What You Need to Know When Submitting an NIH SF424 R&R Grant Application Through the UCLA Office of Contract and Grant Administration (OCGA)

A short “How-to”

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Objectives

- Learn the basics of working with the UCLA OCGA during the National Institutes of Health (NIH) application process

- Learn the basics of an NIH Standard Form 424 Research and Related application (i.e. SF 424 R&R = the electronic NIH proposal)
General Introduction to the UCLA Office of Contract & Grant Administration (OCGA)

Sources of Sponsored Extramural Funding
- **Federal (including NIH)**
- **State**
- **Local Gov’t (County, City)**
- **Non-profit organizations**
- **Foundations**
- **Private (not through OCGA)**

Types* of Sponsored Projects thru OCGA
- **Research**
- **Training and Career Development**
- **Public Service**
- **Other Sponsored Activities**

*NIH offers all of these types

Award Instruments
- **Grants** and Cooperative Agreements
- **Contracts**
- **Subawards and Multi-campus Agreements**
- **Gifts (not through OCGA)**
Why is OCGA Involved?
Hierarchy of Regulations

- Award Terms
- Departmental Policies
- UC and University Policies & Procedures
- Sponsor (NIH) Policies
- Federal Policies and Governmental Law
  - A-21
  - A-110
  - FAR
Today’s Topic

Life Cycle of an Award – OCGA Involved

- Start: Identify Funding
- Prepare Application & Submit Application
- Negotiate Award
- Set Up Award
- Perform Work
- Monitor Project & Manage Funds
- Generate Payment Requests
- Close-out Award
Internal: Prepare & Submit an Application

It’s a Team Effort per UCLA Procedure 910.1

“Approval and Submission of Contract and Grant Proposals”
Internal:
The Key Team Players

Academic Departments or Organized Research Unit

**Principal Investigator(s)**

Chairs/Deans
Department administrator/fund manager
Departmental Research Associate (DRA)
Other as Applicable (ex. Mentors, Fiscal Officer, etc.)

Office of Research Administration

Office of Contract and Grant Administration

(OCGA)
Internal:
Prepare & Submit an Application
- Policies & Procedures
UCLA Procedure 910.1: Approval & Submission of Contract & Grant Proposals

- PI:
  - Develops and prepares a proposal in accordance with prescribed agency and University policies.
  - Complete internal documents-approvals in accordance with prescribed agency and University policies.
  - Ensures that completed “proposal package,” including the final proposal and all required internal documents, is submitted to OCGA (or DRA) for final review and submission as soon as possible, but at least 5* working days prior to agency deadline.

If the 5 “working days” deadline is not met, OCGA cannot accept responsibility for the timely delivery of the proposal to the agency.

--- department may have earlier deadline---

- Chairs/Deans
  - Reviews proposal and accompanying documentation with particular attention to items in their authority

- OCGA

*recently updated from 3 to 5 days*
The “Proposal Package”

= Internal submission documents and the SF 424 R&R

SF 424 R&R =
i.e. the electronic NIH proposal
Proposal Package
Internal Submission Documents

1. The “Goldenrod”

Goldenrod = Request for Proposal Approval and Submission
2. Statements of Financial Interests (research applications)

Federal Law - 42 CFR Part 50, Subpart F, “Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service (PHS) [including NIH] Funding is Sought”

----- Third-party interests (not PHS/NIH agency)
2. Statements of Financial Interests (con’t)

- PI and Investigators disclose via UCLA 740 Form (See UCLA Procedure 925.3)
  - UCLA Personnel with responsibility for design, conduct, or reporting of research must complete 740 Form (UCLA Policy)
  - If positive, prepares 740 supplement form
  - Reviewed by Independent Substantive Review Committee called the Conflict of Interest Review Committee (CIRC); outcome sent to NIH
  - Resubmit if status changes during project (No/Yes)

- **Policy 900** lays out the categories of UCLA employees eligible to serve as PI (ex. Member of the Academic Senate)

