UCLA Reliance on Other UC IRBs, UCLA CTSI IRBs and Beyond

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Research Administration Forum
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What Is an IRB Reliance Agreement?

- By mutual or collective written agreement, one or several IRBs agree to rely on the IRB review of one or several other IRBs.
- The agreement is typically called an “MOU” (Memorandum of Understanding).
How a Reliance Agreement Works*

**Reviewing IRB**
- assumes full responsibility as IRB of record
- reviews entire study
- assures local issues are identified and addressed
- coordinates communication with all PIs

**Relying IRB**
- accepts determinations made by Reviewing IRB in their entirety
- has responsibility for ensuring that
  - Ancillary approvals (MRSC, COI, IBC) are in place
  - Sufficient resources are available

*NOTE: This is model commonly used by commercial IRBs*
Two CTSI’s Involved in IRB Reliance Agreements for UCLA Investigators

UCLA
- Cedars-Sinai Medical Center
- Charles Drew University of Medicine and Science
- LA Biomedical Institute at Harbor UCLA Medical Center
- UCLA

UC Medical Centers
- UC Davis
- UC Irvine
- UCLA
- UC San Diego
- UC San Francisco
How to Use the MOUs

- General process is similar for both UC MOU and UCLA CTSI MOU but because UC process is web-based procedures are slightly different.


- Review information on “UC IRB Reliance Registry for Studies under the UC MOU” on UC Berkeley site at [http://cphs.berkeley.edu/irbreliance.html](http://cphs.berkeley.edu/irbreliance.html)
UNIVERSITY OF CALIFORNIA
NOTICE OF INTENT TO RELY ON ANOTHER UC IRB

Instructions to the Principal Investigator/Lead Investigator at the Reviewing IRB:
1. Read the decision tree for an overview of the process and points to consider when determining which IRB should provide review.
2. Complete the Notice and ensure that information needed by the research of the other UC site is included.
3. Obtain the signature of the Reviewing IRB for the Notice.
4. Submit the completed Notice with your IRB Application Forms to your reviewing IRB.
5. Once approved, you can begin the study. The reviewing PIRL must wait for an Acknowledgment Letter before they can begin.

Instructions to the Principal Investigator/Lead Investigator at the Relying IRB:
1. Read the decision tree for an overview of the process and points to consider when determining which IRB should provide review.
2. Ensure you provide the necessary information, templates, and sign the Notice.
3. Obtain the signature of the Relying IRB for the Notice.
4. Provide the Notice to the Reviewing PIRL.

A. Reviewing Campus Principal Investigator/Lead Investigator:

<table>
<thead>
<tr>
<th>Reviewing Campus Study Title</th>
<th>2. Application Type</th>
<th>3. Review Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>[UC Berkeley]</td>
<td>[UC Davis]</td>
<td>[Full Committee]</td>
</tr>
<tr>
<td>[UC Lawrence Berkeley National Lab]</td>
<td>[UC San Francisco]</td>
<td>[Expedited Review]</td>
</tr>
<tr>
<td>[UC Irvine]</td>
<td>[UC Los Angeles]</td>
<td>[Exempt]</td>
</tr>
<tr>
<td>[UC Oakland]</td>
<td>[UC Riverside]</td>
<td></td>
</tr>
<tr>
<td>[UC San Diego]</td>
<td>[UC Santa Barbara]</td>
<td></td>
</tr>
<tr>
<td>[UC Santa Cruz]</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

4. UC Location Which Will Provide IRB Review:

- [ ] UC Berkeley
- [ ] UC Davis
- [ ] UC Lawrence Berkeley National Lab
- [ ] UC San Francisco
- [ ] UC Irvine
- [ ] UC Los Angeles
- [ ] UC Oakland
- [ ] UC Riverside
- [ ] UC San Diego
- [ ] UC Santa Barbara
- [ ] UC Santa Cruz

5. Funding Information:

<table>
<thead>
<tr>
<th>Type of Funding</th>
<th>Award Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Contract/Grant</td>
<td>Federal Government</td>
</tr>
<tr>
<td>Subcontract</td>
<td>Other Gov. (e.g., State, local)</td>
</tr>
<tr>
<td>Direct/Indirect</td>
<td>Industry</td>
</tr>
<tr>
<td>Project</td>
<td>Other Private</td>
</tr>
<tr>
<td>Equipment</td>
<td>Campus-wide program</td>
</tr>
<tr>
<td>Conference</td>
<td>Departmental Funds</td>
</tr>
<tr>
<td>Other</td>
<td>Other</td>
</tr>
</tbody>
</table>

