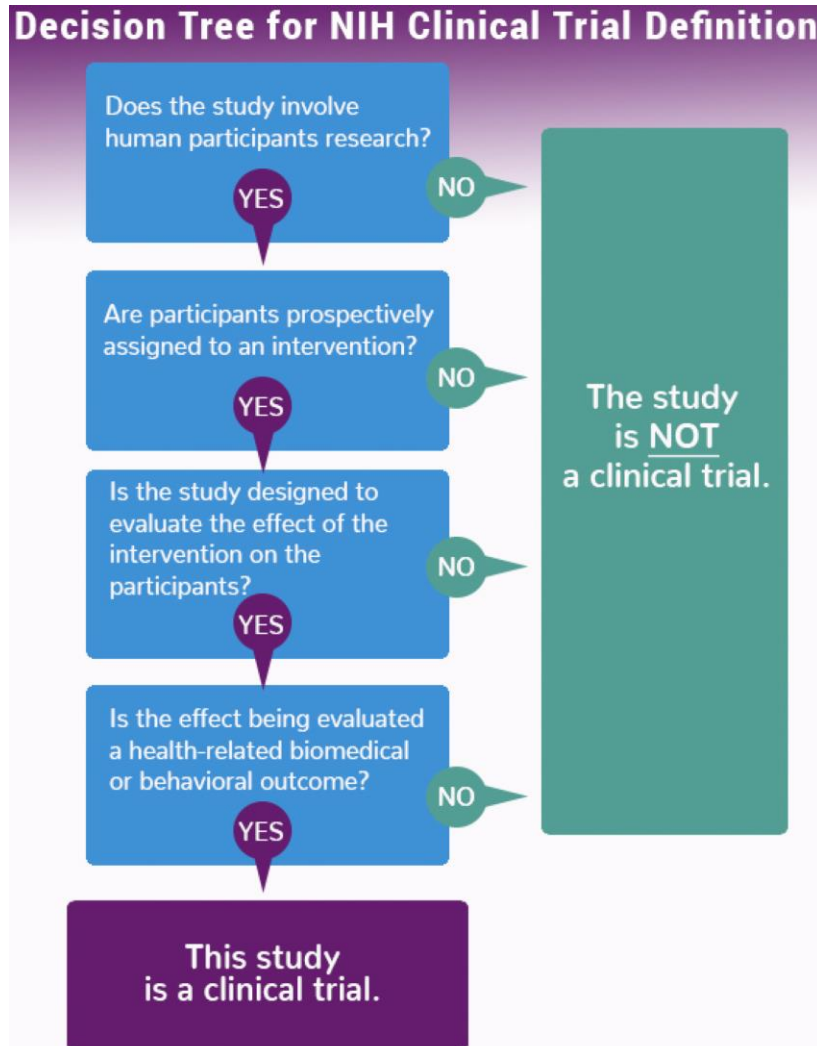# NIH Definition of a Basic Experimental Studies involving Humans (BESH)

Definition of BESH
Basic experimental studies involving humans (BESH) are studies that meet both the definition of basic research and the NIH definition of a clinical trial. BESH therefore are subject to NIH clinical trials policies such as registration and results reporting.

All BESH meet the NIH definition of a clinical trial. But not all clinical trials are BESH.

https://grants.nih.gov/policy/clinical-trials/besh.htm

Decision Tree to Determine if Research Study Meets NIH Criteria for a Clinical Trial

Decision Tree for NIH Clinical Trial Definition

Does the study involve human participants research?

YES / NO

Are participants prospectively assigned to an intervention?

YES / NO

Is the study designed to evaluate the effect of the intervention on the participants?

YES / NO

Is the effect being evaluated a health-related biomedical or behavioral outcome?

YES / NO

The study is **NOT** a clinical trial.

This study is a clinical trial.

Your study is considered to meet the NIH definition of a clinical trial even if:

- Your study uses healthy participants, or does not include a comparison group (e.g., placebo or control)
- Your study is only designed to assess the pharmacokinetics, safety, and/or maximum tolerated dose of an investigational drug
- Your study utilizes a behavioral intervention
- Your study uses an intervention for the purposes of understanding fundamental aspects of a phenomenon

Your study is NOT considered to meet the NIH definition of a clinical trial if:

- Your study is intended solely to refine measures.
- Your study involves secondary research with biological specimens or health information.

https://grants.nih.gov/policy/clinical-trials/CT-decision-tree.pdf
https://grants.nih.gov/ct-decision/index.htm

Case Studies for NIH Clinical Trial

Case #1

The study involves the recruitment of research participants who are randomized to receive one of two approved drugs. It is designed to compare the effects of the drugs on the blood level of a protein.

