

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>.

	When UC Davis is the IRB of Record (Reviewing IRB)	When UC Davis is relying on another UC IRB (Relying IRB)
1 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.	Wait for notification from the Registry. The investigator or coordinator at the Reviewing campus must initiate the request.
2 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.	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.
3 Submit an application with the reliance document to the IRB	Submit a n application for review (or a 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.	While review is occurring at the Reviewing IRB, obtain applicable UC Davis Ancillary Committee approvals. See http://tinyurl.com/AncillaryReviews 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.
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.	Submit to UC Davis IRB through IRBNet: <ul style="list-style-type: none"> • The UC Davis Initial Review Application; • HRP-226 Administrative Approval • 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. <p>Complete submission by clicking "Submit this Package".</p>
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>.

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Step 1: Create a Request and Sign

The initial request is created by the PI/Coordinator at the review campus. Wait for an email from the Registry (ORGS-IRBRELIANCE-SA@ucop.edu) that invites you the reliance.

Step 2: Add Local Context and Sign

Go to <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 shows 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.
- **Key Personnel:** If there are other personnel, 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 or not the reviewing IRB must make additional determinations or require revisions to the documents submitted for review.
- **Conflict of Interest:** Do you or any personnel involved in the design, conduct, or reporting of the protocol have a Related Financial Interest, as defined below?
 - “Related Financial Interest” means any of the following interests in the sponsor, product(s) or service(s) being tested, or competitor of the sponsor held by the

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individual or the individual's immediate family that was received within the last 12 months or that you expect to receive in the next 12 months:

- Ownership interest of any value including, but not limited to stocks and options, exclusive of interests in publicly-traded, diversified mutual funds.
 - Compensation of any amount including, but not limited to honoraria, consultant fees, royalties, or other income.
 - Proprietary interest of any value including, but not limited to patents, trademarks, copyrights, and licensing agreements.
 - Board or executive relationship, regardless of compensation.
 - Reimbursed or sponsored travel by an entity other than a federal, state, or local government agency, higher education institution or affiliated research institute, academic teaching hospital, or medical center.
- "Immediate Family" means spouse, domestic partner, children, and dependents.
 - **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:

<http://research.ucdavis.edu/policiescompliance/irb-admin/researchers/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:

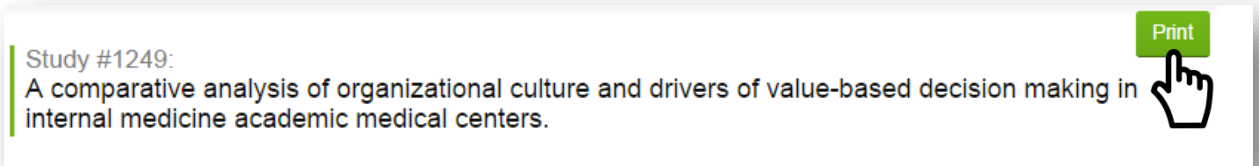
- The project does not meet the federal definition of Human Subjects Research;
- The site is not engaged in the Human Subjects Research.

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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 Coordinator 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:

- **HRP-226 Administrative Approval:** This form is available at <http://research.ucdavis.edu/policiescompliance/irb-admin/researchers/irb-forms/>. You may obtain wet ink signatures or electronic signature via IRBNet. If electronic signature is used, type in “electronic signature” where the signature would have been placed on the form.
- **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. From the General Instructions Page, click “Next”.
 5. You are now in the Initial Review Application. Complete required fields. This application will be a shorter version of the one required for a standard submission.
 - **Principal Investigator Information:** Provide answers to all required fields.
 - **Co-Principal Investigator Information:** If “Yes” is selected for Co-PI, you will be prompted to add his/her information. Complete all required fields and click “Next”.
 - **Primary Contact:** If the PI is the Primary Contact, select “Yes”. If another individual should be included in communication from the IRB sent to the PI, select “No”. Please be aware that if “No” is selected, the individual designated as the Primary Contact must also have full access to the project in IRBNet.

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- **Review Information:** Complete all required fields and click “Next”.
 - Select Yes for whether UC Davis is relying on another IRB
 - Select No for whether an external site is relying on UC Davis IRB
 - Select Yes for whether the review is part of the UC Reliance
 - Provide the UC Reliance Registry Number
 - **Other Project Information:** Complete all required fields and click “Next”.
6. When you get to the Form Complete Page, click “Save and Exit”. The document will now show up in the Designer Page within a blue box.
- **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.
 - **Any applicable ancillary committee approvals/determinations:** Copies will be provided to you by the Committee. For Document Type and Document Description, use the following:

Document	Document Type	Description
Institutional Biosafety Committee	Other	IBC
Conflict of Interest Committee	Other	COIC
Cancer Center Scientific Review Committee	Other	CCSRC
Radiation Use Committee	Other	RUC
Stem Cell Oversight Committee	Other	SCRO
UCDMC Pathology	Other	UCDMC Pathology
Information Technology Evaluation for Research	Other	IT Eval

- **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/>). The criteria for billing is located at: <http://research.ucdavis.edu/policiescompliance/irb-admin/researchers/fees/>

Step 5: Acceptance by Relying IRB

A. wait: Wait for final determination by the UC Davis IRB Administration Office. Designated IRB staff 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 Research Activities or Revise the Submission: If the reliance is accepted by the UC Davis IRB, Human Research activities may commence at UC Davis.

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