Welcome to Module 4, Internal Approvals and Special Considerations. This is not the most exciting module, but nonetheless, a most important one. In this module, we take a brief look at the internal approvals necessary for a proposal to be submitted, or an award processed should the proposal be funded. You will have the opportunity to bookmark many resources that contain detailed information on the topics we touch on here.
Preparing and Routing Proposals

KNOW THE PROCESS

- Depending on where you are in the university, proposals will pass through a particular sequence of reviews and approvals.
- Learn the practices of reviews and approvals for your area.
- There are many resources available.

If you are new to sponsored project administration, or if you are a veteran but working on a proposal which includes unfamiliar elements, consult with your OCGA Officer or Analyst and he/she will help you or will connect you with someone in the community with the expertise to guide you through the process.
These are the basic internal approvals that may need to be in place either before a proposal can be submitted, or an award processed.

- Goldenrod form is always required. These 4 may be required:
  - Conflict of Interest form(s)
  - PI Exception
  - Human/Animal Subjects
  - NIH PI Signature Form
A critical step in the process of submitting proposals for extramural funds at UCLA is the completion and submission of a form entitled "Request for Proposal Approval and Submission." Over the years it has become known as the “Goldenrod," owing to its distinctive color. The Goldenrod form is used for the review and approval of proposals to be submitted to extramural funding agencies. The form is for campus use only and is not forwarded to the sponsor.
A “checklist” of all elements to be considered when submitting a proposal

- Instructions to OCGA concerning proposal submission
- Information required by the campus and Systemwide (UCOP) on the nature of the project
- The on-campus or off-campus location where the project will be carried out
- Whether the project involves the use of human or animal subjects, or other elements requiring special review and approval
- Space for approval by PI, Chair, Dean, and other administrative officials

The GR serves a number of purposes.

It provides instructions to the OCGA concerning the submission of a proposal: the sponsor to which the proposal is to be sent, the number of copies to be submitted, and the date by which the proposal should be submitted.; The GR provides information required by the campus and Systemwide Administration on the nature of the project for which the proposal is being submitted, such as: the title; the Principal Investigator's name and department affiliation; the purpose of the project (research, training, public service, etc) and the amount being requested. It provides the on-campus or off-campus location where the project will be carried out; whether the project will involve the use of human subjects; the use of animal subjects. In addition, the Goldenrod form provides space for the approval of the proposal by the PI, the Department Chair, and/or the Dean of the School or College, and other administrative officials whose review and approval of the proposal are required prior to its submission to the funding agency.
Goldenrods help OCGA identify and track proposals

- Not all sections of GR need to be completed at an early stage of proposal development.
- A draft GR (hand written, if necessary) with information that provides key information OCGA need is acceptable:
  - PI name
    - Department
    - Proposal title
    - Sponsor name and address
    - Type of proposal (new, continuation, renewal)

- When submitting ANY COMPONENT of a proposal (e.g. budget, checklist, cover page) for review, please include a copy of the [draft or final] GR

Goldenrods help OCGA identify and track proposals. Draft goldenrods with minimal information, as indicated here, is helpful.
The Principal Investigator for a grant or contract is the individual who has the primary responsibility for the scientific, technical, and administrative conduct of the project. The term "Project Director" is occasionally used by some sponsors to identify this individual. For the most part, these terms are interchangeable. Occasionally, it may be appropriate for an individual not qualified under the policy to serve as Principal Investigator or Co-Principal Investigator on a project. In this section we discuss the procedure for seeking exceptions to the Principal Investigator eligibility policy.
Policy 900 – PI Eligibility

- Revised October 25, 2001
  - Authority to grant exceptions to the policy delegated from OCGA to the Schools
- The policy describes
  - Who are eligible
  - Who are exempt
  - Who approves exceptions to the policy
- Includes
  - List of titles of eligible employees (faculty and other appointments)
  - Names of authorized officials (Deans, etc.) who may approve exceptions