- **Does the study involve human participants?** Yes, the study involves human participants.
- **Are the participants prospectively assigned to an intervention?** Yes, the participants are prospectively assigned to receive an intervention, one of two drugs.
- **Is the study designed to evaluate the effect of the intervention on the participants?** Yes, the study is designed to evaluate the effect of the drugs on the level of the protein in the participants' blood.
- **Is the effect being evaluated a health-related biomedical or behavioral outcome?** Yes, the effect being evaluated, the level of a protein, is a health-related biomedical outcome.

✓ This study is a clinical trial.

Keyword(s): Drug, Mechanistic

Case Studies for NIH Clinical Trial

Case #32

A study involves the recruitment of children at two schools to monitor eating behavior. Children's food choices will be monitored using a remote food photography method. Food consumption and the accuracy of food monitoring methods will be assessed.

- **Does the study involve human participants?** Yes, the children participating in this study are human participants.
- **Are the participants prospectively assigned to an intervention?** No, not in this context. The study involves observing and measuring eating behavior, but not modifying it. This is an observational study.

❌ This study is not a clinical trial.

Keyword(s): Behavioral, Observational

Information I Need to Consider for a Clinical Trial Application

Additional Review Criteria

Criteria

In addition, for applications involving clinical trials:

A proposed Clinical Trial application may include study design, methods, and intervention that are not by themselves innovative but address important questions or unmet needs. Additionally, the results of the clinical trial may indicate that further clinical development of the intervention is unwarranted or lead to new avenues of scientific investigation.

Scored Review Criteria

The following questions are in addition to the existing research review questions:

Significance

Are the scientific rationale and need for a clinical trial to test the proposed hypothesis or intervention well supported by preliminary data, clinical and/or preclinical studies, or information in the literature or knowledge of biological mechanisms?

For trials focusing on clinical or public health endpoints, is this clinical trial necessary for testing the safety, efficacy or effectiveness of an intervention that could lead to a change in clinical practice, community behaviors or health care policy?

For trials focusing on mechanistic, behavioral, physiological, biochemical, or other biomedical endpoints, is this trial needed to advance scientific understanding?

Additional Review Criteria

Investigator(s)

With regard to the proposed leadership for the project, do the PD/PI(s) and key personnel have the expertise, experience, and ability to organize, manage and implement the proposed clinical trial and meet milestones and timelines?

Do they have appropriate expertise in study coordination, data management and statistics?

For a multicenter trial, is the organizational structure appropriate and does the application identify a core of potential center investigators and staffing for a coordinating center?

Innovation

Does the design/research plan include innovative elements, as appropriate, that enhance its sensitivity, potential for information or potential to advance scientific knowledge or clinical practice?

https://grants.nih.gov/grants/guide/notice-files/NOT-OD-17-118.html

Additional Review Criteria

Approach

Does the application adequately address the following, if applicable?

Study Design

Is the study design justified and appropriate to address primary and secondary outcome variable(s)/endpoints that will be clear, informative and relevant to the hypothesis being tested?

Is the scientific rationale/premise of the study based on previously well-designed preclinical and/or clinical research?

Given the methods used to assign participants and deliver interventions, is the study design adequately powered to answer the research question(s), test the proposed hypothesis/hypotheses, and provide interpretable results? Is the trial appropriately designed to conduct the research efficiently?

Are the study populations (size, gender, age, demographic group), proposed intervention arms/dose, and duration of the trial, appropriate and well justified?

Are potential ethical issues adequately addressed?

Is the process for obtaining informed consent or assent appropriate?

Is the eligible population available?

Are the plans for recruitment outreach, enrollment, retention, handling dropouts, missed visits, and losses to follow-up appropriate to ensure robust data collection?

Are the planned recruitment timelines feasible and is the plan to monitor accrual adequate?

Has the need for randomization (or not), masking (if appropriate), controls, and inclusion/exclusion criteria been addressed?

Are differences addressed, if applicable, in the intervention effect due to sex/gender and race/ethnicity?

Are the plans to standardize, assure quality of, and monitor adherence to, the trial protocol and data collection or distribution guidelines appropriate?

