

Navigating the NIH Proposal Process Part 1

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Overview

- ▶ **Part 1: Background Information**
 - ▶ NIH Website – who, what, how
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 - ▶ Submission Portals
 - ▶ Timeline & Internal Information
 - ▶ Take-a-way

NIH Website – who, what, how

- National Institutes of Health (NIH) is under U.S. Department of Health and Human Services (DHHS)
- DHHS (www.hhs.gov)
 - Mission to support the health and well being of the Nation.
 - 11 operating Divisions
 - Including: Administration for Children and Families, Centers for Disease Control and Prevention, Food and Drug Administration, National Institutes of Health
 - Office of Secretary and many other division heads are by Presidential appointment (some with Senate confirmation and some direct) (Wikipedia re: DHHS Appointments)
 - Website has section on Grants and Contracts (policies, how to register, finding and applying, etc. –high level view)


NIH Website – who, what, how

- ▶ NIH's mission is to seek fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance health, lengthen life, and reduce illness and disability.
- ▶ Comprised of 27 Institutes and Centers such as National Cancer Institute (NCI), National Eye Institute (NEI), National Institute on Aging (NIA), and National Institute of General Medical Sciences (NIGMS)
- ▶ More than 80 percent of NIH's funding (\$41.7B annually) is awarded for extramural research, largely through almost 50,000 competitive grants to more than 300,000 researchers at more than 2,500 universities, medical schools, and other research institutions in every state.
- ▶ About 10% of the NIH's budget supports projects conducted by nearly 6,000 scientists in its own laboratories, most of which are on the NIH campus in Bethesda, Maryland.
- ▶ www.nih.gov
 - ▶ Budget info, Success Rates, Research Portfolio Online Reporting Tools (RePORTER - searchable db. on funded proposals)
 - ▶ FAQs = Grants & Funding, News & Events (conferences), Staff Directory, Organizational Charts for all the NIH Institutes and Centers


National Institutes of Health

- ▶ How to Look for Funding Opportunity Announcements (FOA) -- where to start:
 - ▶ <https://www.nih.gov/grants-funding>
 - ▶ Grants.gov; beta SAM; OU VPVP website
 - ▶ Commercial 'data mining' software
 - ▶ General internet searches
- ▶ Finding your institute
 - ▶ 27 Institutes & Centers (and join listserv or periodically check homepage)
 - ▶ NIH Matchmaker:
https://projectreporter.nih.gov/reporter_matchmaker.cfm

Funding Opportunity Announcements (FOAs)

- Parent Announcements (omnibus; think unsolicited/investigator-initiated avenue) standard receipt dates
- Program Announcements (PAs) (increased interest/priority; usually active for 3 years) standard receipt dates (usually)
 - PAR (PA with special receipt, review, or referral considerations)
 - PAS (PA with set-aside funds as detailed)
- Request for Application (RFAs) – more narrow interest; sometimes funds set aside; usually specific submission date 
- Request for Proposal (RFP) – usually solicits a contract type of proposal (but may still be awarded to OU as another funding vehicle such as a cooperative agreement) usually specific submission date
- Notices (NOT) – announce policy and procedural changes, or changes to any of the above type of announcements.
- NOT, Pas, and RFAs usually have an NIH staff member or office listed to direct questions to

Funding Opportunity Announcements (FOAs)

- Many solicitations will specify if they are for clinical trials or not – if they don't say in the title area then read the announcement closely.
- “Clinical Trials Required/Allowed/Not Allowed” (the 4 Questions) 
<https://grants.nih.gov/policy/clinical-trials.htm>

NIH defines ‘intervention’ as a manipulation of a subject or their environment for the purpose of modifying one or more health-related biomedical or behavioral processes/and/or endpoints. Examples include: drugs...devices; procedures ...; delivery systems...; strategies to change health related behavior...; treatment..., prevention..., and diagnostic strategies. Policy personnel have said to translate the word ‘intervention’ as ‘interaction’.

<https://grants.nih.gov/grants/guide/description.htm>

Reading an opportunity

- Is it current? Correct for what you are doing?
- Are you/OU eligible?
- What is the deadline?
 - <https://grants.nih.gov/grants/how-to-apply-application-guide/due-dates-and-submission-policies/due-dates.htm>
- What is different from the general guidelines?
- Agency Contacts
 - Find the Program Officer & Scientific Review Officer
- NIH's annotated guide:
 - https://grants.nih.gov/grants/Annotated_FOA.pdf

How Guidance 'funnels' down

- Federal Requirements (Uniform Administration Requirements, Cost Principles, Audit requirements [Uniform Guidance – UG])—Code Federal Requirements = CFR Title 2 Parts 1 - 5999
- Agency Guidelines
 - General and sometimes specific (use both)
 - NIH usually has at least both (General Instructions/Standard Instructions plus PA/RFA)
 - Special instructions (NIH calls theirs 'notices')
- State Requirements
- Local Policy

