IRB MOU for Multi-Site Trials

&

IRB Reliance Registry

Jeff Hall · Director Research Policy Development · RPAC · UCOP
UC DEVELOPMENT OF THE IRB MOU & RELIANCE REGISTRY

irbreliance.ucop.edu

2004 ➢ “NorCal” MOU executed

2006 ➢ Systemwide MOU executed

2008 ➢ Systemwide searchable database for MOU conceived

2010 ➢ IRB Directors conceive an on-line to administer MOU and maximize use
      ➢ Initial UCBRAID meeting calls for creation of an MOU and on-line management tool

2010-11 ➢ IRB Directors and UCOP design on-line “Reliance Registry” tool, UCOP/ORGS funds and oversees development

2012 ➢ Selected campus PIs and by IRB staff review Reliance Registry
      ➢ Reliance Registry beta version launched
      ➢ MOU revised to explicitly include full study reviews, clarify use for stem cell research
      ➢ IRB Directors mandate use of Reliance Registry for all studies under the MOU
IRB MOU for Multi-Site Studies
MOU Between and Among Human Research Protection Programs at UC Campuses and LBNL
for IRB Review of Multi-Campus Human Subject Research

USE OF THE IRB MOU HAS INCREASED

NEW APPROVED STUDIES and ASSOCIATED USERS Each Year

There is an aggregate total of 370 studies under the MOU for 2006 to 2012
There is an aggregate total of 758 PIs using the MOU for 2006 to 2012

(through Aug.31)
Campus Use of the IRB Reliance Registry
Percentage of UC Systemwide Registered PI and Research Coordinator users by campus

- UCSF: 37.85%
- UCB: 21.77%
- UCD: 8.52%
- UCI: 10.09%
- UCR: 0.32%
- UCSD: 11.99%
- UCLA: 5.99%
- UCSB: 0%
- LBNL: 1.89%
- UCSC: 1.26%
- UCM: 0.32%
UC IRB Reliance Registry for Studies under the UC MOU

Note: Starting July 1, 2012, UC investigators applying for a new or renewed reliance on another UC IRB will be required to do so using the UC Online Reliance Registry. Paper NOLTRs will no longer be processed after that date. Please see the instructions below. For additional assistance, please contact Sylvie Kim at sylviekim@berkeley.edu.

UC Berkeley is transitioning to the online UC IRB Reliance Registry for all studies in which our investigators rely on another UC campus or Lawrence Berkeley National Lab IRB review or vice versa by means of the UC System Memorandum of Understanding (MOU). The paper version of the Notice of Intent to rely on one UC IRB (NOLTR) will be phased out and all new reliance requests, renewals and amendments will need to be submitted via the online registry.

Below is a summary of the process for Reviewing and Relying investigators. For detailed information, see:

- Reviewing Campus PI or Research Coordinator
- Relying Campus PI or Research Coordinator
- Diagram of Process of Registering New Multi-Site Study into the Reliance Registry

Registration

All first-time users must register with the UC IRB Reliance Registry before they create a new reliance request.

- If you are the Reviewing PI, go to http://irbreliance.uccp.edu
- For first-time registration, click “Register” and complete the “User Registration” form. A temporary password will be sent to your email address. Use the temporary password to log in to the Registry and create a new password. Registration is now complete.

Creating a New Reliance Request

- If you are the Reviewing PI, click the Create Request tab and disclose if your study involves Veteran Administration. Complete the information regarding your role in the study and the other required fields marked by an asterisk. Make sure to save your entries if you need to log out at any time.
- If you are a Student Investigator for the Reviewing or Relying Campus, you must identify yourself as a Research Coordinator.
EASE OF USE: CLEAR, ONLINE FORM (Before and Now)

<table>
<thead>
<tr>
<th>Instructions to the Principal Investigator/Lead Investigator at the Reviewing IRB</th>
<th>Instructions to the Principal Investigator/Lead Investigator at the Relying IRB</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Read the document for an overview of the process and points to consider when determining which IRB should provide review.</td>
<td>1. Read the document for an overview of the process and points to consider when determining which IRB should provide review.</td>
</tr>
<tr>
<td>2. Complete the Notice and ensure that information about the research at the other UC site is included.</td>
<td>2. Ensure you provide the necessary information, complete, and sign the Notice.</td>
</tr>
<tr>
<td>3. Obtain the signature of the Relying PI on the Notice.</td>
<td>3. Provide the Notice to the Reviewing PI.</td>
</tr>
<tr>
<td>4. Submit the completed Notice with your IRB Application Forms to your Reviewing IRB.</td>
<td>4. Wait for the Acknowledgement Letter from the Relying Campus IRB.</td>
</tr>
<tr>
<td>Once approved, you can begin the study. The Relying PI must wait for their Acknowledgement Letter before they can begin.</td>
<td>5. You can begin the study.</td>
</tr>
</tbody>
</table>

