Everything You Need to Know About the NIH (well almost)

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NIH, THE WORLD'S LARGEST FUNDER OF BIOMEDICAL RESEARCH

Where Do You Begin?

- **NIH Grants Policy Statement (NIH-GPS):** https://grants.nih.gov/policy/nihgps/index.htm

  (especially Sections 4 and 7 for the CRA exam)

- **NIH Funding Frequently Asked Questions:** https://grants.nih.gov/faqs#

The NIH is Part of the US Department of Health and Human Services

- NIH is one of 8 Public Health Service (PHS) agencies within DHHS (*ACF, AHRQ, CDC, CMS, FDA, HRSA, NIH, and SAMHSA).*

- NIH consists of 27 Institutes and Centers (ICs). Only 24 of these ICs actually make awards.

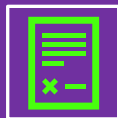- Each awarding IC has its own mission and priorities, and the discrete funding mechanisms it uses.

National Institutes of Health

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Office of the Director  ←  Office of Extramural Research
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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 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 on Drug Abuse	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 Institute On Minority Health and Health Disparities	National Center for Complementary and Integrative Health	Fogarty International Center	National Center for Advancing Translational Sciences	National Library of Medicine	National Institute of Biomedical Imaging and Bioengineering

NIH Clinical Center	Center for Information Technology	Center for Scientific Review

No funding authority

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NIH Uses 4 Funding Instruments

$ Grants (various activity codes)
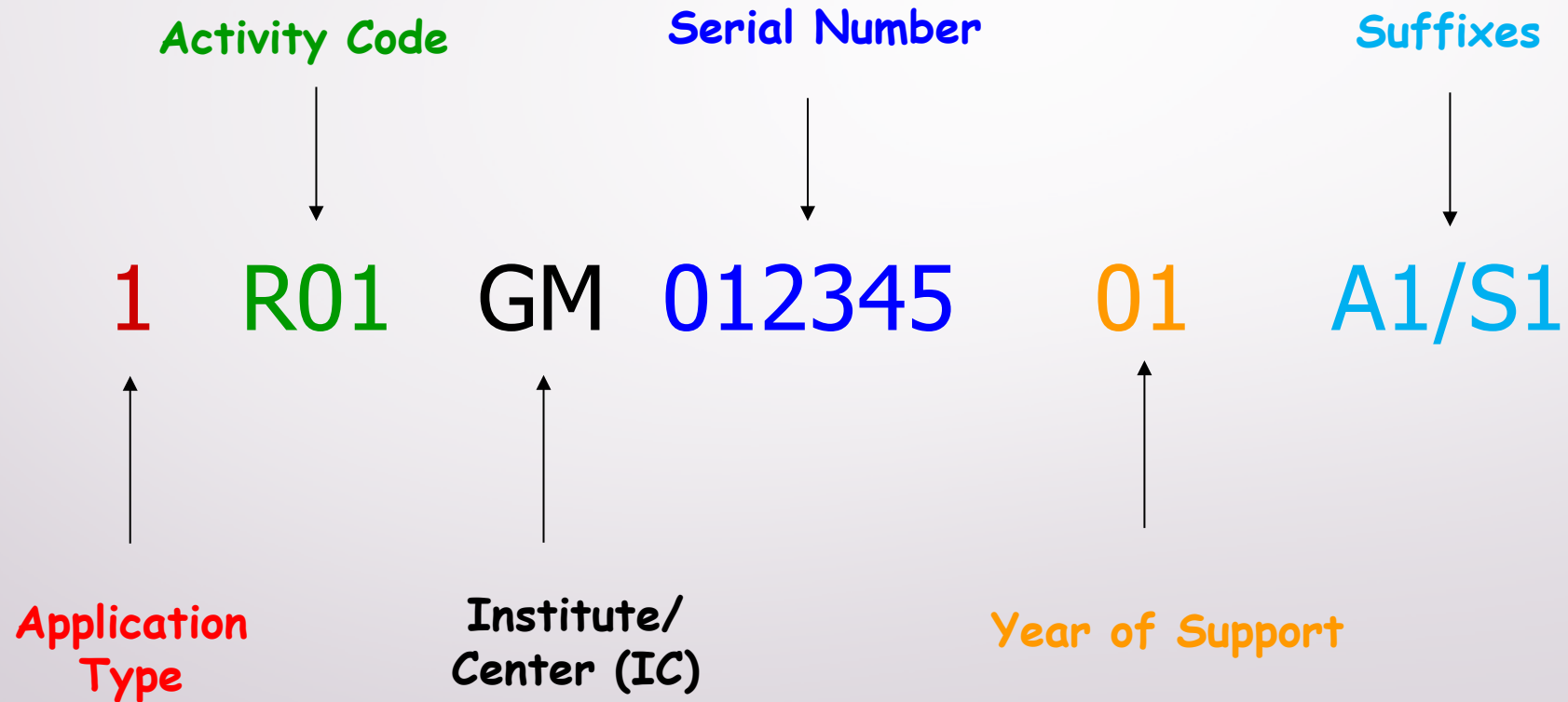
🤝 Cooperative Agreements (U-series)

📄 Contracts (N-series)

🏛 Other Transactional Authorities (OT-series)

Only a few ICs use all four funding instruments.