NIH General Guidance

- ▶ [How to Apply - Application Guide | grants.nih.gov](https://grants.nih.gov) (mid to bottom of page)
 - ▶ G is the General Guidelines and includes everything
 - ▶ Filtered is portions based on the type of application you are submitting
- ▶ General Guidelines called 'SF 424 (R&R) Version _'
 - ▶ Currently F series
 - ▶ When they change the forms series new guidelines are common
 - ▶ Issue date is on the front
 - ▶ It may be updated without re-issue
 - ▶ Stay informed of policy changes and updates (may be posted as an update in the guidelines or via a Notice
 - ▶ For example, over 20 Notices issued between Jan – April 2021
 - ▶ Watch for draft postings in early fall for comment

NIH Submission Portals

- ▶ NIH ASSIST
 - ▶ NIH developed submission system
 - ▶ Normally not used at OU unless a special, multi-project proposal is being done such as COBRE
 - ▶ Requires Special (and advance) permission
- ▶ Grants.gov
 - ▶ Rarely used by OU or OU PIs
 - ▶ Primarily if fellowship being paid directly to PI
 - ▶ If PI desires to use grants.gov for OU submission requires special (and advance) permission
 - ▶ Special instructions (NIH calls theirs 'notices')
- ▶ **System to System (S2S)**
 - ▶ **This is the primary and preferred system used by OU**
 - ▶ This system is used 99% even if only avenue of submission mentioned in the solicitation is grants.gov
 - ▶ **It is a program under CAYUSE** that allows for extra error checks and gives us a copy of the submission
 - ▶ It transmits the submission into grants.gov and we get a grants.gov tracking number
- ▶ Special Instructions may ask for submissions to email addresses – such as NIH Loan Repayment Program (LRP)

Found an Opportunity?

- ▶ You need to complete:
 - ▶ eRA Commons account
 - ▶ ORCID registration (depending on solicitation)
 - ▶ Very rarely grants.gov registration (most submissions done under OU's registration) (Don't register until you talk with ORS)
- ▶ Submit your Info sheet to ORS as early as possible
 - ▶ Helps ORS prioritize workload
 - ▶ Assigns Proposal Services Specialist
 - ▶ Provides critical information for follow-up
 - ▶ Public Health Service Financial Conflict of Interest (PHS FCOI) declaration and processing (also on subawards)

Timeline Before Due Date

8-12 Months

4-8 Months

2-4 Months

2-4 Weeks

1 Week



1. Lit review and prelim data
2. Find an institute (IC) and funding opportunity (FOA)
3. Build your research team
4. **Submit OU Info sheet**
5. Draft a one-page Specific Aims (SA)
6. Send SA to Program Officer (& SRO)
7. Build your review team
8. Write & Review
9. **Preliminary routing to ORS**
10. **Start submitting Application components to ORS**
11. **Complete submission**

NIH Submission Process at OU

1. PI decides they are likely submitting and the solicitation number.
2. PI Submits an OU Information Sheet (Info Sheet).
3. PI considers scope, objectives, personnel; makes draft budget with ORS; makes sure ORS is aware of any subcontracts, collaborators, or consultants.
4. PI sends final budget, draft summary/abstract, and draft budget justification to ORS (subcontract packages also needed at this time).
5. ORS does the routing package; internal routing for permission to submit begins; PI continues work on submission files.
6. ORS pulls application package and starts completing forms and loading budget; notifies PI when routing is complete.
7. PI sends submission files to ORS (we prefer these be sent as soon as you think they are done); individual files are needed.
8. ORS loads submission files, checks formatting if time is available; sends print copy to PI (if time is available)
9. ORS does electronic validation and submission; tracking number given to PI.
10. ORS receives tracking emails; PI receives notice from eCommons; 2-day validation phase is open (ONLY useful if proposal is submitted early).
11. Validation phase closes; proposal enters PO/NIH in processing for sorting to study section.

Take-a-Way

- ▶ Effect of US President changes
- ▶ Program Officers not as cyclic as some federal agencies
- ▶ Decide what institutes your research might fit within
 - ▶ Mission to your research tie-in is at Division/Center level
- ▶ Establish relationship with PO
 - ▶ Volunteer to review
- ▶ Start process early
- ▶ Read the general guidelines
- ▶ Recent notices (biosketch, other support); ORCID, SciENCV, eRACommons registration for all Senior Personnel
- ▶ Learn about NIH and what is on their website
 - ▶ List serves
 - ▶ Training info
 - ▶ Free conferences
 - ▶ NIH also has POD casts on things like writing your research strategy

Contacts for Help

- RIS@ou.edu will answer questions or put you in contact with who can answer your questions for anything pre-award/Office of Research Services (ORS) related.
- Submit an info sheet [Office of Research Services - Proposal Information Sheet | | The University of Oklahoma \(ou.edu\)](#) and someone from ORS will contact you
- Center for Faculty Excellence (CFE) provides proposal assistance to include SciENCv training cfe@ou.edu
- If your question is related to post award then contact Research Financial Services (ReFS) refsinfo@ou.edu