Navigating the NIH Submission Process

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Office of Research Services

November 12, 2025

Agenda

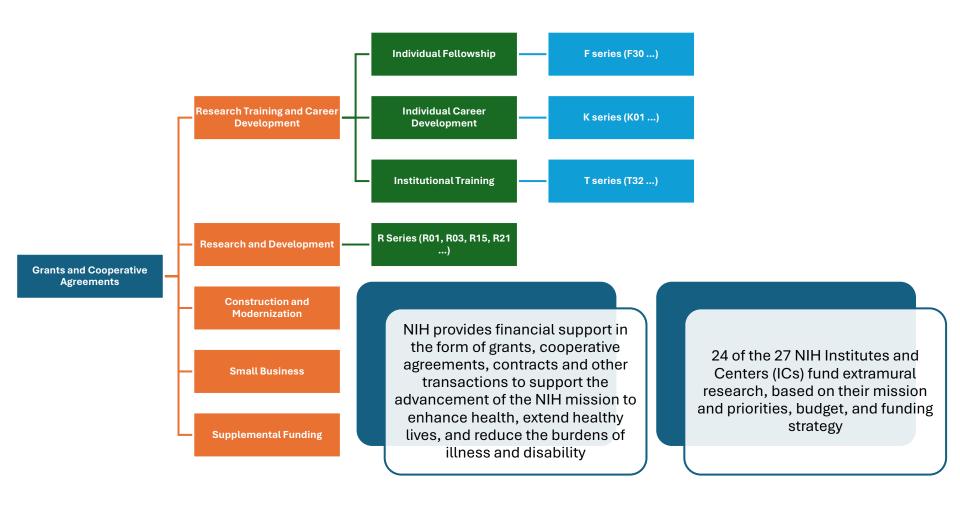
- NIH Overview
- NIH Funding Announcements
- Proposal Preparation Steps
- NIH Budget
- Submission Systems
- NIH Forms and Documents
- Tips and Resources

NIH Overview

- The National Institutes of Health (NIH) is the largest public funder of biomedical research in the world
- NIH is located within the US Department of Health and Human Services (HHS), the United States' principal agency for protecting the health of all Americans and providing essential human services.
- 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.



Categories of Funding Opportunities



NIH Funding Announcements

- Notices of Funding Opportunities (NOFOs)
 - Parent Announcements unsolicited, investigator-initiated, with standard deadlines.
 - Program Announcements (PAs) issued by one or more NIH's Institutes or Centers to highlight areas of scientific interest.
 - Request for Application (RFAs) more narrow interests and sometimes funds are set aside. They usually have a specific submission date.
- Where to find NOFOs:
 - NIH Grants & Funding Webpage https://grants.nih.gov/funding/nih-guide-for-grants-and-contracts
 - Grants.gov
- NIH Matchmaker tool to find NIH Institutes or Centers who have funded similar research projects
 - https://reporter.nih.gov/matchmaker#matchmaker_search

Reading a NOFO

Overview Information

Key dates

Funding opportunity description

Eligibility information

Submission requirements

Agency points-of-contact

Review criteria

Award information

Award administration

Department of Health and Human Services

Part 1. Overview Information

Participating Organization(s)

National Institutes of Health (NIH)

Components of Participating Organizations

NATIONAL INSTITUTES OF HEALTH (NIH)

This Notice of Funding Opportunity (NOFO) is developed as a Common Fund initiative (http://commonfund.nih.gov/) through the NIH Office of the NIH Director, Office of Strategic Coordination (https://dpcpsi.nih.gov/) All NIH Institutes and Centers participate in Common Fund initiatives. The NOFO will be administered by the National Institute of Dental and Craniofacial Research (NIDCR) (http://www.nidcr.nih.gov).

Funding Opportunity Title

Pillot Projects to Enhance the Human Virome Program (R03, Clinical Trials Not Allowed)

Activity Code R03 Small Grant Program

Announcement Type

Related Notices

- April 4, 2024 Overview of Grant Application and Review Changes for Due Dates on or after January 25, 2025. See Notice NOT-OD-24-084.
 - August 31, 2022- Implementation Changes for Genomic Data Sharing Plans Included with Applications Due on or after January 25, 2023. See Notice NOT-OD-22-198.
 - August 5, 2022- Implementation Details for the NIH Data Management and Sharing Policy. See Notice NOT-OD-22 189.