Is there a plan to obtain required study agent(s)?

Does the application propose to use existing available resources, as applicable?

Additional Review Criteria

Approach: *Data Management and Statistical Analysis*

Are planned analyses and statistical approach appropriate for the proposed study design and methods used to assign participants and deliver interventions?

Are the procedures for data management and quality control of data adequate at clinical site(s) or at center laboratories, as applicable?

Have the methods for standardization of procedures for data management to assess the effect of the intervention and quality control been addressed?

Is there a plan to complete data analysis within the proposed period of the award?

Environment

If proposed, are the administrative, data coordinating, enrollment and laboratory/testing centers, appropriate for the trial proposed?

Does the application adequately address the capability and ability to conduct the trial at the proposed site(s) or centers? Are the plans to add or drop enrollment centers, as needed, appropriate?

If international site(s) is/are proposed, does the application adequately address the complexity of executing the clinical trial?

If multi-sites/centers, is there evidence of the ability of the individual site or center to: (1) enroll the proposed numbers; (2) adhere to the protocol; (3) collect and transmit data in an accurate and timely fashion; and, (4) operate within the proposed organizational structure?

Additional Review Criteria

Study Timeline

Is the study timeline described in detail, taking into account start-up activities, the anticipated rate of enrollment, and planned follow-up assessment?

Is the projected timeline feasible and well justified?

Does the project incorporate efficiencies and utilize existing resources (e.g., CTSAs, practice-based research networks, electronic medical records, administrative database, or patient registries) to increase the efficiency of participant enrollment and data collection, as appropriate?

Are potential challenges and corresponding solutions discussed (e.g., strategies that can be implemented in the event of enrollment shortfalls)?

https://grants.nih.gov/grants/guide/notice-files/NOT-OD-17-118.html

Other Items

- Good Clinical Practice
- Human Subjects and Clinical Trial Information Form
- Human Subjects System
- Posting Informed Consent Forms
- Protocol Templates
- Registration and Reporting

And there is more…

Single IRB for multi-site trials
Data Safety Monitoring Plan

https://grants.nih.gov/policy/clinical-trials/reporting/index.htm

Additional Resources

Research Methods Resources: National Institutes of Health. [Accessed June 29, 2021]. Available from: https://researchmethodsresources.nih.gov/.

Summer Institute on Randomized Behavioral Clinical Trials
https://obssr.od.nih.gov/training/training-supported-by-the-obssr/institute-on-randomized-behavioral-clinical-trials/

THANK YOU

RUSH

Rush University

Pre-Award Grant Management

Workshop: A Guide to Grant Applications

**Jennifer Garcia, CRA**
Director, Sponsored Programs

Roles & Responsibilities

Principle Investigator

- Read and understand the sponsor policies and procedures

- Prepare technical proposal and other required documentation

- Prepare budget and justification

- Obtain internal approvals
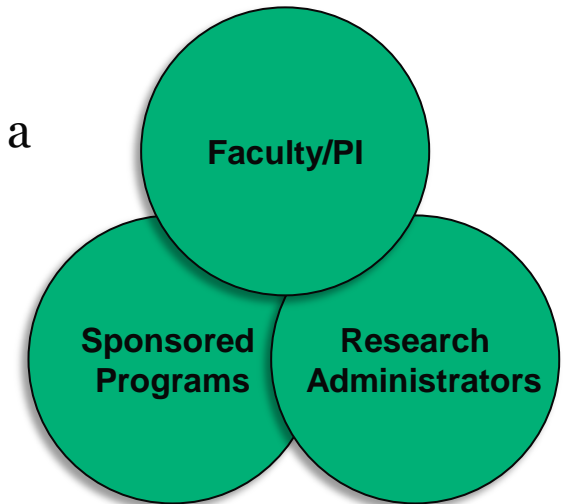
Department Research Administrator

- Notify SPA of intent to submit using the Advance Notice of Submission Form

- Create a timeline to ensure the application is routed to SPA on time.