Prior to October 25, 2001, the Chancellor delegated the authority to approve exceptions to the PI eligibility policy to OCGA. Now it is (more appropriately) delegated to the Schools. The policy also expands the list of individuals who can serve as a PI or Co-PI on a project, and the campus officials who may approve the exception. For example a full-time Adjunct Professor at Associate or Full level in the College of Letters and Science and/or the Henry Samueli School of Engineering and Applied Science, can serve as a PI or Co-PI. A full listing is available in the policy. In a moment, you’ll have an opportunity to bookmark the page that contains the policy and/or obtain a PDF copy.
Letter of Exception to Serve as PI or Co-PI (UCLA Policy 900)

- Letter indicates:
  - Clearly in the best interest of UCLA
  - Space and facilities available
  - UCLA employee appointed @ 50% time or greater
- Letter of exception must be submitted for each new proposal, even revisions.
- Exception must be on file before an award can be processed by OCGA

The designated individual within the School must sign a letter stating the appointment is clearly in the best interest of UCLA; that space and facilities are available, and the individual is a UCLA employee appointed @ 50% time or more and must submit it with each proposal that names that individual as a PI or Co-PI.

If letter is missing for the PI exception, the proposal will be processed but the award will be held until letter is received.
The OCGA Investigator Code Directory is a handy tool to quickly look up whether an individual is eligible to serve as a PI or Co-PI. It is also a great resource for obtaining PI codes. Here we typed in the last name of “Smith”
Here are the results for Smith. It is very clear who is eligible to serve as a PI, and who requires an exception. Although an exception may have been granted in the past, those approvals are applicable for a single proposal. The policy does not recognize blanket approvals.
If a proposal contemplates the use of human or animal subjects for research purposes, the proposed use must be reviewed and approved by the appropriate campus committees. Except for renewal or continuation/progress reports, the approval notice for use of human or animal subjects is not required at the time the proposal is submitted. Most proposals require the IACUC or IRB assurance numbers, shown here, and also available on OCGA's Commonly Needed Information page.
Humans and Animals

- If approval date is included in the submission:
  a. Provide OCGA with approval notice at time of submission
  b. Approved protocol must apply to the proposal being submitted (amend if necessary)

- Competing renewals and progress reports must have approvals in place at application stage

- NIH policy allows Just-in-Time approval for both human subject (IRB) and animal subject (IACUC) use

- OCGA will not process the award until subject use approvals are on file

When submitting an approval to OCGA, make sure the approval is for the correct proposal. Sometimes a single approval can cover many projects, but those projects/proposals must be identified on the approval form. An award cannot be issued by the sponsor and/or or processed by OCGA until the approval is on file.
Human Subject Education Certification

- All key personnel involved in human subject research
- Web-based instruction through Collaborative Institutional Training Initiative (CITI)
- Required by UCLA (and NIH)
- The Health Insurance Portability and Accountability Act of 1996 (HIPAA)

After completion of the on-line human subjects course, a certificate can be printed signifying course completion. It will indicate which type of certification has been achieved. If both courses (human and HIPAA) are completed, a certificate for each must be printed.

HIPAA: Federal law that provides safeguards to protect the health information of individuals obtaining healthcare in the USA.
The University's overall policy on conflict of interest is that none of its faculty, staff, managers or officials shall engage in any activities which place them in a conflict of interest between their official activities and any other interest or obligation. Within the research arena, however, Investigators are permitted to seek support from organizations in which they have financial interests as long as those interests are reviewed by the campus Conflict of Interest Review Committee (CIRC) and steps are taken to manage, reduce or eliminate potential conflicts of interests.

A financial conflict of interest is a situation in which an individual's financial relationships may compromise, or have the appearance of compromising, the individual's professional judgment in conducting or reporting research. Personal financial interests are disclosed to UCLA by Principal Investigators and other Investigators using the CA State Form 700-U, UCLA 700-U Addendum, UCLA Form 740, and various disclosure supplements. Completion of these forms is mandated by State of California and federal regulations, and UC and UCLA policies and procedures.