Sample Grant Number Used by HHS Agencies

Activity Code

Serial Number

Suffixes

1   R01   GM   012345   01   A1/S1

Application Type

Institute/ Center (IC)

Year of Support

Application Type

- New Competing - Type 1 (New)

- Competing Continuation - Type 2 (Renewal)

- Supplement - Type 3

  - Competitive - outside the original scope (Revision)

  - Administrative - within the original scope

- Extension (limited use) - Type 4

- Noncompeting Continuation - Type 5 (Continuation)

- Successor-In-Interest/Name Change – Type 6

- Change of Recipient Institution – Type 7

- Change of Institute, Noncompeting – Type 8 (Continuation)

- Change of Institute, Competing – Type 9 (Renewal)

24 Funding ICs and the NIH-OD

AA - NIAAA	**DA** - NIDA	**EY** - NEI	**MD** - NIMHD
AG - NIA	**DC** - NIDCD	**GM** - NIGMS	**MH** - NIMH
AI - NIAID	**DE** - NIDCR	**HD** - NICHD	**NR** - NINR
AR - NIAMS	**DK** - NIDDK	**HG** - NHGRI	**NS** - NINDS
AT - NICCIH	**EB** - NIBIB	**HL** - NHLBI	**TR** - NCATS
CA - NCI	**ES** - NIEHS	**LM** - NLM	**TW** - FIC

Translation at… https://www.nih.gov/institutes-nih/list-nih-institutes-centers-offices

Alphabet Soup of NIH Grants

- Research Project Grants (mostly R and U awards. not all RPGs are Rs; not all Rs are RPGs)

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

- Center Grants (most P awards)

- Other Research Grants (alphabet blur)

- Research Career Grants (K awards)

- Training Grants (T awards)

- Fellowships (F awards)

Grant Activity Code Facts

- Although NIH has over 240 active activity codes, only 110-120 are awarded across NIH each year.

- Some codes awarded every year; some not.

- One ICs may award ca. 50 different activity codes; one IC may award only 12; the median across the ICs is ~35 different activity codes

- ~30 codes awarded by more than half of the IC's

- ~30 codes each awarded by only 1 IC (not counting codes unique to the OD)

Why Are These Facts Important?

- Critical to remind PIs to look at each IC's web page to see what mechanisms/activity codes each supports

- Essential to review relevant notices from the *NIH Guide*

- Invaluable for PI's to talk to Program staff at an IC.

    Comprehensive List of Activity Codes

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

    and

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

Notice of Funding Opportunity (NOFO) aka Funding Opportunity Announcement (FOA)

All applications are submitted in response to a Funding Opportunity Announcement (FOA) published in the *NIH Guide for Grants and Contracts* and posted on Grants.gov.

- **RFA** – Request for Applications – one receipt date (typically) and funds set aside to fund (grants or cooperative agreements)

- **RFP** – Request for Proposal (contracts)

- **PA** – Program Announcement: both solicited and unsolicited (aka parent announcements); growing use of Notices of Special Interest (NOSI) rather than topic-specific PAs, replacing IC-issued PAs

- **PAR** – Program Announcement reviewed by the Institute/Center not Center for Scientific Review (CSR)

- **PAS** – Program Announcement with set aside funds (not common)

- **NOSI** – Notice of Special Interest – IC(s) research priority that typically directs applicants to use a parent PA to apply

A NOFO includes…

- Opportunity title and description
- Participating ICs
- Due dates
- PI and institution eligibility
- Award information, including the NOFO ID number
- Submission requirements
- Review criteria
- Award administration
- Agency points of contact

Importance of the NOFO (FOA)

- Details participating ICs

- Describes opportunity, including defining whether clinical trials are required, not allowed or optional

- Defines eligible PIs & institutions

- Submission requirements, including budget format; may dictate budget caps or identify unallowable cost items

- Details review criteria

- Gives deadlines and any other requirements

- Provides IC points of contact

Searching the NIH Guide to Grants and Contracts

Weekly Table of Contents

Weekly NIH Funding Opportunities and Notices for January 07, 2022

Policy Notices

- Publication of the Revised NIH Grants Policy Statement (Rev. December 2021) for Fiscal Year 2022
  (NOT-OD-22-050)
  National Institutes of Health

General Notices

- Notice of Clarification Regarding Institutional Eligibility for PAR-21-173 "Support for Research Excellence First Independent
  (NOT-GM-22-024)

  National Institute of General Medical Sciences

- Notice of Clarification Regarding Institutional Eligibility for PAR-21-169 "Support for Research Excellence (SuRE) Award (R1
  (NOT-GM-22-025)