- Assist the PI with preparing the application and budget

- Create the master project and grant workspace in the Rush Research Portal

- Route the budget for consultation through the portal

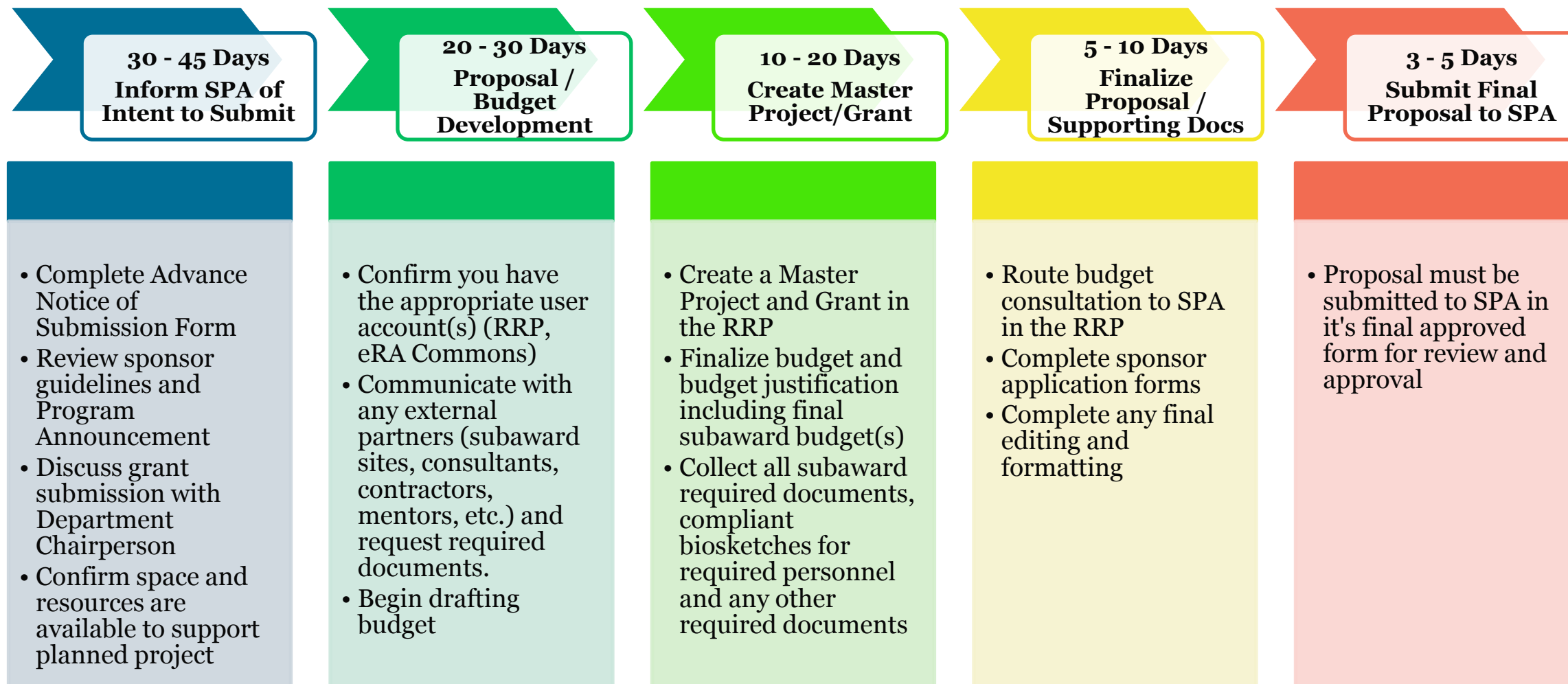- Generate and complete the SF424 Forms

Faculty/PI

Sponsored Programs

Research Administrators

RUSH
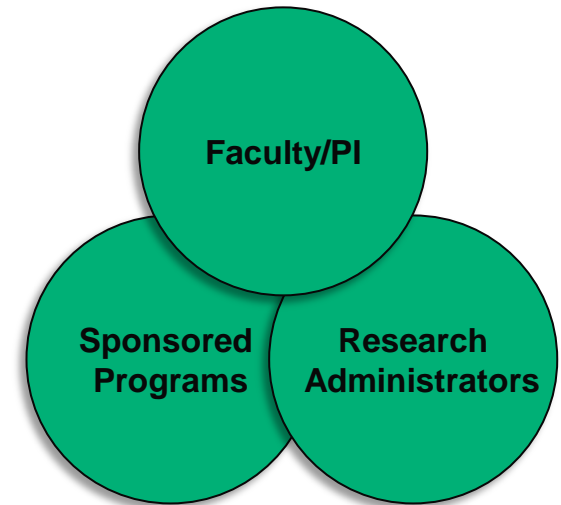
Roles & Responsibilities

Sponsored Programs

- Assure compliance with Federal laws and regulations, and NIH policies and procedures