Resources for COI are on the Research Policy and Compliance Office’s website
Investigators’ Statement of Financial Interests
Federal

- PI and other Investigators disclose personal financial interests related to the research using UCLA Form 740 (See Procedure 925.3)
  - PI: UCLA employee who has primary responsibility for the scientific and technical conduct, reporting, fiscal and programmatic administration of a sponsored project
  - Investigator: UCLA employee who shares responsibility for the design, conduct, or reporting of the results of a sponsored project
  - Please note: Disclosure thresholds for the PI and other Investigators are the same

- Reviewed by Conflict of Interest Review Committee (CIRC)

Investigators submitting proposals to the National Science Foundation and the Public Health Services (including NIH) are required to disclose financial interests that may be related to the work performed under a sponsored project using UCLA Form 740.

Investigators indicating that they have a financial interest related to the work performed under a sponsored project must provide additional information on a “Disclosure Supplement” form.
The top portion of Form 740 and Line 1 in the box MUST be completed by the PI. Lines 2 through 5 should be completed by the other Investigators.

The top portion of Form 740 should be completed by the PI, who should use line one in the box to disclose whether or not he/she has a personal financial interest related to the research. The other Investigators identified by the PI should use lines two through five to indicate whether they have financial interests to disclose. Multiple forms can be used if needed, and the top portion and line one of each form should be completed by the PI.
Under California law, Principal Investigators are required to disclose financial interests in a non-governmental organization (such as a non-profit or for-profit organization) that provides support for a research project using **Form 700-U**. Principal Investigators who indicate that they have a financial interest in the non-governmental sponsor of a project must provide additional information using a “Disclosure Supplement” form.
Investigators’ Statement of Economic Interest – Non-governmental

- Other Investigators disclose personal financial interests in the sponsor using the 700-U Addendum (see Procedure 925.2)
  - PI identifies Investigators who share responsibility for the design, conduct, or reporting of the results of a sponsored project and should also disclose financial interests
  - Please note: Disclosure thresholds for PIs and other Investigators are different

- Reviewed by Conflict of Interest Review Committee (CIRC)

Per UCLA Procedure 925.2, other Investigators (including Co-PIs) should use the 700-U Addendum form to disclose any financial interest(s) in a non-governmental sponsor of research. The PI will determine which personnel qualify as “Investigators” and use this form to identify those individuals. The PI and each of the Investigators identified on the form must sign the 700-U Addendum.
Per California state law, the Form 700-U must be completed by the PI and signed in ink under penalty of perjury. The original form with an ink signature should be submitted to your Officer or Analyst along with other proposal materials.
Disclosure Supplements

- PIs and other Investigators who report a financial interest on Form 700-U, the 700-U Addendum, or UCLA Form 740 must complete a “Disclosure Supplement”

- Note: For an industry-sponsored clinical trial, the PI and/or Investigator(s) should complete the “Industry Clinical Trial Specific Supplement”

PIs and other Investigators who indicate that they have a financial interest to report must complete a “Disclosure Supplement.” Please note that an “Industry Clinical Trial Specific Supplement” should be completed online and then printed for signature and submission in conjunction with industry-sponsored clinical trials.
The PI should complete the top portion of the form and use the “Disclosure and Certification” portion of the 700-U Addendum to indicate whether there are other Investigators who share responsibility for the design, conduct, or reporting of research. The Investigators identified by the PI should print and sign their names in the box provided and indicate whether or not they have any financial interests to report.
The Conflict of Interest disclosure matrix
NIH PI Signature Form – A compliance requirement

- Effective 5/06, the signature of the PI no longer required as a part of a submitted application
  - applicant organization agrees to secure and retain a written assurance from the PI prior to application submission
  - must be available to the sponsoring agency or other authorized HHS or federal officials upon request
- When multiple PIs are proposed in an application, this assurance must be retained for all named PIs

The signature of the PI is no longer required as a part of a submitted application. Instead, a new compliance requirement was implemented whereby the applicant organization agrees to secure and retain a written assurance from the PI prior to submitting an application to the PHS. While this assurance is no longer required as part of the submitted application, it remains a compliance requirement. Therefore, organizations must retain a unique signature and date for each submitted application. This assurance must be available to the sponsoring agency or other authorized HHS (Health and Human Services) or federal officials upon request. When multiple PIs are proposed in an application, this assurance must be retained for all named PIs.
NIH PI Signature Form