  National Institute of General Medical Sciences

- Notice of NIMH Intent to Issue Funding Opportunity Announcements and Notice of Special Interest for COVID-19 and Menta
  (NOT-MH-22-105)

  National Institute of Mental Health

Once in the NOFO…

Required Application Instructions

It is critical that applicants follow the Research (R) Instructions in the SF424 (R&R) Application Guide, except where instructed to do otherwise (in this FOA or in a Notice from the *NIH Guide for Grants and Contracts*). Conformance to all requirements (both in the Application Guide and the FOA) is required and strictly enforced. Applicants must read and follow all application instructions in the Application Guide as well as any program-specific instructions noted in Section IV. When the program-specific instructions deviate from those in the Application Guide, follow the program-specific instructions. **Applications that do not comply with these instructions may be delayed or not accepted for review.**

There are several options available to submit your application through Grants.gov to NIH and Department of Health and Human Services partners. You **must** use one of these submission options to access the application forms for this opportunity.

1. Use the NIH ASSIST system to prepare, submit and track your application online.

   Apply Online Using ASSIST

2. Use an institutional system-to-system (S2S) solution to prepare and submit your application to Grants.gov and eRA Commons to track your application. Check with your institutional officials regarding availability.

3. Use Grants.gov Workspace to prepare and submit your application and eRA Commons to track your application.

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Part 2. Full Text of t

A button within the announcement allows applicants to access the NIH ASSIST application package directly from the NIH Guide. Other options are institutional S2S solutions or the Grants.gov workspace.

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Application Submission System & Interface for Submission Tracking (ASSIST)

Used to prepare and submit grant applications electronically	Secure web-based data entry	Collaboration of multiple users	Pre-submission validation of many NIH and Grants.gov business rules
Pre-population of data from eRA Commons profiles	Pre-submission print/preview of application in NIH format	Submission status tracking for both Grants.gov and eRA Commons within a single system	Ability to import subaward budget data from external sources
	Ability to copy application data (excluding attachments) from one announcement to another	Supports all NIH single and multi-project grant applications	

http://grants.nih.gov/grants/ElectronicReceipt/assist.htm
https://era.nih.gov/files/ASSIST_user_guide.pdf

What are "Standard Deadlines"

- These apply when specific deadlines are not given in the NOFO: RFAs nearly always have specific deadlines.

- Are activity code-specific: e.g., the standard deadline for the R01 is different that the R21

- Occur three times per year: generally January-March, May-July and September to November

- All AIDS and AIDS-related activity codes have three single deadlines.

- When *any* NIH deadline falls on a weekend or holiday, the actual deadline becomes the next business day.

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

Submission Policies

Policies include:

- Due dates on holidays/weekend/NIH closure

- Late applications

- Guidelines when experiencing system issues

- Continuous submission for PIs serving on some study sections

- Required prior agreement for $500,000+ direct costs

- Post submission of application materials

- Resubmission of unfunded application

- Overlapping applications

Late Submissions

- Advance permission is NEVER given

- Requires a cover letter explaining specific reasons for the delay.

- Timing and circumstances under which NIH might consider a late submission is found in the NIHGPS 2.3.9.2 and the [NIH Late Application Policy](#).

Clinical Trials

- **Phase I:** First-time test of a new intervention in a small group (usually 20-80 persons) to determine safety. Often healthy volunteers.

- **Phase II:** Study intervention in a larger group (several hundred persons) to determine efficacy.

- **Phase III:** Study the intervention in large groups (several hundred to several thousand persons), by comparing the intervention to other standard or controlled experimental interventions.

- **NIH-Defined Phase III:** Aim is to provide scientific evidence that would support a change in health policy or standard of care.

- **Phase IV:** Study conducted after an intervention has been marketed, to monitor effectiveness and adverse effects in the general population.

Clinical Trials

- Certain Clinical Trials funded by NIH are subject to the **FDAAA**

(Food and Drug Administration Amendments Act of 2007)

http://grants.nih.gov/ClinicalTrials_fdaaa/

  - Registering the clinical trial in ClinicalTrials.gov,

  - Certifications,

  - Enrollment of the Human Subjects

  - Reporting the data (including after the POP has ended)

- Implementing the FDAAA Requirements:

  http://grants.nih.gov/ClinicalTrials_fdaaa/steps.htm

Clinical Trials – NIH Definition

- 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.

- NOFOs designated clinical trial required, clinical trial optional, clinical trial not allowed.

- Clinical Trial Requirements for Grants and Contracts includes decision tool. Essential to correctly determine to prevent application being returned without review.

Clinical Trials

- NIH requires all clinical trials funded in whole or in part through NIH extramural and intramural programs to register in ClinicalTrials.gov even behavioral interventions and Phase 1 clinical trials not considered "applicable" under the FDAAA

- As part of the application required to submit a plan for dissemination of NIH-funded clinical trial information that will address how expectations of this policy will be met.

