



Sponsored Projects (Pre-award)

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Presentation Overview

- Define “Sponsored Projects” and “Pre-award”
- Discuss research at UC
- Cover four important UC policies
- Review pre-award sponsored projects processes
- Brief overview of research protection concerns
- Hot topics in sponsored projects
- Take-home points

What are Sponsored Projects?

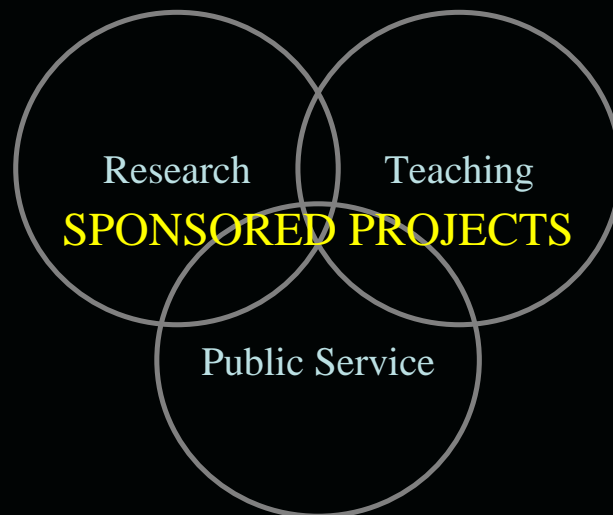
- Awards made to UC by external sponsors for the purpose of supporting the University's research, training and public service programs, including:
 - Awards made to a UC campus by another campus, UCOP or UC managed national lab
- Extramural awards, sponsored programs, sponsored projects – all synonymous

Life Cycle of a Sponsored Project

Proposal Preparation Proposal Review Institutional Signature and Submission to Sponsor	Sponsor Review	Award Negotiation and Acceptance	Project Period				Closeout
			1st Budget Period	2nd Budget Period	3rd Budget Period	No Cost Time Extension	
							
Pre-award							

Research at UC

UC's Mission



Impact of UC Research

- Social and political impact
 - Creating knowledge and advancing human understanding of our world and beyond
 - Assessment and establishment of public policy
 - Quality of life improvements
 - Education
 - Health care
 - Communications and technology
 - Transportation
 - Environment
- Economic impact
 - An important part of UC's economic impact on California's economy
 - Inventions – from concept to market place

How is Research Supported at UC?

- Sponsored projects (grants & contracts)
 - Governmental entities
 - Public non-governmental entities
 - Private non-profit entities
 - Private for-profit entities
 - UC systemwide programs
- FY 05 – \$3.98 billion in sponsored project funding
 - \$2.74 billion (69%) from federal sources

How is Research Supported at UC?

- Campus seed and bridge funding
- Gifts
- Transactions that are neither gifts nor awards of extramural funds
 - Material transfer agreements
 - Software and computing licenses
 - Equipment and instrumentation loans

Funding Mechanisms & Characteristics

GIFT	GRANT	CONTRACT
Not tied to specific performance dates	Specific period of performance	Specific period of performance
Irrevocable	Revocable	Revocable
No obligations beyond routine stewardship reporting	Technical, financial and invention reports to sponsor	Technical , financial and invention reporting, as well as work product deliverables (e.g., software, source code, schematics, designs, etc.)
Unrestricted	Terms & conditions	Less flexible terms & conditions
Donation of cash or other tangible asset	Financial assistance	Purchase transaction
No scope of work	PI's scope of work	Sponsor's scope of work
Selection made at donor's sole discretion	Awarded based on peer review recommendation	Awarded based on low bid/project design selection process

Obligations

- UC assumes certain obligations by accepting sponsored projects
 - Compliance with federal regulations
 - Perform research or project with integrity
 - Stewardship of public assets
 - Upholding the public trust

Reputation is everything!



UC Policies

University Regulation No. 4

“Special Services to Individuals and Organizations”

- Character of undertakings and use of facilities
 - Extend knowledge or increase teaching effectiveness
 - Not for activities of a purely commercial character
- Appropriate approvals prior to incurring commitments or expending funds
- Full recovery of expenses incurred
- Publication rights and ownership of records
- Use of University name
- Patent agreement

UC Presidential Policy

Issued December 15, 1994 -

“No solicitation or application for extramural support of research, training, public service programs shall be made officially in the name of The Regents without the prior approval of The Regents or of an authorized official of the University

“It is the policy of the University of California that employees who receive any part of their salary through the University, or whose activities use any University resources or facilities, must submit their proposals for extramural support through the appropriate local contracts and grants office.”

