

Partnering with the Office of Intellectual Property and Industry Sponsored Research

December 10, 2013

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UCLA Office of Intellectual Property & Industry Sponsored Research

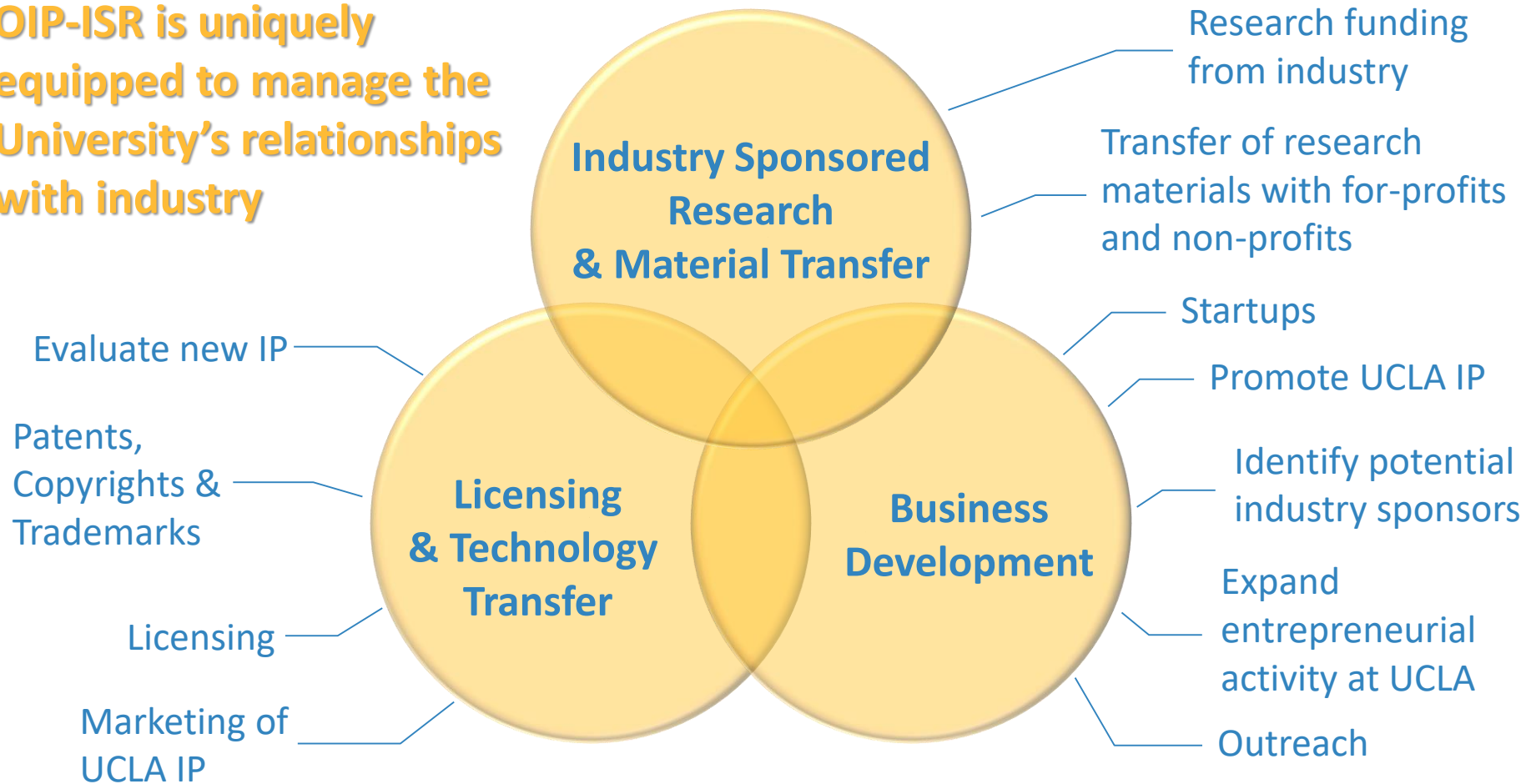


Overview

- Overview of OIP-ISR
- Considerations for Sponsored Proposals
- Distinguishing between OCGA, CTO and OIP
- Proposal Toolkit
- Best Practices