- Provide technical assistance with the preparation of the grant proposal

- Review and submit the proposal to the federal agency

- Approve draft budget and justification

- Respond to sponsor requests for additional information
  - *JIT, No cost extension, Post submission material, Prior approval request*

- Review the award notice or executed contract directing Fund Accounting to establish a new fund

- Note any restrictions or conditions placed upon the award document

- Establish outgoing subaward agreements

- Review and executed incoming subaward agreements

Faculty/PI

Sponsored Programs

Research Administrators

Application Timeline

30 - 45 Days Inform SPA of Intent to Submit	20 - 30 Days Proposal / Budget Development	10 - 20 Days Create Master Project/Grant	5 - 10 Days Finalize Proposal / Supporting Docs	3 - 5 Days Submit Final Proposal to SPA
• Complete Advance Notice of Submission Form • Review sponsor guidelines and Program Announcement • Discuss grant submission with Department Chairperson • Confirm space and resources are available to support planned project	• Confirm you have the appropriate user account(s) (RRP, eRA Commons) • Communicate with any external partners (subaward sites, consultants, contractors, mentors, etc.) and request required documents. • Begin drafting budget	• Create a Master Project and Grant in the RRP • Finalize budget and budget justification including final subaward budget(s) • Collect all subaward required documents, compliant biosketches for required personnel and any other required documents	• Route budget consultation to SPA in the RRP • Complete sponsor application forms • Complete any final editing and formatting	• Proposal must be submitted to SPA in it's final approved form for review and approval

Common Application Errors

1. Not following agency specific instructions in the FOA/PA

2. Not converting PDF files into a flat file – uploading PDF documents with editable fields

3. Missing or incorrect eRA Commons user names

4. Biosketch is on outdated form; incorrect/missing information

5. Senior/key person profiles are missing for ALL individuals noted as key personnel

6. The Facilities & Other Resources and Equipment files are missing for the subaward site

7. Subrecipient Commitment Form/LOI missing or not endorsed by authorized official

8. Uploading unallowable appendix materials

9. Missing a study record in the PHS Clinical Trials Human Subjects Page, if human subjects are involved

10. Missing Foreign Justification, if there will be a foreign collaborator or partner on the grant

Common Budget Errors

1. Exceeding the FOA budget amount
2. Submission of modular budget, when detailed budget is required
3. Budget exceeds $500k DC without prior approval
4. Costs in budget differ from the justification
5. Including additional details in the Modular Budget Justification – only requires personnel justification
6. Salaries exceed the NIH salary cap
7. Using percent effort vs. calendar month/person month
8. Using the incorrect IDC rate and/or fringe benefit rate
9. Not requesting the money you truly need to do the proposed work
10. Not requesting a budget consultation from SPA ahead of the deadline

Resources and Links

Find Funding Opportunities

       https://www.rushu.rush.edu/research/office-research-affairs/funding-opportunities

Notify SPA of planned submission – Advance Notice of Funding Submission

       https://redcap.rush.edu/redcap/surveys/index.php?s=8EMMCFT4NN

Request an eRA Commons account

       https://redcap.rush.edu/redcap/surveys/index.php?s=78EW3WK7PH

SPA Recommended Timeline for Submissions

       https://www.rushu.rush.edu/sites/default/files/SPA%20Recommended%20Proposal%20Submission%20Timeline.pdf

Other Resources – SPA excel budget template, subrecipient commitment form, RRP Grant Walkthrough

       https://www.rushu.rush.edu/research/office-research-affairs/sponsored-programs-administration/sponsored-research-resources

Quick Reference Institutional Information – Current IDC and fringe rates, DHHS Rate Agreement, NIH salary cap, SAM expiration

       https://www.rushu.rush.edu/research/office-research-affairs/sponsored-programs-administration/quick-reference-institutional-information

Contact Us

Jennifer Garcia
Director, Sponsored Programs Administration
Phone: (312) 942-3554

Yvonne Harris
Senior Grant and Subaward Specialist
Phone: (312) 563-1990

Lorraine Gibson
Senior Grant and Subaward Specialist
Phone: (312) 942-2411

Jennifer Stadler
Grant and Subaward Specialist
Phone: (312) 563-1989

RUSH

Rush University Medical Center

Post Award Grant Management

July 1, 2021

Kristin Moody

Associate Vice President, Basic & Translational Operations

Office of Research Affairs

New Award Set-up

Review the Budget and make changes as needed; the submitted budget is just a reasonable approximation of what you intend to spend.