- Assurances must include following certifications:
  1. the information submitted within the application is true, complete and accurate to the best of the PI's knowledge
  2. any false, fictitious, or fraudulent statements or claims may subject the PI to criminal, civil, or administrative penalties
  3. the 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

- PI must complete, sign and date the document containing the assurances
  - The signed form/document can be sent to OCGA by fax, email attachment, or in paper form

- The NIH PI Signature Form (PDF fillable) is available on the OCGA website

The assurances must include at least the following certifications: (1) that the information submitted within the application is true, complete and accurate to the best of the PI's knowledge; (2) that any false, fictitious, or fraudulent statements or claims may subject the PI to criminal, civil, or administrative penalties; and (3) that the 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.
Special Considerations

- PI Effort reflected in proposals
- Program Income
- Stem Cell Research
- Coordinated Proposal Submission with the UCLA Corporate, Foundation and Research Relations (CFRR) Office
- Export and Trade Regulations

Now we'll examine some special considerations that can delay the preparation and submission of a proposal, or impact the processing and/or administration of a subsequent award.
Effort Reporting

- Mandated by OMB Circular A-21 (Section J-8)
- A method of certifying effort spent on a federally funded project substantiates the salaries actually charged

- It is critical to be mindful of the level of effort cited in proposals, progress reports, and no-cost time extensions

Effort reporting is an important and sensitive topic. It is a requirement of OMB Circular A-21 as a method of certifying to federal sponsors that the effort spent on a federally funded project substantiates the salaries actually charged to the project. It is critical to be mindful of the level of effort cited in proposals and progress reports, as they have to be reported.
The level of effort reported on the Effort Reporting System should correlate to data in several campus systems.

In this slide, we see the various sources where effort is reported, and must correlate with one another.
Program Income is an important consideration in preparing a proposal that contains it. Here is a snapshot of page 2 of the Grants.gov cover sheet, where there is a specific line for program income.
What is Program Income?

- Income generated from a sponsored activity
  - fees collected for services performed
  - use or rental of property acquired under federally funded projects
  - sale of items resulting from award
  - license fees and royalties (with exceptions)
  - interest on loans made with award funds

- Should be discussed in proposal narrative and/or budget justification

If you know your project is going to have program income, it is important to estimate it as accurately as possible and discuss it in the budget justification. There are three different methods in which federal sponsors may handle program income, which is discussed in more detail in Course 3, Setting up the Award and Incurring Expenses. For now, in this course, it is sufficient to be aware that if a proposal contains program income, it must include details about it.
Due to the federal regulations and overall sensitivity to the issue of Stem Cell Research, there are reviews that must take place if a project contemplates use of stem cells.
Stem Cell Research

- Review and approval by the Embryonic Stem Cell Research Oversight (ESCRO) Committee is required
  - regardless of funding source
  - regardless of the applicability of state or federal law

- Must submit a human subjects research application to the IRB and receive approval prior to initiating the research

Review and approval by the Embryonic Stem Cell Research Oversight (ESCRO) Committee is required for all research involving derivation of hESC (stem cell) lines, regardless of the source of funding or the applicability of state or federal law.

Investigators, who plan to conduct hESC research with any individual cells or cell lines, whether or not such cells will be put into human subjects and regardless of the source of the cells, must submit a human subjects research application to the IRB and receive approval prior to initiating the research.

The ESCRO and IRB are two of several committees that may be required to review hESC research. The other committees include the Animal Research Committee (ARC), the Institutional Biosafety Committee (IBC), among others required by laws, regulations, or institutional policy.
Stem Cell Research – NIH applications

- If the proposed project involves human embryonic stem cells, list the registration number of the specific cell line(s) from the stem cell registry found at: http://stemcells.nih.gov/research/registry/

- If a specific line cannot be referenced at the time of application submission, include a statement that one from the registry will be used.

