Partnering with the Office of Intellectual Property and Industry Sponsored Research

December 10, 2013

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Officer, Industry Sponsored Research
UCLA Office of Intellectual Property & Industry Sponsored Research

Driving Innovation to Market.
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

- Evaluate new IP
- Patents, Copyrights & Trademarks
- Licensing & Technology Transfer
- Licensing
- Marketing of UCLA IP
- Industry Sponsored Research & Material Transfer
- Research funding from industry
- Transfer of research materials with for-profits and non-profits
- Startups
- Promote UCLA IP
- Identify potential industry sponsors
- Expand entrepreneurial activity at UCLA
- Outreach

Driving Innovation to Market.
Types of Industry Engagement

OIP-ISR

- Sponsored Research
- Material Transfer
- Consortia
- Flow Through Awards
- Fellowships
- Unfunded Collaborations
- Technology Transfer
- Start Ups

Driving Innovation to Market.
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

<table>
<thead>
<tr>
<th>Type of Program</th>
<th>On-Campus</th>
<th>Off Campus</th>
</tr>
</thead>
<tbody>
<tr>
<td>Research</td>
<td>54.0% (7/1/10-until amended)</td>
<td>26.0% (7/1/10-until amended)</td>
</tr>
<tr>
<td>Instruction</td>
<td>37.0% (7/1/10-until amended)</td>
<td>26.0% (7/1/10-until amended)</td>
</tr>
<tr>
<td>Other Sponsored Activities</td>
<td>35.0% (7/1/10-until amended)</td>
<td>26.0% (7/1/10-until amended)</td>
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</tbody>
</table>
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:

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

EXTRAMURAL PROPOSAL APPROVAL AND SUBMISSION SUMMARY

1. Principal Investigator(s)/Co-PIs (Not Co-Investigators)
   - First Name
   - MI
   - Last Name
   - Employee ID
   - Email Address

2. Department or Organized Research Unit (ORU)
   - Administering Department Name:
   - Account #:
   - Cost Center:
   - Recharge ID:
   - Dept. Contact Name:
   - Extension:
   - Email Address:

3. Proposal Identification
   - Proposal Title:
   - Project Begin Date:
   - Project End Date:

4. Award/Proposal/Program Type
   - Award Type:
   - Program Type:
   - Special Program Type:

5. Sponsor Information (if UCLA award is a subcontract or grant, indicate both Sponsor & Sponsor Below)
   - FQARAS/PF# (if applicable):
   - PI's: (if different):
   - Sponsor Due Date/Time (Pacific):
   - Sponsor Name:
   - Contact Name:
   - Email Address:

6. Proposal Checklist
   - PI Exception Required?:
   - Check Requirements and Look up Eligibility. If yes, attach approval form (Sample Approval Form)
   - On Campus Space? Indicate location: Building:
   - Off Campus Space? Indicate location:
   - Outgoing Agreements?:
   - PI signature below indicates review and approval of cost reasonableness. (See Subaward Initiatives and Management)
   - Does this project involve activities outside the U.S. or partnership with International Collaborators?
   - Is any Cost Sharing/Matching proposed in this application? (Do not include unfunded effort or salary cap differential here.)
   - If yes, required by sponsor? (Yes mandatory committed) (No voluntary committed)
   - Source F&A:
   - Is any unfunded effort proposed in this application? (Do not include salary cap differential here)

7. Additional Forms Required
   - Yes: COI (Disclosure Requirements)
   - Yes: Sponsor/Prime Sponsor is Federal Public Health Service (PHS) or agency that has adopted the PHS regulations
   - Yes: provide names of other investigators on page 1 (See UCLA Policy 326)

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 Rate (%):

9. Remarks

10. Acceptance Responsibility
   - Principal Investigator (sign here)
   - Date:
   - ORU (or Chief Medical Center Director) (sign here)
   - Date:

For OCGA/CT/OFR (F&A Use Only)
- EIC Water Requested?
- Date:
- EIC Water Type:
- EIC Water Tracer:
# Industry-Sponsored Research Checklist

**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 1b)

**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 scholar)?**

**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:

**2) 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
- 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
- YES, if YES, please explain:

**4) Will any non-UCLA employees, including visiting scientists/scholars or volunteers, be asked to perform research or related tasks in the conduct of this research project?**
- NO
- YES, if YES, please explain:

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

**IF THIS INVOLES AN SBIR OR STTR PROPOSAL, please continue to question 5. 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
- YES, if YES, please list the address of the Sponsor’s research facility:

**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:**
- SBRG 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 I 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:**
**Form 700 U**