Regents Standing Order 100.4 (dd)

- Delegates authority to request extramural support to the President
- Delegated to Sr. V.P. - Business and Finance and Chancellors

Typically, *only* the following individuals can legally sign proposals or accept awards:

- Chancellor
- Vice-Chancellor for Research
- Staff in campus Sponsored Programs Office
 - Director, Contract and Grant Officers

~~DA~~

~~PI~~

Principal Investigator (PI) Eligibility Policy

- Eligibility may vary from campus to campus
 - Must be a member of the Academic Senate
 - Other qualified appointment
 - Generally, appointment must be 50% or more of full time
 - By exception
- PIs are required to:
 - Assume responsibility for the scientific, administrative and financial management of a sponsored project
 - Personally participate to a significant degree
 - Fronting is not acceptable

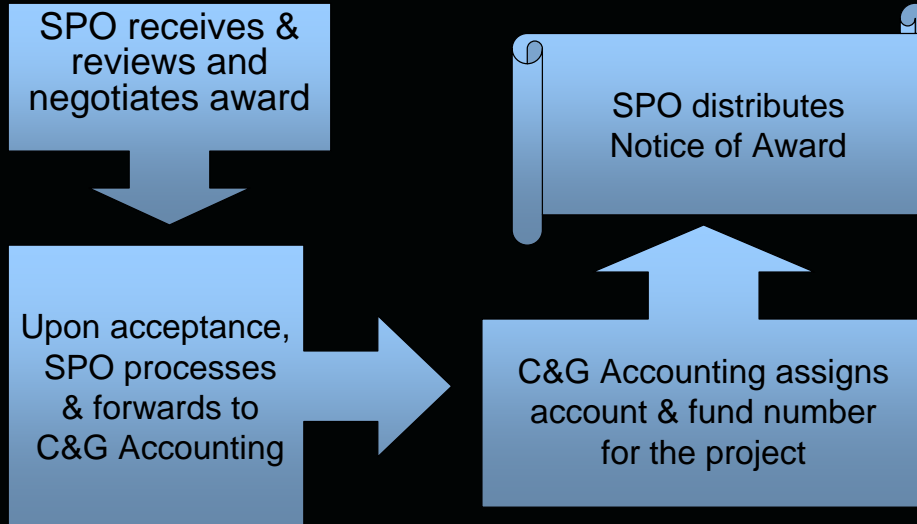


Sponsored Projects Pre-award Processes

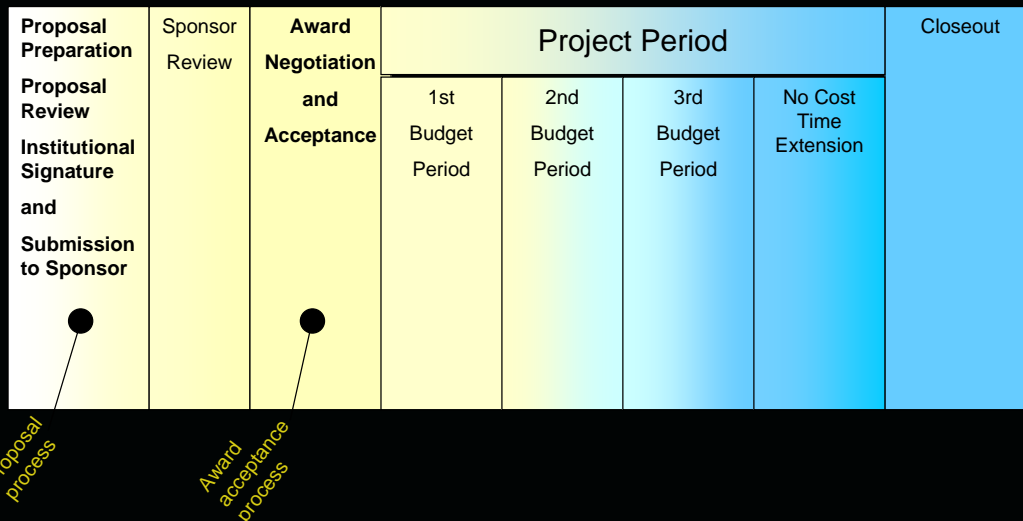
Proposal Development, Routing and Approval Process