Funding Opportunity Number (FON) RFA-RM-25-006

Companion Funding Opportunity None

Number of Applications See Part 2 Section III. 3. Additional Information on Eligibility

Assistance Listing Number(s) 9:

Funding Opportunity Purpose

The Common Fund Human Virome Program (HVP) aims to extensively and comprehensively characterize the human virome and create tools, models, and methods that will enable an in-depth study of its variation and composition in relation

Understanding Due Dates in the NOFO

Open Date (Earliest Submission Date) Letter of Intent Due Date(s)		September 22, 2025				
		October 24, 2025 Not Applicable				
New	Renewal / Resubmission / Revision (as allowed)	AIDS - New/Renewal/Resubmission/Revision, as allowed	Scientific Merit Review	Advisory Council Review	Earliest Start Date	
November 24, 2025	Not Applicable	Not Applicable	March 2026	May 2026	July 2026	
pplicants are encourage	y 5:00 PM local time of applica d to apply early to allow adeque accepted for this Notice of Fu	ate time to make any corrections to errors found in	the application during the s	ubmission process by the d	ue date.	
Expiration Date		November 25, 2025				
Expiration Date Oue Dates for E.O. 12372		November 25, 2025 Not Applicable				

Early-Stage Investigators

An early-stage investigator (ESI) is a Program Director/Principal Investigator (PD/PI) who has

- completed their terminal research degree or end of postgraduate clinical training, whichever date is later, within the past 10 years and
- who has not previously competed successfully as PD/PI for a substantial NIH independent research award.

NIH is committed to supporting ESIs

- Reviewers give early-stage investigators special consideration
- Applications with meritorious scores may be prioritized for funding
- NIH has programs targeted specifically for this population

More Information for Early-Stage Investigator Policies:

Early Stage Investigator (ESI) Policies | Grants & Funding

Proposal Preparation Steps

Submit information sheet (<u>InfoSheet</u>) to ORS at least four weeks before the sponsor deadline.

Receive budget/budget justification templates from your Proposal Services contact.

Provide internal routing documents which include a draft summary, final budget, and budget justification, to your PS two weeks before the deadline. If you have a subcontract, it's best to allow for extra time.

Send final, required submission documents to your PS at least three business days prior to deadline to be uploaded into the submission system. Work with them to ensure all documents are included and complete. Review draft of entire proposal before granting permission to submit.

After ORS submits the proposal, the PI will receive a conformation email from eRA Commons.

NIH Budgets

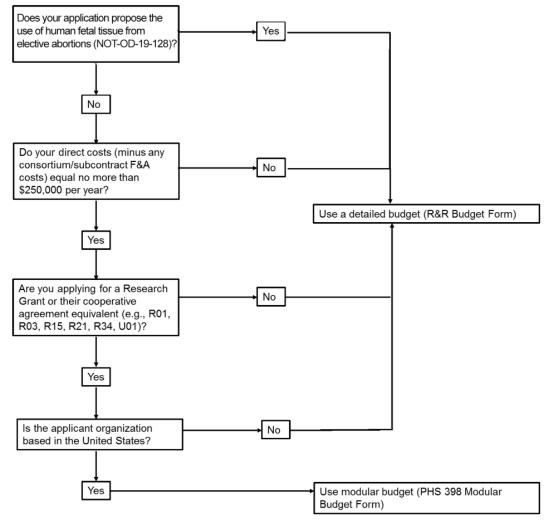
- Cost Considerations- costs must be actual, allowable, reasonable, necessary and consistent.
- NIH Grants Policy Cost
 Principles:
 https://grants.nih.gov/grants/policy/nihgps/HTML5/section 7/7.2 the cost principles.htm
- NIH uses 2 different budget formats: Modular and Detailed

	Modular	Detailed
When to use	Max module is \$250,000 direct cost/year	Any budget request over \$250,000 direct cost/year
Budget	\$25,000 modular increments	Normal, detailed budget
Justification	Only required for personnel expenses and an additional narrative, as needed – i.e. F&A exclusions & requesting different modules per year.	Normal, detailed budget justification
Subcontracts	Abbreviated Consortium budget justification	Normal, detailed budget justification
NIH Form	PHS398 Modular Budget	R&R Budget



The UNIVERSITY of OKLAHOMA

Modular vs. Detailed Budget Flow Chart



Develop Your Budget | Grants & Funding



Budget Considerations

- When requesting more than \$500,000 in direct costs in any one budget period, approval from the Institute or Center is required prior to submitting the application.
- Congress restricts the amount of direct salary paid to an individual under an NIH grant. The current Salary Cap, for Executive Level II is \$225,700 (Office of Personnel Management Salaries & Wages).
- Internally, you will have an OU spreadsheet which is a detailed budget that routes for internal approval.
- Your PS will load the budget in the application based on whether a modular or detailed budget is required.

NIH Submission Portals

NIH ASSIST

• NIH-developed submission system, normally not used at OU except for special, multi-project proposals.

Grants.gov Workspace

 Rarely used by OU or OU PIs and is primarily for fellowships paid directly to a PI.

