This session will *not* be recorded, but this PowerPoint can found
https://medschool.ucla.edu/research/researcher-resources/administrative-support/department-medicine-office-research-administration/fund-management-training

NIH Pre-Award Basics

UCLA DEPARTMENT OF MEDICINE
OFFICE OF RESEARCH ADMINISTRATION
ZOOM TRAINING

Follow-Up from Last Week…

- Proposal Intake Form
  - [DGSOM Version (aka UCLA Health)](#)
    - Mednet login required
    - Allows up upload of budget justification
  - [Non-DGSOM Version](#)
    - Open to all users
  - [PDF Version](#)

Sponsor Guidelines

Proposal Application Guidelines

- **Read all sets of guidance thoroughly!**

  - Save PDF of all sets of guidelines, highlight important pieces of information.

  - Guideline Checklist

- In some cases there may be multiple sets of guidelines. For example, NIH has:

  - **SF424 (R&R)** – generic, "vanilla" guidelines that cover the standard proposals – i.e. formatting, page limitations & general content info.

  - **NIH Grants Policy Statement** – terms & conditions of NIH grant awards. NIH's interpretation of the Uniform Guidance, a.k.a. cost principals. Although this policy governs the funded award (post-award), it is important to be familiar with them at the proposal preparation stage.

  - **Notices of Funding Opportunities (NOFOs – aka FOAs)** – see next slide.

  - Notice of Special Interest (NOSI) – see slide #9

Notices of Funding Opportunity (NOFO)

- Known as Funding Opportunity Announcements (FOA) prior to March 2023.

- NOFOs are NIH's way of advertising available grant support. These proposal specific instructions supersede anything in the SF424 guidelines. Provides: information on award, eligibility, evaluation criteria, required components, how to submit, etc.

- Types of NIH NOFOs:
  - Program Announcement (PA) *– treated as investigator-initiated*
    - PAR
    - PAS
  - Request for Application (RFA) *– solicits grant or cooperative agreement to meet specific need. Usually single application receipt date.*
  - Request for Proposal (RFP) *– solicits contract to meet specific need. Usually single application receipt date.*

Solicited vs. Unsolicited

- **Solicited** (also known as Targeted or Sponsor-Initiated Research) – Research funded as a result of Sponsor/Institute set aside dollars for a specific scientific area. Sponsors solicit applications using research initiatives.

- **Unsolicited** (also known as Investigator-Initiated Research) – Research funded as a result of an investigator, on his or her own, submitting a research application.

  - For NIH, PIs can submit unsolicited proposals using the NIH's Parent Announcements (see next slide).

Parent Announcements

- Electronic grant applications must be submitted in response to an NOFO. For applicants who wish to submit what are termed Investigator-Initiated or Unsolicited applications, NIH has developed Parent Announcements. Responding to such an umbrella Parent NOFOs ensures that the correct application package is used and enables NIH to receive the application from Grants.gov.

- Some NIH Institutes or Centers may not participate in all parent announcements. Read the NOFO "Components of Participating Organizations" to confirm participation!

  - Example: Parent R21

- Parent Announcements are a subset/type of Program Announcement

Program Announcement (PA)

- A formal statement about a new or ongoing extramural activity or mechanism. It may serve as a reminder of continuing interest in a research area, describe modification in an activity or mechanism, and/or invite applications for grant support. Most applications in response to PAs may be submitted to a standing submission date and are reviewed with all other applications received at that time using standard peer review processes.

- NIH may also make funds available through

  - **PARs** – PAs with special receipt, referral, and/or review considerations

  - **PASs** – PAs with set-aside funds

- Unless otherwise specified in the PA, new applications (and associated renewal and revision applications) submitted in response to PAs are treated as investigator-initiated.

Notice of Special Interest (NOSI)

- Succinctly highlight a specific topic of interest, for example a specific area of research or program

- Direct applicants to one or more active NOFOs (often parent announcements) for submission of applications for the initiative described

- Usually contains additional instructions and/or eligibility criteria. Examples of special instructions:

  - Always: Must include NOSI announcement # in the Agency Routing Identified field (box 4B) of the SF424 RR form.

