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>
<thead>
<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>
</tr>
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<tr>
<td>1</td>
<td>Create a request and sign 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>
<td>Wait for notification from the Registry. The investigator or coordinator at the Reviewing campus must initiate the request.</td>
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<tr>
<td>2</td>
<td>Add local context and sign 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>
<td>Log into the Registry and search for the study using the reliance number. Provide information specific to which activities will be conducted at UC Davis in the fields provided. 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 UC Davis PI signs.</td>
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<tr>
<td>3</td>
<td>Submit an application with the reliance document to the IRB 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>
<td>While review is occurring at the Reviewing IRB, obtain applicable UC Davis Ancillary Committee approvals. See Ancillary Reviews for more information. After receiving approval from the Reviewing IRB, human research activities at UC Davis must wait for UC Davis IRB to accept the reliance.</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 Davis Reliance Team 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. | Submit to UC Davis IRB through IRBNet:  
• The UC Davis Initial Review Application;  
• Initial approval letter from the Reviewing IRB;  
• The approved protocol;  
• The approved subject facing document(s);  
• The Investigator Brochure, if applicable;  
• The Reliance Fee Form, if applicable;  
• 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 subject research commences at the site. | UC Davis IRB will review submitted documents and determine whether to accept or decline the reliance. The UC Davis Reliance Team will update the Registry and send notification to all parties. |

If the reliance is declined by either IRB, the UCD Reliance Team 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.
A New Reliance Request: UC Davis is Relying (Relying IRB)

**Step 1: Receive Reliance Invite**
The initial request is created by the PI/Coordinator at the reviewing campus. Wait for an email from the Registry (ORS-IRBRELIANCE-SA@ucop.edu) that invites you to the reliance.

**Step 2: Add Local Context and Sign**
Go to [https://irbreliance.ucop.edu/site/about](https://irbreliance.ucop.edu/site/about) and follow the instructions for Accepting to Rely.

Guidance for entering the study details:

- **Award Information**: Identify the type of funding that UC Davis will receive for the conduct of this project by checking the appropriate box(es).
- **Relying Sponsor(s)**: Identify the source(s) of funding that UC Davis will receive for the conduct of this project.
- **Recruit Subjects**: Select “Yes” if subjects will be directly recruited or you will access private and identifiable information. Otherwise select “No”. **If this option is left blank, there will be technical glitches later in the process that have potential to delay processing of the reliance request.**
  - **Additional Fields**: The following fields show up only when “Yes” is selected for “Recruit Subjects”. Provide information as noted below.
    - **Brief Description**: This can be left blank
    - **Potential Subjects**: Provide a description of the population under study
    - **Consent Process**: State whether the consent process will be conducted exactly as described in the approved protocol. If not, clarify how the consent process will be conducted, some examples are:
      - UCD HRP-090 and HRP-091 will be followed
      - A waiver of consent process is requested
- **Summary Scope**: Provide a description of the activities to be conducted at UC Davis. Do not provide a copy of the information from the Main Study page. If you will be following the approved lead site protocol as written, write "UCD research team will follow the lead site protocol as approved."
- **Key Personnel**: If there are other personnel who will assist with the reliance, list them here. When adding personnel, all fields are required. Skip this section if you do not have Key Personnel.
  - Please note that it is not possible to remove Key Personnel or make corrections to Key Personnel once they have been added.
- **Additional Questions**: Select “Yes” or “No”, as applicable. **Do not skip these questions.** The IRBs must know if there is a conflict of interest and if radiation is used for the research. The answers to these questions are directly related to the criteria for approval and whether to not the reviewing IRB must make additional determinations or require revisions to the documents submitted for review.
• **Conflict of Interest:** Do any personnel responsible for the design, conduct or reporting of the protocol have any 'Significant Financial Interests' (as defined in UC Davis PPM 230-05.II.G) RELATED to the work to be conducted under the proposed project, as defined below?

  **SFI:** Significant financial interest (per PPM 230-05 II.1) - anything of significant monetary value, including but not limited to salary or other payments for services; equity interests (e.g. stocks, stock options or other ownership interests); intellectual property rights (e.g., patents, copyrights and royalties from such rights); or holding a position as an office, director, agent, or employee of a business entity. "Significant financial interest" includes such interests held by a Principal Investigator or other Investigators and by their spouses, domestic partners and/or dependent children.

  **Related:** (per PPM 230-05, Exhibit A III.B) When completing the Supplemental Form for a project sponsored by the federal government or other agency for which Form 800 is required, Principal Investigator and other Investigators shall consider all significant financial interests to determine if any are related to the (sponsored) project.

• **Uses Radiation:** Does your study involve radiation?

• **Assurances:**
  - **For the UCD PI:** Review the bulleted items. If you agree to these conditions, click “Sign and Finish”. Your electronic signature will be recorded when you click the button. The reliance is updated.
  - **For the Research Coordinator:** If you are designated as a Research Coordinator in the registry, click “Save”. While a Coordinator can edit information in the Registry, he/she may not electronically sign the reliance. The reliance request will not move forward until the PI electronically signs. Please instruct your PI to log into the registry to confirm information and electronically sign the assurances through the registry.