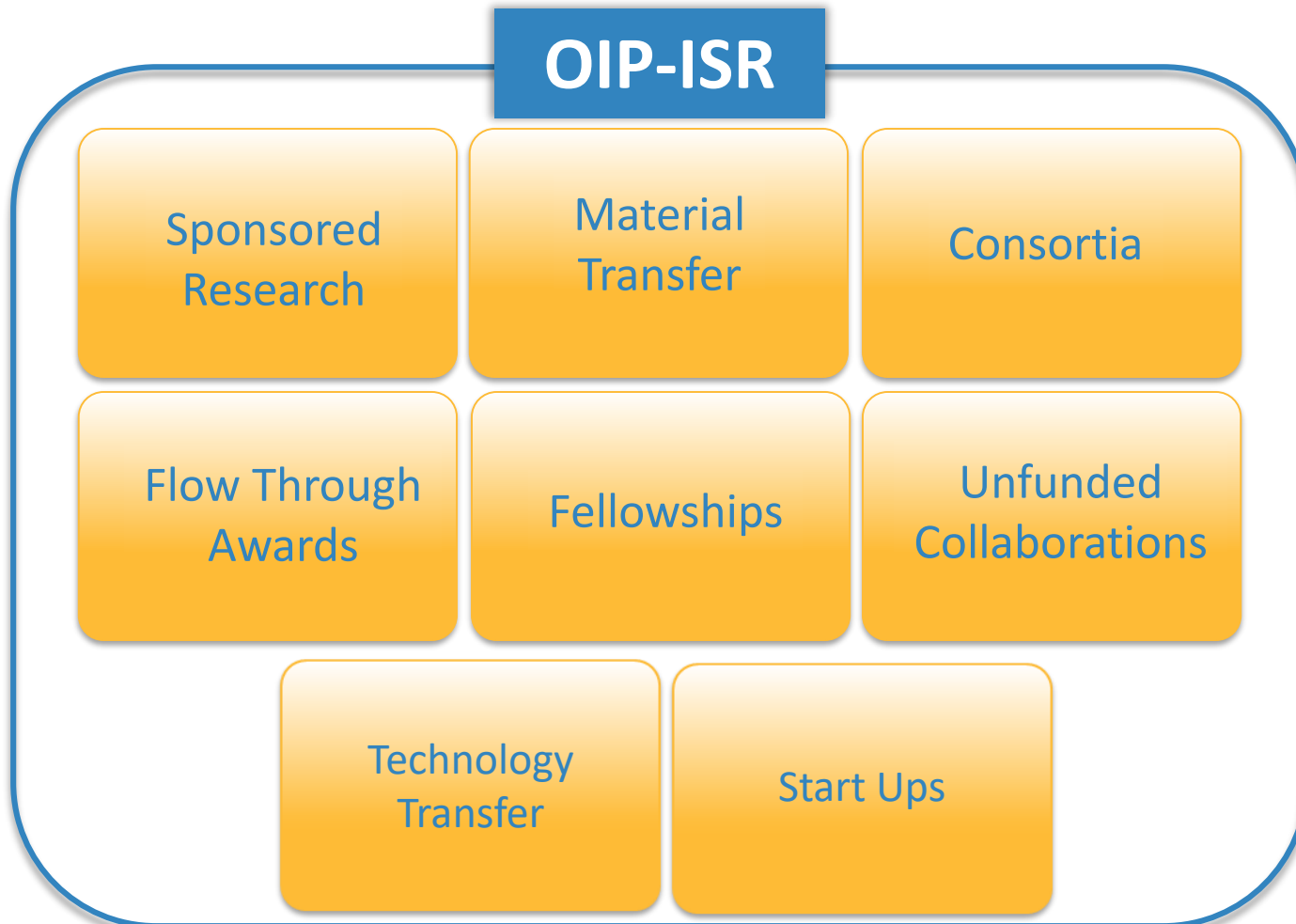
The Office of Intellectual Property & Industry Sponsored Research

**OIP-ISR is uniquely
equipped to manage the
University's relationships
with industry**



Driving Innovation to Market.

Types of Industry Engagement



Destination: Fund Number



Sponsored Research. Now what?!

- Describe the work to be done
- Purpose: Research, Fellowship, Training . . .
- Who is the sponsor: Federal, state or local Gvnt, non-profit foundation or for-profit company
- Facilities and Administrative Rate differs
- Different Offices within UCLA Handle different types of engagements

Classification of Proposal

Indirect Cost Rate / F&A

Facilities and Administrative Cost Rates July 1, 2010 through June 30, 2016		
Type of Program	On-Campus	Off Campus
Research	54.0% (7/1/10-until amended)	26.0% (7/1/10-until amended)
Instruction	37.0% (7/1/10-until amended)	26.0% (7/1/10-until amended)
Other Sponsored Activities	35.0% (7/1/10-until amended)	26.0% (7/1/10-until amended)

Clinical Trial Defined

- At UCLA, a clinical trial is defined as:
“The controlled **clinical testing** in **human subjects** of investigational new drugs, devices, treatments or diagnostics or comparisons of approved drugs, devices, treatments or diagnostics, to assess their safety, efficacy, benefits, costs, adverse reactions, and/or outcomes...”