  - Budget limitations

  - Time limitations

APPLICATION FOR FEDERAL ASSISTANCE **SF 424 R&R**	2. DATE SUBMITTED 05/09/2022	Applicant Identifier
	3. DATE RECEIVED BY STATE	State Application Identifier
1. TYPE OF SUBMISSION ○ Pre-application ○ Application ● Changed/Corrected Application	4. a. Federal Identifier	b. Agency Routing Number NOT-DE-21-019 c. Previous Grants.gov Tracking ID GRANT13611167

Request for Application (RFA) & Request for Proposal (RFP)

- **RFA** – A formal statement that solicits grant or cooperative agreement applications in a well-defined scientific area to accomplish specific program objectives. An RFA indicates the estimated amount of funds set aside for the competition, the estimated number of awards to be made, and the application submission dates. Applications submitted in response to an RFA are usually reviewed by a Scientific Review Group (SRG) specially convened by the awarding component that issued the RFA.

- **RFP** – Announces that NIH would like to award a contract to meet a specific need, such as the development of an animal model.

- RFAs & RFPs have a single application receipt date and are published in the NIH Guide for Grants and Contracts.

Summary of Types of NOFO

Type of Funding Opportunity Announcement	Receipt Date	Money Set Aside	Peer Review	Specificity of Topic	Advantage to Applicant
Parent Announcements	Standard receipt dates, usually open for three years	None	In Center for Scientific Review (CSR) or in an IC, by one of many review committees	Non-specific, investigator-initiated "unsolicited" research. Not all ICs participate in all parent FOAs.	May submit any topic within the breadth of the NIH mission. Competition tied mainly to an IC's overall payline
IC-Specific Program Announcements (PA)	Standard receipt dates, usually open for three years	No set asides (unless PAS); high-priority applications may be funded beyond the payline	In CSR or in an IC, by one of many review committees (unless PAR)	Often broadly defined or a reminder of a scientific need; investigator-initiated "unsolicited" research	Competition tied mainly to the IC's overall payline
Request for Applications (RFA)	Single	Specifies funds and targets number of awards	Usually in and IC, but sometimes in CSR. Same review committee for all applications. Usually reviewed by a Scientific Review Group, called a Special Emphasis Panel, that is convened on a one-time basis	NIH-Requested Research; Well-defined scientific area	Competition depends on number of applicants and dollars set aside

- Payline: A percentile-based funding cutoff point determined by balancing the projected number of applications coming to an NIH Institute with the amount of funds available.

Application Types

Competing Applications

- **New** – An application not previously proposed.

- **Resubmission** – An application that has been <u>previously submitted, but was not funded, and is being resubmitted for new consideration</u>. Applicants must make significant changes to the application and can only resubmit once the summary statement is available. <u>Only 1 resubmission allowed</u>.

- **Renewal aka Competing Continuation** – An application requiring competitive peer review to <u>continue beyond the current project period</u>.

- **Revision aka Supplement** – A request of an <u>increase of support funding</u> in the current budget period <u>for expansion of</u> the project's approved <u>scope</u> or research protocol. Applicants must apply and undergo peer review.

Non-Competing Applications

- **Non-Competing Continuation aka Progress Reports/RPPR** – A year of continued support for a funded grant. Progress reports for continued support do not undergo peer review, but are administratively reviewed by the Institute/Center and receive an award based on prior award commitments. In other words, submitted near the end of each <u>budget period</u>, except last budget period.

Non-Competing Applications

- Example: An award with a project period of July 1, 2021– June 30, 2024 would have 3 budget periods:
  - (1) July 1, 2021 – June 30, 2022*
  - (2) July 1, 2022 – June 30, 2023*
  - (3) July 1, 2023 – June 30, 2024**

- Always check the NOA to confirm RPPR due dates!

*NIH progress reports are typically due 1.5-2 months before each budget period end date, *except the last budget period*. In this example, May 1st or May 15th.
  - Note: Some Ts can be due 4 months prior to budget period end.

**NIH final reports are due 90 days after project period end date. In this example, September 30, 2024.

Sponsor Due Dates

NIH [Standard Due Dates](#) for Competing Applications

- Grant applications & associated documents (i.e. reference letters) are due 5:00 PM **local** time **of the application organization**.