**Step 3/4: IRB Submission**

**A. Ancillary Committees:** While the project is under review with the Reviewing IRB, begin to seek and obtain local ancillary committee approval/determinations. Information about ancillary committees is available at: [https://research.ucdavis.edu/policiescompliance/irb-admin/researchers/irb-submissions/ancillary-revs/](https://research.ucdavis.edu/policiescompliance/irb-admin/researchers/irb-submissions/ancillary-revs/)

**B. Wait:** Wait for Local Ancillary Reviews and the Reviewing IRB to update the UC Reliance Registry before submitting your documents to UC Davis IRB.

If the Reviewing IRB declines the reliance, the reliance request process stops. The project must be submitted to UC Davis IRB for review or determination following the normal submission process.

The IRB may decline the reliance for several reasons, including but not limited to:

- The project does not meet the federal definition of Human Subjects Research;
- The site is not engaged in the Human Subjects Research.
A New Reliance Request: UC Davis is Relying (Relying IRB)

The Reviewing IRB will note the reasons for declining the reliance within the Registry. If you would like an explanation of the notation, contact the UC Reliance Team by email at HS-IRBreliance@ucdavis.edu for clarification.

C. Print a Copy of the Reliance Request: If the Reviewing IRB agrees to the reliance, generate a copy of the Reliance Request by clicking on the green “Print” button.

Save a copy of the PDF document to your desktop. Label the file as UC Reliance Request #[insert reliance number]. For the above example, the filename will be “UC Reliance Request #1249”. This copy will need to be included in the submission package to UC Davis IRB via IRBNet.

D. Submission to UC Davis IRB for Reliance: Create a New Project through IRBNet. Submit the following documents:

- **UC Davis Initial Review Application**: This form is accessed through IRBNet. To access the form, follow the steps below.
  1. Go to the “Designer Page”. Click on “Start a Wizard”.
  2. Select “UC Davis – Initial Review Application” from the dropdown menu.
  3. You will be prompted to create a new wizard or clone one. Select “Create a New Wizard from Scratch” and click “Continue”.
  4. You are now in the Initial Review Application. Complete all required fields.
     - **Review Information**:
       - Select "Yes" for whether UC Davis is ceding review to another IRB
       - Select "No" for whether UC Davis IRB is reviewing this research for external sites
  5. When you get to the Form Complete Page, click “Save and Exit”. The document will now show up in the Designer page. You can save and exit at any point in the wizard. To continue, click the pencil icon to the right of the document on the Designer page.

- **Approval Letter from the Reviewing IRB**: This should be provided to you by the PI at the Reviewing Site and is available through the Registry.

- **Approved Protocol**: This should be provided to you by the PI at the Reviewing Site.

- **Approved Subject-Facing Materials (consent, recruitment, etc.)**: This should be provided to you by the PI at the Reviewing Site.
A New Reliance Request: UC Davis is Relying (Relying IRB)

- **Investigator Brochure (if applicable):** This should be provided to you by the PI at the Reviewing Site or the sponsor. If you obtain it from the sponsor, ensure the version you have is the most recently reviewed and approved version.

- **Any applicable ancillary committee approvals/determinations:** Copies will be provided to you by the ancillary committee. For Document Type and Document Description, use the following:

<table>
<thead>
<tr>
<th>Document</th>
<th>Document Type</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Institutional Biosafety Committee</td>
<td>Other</td>
<td>IBC</td>
</tr>
<tr>
<td>Conflict of Interest Committee</td>
<td>Other</td>
<td>COIC</td>
</tr>
<tr>
<td>Cancer Center Scientific Review Committee</td>
<td>Other</td>
<td>CCSRC</td>
</tr>
<tr>
<td>Radiation Use Committee</td>
<td>Other</td>
<td>RUC</td>
</tr>
<tr>
<td>Stem Cell Oversight Committee</td>
<td>Other</td>
<td>SCRO</td>
</tr>
<tr>
<td>UCDMC Pathology</td>
<td>Other</td>
<td>UCDMC Pathology</td>
</tr>
<tr>
<td>Information Technology Evaluation for Research</td>
<td>Other</td>
<td>IT Eval</td>
</tr>
</tbody>
</table>

- **UC Reliance Request:** The document must show that all relying PIs have signed and that the Reviewing IRB has accepted the reliance. Select “Other” for Document Type and use “UC Reliance Request #XXXX” for Document Description.

- **Sponsor Fee Form:** If the study meets the criteria for billing, submit this form ([http://research.ucdavis.edu/policiescompliance/irb-admin/researchers/irb-forms/](http://research.ucdavis.edu/policiescompliance/irb-admin/researchers/irb-forms/)). The criteria for billing is located at: [https://research.ucdavis.edu/policiescompliance/irb-admin/researchers/irb-submissions/fees/](https://research.ucdavis.edu/policiescompliance/irb-admin/researchers/irb-submissions/fees/)

### Step 5: Acceptance by Relying IRB

**A. Wait:** Wait for final determination by the UC Davis IRB Administration Office. The Reliance Team will conduct an administrative review of the documents submitted to ensure the research plan and consent process would not violate UC Davis Policies and update the Registry and IRBNet accordingly.

You will receive notifications from the Registry and IRBNet.

**B. Begin Human Subject Research Activities or Revise the Submission:** If the reliance is accepted by the UC Davis IRB, Human Subject Research activities may commence at UC Davis.

As with the Reviewing IRB, UC Davis IRB may opt to decline the reliance. The Reliance Team will provide guidance regarding your next steps.