**STATEMENT OF ECONOMIC INTERESTS FOR PRINCIPAL INVESTIGATORS**

<table>
<thead>
<tr>
<th>Please type or print in ink:</th>
</tr>
</thead>
<tbody>
<tr>
<td>NAME (LAST) (FIRST) (MIDDLE)</td>
</tr>
<tr>
<td>TEL. NUMBER</td>
</tr>
<tr>
<td>ACADEMIC UNIT OR DEPARTMENT</td>
</tr>
<tr>
<td>MAIL CODE</td>
</tr>
<tr>
<td>E-MAIL ADDRESS</td>
</tr>
<tr>
<td>Campus:</td>
</tr>
<tr>
<td>ID No.</td>
</tr>
<tr>
<td>TITLE OF RESEARCH PROJECT</td>
</tr>
</tbody>
</table>

### 1. Information Regarding 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)
- [ ] Interim (for renewed funding)
- [ ] Funding was renewed on: __________/_________/__________

### 3. Filer Information - Cont.

- **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

  **Amount is:**

  - [ ] $2,000 - $10,000
  - [ ] $10,001 - $100,000
  - [ ] $100,001 - $1,000,000
  - [ ] Exceeds $1,000,000

- **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

- **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
  - [ ] Exceeds $100,000

- **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:

  **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:**

  - [ ] Gift
  - [ ] Income

  **Amount:** $ __________

  **Date(s):** __________/_________/__________

### 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:** (Type the originally signed statement with your university.)
UNIVERSITY OF CALIFORNIA, LOS ANGELES
Investigators’ Statements of Financial Interests

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 __________________________

☐ NO □ YES, Supplement attached

Print or Type Name of Investigator __________________________

2. Signature of Investigator __________________________ Date __________________________

☐ NO □ YES, Supplement attached

Print or Type Name of Investigator __________________________

3. Signature of Investigator __________________________ Date __________________________

☐ NO □ YES, Supplement attached

Print or Type Name of Investigator __________________________

4. Signature of Investigator __________________________ Date __________________________

☐ NO □ YES, Supplement attached

Print or Type Name of Investigator __________________________
**UCLA PROPOSAL BUDGET FORM**

**University of California Los Angeles**

**Direct Costs:**

<table>
<thead>
<tr>
<th>Name</th>
<th>Payroll Title</th>
<th>Monthly Salary</th>
<th>% of Effort</th>
<th>% of Months</th>
<th>Requested Salary</th>
<th>% Fringe Benefits</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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</tr>
</tbody>
</table>

Check box for additional personnel. List "Additional Personnel" on next page.

**List Graduate Student Researchers (GSRs) Salary and Fringe Benefits**

<table>
<thead>
<tr>
<th># of GSRs</th>
<th>Name</th>
<th>Payroll Title</th>
<th>Monthly Salary</th>
<th>% of Effort</th>
<th>% of Months</th>
<th>Requested Salary</th>
<th>% Fringe Benefits</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>2</td>
<td></td>
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<td></td>
<td></td>
</tr>
</tbody>
</table>

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.

费用率 = (月工资 * 每月工作率 * 月数) * 年数 * 费用

The "Totals" above also exclude Salary and Fringe Benefit amounts from the next page.

<table>
<thead>
<tr>
<th>Consultant(s)</th>
<th>$</th>
</tr>
</thead>
<tbody>
<tr>
<td>Equipment</td>
<td>$</td>
</tr>
<tr>
<td>Supplies and Materials</td>
<td>$</td>
</tr>
<tr>
<td>Travel</td>
<td>$</td>
</tr>
<tr>
<td>Subaward(s)</td>
<td>$</td>
</tr>
<tr>
<td>Other Expenses</td>
<td>$</td>
</tr>
</tbody>
</table>

**Total Direct Costs** $ 

**Indirect Costs:**

<table>
<thead>
<tr>
<th>On Campus Federally-Negotiated Rate(s)</th>
<th>%</th>
<th>MTDC Base:</th>
<th>=</th>
</tr>
</thead>
<tbody>
<tr>
<td>Off Campus Federally-Negotiated Rate</td>
<td>%</td>
<td>MTDC Base:</td>
<td>=</td>
</tr>
<tr>
<td>Other Rate</td>
<td>%</td>
<td>Base:</td>
<td>=</td>
</tr>
</tbody>
</table>

**Total Indirect Costs** $ 

**Total Costs Requested** $ 

**Driving Innovation to Market.**
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
Driving Innovation to Market.

The Contract Process

Receipt of pre-proposal documents

Review
Approval
Policy & Compliance
RFP

Negotiation
Intellectual Property
Confidentiality
Publication

Execution by ISR

Post Award
Issues/Amendments
NCTE

Proposal Submission
To industry sponsor
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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