For purposes of applying the approved 26% Indirect Cost Rate, the following are NOT categorized as Clinical Trials:

- Retrospective Chart Reviews
- Analysis of Existing Medical Data and Records
- Laboratory Research
- Animal Studies
- Federally-Funded projects (OCGA)

WHICH OFFICE?

- OCGA – Extramural funding directly with local, state or federal government entities or non-profits
- Clinical Trials Office – CT agreements; CDAs as a precursor to a CT
- OIP – ISR
 - Material Transfers
 - For-profit sponsors
 - Sub-awards (SBIR/STTR)
 - CDAs
 - Equipment loans
 - Unfunded Collaborations
 - Fellowships
 - Conferences / Other

Proposal Toolkit

Streamlined and
Stress-free!



Extramural Funding:

To get the process started:

- EPASS (updated 2/4/13)
- Industry-Sponsored Research Checklist
- Conflict of Interest Financial Disclosure Forms (Form 700U / Addendum)
- Budget
- Scope of Work



UCLA RESEARCH
EXTRAMURAL PROPOSAL APPROVAL AND SUBMISSION SUMMARY
"EPASS"

[Print](#) [Reset](#)

1. Principal Investigator(s)/Co-PIs (Not Co-Investigators)

	First Name	M.I.	Last Name	Employee ID	Email Address	Extension
PI:						
Other PI/Co-PI:						
Other PI/Co-PI:						
Fellow (if Individual Fellowship):						

Named individuals must sign certification below. Attach additional pages if needed.

2. Department or Organized Research Unit (ORU)

Administering Department Name: _____ FS Code (Dept. Code): _____
 Account #: _____ Cost Center: _____ Recharge ID: _____
 Dept. Contact Name: _____ Extension: _____ Email Address: _____
 Affiliated with Center/ORU: _____
 If "Other Center/Institute" is selected above, please specify name, or if multiple Center(s)/Institute(s) please add additional selection(s) here: _____

3. Proposal Identification

Proposal Title: _____
 Project Begin Date: _____ Project End Date: _____

4. Award/Proposal/Program Type

Award Type: _____ Proposal Type: _____
 Program Type: _____ Special Program Type: _____
 If this EPASS relates to an existing Award or Master Agreement, select an Action Type: _____
 Current Sponsor Award/ ID#: _____

5. Sponsor Information (if UCLA award is a subcontract or subgrant, indicate both Sponsor & Prime Sponsor below)

FOA/RFA/RFP# (if applicable): _____
 Prime FOA# (if different): _____
 Sponsor Due Date/Time (Pacific): _____
 Deadline Type: _____
 Sponsor Name: _____
 Contact (if known): _____ Email Address: _____ Phone #: _____
 Prime Sponsor Name (if applicable): _____

6. Proposal Checklist

Yes	No	
<input type="checkbox"/>	<input type="checkbox"/>	PI Exception Required? (Check Requirements and Look up Eligibility). If yes, attach approval form (Sample Approval Form)
<input type="checkbox"/>	<input type="checkbox"/>	On Campus Space? Indicate location: Building _____ Room: _____
<input type="checkbox"/>	<input type="checkbox"/>	Off Campus Space? Indicate location: _____
<input type="checkbox"/>	<input type="checkbox"/>	Outgoing Agreements? If yes, attach Sub-recipient Commitment Form(s). PI signature below indicates review and approval of cost reasonableness. (See Subaward Initiation and Management)
<input type="checkbox"/>	<input type="checkbox"/>	Does this project involve activities outside the U.S. or partnership with International Collaborators?
<input type="checkbox"/>	<input type="checkbox"/>	Is any Cost Sharing/Matching proposed in this application? (Do not include unfunded effort or salary cap differential here.) If Yes, required by sponsor? <input type="checkbox"/> Yes (mandatory committed) <input type="checkbox"/> No (voluntary committed) Source FAU#: _____
<input type="checkbox"/>	<input type="checkbox"/>	Is any unfunded effort proposed in this application? (Do not include salary cap differential here) Source FAU#: _____
<input type="checkbox"/>	<input type="checkbox"/>	Do you anticipate program income? If yes, specify: _____
<input type="checkbox"/>	<input type="checkbox"/>	Does this proposal involve the use of significant IT resources (beyond basic academic infrastructure); the generation of datasets or digital assets; or a budget with over \$10,000 in IT-related hardware, software, or staff expenditures? (Check additional requirements)