Parent Announcements

Parent announcements are broad funding opportunity announcements allowing applicants to submit investigator-initiated applications for specific activity codes.

- They are open for up to 3 years and use standard due dates.

- Not all NIH ICs participate on all parent announcements.

- Critical to communicate to recipients to confirm an IC's participation in a particular parent NOFO.

New and Early-Stage Investigators

- PI is considered a New Investigator if they have not previously competed successfully as PD/PI for a substantial independent research award.

- An ESI is a New Investigator who is within 10 years of completing his/her terminal research degree.

- The NIH intends to support New Investigators at success rates comparable to those for established investigators submitting new application for R01 support.

- [Policies](#) describe determination and extension information as well as a list of grants a PI can hold and still be considered an ESI

How to Apply

Application Instructions	Description	SF424 (R&R) - Version H (Due dates ON/AFTER Jan. 25, 2023)
G General Instructions	Comprehensive guidance for research, training, fellowship, career development, multi-project, and small business applications	HTML / PDF
F	**Application Guide instructions**	
R	Activity Codes: Research (R), including Research Education (R25), and equivalent Cooperative Agreements (U)	PDF
K Career Development Instructions	Guidance for career development only Activity Codes: Individual Career Development (K), excluding Institutional Career Development (K12, KL2, KM1)	PDF
M Instructions	Activity Codes: Program Project Grants and Center Grants (P) and equivalent Cooperative Agreements (U)	PDF

The specific NOFO: instructions in the NOFO (and NOSI if applicable) always supersede the Application Guide

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Requires Two Systems
to Work Together

Grants.gov – single online Federal portal to find and apply for Federal grant funding involving some 900 grant programs within 26 grant making agencies granting over $350 billion in annual awards

eRA Commons – the NIH system used by NIH and other HHS components that allows applicants/grantees to electronically receive and transmit application and award information after the application has been submitted to Grants.gov.

Important!

Applicant responsibility to ensure applications complete entire submission process—all the way through to the eRA Commons.

Submitting an application to NIH
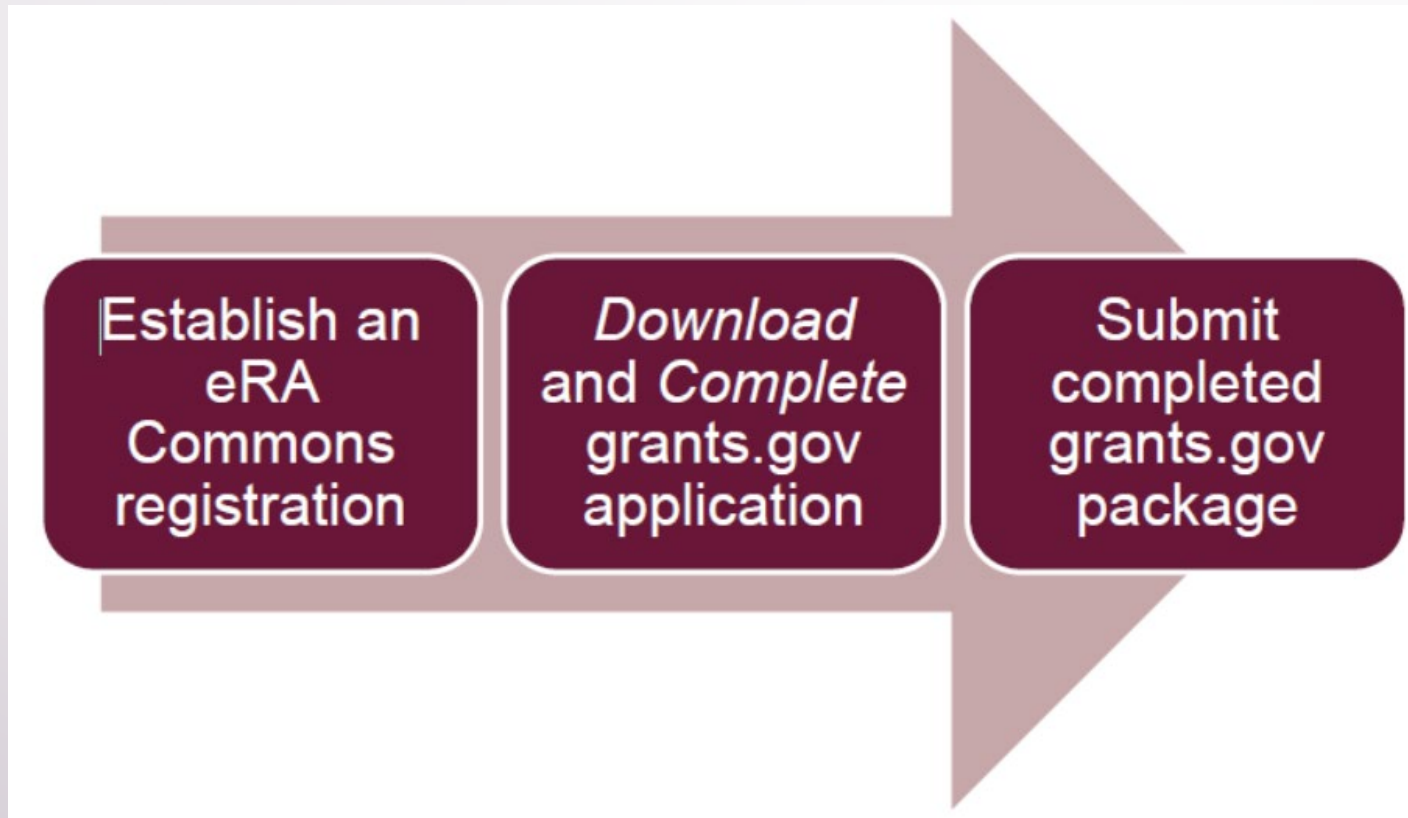
eRA Commons