- NIH recognizes only PI (including multi PI), no CoPI’s

- Letters of Exception must be submitted for each new proposal, even revisions (note: if proposal is a renewal for previously approved exception, letter is not required)

  - *Clearly in the best interest of UCLA*
  - *Space & facilities available*
  - *UCLA employee appointed @ 50% time or greater*
NIH/PHS PI Signature Form (UCLA)

This form complies with the requirements of NIH Notice NOT-OD-06-054 that the PI(s) certifies:

- (1) that the information submitted within the application is true, complete, and accurate to the best of PI’s knowledge; and
- (2) any false, fictitious, or fraudulent statements or claims may subject PI to criminal, civil, or administrative penalties; and
- (3) PI agrees to accept responsibility for the scientific conduct of the project and to provide the required progress reports if a grant is awarded as a result of the application.

--- don’t apply if you can’t certify
5. Subjects: Humans & Animals

Subject use must be explained in the application and the use protocol will have to be approved:

- **Institutional Animal Care and Use Committee (IACUC a.k.a. ARC)**
  Animal Welfare Assurance # A3196-01

- **Institutional Review Board (IRB)**
  Federalwide Assurance # FWA00004642
However, NIH policy allows “Just-in-Time” (JIT) submission of approval for both human subject and animal subject use:

- Application can be marked “pending approval”
- Must submit approvals before award is issued though; NIH will not award without it (except possibly for “delayed onset”)
- i.e. Subject use approval submitted post-proposal but pre-award (i.e. JIT)
- Subject Use Protocol Approval must apply to/denote the proposal being submitted (amend if necessary)
5b. Human Subject Education Certification

- Required for all key personnel involved in human subject research, including any at sub award site(s)

- Collaborative Institutional Training Initiative (CITI) = online education program for UCLA personnel to fulfill requirement

- Certification of Human Subject Education submitted “just-in-time” (JIT) i.e. post-proposal but pre-award
6. Other Items in the Proposal Package

- Proposal from consortia (sub) partner (if applicable)
  - Authorized Official sign-off (i.e. signed by their OCGA)
  - Scope of Work
  - Budget/Budget Justification

- Specific items required in Funding Opportunity Announcement (FOA)
7. The SF424 Proposal
= System to System (S2S) Cayuse
S2S Cayuse = where you produce your SF424

- S2S is a web-based alternative for preparing, validating, and submitting proposals via Grants.gov that does not require use of PureEdge or Adobe Forms for SF424s

Preparing
Validating
Submitting
Storing

- Campus-wide implementation began in November 2008 and use of S2S Grants for eligible submissions became *mandatory* in January 2009 (see [memo](#) from Vice Chancellor Peccei)
S2S Grants Production Environment:  
https://s2sgrants.research.ucla.edu  
   The production environment is available for preparation and submission of  
   actual Grants.gov applications and should not be used for training.

S2S Grants Training/Testing Environment:  
https://s2sgrantstraining.research.ucla.edu/  
   The training environment is available for users to familiarize themselves with the  
   system and/or to conduct training sessions within departments/units.

Departmental Coordinators: are available to assist users with:  
   - Requesting system access  
   - Learning to utilize the system  
   - Providing feedback to the S2S Grants system administrators

ACCESSING THE SYSTEM:  
   S2S is available to all researchers and administrators with a UCLA Logon ID. To request access, contact your Departmental Coordinator

S2S Grants List-serv: self subscribe  
   http://lists.ucla.edu/cgi-bin/mailman/listinfo/s2sgrants

Help: s2sgrantshelp@research.ucla.edu  
   Training Modules: Developing proposals to Grants.gov via S2S
**S2S Application Production (Summary)**