NIH has very specific guidance about use of stem cells in any proposal seeking their support. The NIH Stem Cell Registry lists human embryonic stem cell (hESC) lines eligible for federal funding, which must be addressed in a proposal.
Access to the Research Policy and Compliance Stem Cell Research resources

- Memo on Responsibility for Executing Research and Research-Related Duties
- Responsibility for Agreements - General Guidelines
- Infringement Policy on Research Funded by the Tobacco Industry
- Principal Investigators
- Principal Investigator Roles and Responsibilities
- Guidelines for Submitting Proposals and Receiving Awards through the Univ
- UCLA Guideline for Faculty Participation in SBIR and STTR Programs
- UCLA Policy #TCS Management of Sponsored Projects

- Rando/RAND for Health Services Research
- UC/RAND/UC MOU: MOU Agreement for Collaborative Research
- UC/RAND Joint Institutional Review Board Deferal Mechanism
- Request to Defer Review of Human Subjects Review (Application)
- UC/RAND Memorandum of Understanding and Affiliated IRB Prov:

- Stem Cell Research
  - VIT Operating Guidance Memorandum Dated May 10, 2005 Regarding VIT
  - Attachment A: VIT Memorandum of Understanding with UCI
  - Attachment B: Simple Letter Agreement for Transfer of Materials to UC
  - Attachment C: Important Notice
  - Preliminary Guidance on Conducting Human Embryonic Stem Cell Research
  - Embryonic Stem Cell Research Oversight (ESCOR) Committee
  - Broad Center of Regenerative Medicine and Stem Cell Research at UCLA
  - Stem Cell Applications and Documents
Export Control Regulations
An increase in concern about enforcement and a greater focus on life science and biological materials

- International Traffic in Arms Regulations (ITAR)
- Export Administration Regulations (EAR)
- Office of Foreign Assets Control (OFAC)

ITAR, EAR, and OFAC regulations can all affect research. Together they are known as Export Control Regulations.

ITAR is the acronym for the International Traffic in Arms Regulations. These regulations apply to articles, services, and related technical data that are inherently military in nature, as determined by the State Department.

EAR is the acronym for the Export Administration Regulations and regulates the export of “dual use” goods and services (goods and services having both military and civilian uses) that are identified on the Commerce Control List.

OFAC is the acronym for the Treasury Department’s Office of Foreign Assets Control. The University typically encounters issues arising under the OFAC regulations when researchers engage in collaborations with foreign nationals overseas or seek to teach classes or perform research in foreign countries.

Since 9/11/01, these federal regulations have been used as anti-terrorist tools resulting in an increased concern about enforcement and a greater focus on life science and biological materials.
Export Control Regulations

- **Export**: sending or taking controlled articles out of the US, or disclosing certain information about a controlled article to a foreign government or foreign person
- **Deemed Export**: information about a controlled article transferred to a foreign person in the US
- **Fundamental Research Exclusion**
- **Contact your Analyst or Officer or Claudia Modlin** (cmodlin@research.ucla.edu)
- **See**: [http://www.universityofcalifornia.edu/compaudit/researchcomp/exportctrls/ucexport.html](http://www.universityofcalifornia.edu/compaudit/researchcomp/exportctrls/ucexport.html)

An “export” occurs when someone sends or takes controlled articles out of the US or discloses certain information about a controlled article to a foreign government or a foreign person. The transfer of certain information about a controlled article transferred to a foreign person in the US is known as a “deemed export.”

In order to comply with Export Control Regulations, the University strives to maintain an open environment where the right to publish and disseminate results of research are key. This allows the University to stay within a safe harbor known as the “Fundamental Research Exclusion.” This allows the University to also avoid “deemed export” issues as well.

Note that the University will obtain licenses, if they are required, to allow exports to another country. The University will also acquire licenses to conduct research or to transfer assets to countries or individuals covered under OFAC. Finally note that the University does not normally accept Export Controlled information from outside organizations.