<input type="checkbox"/>	<input type="checkbox"/>	Human Subjects? If yes, indicate IRB#: _____ Delayed Onset <input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>	Are study related patient care costs to be billed to the award OR to a third party payor (i.e. medical insurance/Medicare)? If yes, then a Policy 915 Coverage Analysis is required (refer to www.clinicaltrials.ucla.edu).
<input type="checkbox"/>	<input type="checkbox"/>	Animal Subjects? If yes, indicate ARC#: _____ Delayed Onset <input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>	Human Embryonic Stem Cell Research? If yes, refer to the Stem Cell Policy and Procedures .
<input type="checkbox"/>	<input type="checkbox"/>	Non-UCLA materials/equipment to be used? If yes, indicate type: _____ Source: _____
<input type="checkbox"/>	<input type="checkbox"/>	Biological materials? For more information, see Biological Safety Division website .
<input type="checkbox"/>	<input type="checkbox"/>	UCLA Hospital Services? If yes, Medical Center Director must sign in Approvals section below.
<input type="checkbox"/>	<input type="checkbox"/>	Use of UC IP? If yes, specify case number: _____
<input type="checkbox"/>	<input type="checkbox"/>	Export Control (see RPC Website) – Does the project involve the following:
<input type="checkbox"/>	<input type="checkbox"/>	Shipping or carrying any tangible object or item to a foreign country? If yes, specify: _____
<input type="checkbox"/>	<input type="checkbox"/>	Conducting research or other activities in, taking money to or planning to have money transferred to a foreign country? If yes, specify: _____
<input type="checkbox"/>	<input type="checkbox"/>	Training foreign persons in using equipment, technology, or technical data? If yes, specify: _____
<input type="checkbox"/>	<input type="checkbox"/>	Traveling to or doing research in a country currently under a US Trade or Economic Embargo (See OFAC Website)? If yes, specify: _____

7. Additional Forms Required

<input type="checkbox"/>	<input type="checkbox"/>	COI (Disclosure Requirements)
<input type="checkbox"/>	<input type="checkbox"/>	Sponsor/Prime Sponsor is Federal Public Health Service (PHS) or agency that has adopted the PHS regulations? If yes, provide names of other investigators on page 3 (See UCLA Policy 926).
<input type="checkbox"/>	<input type="checkbox"/>	Sponsor/Prime Sponsor is Federal (other than PHS), CIRP or special research programs managed by the UC Research Grants Program Office (RGPO)? If yes, attach COI Form 740 & Supplement to Form 740 (if applicable). See UCLA Procedure 925.3.
<input type="checkbox"/>	<input type="checkbox"/>	Non-Government Sponsor/Prime Sponsor? If yes, attach Form 700-U, 700-U Addendum and 700-U Supplement, as applicable, unless sponsor is exempt. See UCLA Procedure 925.2
<input type="checkbox"/>	<input type="checkbox"/>	Industry Sponsored Research
<input type="checkbox"/>	<input type="checkbox"/>	Industry Sponsored Non-Clinical Proposal? If yes, attach Industry Sponsored Research Checklist .
<input type="checkbox"/>	<input type="checkbox"/>	Industry Sponsored Clinical Trial? If yes, view the Clinical Trials Administration Office Checklist to determine additional required attachments.

8. Funds Requested

1st Budget Period
 Direct Costs (\$): _____ Excluded Direct Costs (\$): _____ F&A Costs (\$): _____ Total Costs (\$): _____
 All Project Periods (complete only when multiple budget periods are involved)
 Direct Costs (\$): _____ Excluded Direct Costs (\$): _____ F&A Costs (\$): _____ Total Costs (\$): _____
 F&A
 F&A Rate (%): _____ F&A Base Type: _____ If Other, specify: _____

9. Remarks

10. Accepts Responsibility

The investigator(s) certifies to the following: (1) that the information submitted within this application is true, complete and accurate to the best of their knowledge; (2) that any false, fictitious, or fraudulent statements or claims may subject the investigator(s) to criminal, civil or administrative penalties; (3) 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; and (4) that you are not currently debarred, suspended or ineligible to receive federal or non-federal funds. When multiple investigators are proposed in an application this assurance must be obtained by all named investigators.

