UC Reliance Registry Instructions for UC Davis Investigators and Coordinators

To create a new reliance request, follow these steps in the order provided to ensure smooth processing and timely review.

Before beginning the process, ensure that all PIs and coordinators at all UC Campuses who intend to use the UC Reliance Registry have an active account with the Registry. If needed, ask collaborating investigators and/or coordinators to create and activate their account following the instructions for New User Registration at https://irbreliance.ucop.edu/site/about.

<table>
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<tr>
<th>Step</th>
<th>When UC Davis is the IRB of Record (Reviewing IRB)</th>
<th>When UC Davis is relying on another UC IRB (Relying IRB)</th>
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<tr>
<td>1</td>
<td>Create a request and sign</td>
<td>Log into the Registry to create a new collaborative study from “My Dashboard”. Add requested information. The research coordinator may enter information into the Registry, but may not sign the attestation on behalf of the investigator. The reliance request will not move forward until the PI signs.</td>
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<tr>
<td>2</td>
<td>Add local context and sign</td>
<td>Wait for collaborating (relying) PIs to add local context information to the Registry and to sign the reliance assurances before going to Step 3.</td>
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<tr>
<td>3</td>
<td>Submit an application with the reliance document to the IRB</td>
<td>Submit an application for review (or amendment) to the UC Davis IRB through IRBNet. The submission must include a copy of the UC Reliance Request. You may download a copy from the Registry by clicking the green “print” button on the main study page.</td>
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</table>
| 4    | Review and acceptance by the IRB of Record | UC Davis will review the submission with the Reliance Request. The UC Reliance Coordinator will inform all parties of the IRB determinations and update the Registry regarding whether or not UC Davis agrees to serve as the IRB of record. The UC Davis PI is responsible for ensuring all relying sites have the most currently approved documents. | After receiving approval from the Reviewing IRB, human research activities at UC Davis must wait for UC Davis IRB to accept the reliance. Submit to UC Davis IRB through IRBNet:  
• The UC Davis Initial Review Application;  
• Approval letter from the Reviewing IRB;  
• The approved protocol;  
• The approved subject facing document(s);  
• The Investigator Brochure, if applicable;  
• The Sponsor Fee Form;  
• Any applicable Ancillary Committee Approval; and  
• The UC Reliance document. A copy can be downloaded from the Registry by clicking the green “print” button on the main study page. Complete submission by clicking “Submit this Package”. |
| 5    | Acceptance by the Relying IRB | Human research activities may not begin at the relying site until the relying IRB accepts the reliance. Ensure that all relying sites wait for acceptance by the relying IRB before human research commences at the site. | UC Davis IRB will review submitted documents and determine whether to accept or decline the reliance. The UC Reliance Coordinator will update the Registry and send notification to the all parties. |

If the reliance is declined by either IRB, the UC Reliance Coordinator will contact you with further information.

Questions? UC Davis investigators, please contact the Reliance Team at HS-IRBreliance@ucdavis.edu. All other investigators should contact their designated IRB contact person listed at https://irbreliance.ucop.edu/site/irbs.

Version date: 2017-Aug-02
A New Reliance Request: UC Davis is the IRB of Record (Reviewing IRB)
V2017.08.01

Before you begin, ensure all PIs at all participating UC sites have an active account with the Reliance Registry. Otherwise, there will be technical glitches which will prevent the request from moving forward.

Step 1: Create a Request and Sign (UCD PI)
Go to https://irbreliance.ucop.edu/site/about and follow the instructions for Creating a New Study.

Step 2: Add Local Context and Sign (Relying PI)
Wait for the collaborating (relying) PI(s) to add local context information to the Registry and to sign the reliance assurances before going to Step 3.

Step 3: Submission to the IRB (UCD PI)
Submit an application for review (or amendment) to the UCD IRB via IRBNet. Ensure the submission includes:

a) The UC Reliance Document:
   a. Click the green “print” button on the top right of the main study page in the Reliance Registry and save a PDF copy of the document to your desktop.
   b. Upload the Reliance Document to IRBNet. When uploading to IRBNet, identify:
      i. IRBNet Document Type as “Other”
      ii. IRBNet Document Description as “UC Reliance Registry Request #XXXX”

b) UC Davis Initial Review Application: Ensure the application includes required information specific to the reliance and the relying site.
   a. Review Information
      i. Select No for whether UC Davis is relying on another IRB.
      ii. Select Yes for whether an external site is relying on UC Davis
      iii. Select Yes for whether the review is part of the UC Reliance (or MOU)
      iv. Enter the UC Reliance Registry Number
   b. Research Location Information
      i. Research Setting: Include information about the relying campus
      ii. Resources Available: Include resource information for the relying campus
   c. External Sites
      i. Select Yes for whether any external sites are being used
   d. External Site(s) Information
      i. Add the name of the relying campus and the contact information
   e. Multi-Site
      i. Select Yes for whether this is a multi-site study

Step 4: Review and Acceptance by the Reviewing IRB (UCD IRB)
UC Davis will review the submission with the Reliance Request. The UC Reliance Coordinator will inform all parties of the IRB determinations and update the Registry regarding whether UC Davis agrees to serve as the IRB of record.
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The PI is responsible for sending the most currently approved documents (approval letter, protocol, consent document, investigator brochure, scores, surveys, other subject facing materials, etc.) to relying sites.

Step 5: Acceptance by Relying IRB (Relying IRB)

Human research activities may not begin at the Relying site until the Relying IRB accepts the reliance. Ensure the relying sites wait for acceptance by their Relying IRB before human research commences at the site. When the Relying IRB accepts the reliance, a notification from the registry will be sent to the PI and listed coordinator(s).

If the proposed Relying IRB declines the reliance, submit an amendment to revise the study documents and the Reliance Registry. Contact the Reliance Team at HS-IRBreliance@ucdavis.edu for assistance and instructions for revisions.