- is an online interface where grant applicants, recipients and agency staff are able to conduct their research business.

- applicants need Grants.gov to find and apply for grants; the eRA Commons retrieves the application or proposal information from Grants.gov

- following application submission, the eRA Commons becomes the primary site for accessing application status and award information

eRA Commons Capabilities

Institution Administration

- Create and maintain institutional profiles (IPFs)
- Create and maintain user accounts and professional profiles (PPFs)

Status

- Display summary and detail grant info, NoA and other documents, progress report face page, NIH staff contact info
- Link to study section dates and rosters
- PI can access priority score
- PI can access summary statement

eRA Commons Capabilities

Withdraw a processed application

- Submit requests to withdraw a processed application after the two day viewing window has passed using the eRA Commons Prior Approval module.
- Submit electronically by an AOR/SO from within the Electronic Research Administration's (eRA) Commons, navigate from the Prior Approval tab on the landing page
- Applicants will see a status of "Withdrawn" if DRR approves the withdrawal request

Submit Just-in-Time Information

- Enter Institutional Animal Care and Use Committee approval dates
- Enter Institutional review Board approval dates for Human subjects research
- Enter Human subjects education information for key personnel
- Enter other support information for key personnel

http://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-143.html

eRA Commons Capabilities

Submit Research Performance Progress Report (RPPR)

- RPPR form available for download
- Submit RPPR data through the eRA Commons
- PD/PI or their delegate can initiate RPPRs
- Signing officials typically submit the annual RPPR, but may delegate preparation and submission authority to PD/PI
- IRB and IACUC approval dates not required with submission
- SNAP RPPRs due 45 days before the next budget period start date; Non-SNAP RPPRs are due 60 days before the next budget period start date
- Image stored in electronic grant folder for online viewing
- Interim and Final RPPR Due 120 days from period of performance end date for the competitive segment

eRA Commons Capabilities

Federal Financial Report (FFR)*

- Expenditure data

Submit Post-Award Actions

- Submit no-cost extension requestion to automatically update end dates and generate notifications
- Carryover requests
- Change of PD/PI request

Submit Closeout Documents

- Final Progress Report
- Final Inventions Statement
- Links to for Final FFR

eRA Commons Capabilities

Administrative Supplements

- Initiate administrative supplement application within eRA Commons
- Leverage technology available in NIH ASSIST to complete submission

Internet Assisted Review (IAR)

- Submit critiques and scores prior to review meeting
- Review all critiques prior to meeting, reviewers come to the table prepared for discussion, resulting in shorter and more productive meetings
- Electronic critiques facilitate the generation of summary statements
- Laptops (PC and Mac) are easier to use than paper at meeting

Key Elements of Proposal Preparation

- Thoroughly the read NOFO (and NOSI if applicable)

- Human subjects? Check if NIH clinical trial definition met

- Read NOFO again

- Determine if budget must be detailed or modular

- Determine if project involves consortia

- Prepare application with Application Guide in one hand and NOFO in the other

Five NIH Budget-Related Policies

- Modular budgets

- Requests of $500,000 or more direct costs

- Consortium indirects

- Salary cap

- Graduate student compensation

Modular Budget Must Be Prepared If...