Principal Investigator (Required)	Date	Chair/ORU Director/Dean/Medical Center Director (Required)	Date
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____

For OCGA/OCT/OIP/DRA Use Only:
 IDC Waiver Requested? _____ IDC Waiver Type: _____ IDC Waiver Status: _____
 IDC Waiver #: _____ Institution #: _____

UCLA

**INDUSTRY SPONSORED RESEARCH
PROPOSAL CHECKLIST**

Sponsor (Company) Name: UCLA PI Name:

1) Is any university intellectual property (patents, copyrights or software) or Sponsor proprietary information, equipment, or materials being used in this project?
 NO
 YES, university intellectual property, (please continue to question #1a)
 YES, Sponsor proprietary information, equipment, or materials (please continue to question #2)

1a) Who is the lead inventor or author of the university intellectual property and what is his/her UC affiliation (employee or UC affiliate (e.g. student, visiting scientist))?

1b) Has the intellectual property been disclosed to the UCLA Office of Intellectual Property?
 NO
 YES **IF YES**, please list UC Case Numbers or, if it is from another university, please list the name of that university:
IF NO, please list the following:
 Title or Description:
 Inventor/Author(s):
 Patent No if applicable:
 Assignee(s):

1c) Has the intellectual property been licensed or optioned?
 NO (please continue to question #2)
 YES **IF YES**, please list the name(s) of the entity that has licensed or optioned the IP:

2) What proprietary information, materials, or equipment will the Sponsor be providing you to conduct the scope of work?

2a) Will you be conducting the scope of work using Sponsor's materials or equipment in conjunction with any other material or equipment received from a third party (including the Government)?
 NO (please continue to question #3)
 YES **IF YES**, please explain:

3) Will you be conducting the scope of work with funding received from a third party (including the Government) other than the Sponsor?
 NO (please continue to question #4)
 YES **IF YES**, please explain:

4) Will any non-UCLA employees, including visiting scientists/scholars or volunteers, be visiting your lab to perform research or related tasks in the conduct of this research project?
 NO (please continue to question #5)
 YES **IF YES**, please explain:

5) Please attach the following documents to the email when you submit this form.
 Goldenrod
 Scope of Work
 Budget
 PI Exception Letter, if necessary
 Financial Disclosure Forms (700-U, 700-U Addendum, and Supplement, if necessary). For UC Discovery awards and federal government subcontracts, please also attach Form 740.

IF THIS INVOLVES AN SBIR OR STTR PROPOSAL, please continue to question #6. Otherwise, please sign and date below.

6) Per Federal guidelines, does the Sponsor have its own research facilities (or research facilities that it controls)?
 NO (please continue to question #7)
 YES **IF YES**, please list list the address of the Sponsor's research facilities:

7) Please list the name of the Sponsor Representative who will be negotiating the subcontract with UCLA:
 Name: Title: Ph #:

8) Please provide the names of any Sponsor officials or employees who are also UCLA employees, students or trainees:

9) Please list the name of the Sponsor Principal Investigator(s):

10) Does the Sponsor intend to rely on the program and facilities of UCLA's Institutional Animal Care and Use Committee to oversee the performance of its animal research?
 NO
 YES
 Not Applicable

11) Please Attach the following documents (in addition to those listed in question #5):
 Solicitation Number or Copy of Solicitation
 Authorization Letter to participate in SBIR/STTR from Chair and Dean
 Approved exception from the Vice Chancellor for Research to allow a UCLA employee to serve as the Company PI, if applicable.
 For Phase II SBIR/STTR, please also attach Form 740

I confirm that the above information is accurate to the best of my knowledge. If any of the information above should change during the term of the project I will update this form and re-submit it to UCLA Office of Intellectual Property and Industry Sponsored Research (OIP-ISR).

Signature
 Name (Printed) Date

Industry-Sponsored Research Checklist

CALIFORNIA FORM 700-U
FAIR POLITICAL PRACTICES COMMISSION

STATEMENT OF ECONOMIC INTERESTS FOR PRINCIPAL INVESTIGATORS
A Public Document

Date Received
Campus Use Only

Campus: _____

ID No: _____

Please type or print in ink.

NAME (LAST)	(FIRST)	(MIDDLE)	TELEPHONE NUMBER ()
ACADEMIC UNIT OR DEPARTMENT		MAIL CODE	E-MAIL ADDRESS
TITLE OF RESEARCH PROJECT			

Form 700 U

1. Information Regarding Funding Entity

(Use a separate Form 700-U for each funding entity.)