- It is not expected that you will perfectly predict how you will spend your money five years down the road.
- In General, NIH grantees are allowed a certain degree of latitude to rebudget within and between budget categories to meet unanticipated needs and to make other types of post-award changes
- In some cases, a budget may be required for Fund Accounting to set up Activity number and/or add additional funds to the activity.

Work with your Department and/or Research Administrator to allocate Salary and any expenses.

- It is important to do this early, as it may cause other issues during the award.

Review NoA for any special terms and conditions, restrictions and/or requirements.

- If you have questions, you should contact your Department and/or Research Administrator or SPA.

Set up a check in with your Department and/or Research Administrator to review expenses and ensure that salary is allocated correctly.

- Reviews should be done at least quarterly

Changes in Project and Budget

Carryover of Unobligated Balances (less than 25%) from one budget period to any subsequent period.

- Exceptions: Centers (P50, P60, P30 and others), cooperative agreements (U), Kirschstein-NRSA Institutional research training grants (T), clinical trials, and awards to individuals, or if the NoA indicates otherwise.

Cost-related prior approval changes, including research patient care costs and equipment.

- NIH prior approval is not required to rebudget funds for any direct cost item that the applicable cost principles identify as requiring the Federal awarding agency's prior approval, unless the incurrence of costs is associated with or is considered to be a change in scope.

Extension of final budget period without additional NIH funds (no-cost extension)

- The recipient may extend the final budget period of the previously approved project period one time for a period of up to 12 months beyond the original completion date shown in the NoA if: no term of award specifically prohibits the extension, no additional funds are required to be obligated by the NIH, and the project's originally approved scope will not change.

Changes in Project and Budget

Prior written approval may be required before a recipient makes certain budget modifications or undertakes certain activities.

The following are some activities and/or expenditures will require NIH prior approval.

Additional no-cost extension, extension greater than 12 months, or late notification of initial no-cost extension

Capital expenditures- construction, land or building acquisitions

Carryover of unobligated balances

- The NoA will include a term and condition to indicate the disposition of unobligated balances. The term and condition will state whether the recipient has automatic carryover authority or if prior approval is required.

Changes in scope

- A change in scope is a change in the direction, aims, objectives, purposes, or type of research training, identified in the approved project. The recipient must make the initial determination of the significance of a change and should consult with the GMO as necessary.

Change in PI status or senior key personnel

- Significant changes in the status of Senior/Key Personnel specifically named in the NoA including but not limited to withdrawing from the project entirely, being absent from the project during any continuous period of 3 months or more, or reducing time devoted to the project by 25% or more from the level that was approved at the time of initial competing year award.

Change in recipient organization or organization status

Deviation from award terms and conditions

- This includes undertaking any activities disapproved or restricted as a condition of the award.

Foreign component added to grant

Managing Expenses

Allowability of Costs/ Activities

- The cost principles address four tests to determine allowability of costs:

  - **Reasonableness (including Necessity)** A cost may be considered reasonable if the nature of the goods or services acquired or applied and the associated dollar amount reflect the action that a prudent person would have taken under the circumstances prevailing when the decision to incur the cost was made.

  - **Allocability** A cost is allocable to a specific grant, function, department, or other component, known as a cost objective, if the goods or services involved are chargeable or assignable to that cost objective in accordance with the relative benefits received or other equitable relationship.

  - **Consistency** Recipients must be consistent in assigning costs to cost objectives.

  - **Conformance** This test of allowability-conformance with limitations and exclusions as contained in the terms and conditions of award

- Review cost principles and Selected Items of Cost with your Research Administrator or Sponsored Programs office.

Allocation of Closely Related Work

- In general, a cost that benefits two or more projects or activities in proportions that can be determined without undue effort or cost should be allocated to the projects on the basis of the proportional benefit.

- A cost that benefits two or more projects or activities in proportions that cannot be determined because of the interrelationship of the work involved may be allocated or transferred to the benefiting projects on any reasonable basis as long as the costs charged are allowable, allocable, and reasonable under the applicable cost principles.

Managing Expenses

Cost Transfers & Overruns

o Cost transfers to NIH awards that represent corrections of clerical or bookkeeping errors should be accomplished within 90 days of when the error was discovered with supported documentation explaining how the error occurred.

o Transfers of costs from one project to another or from one competitive segment to the next solely to cover cost overruns are not allowable.