- Required by the NOFO   OR

- When the application meets **all of these requirements**:
  - Is for an R01, R03, R15, R21, R34 or their cooperative agreement equivalent
  - Requests no more than $250,000 direct costs (excluding any consortium F&A) in any budget period
  - Does not propose use of human fetal tissue from elective abortions
  - Is not from a foreign organization
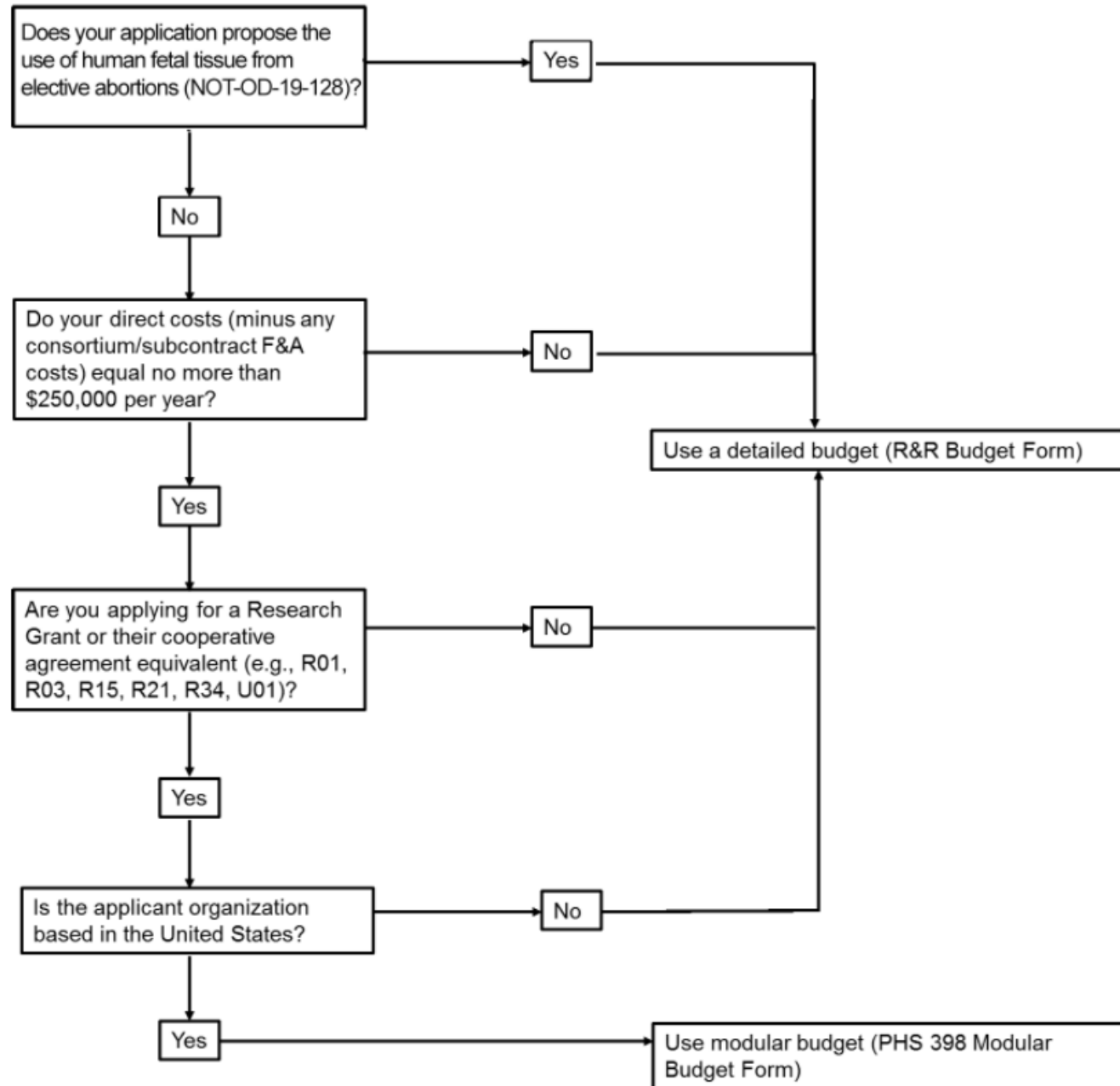
Modular Budgets

- Direct costs requested in modules of $25,000 up to $250,000 each year, excluding any consortium F&A. Prudent to start with a detailed budget. Routinely, same number of modules are requested each year.

- Typically, content of required budget justification limited to a Personnel Justification…a list of all personnel by position, level of effort (person months) and role without individual salary information

- Additional narrative justification is not required if the same number of modules are requested each year OR if in response to a NOFO (e.g., R21) that cannot be spread evenly across budget periods. However, well-justified modular increments or reductions (e.g., equipment in the 1st year; consortium added in 3rd year) may be requested but require additional explanation in the Narrative Justification.

Modular Budget with Subcontract

TUITION & ACADEMIC FEES - AY			$11,680			$0
TRAVEL			$5,000			$0
Domestic		$5,000			$0	
International		$0			$0	
MATERIALS/SUPPLIES			$18,876			$0
field data collection supplies		$18,876			$0	
SUBCONTRACTS^ (see below for SF424 details)			$17,500			$0
(Subcontractor 1)		$17,500			$0	
TOTAL DIRECT COSTS			$102,500			$0
MODULAR BUDGET DIRECT COSTS			$100,000			
INDIRECT COSTS-On Campus Research, Federal/Default Rate			$54,129			$0
FY 10-11 (7/1/09-6/30/11) MTDC @	58.6%	$0			$0	
FY 12 (7/1/11-Project End) MTDC @	59.6%	$54,129			$0	
TOTAL COSTS			$156,629			$0
Base for Indirect Costs through 6/30/11			$0			$0
Base for Indirect Costs 7/1/11-Project End			$90,820			$0

	On/After 7/1/12
Regular Faculty	29.00%
Special Research Faculty	32.25%
Part Time Faculty	20.00%
SMR Faculty/Wage Employee	9.50%
GRA	7.25%
Classified Staff	38.50%

** A U.S. organization submitting an application with direct costs in each year of $250,000 or less (excluding consortium (subc
** A U.S. organization requesting more than $250,000 in annual direct costs and all foreign applicants must complete and subm
If MODULAR budget is to be used, the highlighted line *must be less than or equal to $250,000 annually* and must be in incr
If R&R budget is to be used, the highlighted line must be *above* $250,000 each year.