- Download/locate the Funding Opportunity Announcement (FOA) in(to) S2S
- Complete SF424 application (administrative and research components)
- Clear all Errors, and check if Warnings need correction
  - **Error:** [Other Project Info 6][NIH] The Abstract (labeled 'Project Summary/Abstract') must be included.
  - **Error:** [Research Plan 2.5][NIH] Research Design and Methods attachment must be included
  - **Warning:** [Other Project Info 8][NIH] In most cases, a Bibliography and References Attachment should be included.
- Upload internal documents (ex. Goldenrod, etc.) so proposal “package” is complete
- Create a PDF to send to others (ex. mentor) for review, or give others access to view it in S2S
- PI reviews and approves final version before sending to OCGA
Notify OCGA that final Error-free proposal package is ready in S2S Cayuse for review and submission at least 5 working days prior to deadline (department may have earlier deadline)

OCGA (per UCLA Procedure 910.1):
- Reviews proposal package for compliance with University, campus, and agency requirements
- Determines whether proposal requires administrative corrections. Coordinates any necessary changes with PI/Departmental Administrator(s)
- Electronically signs/submits proposal to the agency
Internal: Why is OCGA Involved in the Application Process

- **UCLA DA 250.10** “To Solicit, Accept and/or Execute Certain Extramural Grants and Contracts”

  =

  OCGA has the delegated “authority to solicit, accept and/or execute certain extramural grants and contracts…PIs are not to submit proposals on their own behalf, or make commitments to sponsors that would disregard these procedures.”

  *Note: even if the sponsor doesn’t require OCGA signature (electronic or otherwise), UCLA does require it*
Submission of NIH SF424 Applications through Grants.gov
What is Grants.gov

- Common portal for submission of all federal grants
  S2S → Grants.gov → eRA (NIH) Commons

- Grants.gov validates it according to their business rules, and an application can get rejected by Grants.gov

- Once Grants.gov sends it to eRA (NIH) Commons, then NIH validates it according to their business rules

- NIH sends e-notification to PI and OCGA upon retrieval and validation
NIH Validation Process in eRA Commons

- PI should access info about the application in Commons via in e-submission area of Status

- If an Error, application is essentially rejected and must be corrected within two weekdays before submission deadline*

- If a Warning(s) only, application is compiled, posted and assigned a Accession # (AN#)

- PI should view the posted application for any transmission problems

- If PI sees problem, must consult with OCGA

- If no Errors or transmission problems, do NOTHING

- [Dr. Rome and/or Adams to discuss Review]

- Now wait for the good news from NIH!!!

*two day window was eliminated
SF 424 Proposal Preparation:

Where to start?

“The Scream” by Edvard Munch

Demo S2S Production
https://s2sgrants.research.ucla.edu
Your Two Best Friends

1. **SF424 (R&R) Application Guide**
   for NIH and Other PHS Agencies – General


2. **Funding Opportunity Announcement (FOA) – Specific**
   (ex. Research Project Grant, Parent R01, FOA # PA-10-067)

REMEMBER –
Follow the Instructions!!
Application Sections
Beyond the PHS 398 Research Plan

- Cover Component – SF424
- Project/Performance Site Locations
- Other Project Information
  (Abstract*, Project Narrative*, Literature Cited, Resources, etc.)
- Senior/Key Person Profile
  (Biographical Sketches*)

- Budget* and Justification
  (Detailed or Modular Budget)
- Cover Page Supplement
- Checklist Component
- Cover Letter

(limit*)
Application Sections

PHS 398 Research Plan Itself

- Intro* (resubmission/revision only)
- Specific Aims*
- Research Strategy*
  - Significance
  - Innovation
  - Approach
- Human Subjects
  - Inclusion of Women/Minorities
  - Targeted/Planned Enrollment
  - Inclusion of Children
- Vertebrate Animals
- Select Agent Research
- Multiple PI Leadership Plan
- Consortium/Contractual Arrangements
- Letters of Support
- Resource Sharing
- Appendix* (limit*)
Start early and leave time for unforeseen problems!

1, 2, 3, 4, 5

Allow time for review and corrections before submission.
Questions?

OCGA

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