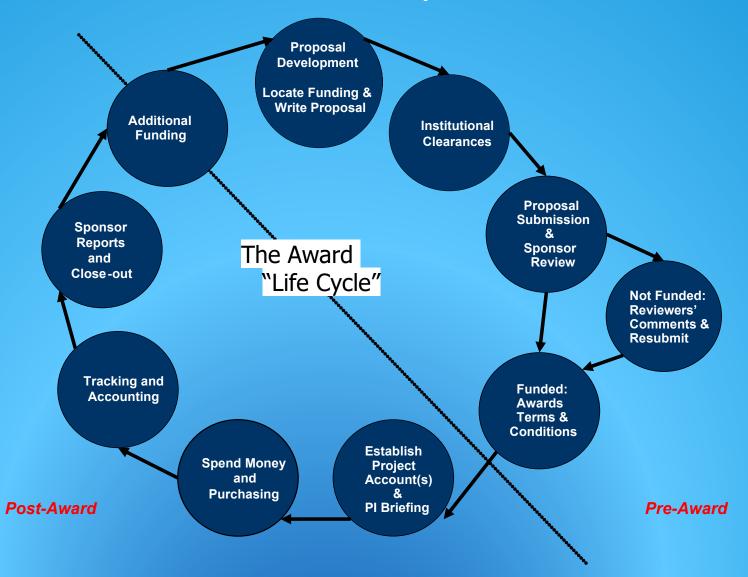
This session will *not* be recorded, but this PowerPoint can found https://medschool.ucla.edu/research/researcher-resources/administrative-support/department-medicine-office-research-administration/fund-management-training

Pre-Award Basics

UCLA DEPARTMENT OF MEDICINE
OFFICE OF RESEARCH ADMINISTRATION
ZOOM TRAINING

Award Life Cycle



Different Funding Sources: Grants/ Cooperative Agreements, Contracts, & Clinical Trials

LEAGUES/CONFERENCES

Grants & Cooperative Agreements

- A grant is a type of financial assistance awarded to an organization for the conduct of research or other program as specified in an approved proposal. For an award to be considered a grant, it will contain the following elements:
 - Statement of work <u>allows the PI significant freedom</u> to change the emphasis within the general area of work as the project progresses
 - Deliverables are minimal, consisting typically of reports
 - Separate accounting procedures are required
 - Grants most often use the <u>cost-reimbursement</u> method of payment
- A cooperative agreement is a type of grant that provides substantial involvement between the sponsor and awardee in carrying out the activity contemplated by the award.

Contracts

- A contract is an agreement to acquire services that primarily benefit the sponsor. For an award to be considered a contract, it normally must contain all of the following elements:
 - Detailed <u>financial and legal requirements</u> included with a <u>specific statement of work</u>
 - A specific set of deliverables and/or reports to the sponsor
 - Separate accounting procedures
 - Legally binding contract clauses
- Contracts, by their nature, are <u>restrictive</u>, meaning there is <u>little</u> <u>flexibility</u> on the part of the academic department to rebudget funds without prior sponsor approval. <u>Invoicing</u> on contracts can be <u>more complex</u>, especially if tied in with milestones or tasks that must be completed by the PI before an invoice can be submitted and/or paid.

Clinical Trials

- The controlled, <u>clinical testing in human subjects of investigational</u> <u>new drugs, devices, treatments, or diagnostics</u>, to assess their safety, efficacy, benefits, costs, adverse reactions, and/or outcomes. Such studies may be conducted under an industry-developed protocol or an investigator-developed protocol.
- **If you're interested in learning more about clinical trials (CT), feel free to join our CT specific training series that starts early August after these sessions end.**

UCLA Central Pre-Award Offices

PLAYERS

UCLA Central Pre-Award Offices

 NON-PROFIT SPONSOR Administration (OCGA)



Office of Contract & Grant

- Grants & Cooperative Agreements OCGA Analyst
- Contracts OCGA Officer
- Clinical Trials OCGA Analyst or Officer
- Grants.gov Grants/S2S < \$500K DC/year DOM DRA (DOM only)
- Hint/Tip: Sponsors with .gov or .org websites
- FOR-PROFIT/INDUSTRY SPONSOR