		Year 1: 08/15/12-08/14/13		
(Subcontractor 1)				
Subcontract Direct Costs		$15,000		
Subcontract Indirect Costs		$2,500		
Total Costs		$17,500	3rd Party Cost Share	$0

Modular Form with Subcontract

Budget Period: 1

Reset Entries   Start Date: 10/01/2009   End Date: 09/302010

A. Direct Costs

	* Funds Requested ($)
* Direct Cost less Consortium F&A	200,000.00
Consortium F&A	17,460.00
* Total Direct Costs	217,460.00

B. Indirect Costs

	Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	* Funds Requested ($)
1.	MTDC	58.5	180,232.00	105,436.00
2.				
3.				
4.				

Cognizant Agency (Agency Name, POC Name and Phone Number)

Indirect Cost Rate Agreement Date

Total Indirect Costs   105,436.00

C. Total Direct and Indirect Costs (A + B)

Funds Requested ($)   322,896.00

Requesting $500,000 or More in Any Year

- Prior approval needed to request $500,000 or more in direct costs in any budget period, excluding consortium F&A.

- Also applies to a group of applications meeting the $500,000 threshold in the aggregate even if no single application in the group requests that much.

- PI must contact an IC Program Officer in writing or by phone no later than 6 weeks before submission and include a cover letter with the application identifying the Program Officer contacted and the IC that has agreed to accept the application.

- Prior approval not required for applications submitted to RFAs that include specific budget limits in excess of $500,000.

- Check *NIH-GPS 2.3.7.2*

Consortium Indirects

- For NOFOs that include a direct cost limit, NIH policy excludes consortium/contractual F&A when determining if an applicant is in compliance with a given NOFO's direct cost limitation.

- For example, with the modular budget format, consortium/contractual F&A costs are not factored into this direct cost limit, but instead, may be requested in addition to the $250,000.

- Check *NIH-GPS 2.3.7.1*

Salary Cap

Since 1990, Congress has legislatively mandated a salary cap for individuals under NIH grants and cooperative agreements. This is still in effect.

...Appropriations Act of 2020 continues to restrict the amount of direct salary of an individual under an NIH grant or cooperative agreement to Executive Level II of the Federal Executive pay scale (used to be Executive Level I). That level effective January 1, 2025 and currently in force is $225,700.

https://grants.nih.gov/grants/notice-files/NOT-OD-25-085.html

Salary Cap

- $225,700 equivalent to 9 month salary of $169,275 or a monthly salary of $18,808.

- Most important to identify salary at cap in the budget justification.

- Remainder is voluntarily cost-shared by the institution.

Lots of examples

https://grants.nih.gov/grants/notice-files/NOT-OD-25-085.html

Graduate Student Compensation

The maximum amount _awarded_ for a graduate student (including salary, fringe benefits, and tuition remission) cannot be greater than the zero level NRSA postdoctoral award….which is currently $62,232 (FY2025). The institution may re-budget and pay a higher amount.

Refer to _NIH Guide Notice_ **NOT-OD-25-105**

NIH Budget Justification

- Describes and explains the amounts in the budget categories.

- The Justification should cover all budget years of the project, not just the first year.

- List names and roles of personnel, their expected level of effort each budget period, and their compensation.

- Describe projected equipment purchases and travel (where, when, why, for how much), supplies, and other costs.

- Justify any significant increase or decrease from year to year.

- A separate justification is required for Subaward/Consortium budgets.

Additional Documents Required

- Data Sharing Plan
  - Required for all NIH-supported research that results in the generation of scientific data, regardless of funding mechanism
  - See NIHGPS 8.2.3.1
- Model Organism Sharing Plan
  - If model organisms are to be a product of the research
  - See NIHGPS 8.2.3.2
- Genomic Data Sharing Plan
  - If generating "large-scale human or non-human genomic data"
  - See NIH GPS 2.3.7.10
- Multi-PD/PI Leadership Plan
  - See NIH GPS 9.3

NIH's RCR Training Requirement

- Responsible Conduct of Research Training

- Effective since January 25, 2010

- Affects certain types of awards (F, K, R25, R36, T)

- Applies to all trainees, fellows, students and post docs who work on these projects

- *Must incorporate formal & informal training and mentoring (including face-to-face)*

- See NOT-OD-22-055 and NOT-OD-10-019

Financial Conflict of Interest

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

- All FCOI must be disclosed before a PHS proposal can be submitted (sub recipients, consultants, and collaborators must disclose, as well).