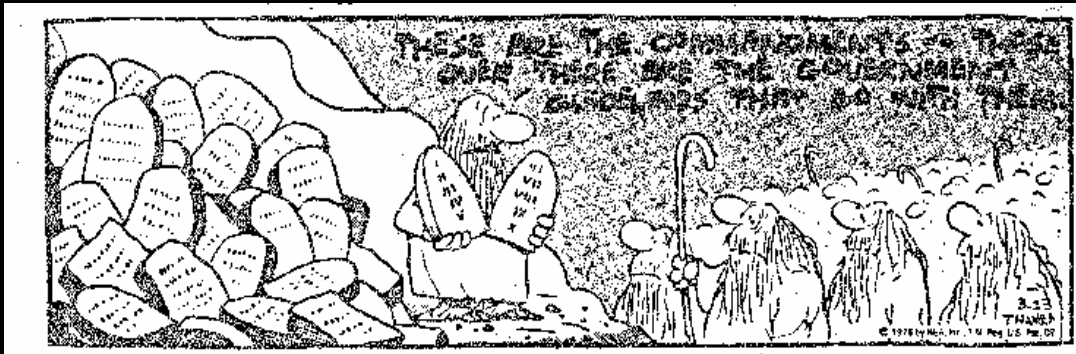
Award Acceptance Process



Pre-award Processes in the Life Cycle



Research Integrity and Compliance



“THESE ARE THE COMMANDMENTS – THOSE OVER THERE
ARE THE GOVERNMENT GUIDELINES THAT GO WITH THEM”

Conflict of Interests

A situation where an individual's outside financial interest(s) or obligations bias, or have the potential to bias, the conduct and management of a research project.

Conflict of Interests

- Unmanaged or undisclosed conflict of interest may lead to
 - Misuse of UC facilities for personal gain
 - Improper direction of students or UC staff
 - Delays in publishing research results
 - Improper channeling of research funds
 - Failure to recognize UC's interests
 - Scientific misconduct
 - Erosion of public trust

Conflict of Interest

- Disclosure = protection for the
 - PI
 - Institution
 - Integrity of the research
 - Public at-large

External Conflict of Interest Requirements

- State of California Political Reform Act
 - Disclosure of financial and management interests in non-governmental research sponsors
 - PI and Co-PIs disclose on behalf of themselves, their spouses and dependent children
 - Various thresholds for disclosure related to:
 - Investments
 - Income/gifts
 - Positions (e.g., board of directors, scientific board, etc.)

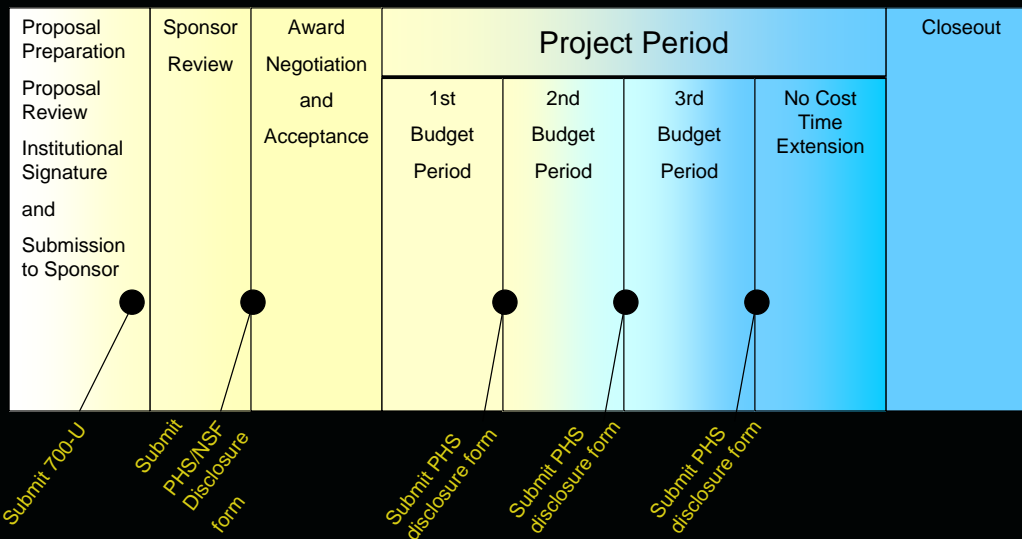
External Conflict of Interest Requirements