A. Reviewing Campus Principal Investigator/Lead Investigator:

1. Reviewing Campus Study Title:
   - [ ] New
   - [ ] Modification
   - [ ] Renewal
   - [ ] Continuing Review (Continuing Review)

2. Application Type:
   - [ ] Expedited Review (Exempted)

3. Review Type:
   - [ ] Full Committee
   - [ ] Expedited Review
   - [ ] Exempt
   - [ ] Exempt

4. UC Location Which Will Provide IRB Review:
   - UC Berkeley
   - UC Los Angeles
   - UC Irvine
   - UC Riverside
   - UC San Diego
   - UC Santa Barbara

5. Funding Information

   a. Type of Funding
      - Contract/Grant
      - Subcontract
      - Drug/device donation
      - Departmental
      - Gift
      - Student project
      - Other

   b. Award Information
      - [ ] Federal Government
      - [ ] Other (e.g., State, local)
      - [ ] Industry
      - [ ] Other Private
      - [ ] Campus/UC-Wide program
      - [ ] Departmental Funds
      - [ ] Other

   Have funds been awarded?
   - [ ] Yes
   - [ ] No
   - [ ] Pending

6. Who is the Primary Awardee Institution?

7. Who is the PI on this award?

8. PUELI on the IRB Application:

   Name and degree
   - University Title
   - Department

   Mailing Address
   - Phone Number
   - E-mail Address

   Contact Person
   - Name and degree
   - University Title
   - Department

   Mailing Address
   - Phone Number
   - E-mail Address

   Additional Contact Person (if any):
   - Name
   - University Title
   - Department

   Campus Mailing Address (Box No.)
   - Phone Number
   - E-mail Address

Notice of Intent to Reli
Page 1 of 4
February 2009
BENEFITS FOR INVESTIGATORS & RESEARCH ADMINISTRATORS

COMMUNICATION/CLARITY ABOUT NEXT STEPS:
emails vs. on-line dashboard

Dear Dr. Huang,

The UC Irvine IRB reviewed and approved protocol HSR 2011-0142, "Adjudicating CDC and Claims-Based Criteria for Hospital Associated Infections".

The UC Irvine IRB Approval Letter and NOTIRs are attached to this email. A courtesy copy of this email has been sent to the Principal Investigator(s) Coordinator.

If you have any questions, please feel free to contact me.

Sincerely,

Jessica Sheldon

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NOTIR Archive (updated thru 7.31.11)

UC Irvine IRB Approval Letter for protocol HSR 2011-0142 - Message 14

You forwarded this message on 6/5/2013 2:27 PM.

From: Jessica Sheldon [jessica.sheldon@research.ucd.edu]
To: susan.huang@ucd.edu
Cc: adina.gordon@ucd.edu; teherani@ucd.edu; timon@ucsd.edu; rubin1@rednet.ucd.edu; steven@ucdavis.edu; catherine.li@ucsd.edu; elodie.martin@ucd.edu; dragana nikolic@ucd.edu
Subject: UC Irvine IRB Approval Letter for protocol HSR 2011-0142

Message: http://www.research.ucd.edu/public/IRB/NOTIRs/archive

[Messages and attachments included]
DATABASE/TRACKING (1)  
(manually sorted folders Vs. a Searchable Database*)