System to System (S2S)

- Primary and preferred system used by OU used to submit NIH proposals most of the time.
- Program within Cayuse that allows for extra error checks and draft copies of the proposal for review before submitting.
- Transmits the submission to Grants.gov and provides a tracking number.

eRA Commons Registration

- An **eRA Commons** registration is required for all individuals listed on the grant application.
 - Submit an eRA Commons account request
- Upcoming ORCID iD Requirement: As part of the transition to Common Forms in 2026, all senior/key personnel on the application must have an ORCID iD linked to their eRA Commons profile when using SciENcv to generate NIH Biosketches.

How to Apply for an NIH Grant

- How to Apply –
 Application Guide |
 Grants & Funding
- Advice on
 Application Sections
 | Grants & Funding

Form-by-Form, Field-by-Field Application Instructions

Determine the Correct Application Instructions for Your Activity Code

G General Instructions	Comprehensive guidance, including standard instructions that apply to all applications and all program-specific instruction call-out boxes (research, training, fellowship, career development, multi-project, and small business)	Alert Updated March 18, 2025. See Significant Changes.
R Research Instructions	Standard instructions that apply to all applications plus research instruction call-out boxes. Activity Codes: Research (R), including Research Education (R25), and equivalent Cooperative Agreements (U)	PDF
Career Development Instructions	Standard instructions that apply to all applications plus career development instruction call-out boxes. Activity Codes: Individual Career Development (K), excluding Institutional Career Development (K12, KL2, KM1)	PDF
T Training Instructions	Standard instructions that apply to all applications plus training instruction call-out boxes. Activity Codes: Institutional Training (T), including International Training (D43, D71, U2R) and Institutional Career Development (K12, KL2, KM1)	PDF
Fellowship Instructions	Standard instructions that apply to all applications plus fellowship instruction call-out boxes. Activity codes: Fellowship (F)	PDF
M Multi-Project Instructions	Standard instructions that apply to all applications plus multi-project instruction call-out boxes. Activity Codes: Program Project Grants and Center Grants (P) and equivalent Cooperative Agreements (U)	PDF
SBIR/STTR B Instructions	Standard instructions that apply to all applications plus small business instruction call-out boxes. Activity Codes: R41-R44, SB1, U43, U44, UB1, UT1, UT2	PDF

Research and Related (R&R) Project Information Documents

Standard proposal files needed from the PI/PD are:

- Project Summary/Abstract
- Project Narrative
 - 1 page
 - o Relevance of research to public health

Project Performance Sites Form

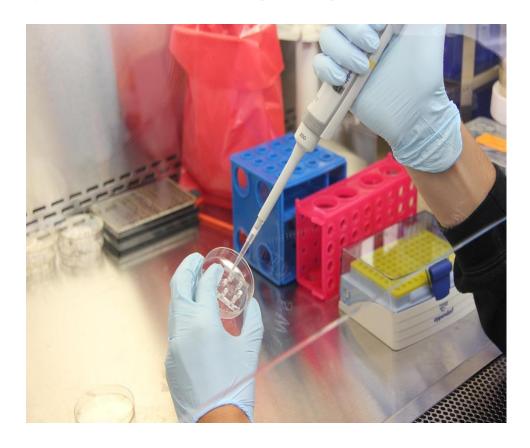
- Biosketch
- Signed Letter of Intent to Form a Subcontract Agreement
- Detailed budget justification
- R&R Budget Form
- Letter of Support from PI

Research and Related (R&R) Project Information Documents (continued)

- Bibliography & References Cited
 - o Required on all submissions unless otherwise noted in solicitation
 - Should cite any reference included in the Research Plan form and the Human Subjects and Clinical Trials Information form
 - No page limit but you are expected to be concise
- Facilities and Other Resources
 - o Required on all submissions unless otherwise noted in solicitation
- Equipment
 - o Required on all submissions unless otherwise noted in solicitation
 - All available resources to support the proposed work
 - Scientific environment and how it contributes to probability of success
- Other Attachments only if requested in the NOFO

Public Health Service (PHS) Research Plan Documents

- Introduction File
- Research Plan Section
 - Specific Aims
 - Research Strategy



Public Health Service (PHS) Research Plan Documents (continued)

- Other Research Plan Section
 - Vertebrate Animal
 - Select Agent Research
 - Multiple PD/PI Leadership Plan
 - Consortium/Contractual Arrangements
 - Letters of Support
 - Resource Sharing Plan(s)
 - Data Management and Sharing Plan
 - Authentication of Key Biological and/or Chemical Resources



NIH Policy on Foreign Subawards

• **Effective May 1, 2025,** NIH will not issue subawards to foreign entities (new, renewal, or non-competing continuation). Additionally, NIH will no longer accept prior approval requests to add a new foreign component or subaward to an ongoing project (NOT-OD-25-104).