If you encounter any of these situations in proposal guidelines, if you become aware of any travel plans or payments to embargoed or sanctioned nations under OFAC, or if you are asked to ship tangible items out of the United States please consult with your OCGA Analyst or Officer, or Claudia Modlin in the Research Compliance Policy Office.
Coordinated Proposal Submission with the UCLA Corporate, Foundation and Research Relations (CFRR) Office

- Some corporations and foundations have requested that CFRR facilitate their relationship with UCLA
- If a proposal requires a coordinated proposal submission, OCGA will assist

Some corporations and foundations have requested that the UCLA Corporate, Foundation and Research Relations (CFRR) facilitate their relationship with UCLA. If a proposal you are preparing requires a coordinated proposal submission, let OCGA know. They will assist in the process.
Routing Proposals through OCGA

- Proposal submission procedures and schedules within an academic department or school should be followed prior to submitting the proposal to OCGA.
- UCLA Procedure 910.1: “delivered to OSR [OCGA] for final review and submission to the funding agency as soon as possible, but at least 3 working days prior to date proposal must be mailed to meet the agency deadline. If the "3 working days" deadline is not met, OSR cannot accept responsibility for the timely delivery of the proposal to the agency.”
- FOR ELECTRONIC SUBMISSION, WE RECOMMEND GIVING OCGA FIVE DAYS BEFORE THE DEADLINE TO REVIEW AND SUBMIT

Principal Investigators should be aware that many academic departments and schools have procedures and schedules for the submission of proposals. These procedures should be followed prior to submitting the proposal to OCGA. The UCLA procedure regarding submission of proposals is available in the resources tab.

Start early and leave time for unforeseen problems!
Allow time for review and corrections before submission.
A Complete Proposal Package includes:

- Original GR signed by the PI, Co-PI, Chair(s) and/or Dean(s)
- If paper submission - sufficient copies to be mailed to sponsor
- One full copy plus an “EFM” copy for OCGA
  - The “EFM” copy consists of cover page, abstract, budget, and budget justification
- Proposal guidelines
  - Paper copy for OCGA’s files

When the proposal has been completed, the Goldenrod filled out and signed, and all of the other requirements completed, the department forwards the proposal package to the Office of Contract and Grant Administration. The proposal package typically contains the items identified here.
A Complete Proposal Package includes:

- All required approvals applicable to the proposal:
  - Human/Animal subjects approvals
  - ESCRO/Stem cell research
  - Approval for exception to PI policy
  - Conflict of Interest forms
  - NIH PI Signature form
  - Biohazards
  - Any other approvals that may be required

Upon timely receipt of proposal package, OCGA will review to determine:

- The PI is eligible, and if not, approval for exception is in place
- All required approval signatures have been obtained on GR, and other administrative requirements have been met
- The proposal budget is compliant with UC and sponsor policies/procedures
  - The correct F&A and fringe benefit rates properly applied
- The application complies with all the sponsor’s instructions for proposal preparation
- The sponsor terms and conditions are acceptable to the University

A complete proposal package also includes all required approvals applicable to the proposal as shown here.
After review of Proposal Package, OCGA will (if applicable):

- Signs Goldenrod
- Signs proposal
- Prepare the transmittal letter
- Prepare any representations and certifications that may be required
- Package and mail the proposal *OR*
- Depending on system and sponsor, “push the button” to submit electronically

Upon completion of the review of the proposal, the Grant Analyst or Contract Officer signs the Goldenrod. If the proposal is paper, signs the proposal itself. If appropriate, the Grant Analyst or Contract Officer may prepare a letter transmitting the proposal to the sponsor, complete any representations and certifications, and then submits the proposal in accordance with the instructions set forth on the Goldenrod or program guidelines.
Let’s Recap
Let’s Recap

- Internal approvals required pre-proposal submission
  - Fully signed Goldenrod
  - PI Signature form (if NIH)
  - Conflict of Interest forms

- A variety of additional approvals maybe be required to be on file prior to the submission of a proposal and/or prior to the processing of an award
Let’s recap

- Proposal packages should be submitted to OCGA at least three working days prior to deadline for paper submissions; FIVE DAYS if submission is electronic.
Let’s Recap

- Special considerations
  - PI effort reflected in proposals
  - Program income
  - Stem cell research
  - Coordinated proposal submission with the UCLA Corporate, Foundation and Research Relations (CFRR) office
  - Export and Trade Regulations
You have completed Module 4, Internal Approvals and Special Considerations

Grab your calculator and roll up your sleeves, you are going to prepare a proposal budget in Module 5…