TDG or CTC&SR

- Research Contracts & Grants (excluding Clinical Trials) <u>Technology Development</u> <u>Group (TDG)</u>
- Clinical Trials only <u>Clinical Trials Contracts & Strategic Relations (CTC&SR)</u>
- Hint/Tip: Generally sponsors with .com websites

Pre-Award Office Matrix

		Grants											
		Cooperative											
Sponsors Types	Contracts	Agreements	Clinical Trials										
Non-Profit	OCGA / DOM DRA*	OCGA / DOM DRA*	OCGA										
For-Profit/Industry	TDG	TDG	CTC&SR										
* for grants.gov applications ≤ \$500,000 DC/year, except Ts (training) and F (fellowship) series													
OCGA	Office of Contract & Gra	nt Administration											
DOM DRA	Department of Medicine	e Departmental Research	n Associate										
TDG	Technology Developme	nt Group											
CTC&SR	Clinical Trials Contracts	& Strategic Relations											

Periods of Performance

DURATION

Project Period

- The Project Period is the total time for which support of a project has been programmatically approved.
- A project period may consist of one or more budget periods.
- See sample 3 year project period below:

Months	1	2	3	4	5	6	7	8	9	10	11	12	1	2	3	4	5	6	7	8	9	10	11	12	1	2	3	4	5	6	7	8	9	10	11	12
Years	Budget Period 1: Year 1							Budget Period 2: Year 2											Budget Period 3: Year 3																	
Project	1 Project Period																																			

Budget Period

- A budget period is the interval of time, usually 12 months, into which the project period is divided for budgetary and funding purposes.
- 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**

*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.

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

Sponsor Guidelines

RULES

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:
 - <u>SF424 (R&R)</u> 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 <u>Uniform Guidance</u>, 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.
 - <u>Funding Opportunity Announcement (FOA)*</u> proposal specific instructions.
 These instructions supersede anything in the SF424 guidelines. *NIH's new terminology = Notices of Funding Opportunities (NOFOs)!

Due Dates

- Sponsor Due Dates:
 - FOA will almost always provide a hard due date AND <u>TIME</u>
- Internal Due Dates:
 - DOM DRA 3 Day Submission Policy
 - OCGA 5 Day Submission Policy
- Make sure to communicate due dates with all parties, PI/MPI, Co-Investigators, Subaward Institutions, to allow sufficient time for review, edit, upload, central office review and submission

Electronic Submission Tools

TRANSPORTATION

Electronic Submission Websites

- Cayuse/S2S
- NIH ASSIST
- ProposalCENTRAL
 - Sample sponsors ACS, ALA, AHA, etc.
- <u>SmartSimple</u>
 - UC Sponsors TRDRP, BCRP, CHRP, etc.
- eBRAP
 - CDMRP/DOD
- CIRM Grants Management Portal

- HRSA Handbook
- NSF Research.gov (previously FastLane)
- Some Sponsors still request proposal documents to be submitted "electronically" via email. Emailed applications must be reviewed/signed off/submitted by a UCLA Central Pre-Award Office. Pls/FMs are not authorized to submit on behalf of the University.

Access

- Each website/portal requires a logon and password.
- Make sure you have your account set up early in the submission process. Provisioning of access can sometimes take time!
- Some websites/portals require the PI to grant access to FM in order to assist.
- Discussion Point/Food for Thought: PI vs. FM upload/completion of proposal

5 Minute Break!

Proposal Documents

EQUIPMENT

Typical Proposal Sections (general recommendation)

FUND MANAGER (FM)

- SF424 RR/Face Page
- Performance Sites
- Biographical Sketch for all Key Personnel (KP)
- Budget (5/25/22 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.