Accelerated or Delayed Expenditures

o The GMO monitors recipient expenditure rates under individual grants within each budget period and within the overall project period.

o Although NIH allows recipients certain flexibilities with respect to re-budgeting, NIH expects the rate and types of expenditures to be consistent with the approved project and budget and may question or restrict expenditures that appear inconsistent with these expectations.

o Accelerated or delayed expenditures may result in a recipient's inability to complete the approved project within the approved budget and period of performance.

o In these situations, the GMO may seek additional information from the recipient and may make any necessary and appropriate adjustments.

Effort Reporting

The Effort Certification Process is a method for confirming that charges made to sponsored awards are reasonable in relation to the work performed.

- o Uniform Guidance requires that institutions receiving federal awards maintain systems and procedures for documenting the distribution of effort and associated payroll charges to individual sponsored agreement.

This is done by reviewing, updating and preparing salary allocations, and certifying effort.

- o The report includes both federal and non- federal activities for 100% effort. Effort is based on 100% of an individual's activities for which he or she is compensated.

- o Federal Awards typically restrict the amount of direct salary paid on grants (Salary Cap). For individuals who salary exceeds the applicable salary cap, a through review of the effort should be completed to ensure that no amounts are being paid above the cap.

Effort reports are required for all faculty and staff with effort allocated to Federal Sponsored projects.

- o At Rush, Effort Certification is done quarterly during the Fiscal year.

- o An effort Certification report is a legal document stating that the certifier confirms the effort on the sponsored project(s) is accurate and appropriate. In the event of an audit, this document will be examined.

Progress Reporting

Progress reports are required annually to document grantee accomplishments and compliance with terms of award.

The Research Performance Progress Report (RPPR) is used by grantees to submit progress reports to NIH.

Annual RPPR- typically due 45 days before next budget period start date

Use to describe a grant's scientific progress, identify significant changes, report on personnel, and describe plans for the subsequent budget period or year.

Final RPPR- Due 120 days from period of performance end date for the competitive segment

Use as part of the grant closeout process to submit project outcomes in addition to the information submitted on the annual RPPR, except budget and plans for the upcoming year.

Interim RPPR- Due 120 days from period of performance end date for the competitive segment

Use when submitting a renewal application. The Interim RPPR will serve as the Final RPPR for the project. If the application is funded, the Interim RPPR will serve as the annual RPPR for the final year of the previous competitive segment. The data elements collected on the Interim RPPR are the same as for the Final RPPR, including project outcomes.

Progress Reporting

The RPPR requests various types of information, the information related to budgets:

Participants and Other Collaborating Organizations
- What individuals have worked on the project?
  - *Provide update on PD/PI effort and every person who has worked at least one person month per year on project during the reporting period.*
- Level of Effort
  - *Will there be a reduction of 25% or more for the PD/PI or senior/key personnel designated in the award, or a reduction below the minimum effort required by the NoA?*
- New Senior/Key Personnel?
- Changes in Other Support for senior key/personnel?
  - *Must upload active other support*

Estimated Unobligated Balance
- If the estimated unobligated balance is over 25% and explanation must be provided.
  - *Delays in study due to animals, personnel, equipment, space, etc*
- If authorized to carryover balance, must provide a general description of how it is anticipated that the funds will be spent.
  - *Prior approval may be required and must be written request with justification for carryover*

Award Closeout

Recipients must submit a final FFR (Federal Financial Report), Final RPPR, and Final Invention Statement and Certification within 120 days of the end of the period of performance.

The reports become overdue the day after the 120 calendar day period ends and could impact future funding for your institution if not submitted timely. All closeout Documents are submitted electronically via eRA Commons.

- Final FFRs must indicate the exact balance of unobligated funds and may not reflect any unliquidated obligations. A Final FFR is required for:

  - Any grant that is terminated

  - Any grant that is transferred to a new recipient

  - Any award, which will not be extended through award of a new competitive segment

- A Final RPPR required for any grant that is terminated and any award that will not be extended through award of a new competitive segment.

- Final Invention Statement

  - Must be submitted whether or not the funded project results in any subject inventions, and whether or not inventions were previously reported.

  - Must list all inventions that were conceived or first actually reduced to practice during the course of work under the project covering the period from original award through completion or termination.

Thank you.