- Cycle due dates separated by activity code/mechanism.

- Renewal/Resubmission/Revision applications may have different due dates than New applications.

- AIDS & AIDS-related dates apply to all activity codes.

- Provides *Earliest* Project Start Dates.

NIH PI Continuous Submission (CS)

- **What?** Allows appointed members (i.e. those that serve the NIH in various capacities) to submit their research grant applications (R01, R21, or R34) with standard due dates only (i.e. does not apply to applications with specific due dates) on a continuous basis & have those applications undergo review in a timely manner.

- **Why?** Commitment to recognize outstanding service in the NIH peer review process and/or Advisory Groups

- **Who?** Check eligibility status for CS

- **How** does this affect UCLA internal due dates?
  - OCGA (5 day policy) vs. DOM DRA (3 day policy)
  - "Soft" deadline vs. "hard" deadline
  - Must include Cover Letter that states eligibility of PI for CS

NIH PI Continuous Submission (CS)

- Dates are provided in eRA Commons that reflect the last date the PI's error-free continuous submission-eligible application must be received by NIH.

- Although there are no deadlines for CS, there are cutoff dates for an application to be assigned to a specific National Advisor Council round.

- For MPI (multiple PI) submissions, only 1 of the PIs need to be eligible for CS for the application to qualify for CS benefits. Does not need to be the contact PI.

- DOM DRA/OCGA does NOT double check eligibility status. This is a PI responsibility.

NIH Policy for Late Application Submission

- Different from Continuous Submission privileges

- Two week window of consideration after the application due date
  - Does not apply to any NOFOs that specifically state "No late applications will be accepted for this Funding Opportunity Announcement…"

- Temporary or ad hoc service by a PD/PI on an NIH advisory group during the two months preceding or the two months following the application due date.
  - For PIs who are eligible for CS, this policy applies to activities not covered under CS (i.e. *other than* R01, R21, R34 opportunities that use standard due dates)

- Other acceptable reasons for late submissions: death of immediate family member, sudden acute severe illness of PI or immediate family member, weather/natural disasters or other emergency situations

- **MUST** include cover letter to explain reason for late submission

5 Minute Break!

Electronic Submission Tools

NIH Methods Electronic Submission: Cayuse S2S vs. NIH's ASSIST

CAYUSE SYSTEM-TO-SYSTEM (S2S) – 05/17/23 CLASS!

- Purchased by the University from Evisions, Inc. to easily facilitate proposal development and electronic submission

- Available for use with all grants.gov applications: NIH, DOD, NSF, HRSA, AHRQ, etc.

- Sends the information to Grants.gov upon submission

- Be on the lookout for OCGA's Monthly Training (MT) for both Cayuse & ASSIST training

ASSIST (APPLICATION SUBMISSION SYSTEM & INTERFACE FOR SUBMISSION TRACKING)

- NIH's online system for proposal submission

- Originally launched for **multi-project** applications (Ps)

- Has since expanded to include R01, K (excluding KM1 and K12), R03, and R21 applications

- Use ASSIST for Ps and Cayuse for all else

- Use NIH eRA Commons ID to login.

NIH eRA Commons

- Online interface where grant applicants and grantor agencies can access and share administrative information relating to research grants. You will use eRA commons throughout the lifecycle of a grant - from application submission to grant closeout.

- FMs should request user name & password with Assistant role to:
  - Assist PI's RPPRs/Progress Reports
  - Work on ASSIST applications
  - Status access allows FMs to view/download submitted proposals/RPPRs & notice of awards (NOAs)
  - xTrain access allows FM to initiate, review & edit appointments/amendments/ termination notices and trainee rosters

Proposal Documents

Typical NIH Proposal Sections

FUND MANAGER (FM)

- SF424 RR/Face Page

- Performance Sites

- Biographical Sketch for all Key Personnel (KP)

- Budget (05/25/22 class!)

- Internal Proposal Paperwork

FM reviews all PI section to confirm they comply with Sponsor guidelines – font, margins, page limitations, etc.