<table>
<thead>
<tr>
<th>Title of Study</th>
<th>Status</th>
<th>Actions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Measuring the benefits of sanitation, water quality, and nutrition interventions for improving health and development in rural areas</td>
<td>rely on complete</td>
<td>Details</td>
</tr>
<tr>
<td>Mobilization of Patients in the Intensive Care Unit</td>
<td>rely on complete</td>
<td>Details</td>
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<tr>
<td>Ultrasound Study of Chorionic Villus Sampling</td>
<td>rely on complete</td>
<td>Details</td>
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<tr>
<td>Neurological and Reproductive Effects of Radiation on Workers</td>
<td>rely on complete</td>
<td>Details</td>
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<tr>
<td>Stress, Eating, and Early Development</td>
<td>rely on complete</td>
<td>Details</td>
</tr>
<tr>
<td>Are Eilittes Bisected? Partnership and Ideology in California's Supervision of Direct Democracy</td>
<td>rely on complete</td>
<td>Details</td>
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<tr>
<td>Health Access Program for Prevention, Empowerment, and Networking for Women (HARPEN)</td>
<td>rely on complete</td>
<td>Details</td>
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<tr>
<td>HIV Prevalence Among Street Youth in Kisumu, Kenya</td>
<td>rely on complete</td>
<td>Details</td>
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<tr>
<td>Predicting and Improving Clinical Outcomes in Bacterial Keratitis</td>
<td>rely on complete</td>
<td>Details</td>
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<tr>
<td>A Direct Observation Study of Provider-Patient Communication about Ovarian Cancer</td>
<td>rely on complete</td>
<td>Details</td>
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<tr>
<td>Quality of Women's Experiences with Substance Use, Treatment, and Housing</td>
<td>rely on complete</td>
<td>Details</td>
</tr>
<tr>
<td>National Study of Physician Organizations III</td>
<td>rely on complete</td>
<td>Details</td>
</tr>
<tr>
<td>Correlation of age and bone regeneration with stem cell colony formation and differentiation in culture</td>
<td>rely on complete</td>
<td>Details</td>
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</table>
Is UC MOU and the IRB Reliance Registry the only one out there?

- Harvard Mass. General used the UC MOU as a model.
- Vanderbilt University piloting a system (IRBShare) for CTSAs (see below)
- UCLA has developed an MOU for use with its non-UC CTSI partners
<table>
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<th>Remaining Challenges</th>
<th>Potential Next Steps</th>
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<td>Expanding industry-sponsored research&lt;br&gt;• Reluctance of PI to assume lead PI responsibilities&lt;br&gt;• Getting investigators and sponsors to start up front with collaborations</td>
<td>• Admin. relief for the reviewing PI in industry-sponsored studies&lt;br&gt;• Revise price structure for reviewing IRBs and developing a mechanism to defray costs incurred at relying campuses&lt;br&gt;• collaborative relationships w/faculty&lt;br&gt;• Use private IRB/ single systemwide IRB for industry sponsored studies</td>
</tr>
<tr>
<td>Increasing use of the MOU:&lt;br&gt;• By research fields&lt;br&gt;• By individual PIs</td>
<td>Increase Awareness&lt;br&gt;• survey to PIs re registry&lt;br&gt;• Faculty-to-faculty outreach&lt;br&gt;• UC outreach to other institutions: use of UC MOU with non-UC institutions&lt;br&gt;• Outreach to sponsors to let them know of MOU&lt;br&gt;• Closer Collaborate w CTA negotiators&lt;br&gt;• Cost incentive for use?</td>
</tr>
<tr>
<td>Measuring impact/outcomes</td>
<td>Enhance reporting functions&lt;br&gt;Identify baseline- how many studies conducted at 2 or more campuses enhance recruitment speed&lt;br&gt;Show decreased cycling times</td>
</tr>
<tr>
<td>IRB determinations re/ use for MOU for exempt research</td>
<td>Suggestions?</td>
</tr>
<tr>
<td>Opt outs by relying campus IRBS</td>
<td>“Segmenting” reviews so local IRB reviews only the portion of the study that occurs locally</td>
</tr>
<tr>
<td>Non-starters/withdrawals due to ancillary committee refusals, local context issues, local COI, etc.</td>
<td>Parallel MOUs for ancillary committees</td>
</tr>
<tr>
<td>Complying with HIPAA (protecting subject privacy)</td>
<td>Systemwide training of campus data stewards re MOU w/ regard to other UC campus waiver approval</td>
</tr>
<tr>
<td>Ongoing quality assurance and process improvement</td>
<td>Analysis of metric and process improvements &amp; comparison with baseline data: next in 6 months</td>
</tr>
</tbody>
</table>
For more information about the presented data, and the UC IRB Reliance Registry please contact:
Jeff.Hall@ucop.edu
Dragana.Nikolajevic@ucop.edu