- PHS/NSF
 - Disclosure by all personnel involved in the design, conduct or reporting PHS or NSF funded research
 - Includes spouse and dependent children
 - Any interest in private, non-profit or public entities in an area related to the research that could
 - Affect the conduct of the research
 - Be affected by the research outcomes

Conflict of Interest Committee

- Faculty committee advisory to the Vice Chancellor for Research reviews disclosures
 - Reasonably appear to be directly and significantly affected by the project?
 - Reasonably appear to directly affect the design, conduct or reporting of the project?
 - Is the research appropriate to the University?
 - Is the teaching and research environment open?
 - Are UC policies, guidelines and regulations being followed?
 - Does the award impose any publication or dissemination restrictions or approvals?

Conflict of Interest Processes in the Life Cycle



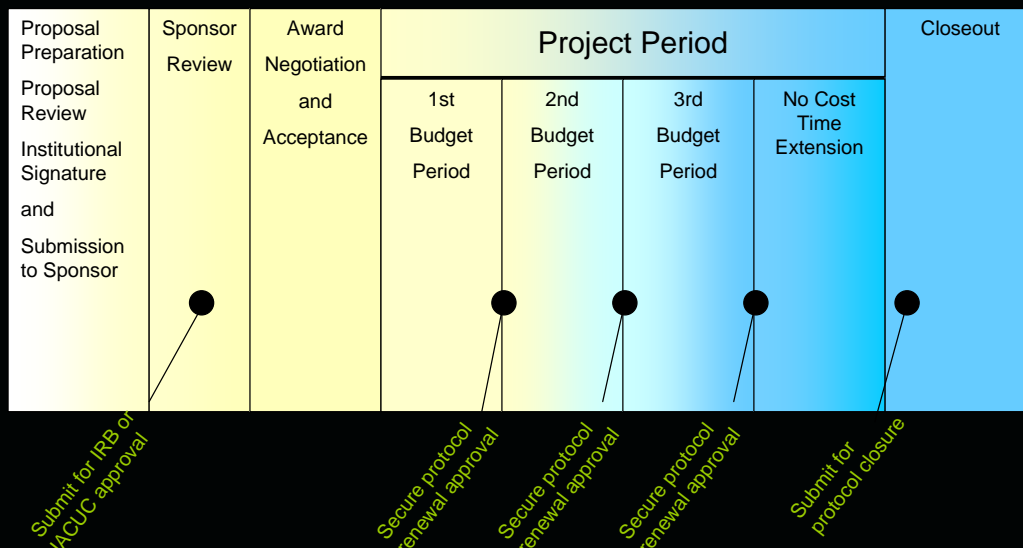
Human Research

- Any systematic investigation that is designed to develop or contribute to generalizable knowledge and which uses living humans or identifiable information about living humans
 - Regulations and policies apply to all human research regardless of funding source
 - All human research must be registered and approved by the campus IRB before recruiting subjects and commencing human research
 - All research staff must have received training before engaging in human research

Animal Use in Research & Training

- Use of animals must comply with Federal regulations regardless of funding source
 - Animal generally means a live vertebrate
 - All animal procedures must be approved by the campus IACUC prior to commencing project work that involves animals
 - All personnel must have received training regarding the handling and use of animals

IRB and IACUC Processes in the Life Cycle



Environmental Health & Safety

- Research must comply with health and safety regulations and standards
 - Approved use of biohazards and other toxic materials
 - Determination of whether projects will have a potential impact on the environment
 - Registration and review of research involving rDNA and certain pathogens
- Various committees
 - Institutional Biosafety Committee
 - Radiation Safety Committee
 - Embryonic Stem Cell Research Oversight Committee
 - Some schools have Dean's Review Committees

Hot Topics in Sponsored Projects

- Fraud and mismanagement
- Export controls
 - Compliance with regulations
 - Contract terms that
 - Restrict participation of foreign persons or implement facility access controls
 - Seek to classify UC research projects
 - Impose publication restrictions or require prior approval
- Subrecipient monitoring
- Cost sharing
- Effort reporting
- Effective oversight of research
 - Research subject protections
 - Conflict of interest review & management
 - Select Agents registration and security requirements
 - Scientific misconduct

Take Home Points

- Research is an important and integral part of UC's mission
- As stewards of public funds UC has an obligation to do the right thing
 - Reputation is everything
- Submit proposals and direct awards through local SPO
- Comply with research regulations
- **ASK QUESTIONS!**