- Prior to expenditure of any NIH funds under a new award (supplemental, or incremental funding, too), an institution must report to NIH the existence of any conflicting financial interest and assure that the interest has been managed, reduced or eliminated.

A research administrator should be aware of potential sources of conflict, e.g. consulting.

Peer Review Process

First level of review – Scientific Review Group (SRG)

- Composed primarily of non-federal scientists who have expertise in relevant scientific disciplines and research areas

- Receive access to grant applications ~ 6 weeks prior to peer review meeting

- Prepare a written critique of each proposal based on review criteria and judgment of merit

- Assign a numerical score to each review criterion; ultimately applications are either "discussed" (scored) or "not discussed" (not scored)

- Make recommendations concerning the scientific and technical merit of applications in the form of final written comments and numerical scores

- Make recommendations concerning protections for human subjects, welfare of vertebrate animals, and other areas as applicable for the application

- Make recommendations concerning appropriateness of budget requests

Peer Review Process

Current Review Criteria

- **Factor 1 Importance of the Research (**Significance and Innovation) – Does the project address an important problem? Does the application challenge and seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions? Scored 1-9

- **Factor 2 Rigor and Feasibility** (Approach) – Are the overall strategy, methodology, budget and analyses sufficient and well-reasoned and appropriate to accomplish the specific aims of the project? Scored 1-9

- **Factor 3 – Expertise and Resources** (Investigator and Resources) Are the PD/PIs, collaborators, and other researchers well suited to the project? Does the PD/PI have suitable and sufficient facilities, equipment and institutional support to carry out the research plan? Appropriate or gaps identified (requiring explanation)

Peer Review Process

Additional Review Criteria – reviewers will evaluate the following but will not give separate scores for these items:

- Protections for Human Subjects
- Inclusion of Women, Minorities, and Children
- Vertebrate Animals
- Biohazards
- Select Agents
- Resource Sharing Plans
- Budget and Period Support
- Resubmission
- Renewal
- Revision
- Applications from Foreign Organizations have an extra review step:

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

Scoring Guidance Table

Impact	Score	Descriptor	Additional Guidance on Strengths/Weaknesses
High	1	Exceptional	Exceptionally strong with essentially no weaknesses
	2	Outstanding	Extremely strong with negligible weaknesses
	3	Excellent	Very strong with only some minor weaknesses
Medium	4	Very Good	Strong but with numerous minor weaknesses
	5	Good	Strong but with at least one moderate weakness
	6	Satisfactory	Some strengths but also some moderate weaknesses
Low	7	Fair	Some strengths but with at least one major weakness
	8	Marginal	A few strengths and a few major weaknesses
	9	Poor	Very few strengths and numerous major weaknesses

Second Level of Peer Review: What Does an Institute's Advisory Council Do?

Meets 3 or 4 times a year to conduct a second level of review

Assures Quality and Fairness of Peer Review

Votes Concurrence or Non-Concurrence with the IRG recommendation

Votes for High/Low program priority (HPP/LPP)

Evaluates program priorities and relevance

Approval of new program initiatives and concept clearances

Advises on policy

Funding Factors IC Considers in Making Awards

- Scientific Merit
- Contribution to the Mission of the IC
- Program Balance
- Availability of Funds/Funding Strategy

After Proposal Submission Prior to Award

Just In Time (JIT) – Mechanism used by NIH to request more timely information prior to making the final award decision, ideally submitted via eRA

- **Other Support** for all key personnel identified in the proposal

- **IRB** and/or **IACUC** approval dates if project includes human or animal subjects

- **Human Subject Education** Information (documentation of HS protections training)

Pre-Award Review

- Sufficient levels of effort are committed

- No scientific, budgetary, or commitment overlap.

  - Scientific overlap occurs when substantially the same research is proposed in more than one application.

  - Budgetary overlap occurs budgetary items are requested but already are provided by another source.

  - Commitment overlap occurs when an individual's time commitment exceeds 100 percent.

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

The Notice of Award (NoA)

Legally binding contract between NIH and the institution that includes:

- Identifies PI(s) , Project and Award Number

- Establishes funding level

- Establishes period of support: Budget Period vs. Project Period

- Designates if award is under SNAP (streamlined noncompeting award process) and automatic carryover

- Sets forth terms and conditions, including reporting requirements

- NIH Contact Information

  - Program Official (technical side)

  - Grants Management Specialist (fiscal and administrative side)

- What constitutes acceptance of the award?

Funding for the next budget period?

- Except for "multi-year" awards, most NIH awards are funded one year at a time (budget period).

    - Competitive Segment is the project period (1-5 years)

    - Budget period is one year or less.

- Submitting an annual Progress Report through eRA Commons using the **RPPR** (Research Performance Progress Report).

- New Notice of Award for new budget period will be issued once annual report is accepted.