Effective September 30, 2025:

- Foreign collaborations are not nested under the prime award
- Instead, foreign work will be tracked through linked but independent awards, while scientific progress will still be reported by the prime recipient
- Applies to all NIH grants and cooperative agreements (new, renewal, and noncompeting) to both domestic and foreign entities
- Does not apply to:
 - Foreign consultants
 - Purchases (unique equipment or supplies) from foreign vendors

NIH Financial Conflict of Interest Disclosure and Training Requirements Before Submission

New NIH Requirement (Effective Oct. 1, 2025):

- Institutions must provide training on **disclosure of Other Support**. (Policy Notice: NOT-OD-25-133)
- All senior/key personnel must complete this training prior to proposal submission.
- Training available via Navex Disclosure Management System.

PHS-FCOI Disclosure

- Required for all senior/key personnel listed on the grant application.
- Complete through http://ors.ou.edu/fcoi/fcoireport.asp

ORS Submission Policy

ORS submission policy requires all final proposal documents be uploaded **at least three business days** prior to the sponsor submission deadline.

Proposal documents uploaded at least three business days prior to the submission deadline will be reviewed for compliance.

Documents uploaded *later than* three business days will be submitted without a review or compliance check.

 The PI and their respective Department or College will assume the responsibility for any rejections due to non-conformity/non-compliance. This includes resolving any financial discrepancies with the budget.

Key Takeaways



Hyperlinks and URLs are only allowed when specifically noted

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PDF - Use Flattened PDFs; disable security features like password

- Do not use the appendix or other sections to circumvent page limits
- Decide what institutes your research might fit within. Read the entire NOFO- contact the IC to talk about "fit". <u>Highlighted Topics | Grants & Funding</u>
- Establish relationship with Program Officer(s)
- Stay up to date with all recent notices biosketch, other support, ORCiD, SciENcv, eRA Commons registration
- Ask ORS if you need help with your NIH proposal; let your PDS know of any difficulties you may encounter with logging in or uploading documents.

Resources

- NIH Resources
 - o Review | Grants & Funding (nih.gov)
 - Peer Review Policies and Practices | Grants
 & Funding (nih.gov)
- ORS Website: https://www.ou.edu/research-norman/research-services/
- ORS Training Website:

 https://www.ou.edu/research norman/research-services/training
- ORS FAQs: https://www.ou.edu/research-norman/research-services/faq
- Center for Faculty Excellence (CFE); The Research & Creative Activities Team: https://www.ou.edu/cfe/research
- ProposalShortTips.pdf
- Proposal Development Page



Contact Information

- Research Information Services
 (ris@ou.edu) can answer general
 questions or direct you to the appropriate
 person
- Sogol Rasouli, Associate Director of Research Information Services (Sogol.rasouli@ou.edu)
- Bonnie VanWinkle, Associate Director, Proposal Services (<u>bvanwinkle@ou.edu</u>)
- Leslie Flenniken Kelly, Associate
 Director of Award Administration
 (lflenniken@ou.edu)
- Jennifer O'Hern, Faculty Relations and Operational Excellence Manager (jennifer.ohern@ou.edu)



CoRA for Frequently Asked Questions and Website Navigation



HOME

ABOUT >

RESEARCH SERVICES *

RESEARCH SUPPORT ▼

CORPORATE PORTAL

CENTERS & INSTITUTES *

NEWS & EVENTS ▼

Office of Research Services

Federal Grant and Assistance Directives FAQ Now Available

In a recent **communication**, President Harroz acknowledged questions and concerns raised by recent federal executive orders and Executive Branch communications related to federal assistance and grants essential to the university's research enterprise. **Additional information is now available online** and will be updated as needed.

The goal of the Office of Research Services (ORS) under the Vice President for Research and Partnerships (VPRP) is to function as a highly trained, customer service-oriented organization whose primary purpose is to support externally funded research and sponsored activities within the university community. ORS has responsibility for pre-award and award administration on the Norman campus and Norman campus-related programs on the Tulsa campus. ORS is the institutional unit authorized by the Board of Regents to submit proposals to and accept awards from external entities for financial support in the form of grants, contracts, and cooperative or other agreements.

For general questions, call the ORS main phone number, (405) 325-4757, or contact us at ris@ou.edu.

Calculate Your Submission Processing Timeline(MM/DD/YYYY):

mm/dd/yyyy 📰

https://www.ou.edu/research-norman/research-services/research-services-home

Quick links

Submit Proposal Information Sheet

Cayuse Research Administration

Staff Directory

Obtaining Accounts and Registrations





Questions