Name of Entity: _____

Address of Entity: _____

Principal Business of Entity: _____

Amount of Funding: \$ _____

Estimated Actual

2. Type of Statement (Check at least one box)

Initial (for new funding)

Date of initial funding: ____/____/____

Interim (for renewed funding)

Funding was renewed on: ____/____/____

3. Filer Information

A. Are you a director, officer, partner, trustee, consultant, employee, or do you hold a position of management in the entity listed in Part 1? No Yes

Title: _____

B. Do you, your spouse or registered domestic partner, or your dependent children have an investment of \$2,000 or more in the entity listed in Part 1 above? No Yes - value is:

\$2,000 - \$10,000 \$10,001 - \$100,000
 \$100,001 - \$1,000,000 Exceeds \$1,000,000

Date Disposed: ____/____/____, if applicable

C. Have you received income of \$500 or more from the entity listed in Part 1 during the reporting period? No Yes - amount is:

\$500 - \$1,000 \$1,001 - \$10,000
 \$10,001 - \$100,000 Exceeds \$100,000

Was this income received through your spouse or registered domestic partner? No Yes

3. Filer Information - Cont.

D. Have you received loans from the entity in Part 1 for which the balance exceeded \$500 during the reporting period? No Yes - highest balance:

\$500 - \$1,000 \$1,001 - \$10,000
 \$10,001 - \$100,000 Exceeded \$100,000

If you checked "yes," was the loan:

Secured Unsecured Interest rate: _____%

Was the loan entirely repaid within the last 12 months?

No Yes

E. Have you received gifts from the entity listed in Part 1 within the last 12 months valued at \$50 or more? No Yes - describe below.

Description: _____

Value: \$ _____ Date Received: ____/____/____

F. Has the entity in Part 1 paid for your travel during the reporting period? No Yes - describe below.

Type of Payment: (check one) Gift Income

Amt: \$ _____ date(s): ____/____/____
(If applicable)

Description: _____

4. Verification

I have used all reasonable diligence in preparing this statement. I have reviewed this statement and to the best of my knowledge the information contained herein and in any attached schedules is true and complete. I certify under penalty of perjury under the laws of the State of California that the foregoing is true and correct.

Date Signed _____
(month, day, year)

Signature _____
(File the originally signed statement with your university.)

UNIVERSITY OF CALIFORNIA, LOS ANGELES
Investigators' Statements of Financial Interests

**700-U
Addendum**

Under UCLA Policy 925, the Principal Investigator and all other UCLA Investigators who share responsibility for the design conduct, or reporting of research must disclose their personal financial interests in any organization(s) that will fund or support research or is an intermediary acting for the sponsor.

PI's name: _____

Funding Entity: _____

Title of Research Project: _____

IRB/ARC No(s) (if applicable): _____

Industry supported Clinical Trial: No Yes **If yes, each investigator with Significant Financial Interests to disclose should complete the **Industry Clinical Trial Specific Disclosure Supplement Form**.*

Reason for Disclosure: New Application Additional Support IRB Request

Disclosure and Certification

The Principal Investigator's signature below certifies either that all individuals required to make disclosures of Significant Financial Interests have been listed on this form, or that no other individuals working on the research are required to make such disclosure:

Are there other Investigators who share responsibility for the design, conduct, or reporting of the research? NO YES
If YES, those Investigators should sign and complete the section below.

Signature of Principal Investigator _____ Date _____ For PI Only: Please attach State of California Form 700-U

Do you, your spouse or registered domestic partner, or dependent children have a Significant Financial Interest (as defined below) to report?

1. _____ Signature of Investigator Date	<input type="checkbox"/> NO	<input type="checkbox"/> YES, Supplement* attached

Print or Type Name of Investigator		
2. _____ Signature of Investigator Date	<input type="checkbox"/> NO	<input type="checkbox"/> YES, Supplement* attached

Print or Type Name of Investigator		
3. _____ Signature of Investigator Date	<input type="checkbox"/> NO	<input type="checkbox"/> YES, Supplement* attached

Print or Type Name of Investigator		
4. _____ Signature of Investigator Date	<input type="checkbox"/> NO	<input type="checkbox"/> YES, Supplement* attached

Print or Type Name of Investigator		

**Form 700U
Addendum**

UCLA Office of Intellectual Property & Industry Sponsored Research

UCLA PROPOSAL BUDGET FORM University of California Los Angeles

Budget Period: From _____ Through _____ Year _____ of _____

Direct Costs:

List Personnel Salary and Fringe Benefits

Name	Payroll Title	Monthly Salary	# of Months	% Effort	Person Months	Requested Salary	* Fringe Benefits %	Amount	Total
Check box for additional personnel. List "Additional Personnel" on next page.									
List Graduate Student Researchers (GSRs) Salary and Fringe Benefits									
# of	Name	Payroll Title	Monthly Salary	# of Months	% Effort	Person Months			
Fringe Benefit Rate % and Tuition Remission Calculation:						\$	\$	\$	
* Enter the appropriate Fringe Benefit Rate %. For example: 17.0% enter 17 in the box. The budget form will calculate the Fringe Benefit Amount and the Total automatically.						The "Totals" above also include Salary and Fringe Benefit amounts from the next page.			
Tuition Remission:	# of GSR's:		x	# of Months:		x	Tuition Remission Rate:		=
Tuition Remission:	# of GSR's:		x	# of Months:		x	Tuition Remission Rate:		=
Tuition Remission:	# of GSR's:		x	# of Months:		x	Tuition Remission Rate:		=
Tuition Remission:	# of GSR's:		x	# of Months:		x	Tuition Remission Rate:		=
Consultant(s)									\$
Equipment									\$
Supplies and Materials									\$
Travel									\$
Subaward(s)									\$
Other Expenses									\$
Total Direct Costs									\$