PRINCIPAL INVESTIGATOR (PI)*

- Project Summary/Abstract

- Project Narrative

- Bibliography/References Cited

- Facilities & Other Resources/Equipment

- Budget Justification

- Research Plan – including Specific Aims, Research Strategy, Human & Animal Subjects, etc.

Understanding NIH Award Numbers

NIH Grant Numbers

- Example: 2 P01 HL030568-26A1

  - 2 = **Type Code**: type of application

  - P01 = **Activity Code**: differentiates research-related programs supported by NIH. aka mechanism

  - HL = **Institute Code**: 2 letter code for name of the NIH Institute or Center (IC) assigned

  - 030568 = **Serial #**: unique 5 or 6 digit # assigned by Center for Scientific Review (CSR) that identifies the specific application

  - 26 = **Support Year**: year of support

  - A1 = **Suffix Code** (if applicable): identifies Supplements (S1), Resubmissions (A1), or a fellowship institutional allowances

Example: 2 P01 HL030568-26A1
Common NIH Type Codes aka mechanism

- Type 1 – New

- Type 2 – Renewal (Competing Continuation)

- Type 3 – Additional Support

  - Competing Revision – expands scope of work

  - Administrative Supplement – covers increased costs

- Type 5 – Non-competing Continuation

- Type 7 – Change in Grantee Institution

- Type 9 – Change in NIH Awarding Institute

NIH Definitions of Most Common Type Codes

- **New** (Type 1) – refers to an application not previously proposed.

- **Renewal, aka Competing Continuation** (Type 2) – An application requiring competitive peer review and Institute/Center action to continue beyond the current competitive segment. In other words, submitted during/after last year of <u>project period</u>.

- **Non-Competing Continuation aka Progress Reports** (Type 5), – A year of continued support for a funded grant. Progress reports for continued support do not undergo peer review, but are administratively reviewed by the Institute/Center and receive an award based on prior award commitments. In other words, submitted near the end of each <u>budget period</u>, except last budget period.

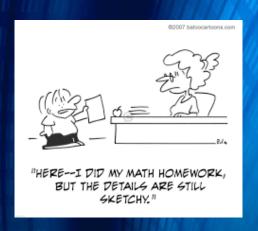# Example: 2 P01 HL030568-26A1
Common NIH Activity Codes

- T&F Series – Research Training & Fellowships

- K Series – Career Development Awards

- R Series – Research Grants

- U Series – Cooperative Agreements

- P Series – Program Projects/Center Grants

- Comprehensive list

Example: 2 P01 HL030568-26A1
Institute Codes

- The NIH is made up of 27 Institutes and Centers (IC), each with a specific research agenda, often focusing on particular diseases or body systems.

- Each of them has a 2 letter code associate, e.g.

  - CA = NCI – National Cancer Institute

  - HL = NHLBI – National Heart, Lung, Blood Institute

  - AI = NIAID – National Institute of Allergy and Infectious Diseases

Example: 2 P01 HL030568-26A1
NIH Definitions of Suffix Codes

- **Resubmission** (A1) – An application that has been <u>previously submitted, but was not funded, and is being resubmitted for new consideration</u>. Applicants must make significant changes to the application and can only resubmit once the summary statement is available.

  - Previous NIH term was "revision".

- **Revision** (S1) – A request of an <u>increase of support funding</u> in a current budget period <u>for expansion of</u> the project's approved <u>scope</u> or research protocol. Applicants must apply and undergo peer review.

  - Previous NIH term was "competing supplement".

Homework in preparation for Budget Class (05/24/23)

Review Proposal Budget Preparation PowerPoint prior to class!

Links from Today's Class

- **NIH Forms & Applications**
  - **SF424 (R&R) Forms and Instructions** (Grants.gov)
  - **Parent Announcements**
  - **Standard Due Dates**
  - **PI Continuous Submission (CS)**
  - **Late Application Submission**

- **NIH Glossary & Acronym List**

- NIH Systems
  - **eRA Commons**
  - **ASSIST**
  - **Cayuse S2S**

Survey Link
http://goo.gl/forms/C3gdjsL5y1

We appreciate if you would take a few moments to complete a short 7 question anonymous survey to help us improve your training experience. Thank you!