6. Who is the Primary Awarding Institution?

7. Who is the PI on this award?

8. PIRL on the IRB Application:

<table>
<thead>
<tr>
<th>Name and degree</th>
<th>University Title</th>
<th>Department</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mailing Address</td>
<td>Phone Number</td>
<td>Email Address</td>
</tr>
<tr>
<td>Contact Person</td>
<td>Name and degree</td>
<td>University Title</td>
</tr>
<tr>
<td>Mailing Address</td>
<td>Phone Number</td>
<td>Email Address</td>
</tr>
<tr>
<td>Additional Contact Person(s)</td>
<td>Name and degree</td>
<td>University Title</td>
</tr>
<tr>
<td>Campus Mailing Address (Box No.)</td>
<td>Phone Number</td>
<td>Email Address</td>
</tr>
</tbody>
</table>

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Overview of How UC and UCLA CTSI MOUs Work

After Investigators confer with each other and their IRBs to determine which IRB reviews study,

1. Relying PI registers by completing (on-line) form which outlines his/her institution’s role in study

2. Lead PI (at reviewing institution) submits usual IRB application and uploads PDFs of completed registrations from Relying Pis

3. Reviewing IRB reviews entire study including Relying PI PDFs
4. **Reviewing IRB** sends **IRB Approval Letter** to Reviewing PI and Relying IRBs

5. **Relying IRBs** review local PI registration and if other approvals are in place, resources are sufficient, and local concerns addressed, accepts reliance on Reviewing IRB

6. **Relying IRB** sends **Acknowledgement Letters** to Reviewing Campus, Relying PIs and Relying IRBs—automatically generated
Which IRB Reviews Multi Site Study?

Considerations:
- Recipient of prime award
- Primary Study Site
- IRB expertise

Easiest Choice: If the prime grantee and location where all or most of study recruitment and procedures occur is the same site, IRB review will be at that site.
Examples of UCLA IRB Reviewing for UCSF

- Study to assess the effects of nutrition training on primary outcomes for men living with AIDS in improving body composition and immune status as assessed at several follow up points; and …

- Project to develop educational programs to train nurses, physicians, and physical therapists about the 5P Fall Prevention Method, implement the 5P Method at Santa Monica UCLA Medical Center and UCSF’s Moffitt-Long Hospital Complex, assess its effectiveness and examine the cost implications for the hospitals and ….
UCLA IRB Reviewing for All 5 UC Medical Centers and Cedars Sinai

- Study to examine how different tertiary cancer centers provide post-treatment survivorship care, and how well the existing models of care at each site facilitate adherence to guideline recommendations for surveillance, adherence to adjuvant endocrine therapy, and management of common post-treatment symptoms.
Important PI Caveats

- **Lead PI** serves function similar to Coordinating Center and assumes additional responsibilities related to coordination of activities.

- **Relying PI** cannot begin study activities until:
  - Reviewing IRB has approved study,
  - All local ancillary approvals (MRSC, IBC, COI) are in place, and
  - Relying IRB has acknowledged approval in writing.
Important Caveats when Relying on Another IRB

Relying PI must

- **modify informed consent form** to include local contact information (see handout) unless one ICF with local information is submitted for initial review.

- **coordinate renewals or amendments** with Lead PI.

- **monitor and report unanticipated problems** to Reviewing IRB. Coordinate with Lead PI.

- notify Reviewing PI when **closing study at local site or withdrawing** from MOU.
Other External IRBs Available to UCLA Researchers

See OHRPP website for details:

- The National Cancer Institute Central IRB (NCI CIRB) for some oncology groups studies (submit through webIRB)
- Western IRB
- Rand
- Rarely, others may approved on a case-by-case basis
Where to Go for Help

- **OHRPP Website:** External IRBs
  [http://ohrpp.research.ucla.edu/pages/external-irbs#ucla-rand](http://ohrpp.research.ucla.edu/pages/external-irbs#ucla-rand)

- **OHRPP Senior Staff, including:**
  - Augustine Fernandes: 983-3155; [augustine.fernandes@research.ucla.edu](mailto:augustine.fernandes@research.ucla.edu)
  - Alison Orkin: 206-3969; [aorkin@research.ucla.edu](mailto:aorkin@research.ucla.edu)
  - Sharon Friend: 825-5855; [sfriend@research.ucla.edu](mailto:sfriend@research.ucla.edu)