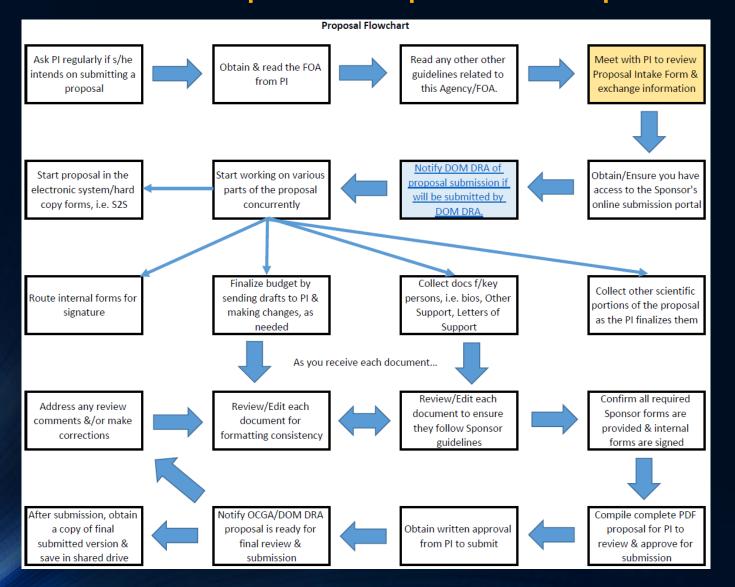
Internal Proposal Paperwork

- <u>EPASS</u> (Extramural Proposal Approval and Submission Summary)
 - <u>Electronic EPASS Portal</u>: Extremely important for correct award setup
- Conflict of Interest (COI) Disclosure Forms
 - Federal PHS agency: eDGE date on third page of EPASS
 - Non-PHS Federal agency (i.e. DOD): Form 740
 - Non-government entity: <u>Form 700U</u> and <u>700U Addendum</u>. <u>Exempt entities</u>.
 - UCLA requires <u>DocuSign</u> signatures
- DOM PI Responsibilities for human subjects research only
- PI Exception Form
 - For PIs who are not Policy 900 PIs

Basic Pre-Award Steps

PLAY BOOK

General Step in Proposal Preparation



Additional Resource:

Preparation

Proposal Intake Form (Online)

Proposal Intake Form (PDF)

<u>Proposal</u> <u>Preparation</u> <u>Timeline</u>

Pre-Award Strategies

STRATEGIES

- Send out monthly emails to all PIs requesting information on upcoming proposal deadlines.
- Start EARLY...and follow-up often!
- Web search for agencies guidelines, instructions & forms. Read through guidelines thoroughly, highlighting important instructions.
- Meet with your PI. Use the <u>Proposal Intake Form</u> to help guide your discussion.
- Create a <u>checklist</u> of required submission items/documents. If the
 agencies does not explicitly provide one, use the proposal's Table of Contents
 as a guide.
- Ask your colleagues for examples of similar proposals that were successfully funded. *Never share a PI's proposal without explicit approval from the PI.
- Review all documents provided to you for compliance with agencies guidelines, and format to create consistency within the proposal.
- Ask for help if you need it!

Determine the proposal's complexity

- Have you submitted to this agency before, and are aware of their guidelines/policies?
- Is it a <u>limited submission</u>?
- Subawards, foreign and/or domestic?
- Detailed budget vs. Modular budget?
- Paper vs. Electronic vs. Both?
- Number of Key Personnel?
- PI's habits, e.g. always late/always early, expectations, etc.?
- Animals and/or human subjects?
- Budget over \$500,000 direct cost in any given year?
- Agency provides only non-fillable forms?
- Will the grant be submitted via OCGA/TDG/CTC&SR or DOM DRA?
- Do you have numerous proposals due on, or around, the same deadline?

Links from Today's Class

- <u>DOM ORA Website Pre-Award Sections</u> (includes pre-award manual, forms & reference material)
 - Proposal Flow Chart
 - <u>Proposal Preparation</u>
 - Proposal Intake Form (Online) | Proposal Intake Form (PDF)
 - FOA Questions
 - Proposal Document Checklist
- OCGA Proposal Preparation
 - Commonly Needed Information
 - Budget Preparation
- Conflict of Interest (COI)



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!