Indirect Costs:

On Campus Federally-Negotiated Rate(s)		%	x	MTDC Base:		=		=	
		%	x	MTDC Base:		=		=	
Off Campus Federally-Negotiated Rate		%	x	MTDC Base:		=		=	
Other Rate		%	x	Base:		=		=	
Total Indirect Costs									\$
Total Costs Requested									\$

Budget Template

How long does it take for a research agreement to be approved?

- If the sponsor agrees to use the standard UCLA research agreement without negotiation of additional terms, an agreement can be signed by OIP as soon as the completed proposal package with all signatures and approvals is received.
- If the sponsor requires negotiation of contract terms or has extended internal review, significant delays can occur.

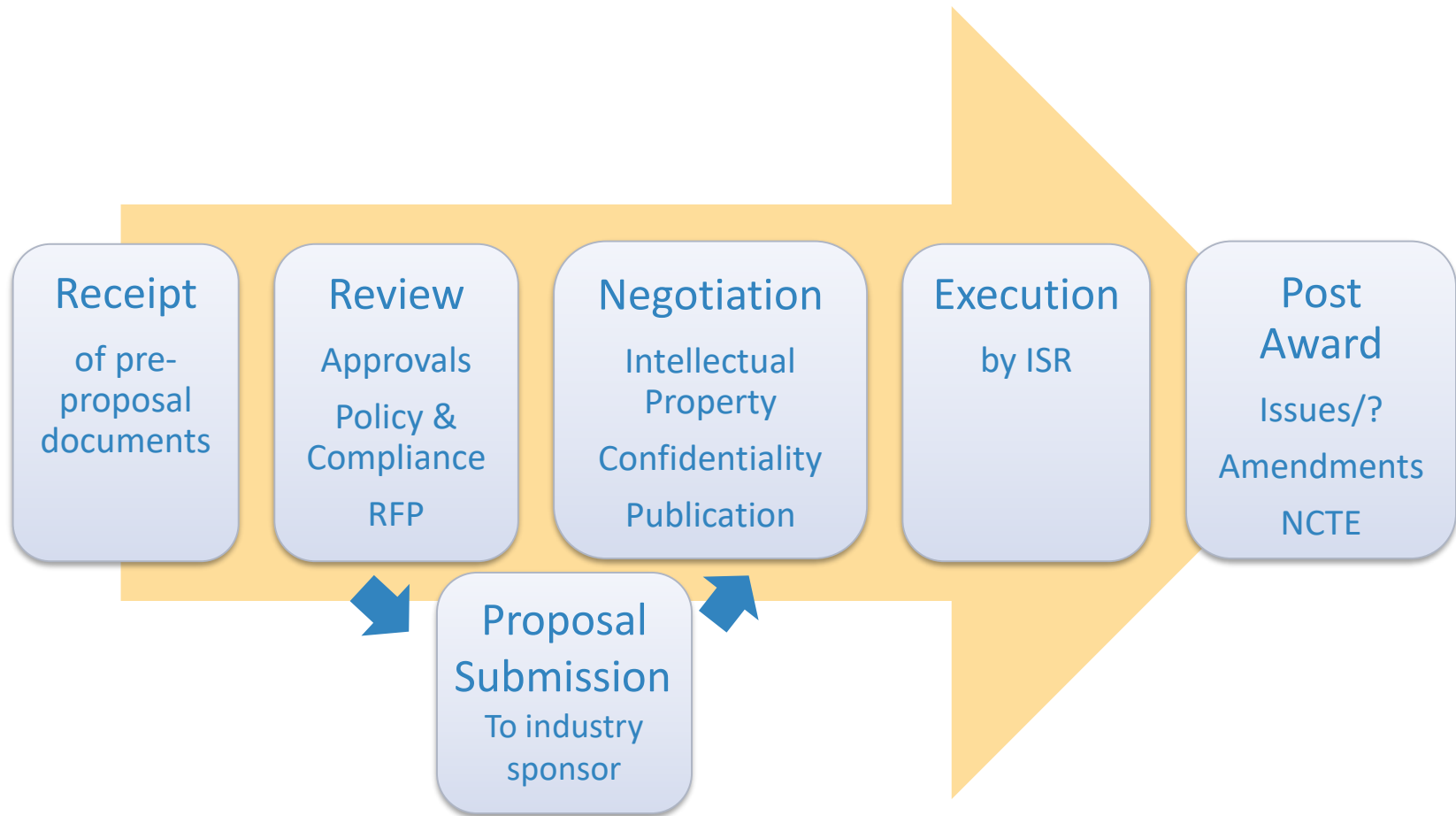
Potentially Problematic Provisions

- Publication Restrictions
- Intellectual Property Ownership and Usage
- University Indemnification of 3rd parties
- Governing Law
- Recovery of less than all University Costs
- Penalty Clauses
- Conflict Resolution

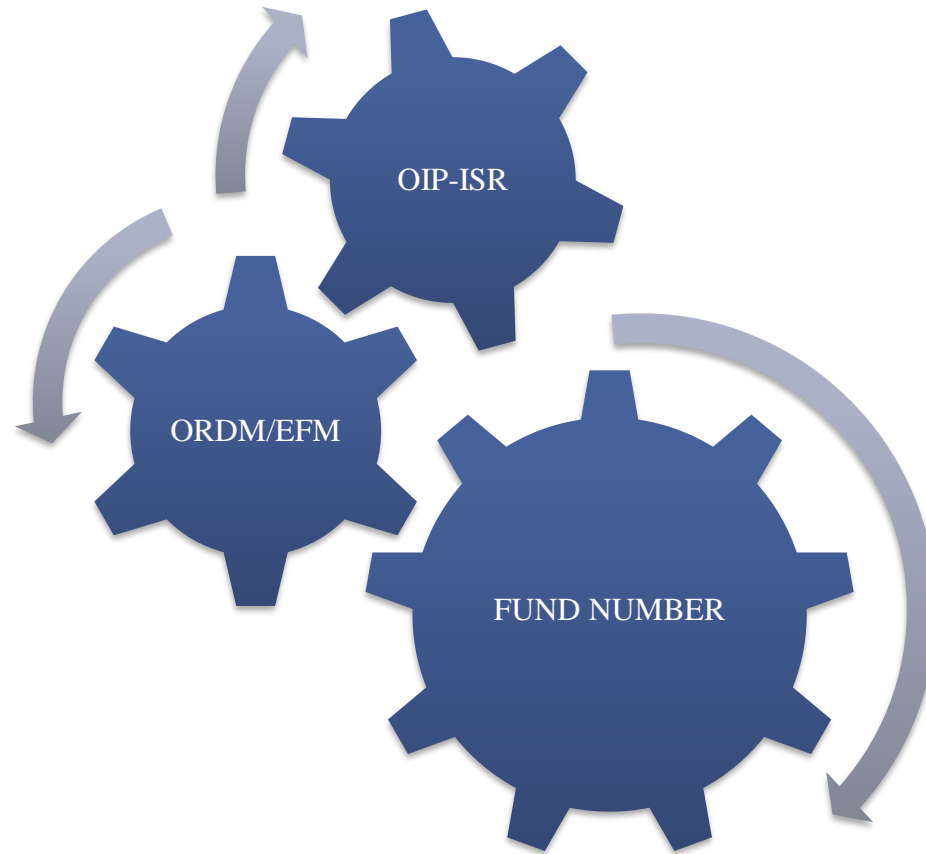
Potential Internal Delays

- Conflict of Interest Review Committee (CIRC)
- Incorrectly categorizing the Type of Contract – i.e., Personal Consulting Agreement versus UCLA Subcontract
- Budget Errors
- Policy Exceptions
- Administrative Approvals
 - Embryonic Stem Cell Research Oversight Committee (ESCRO)
 - Institutional Review Board – human research?
 - Office of Animal Research Oversight (OARO/ARC) – Care and use of animals
 - Institutional Bio-safety Committee (IBC) – Hazardous Biological materials

The Contract Process



UCLA INTERNAL PROCESS



BEST PRACTICES



BEST PRACTICES

- Timely submit all internal proposal documents
- Obtain signatures and administrative approvals
- Consistent details among all documents
- Fill out all the information requested
- Investigator time/effort reflected in the budget
- Include correct indirect cost rate
- Prepare a coherent budget – use budget template
- Submit PI exception letter, if needed
- REVIEW, REVIEW, REVIEW

Questions?



Office of Intellectual Property &
Industry Sponsored Research

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Thank you!

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