HOW TO WORK WITH THE IRB

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Learn About:

- The IRB structure, submission and review process
- IRB Offered Training
- IRBNet
- Navigate the IRB Website (Investigator’s Manual, SOPs, Forms, Checklists)
- Research Personnel List
- Subject Recruitment
- Typical Issues with Investigator Initiated Research
- Reportable New Information
- Conflict of Interest
- Reliance
UC Davis IRB Structure
About the Committees, Submission Process, and Timelines
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<td>Intake Analysts</td>
<td>Screen and route applications</td>
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<td>Committee Analysts</td>
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<td>Non-committee Reviewers</td>
<td>Conduct Expedited Review</td>
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<td>Training &amp; Education Analyst</td>
<td>Manages Education Program</td>
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<td>AAHRPP Analysts</td>
<td>Manage Accreditation Program</td>
</tr>
<tr>
<td>Director</td>
<td>Oversees and Manages all IRB functions</td>
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</table>
Full Committee Review: “At the Top”

**Convened Meeting:** Greater than minimal risk research and submissions not exempt or subject to expedited review

**Expedited:** Various categories of non-exempt, minimal risk research (HRP-313)

**Exempt:** Various categories of minimal risk research (HRP-312)

**Not Human Subjects Research:** Activities that do not meet the definition of “Human Research” are not subject to IRB oversight. (HRP-310)
<table>
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<th>Committee A</th>
<th>Biomedical</th>
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Hold On.

Some studies are not ready for review in Full Committee...

Committee Analysts can move a study to a future committee meeting agenda if it is not ripe for review or if it “misses” the boat.

Don’t miss the boat...

Common Reasons Why Initial Review of IRB Protocols May Be Delayed to Later Agendas:

- The submission is missing required ancillary approvals (RUC, CCSRC, SCRO, etc.)
- The protocol or HRP-503 is missing information needed for the IRB to make required determinations (e.g. subject recruitment, data monitoring for compliance and safety and protections for participant privacy and confidentiality)
- The consent form is missing, only the sponsor model consent is supplied, or the supplied consent does not contain information consistent with the UC Davis consent template.
- For studies involving devices, the investigator or sponsor does not provide sufficient information for an IDE Exemption, Non-Significant Risk or Significant Risk Determination and there is no evidence that an IDE has been obtained.
- A conflict of interest (COI) has been identified but no information about the COI is provided. The IRB must have sufficient information about the COI to make required determinations. This information is usually given to the IRB by providing the Forms 700U and 800.
- Sections of the electronic Initial Review Application Form are not completed or marked Not Applicable (N/A) when the section is applicable.
- For studies involving an investigational drug or biologic, the investigator brochure has not been provided; and for studies involving an approved drug, the investigational brochure or package insert is not provided.
# IRB Determinations

<table>
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<th>Determination</th>
<th>Meaning</th>
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<tbody>
<tr>
<td><strong>Approval</strong></td>
<td>Ethical criteria are satisfied for the conduct of research. Research can begin when all other institutional approvals have been obtained.</td>
</tr>
<tr>
<td><strong>Approval with Administrative Comment</strong></td>
<td>Ethical criteria are satisfied for the conduct of research. Research can begin when all other institutional approvals have been obtained. The IRB provides an administrative comment about some aspect of the project or its conduct outside of criteria for approval.</td>
</tr>
<tr>
<td><strong>Approval with Modifications Required</strong></td>
<td>The IRB requires modifications in order to approve the research. Research cannot commence until a final approval is received.</td>
</tr>
<tr>
<td><strong>Deferral</strong></td>
<td>The IRB cannot approve the research as submitted and describes reasons or modifications that might make the research approvable; the IRB requests additional information from the researcher.</td>
</tr>
<tr>
<td><strong>Disapproval</strong></td>
<td>The IRB cannot approve the research as submitted and cannot describe modifications that might make the research approvable.</td>
</tr>
<tr>
<td><strong>Exempt</strong></td>
<td>Certain categories of Human Research may be exempt from regulation but require IRB administrative review; the institution, not the researcher, determines exemption.</td>
</tr>
<tr>
<td><strong>UC Davis is Not Engaged</strong></td>
<td>UC Davis is not engaged such that a particular non-exempt human subjects research project or activity is not subject to IRB oversight.</td>
</tr>
<tr>
<td><strong>Not Human Subjects Research</strong></td>
<td>Activities that do not meet the Institutional definition of “Human Research” are not subject to IRB oversight.</td>
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# Submission Review Cycle in Days

<table>
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<tr>
<th>Day 1-3</th>
<th>Day 4</th>
<th>Day 11</th>
<th>Day 12</th>
<th>Day 13-14</th>
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<tbody>
<tr>
<td>Screening Period Analyst Selection &amp; Admin Review</td>
<td>Level of Review is Determined Assignments Full Board/Expedited</td>
<td>Picked up by a Reviewer</td>
<td>Review Period Concerns are identified and sent to Research Team</td>
<td>Review Period and Researcher Responses</td>
</tr>
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<table>
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<tr>
<th>Day 15</th>
<th>Day 16-20</th>
</tr>
</thead>
<tbody>
<tr>
<td>Researcher Responses - Green Lock (Revisions Complete)</td>
<td>Review Complete Determination Letter Published</td>
</tr>
</tbody>
</table>

Review periods can vary based on number of current submissions, staffing needs, full committee schedules.
IRB Offered Training
IRB Training and Education Requirements

Who is required to have training?

- Principal Investigators and Co-Investigators
- Research staff listed on the research personnel list
- Individuals who obtain informed consent from prospective participants in research
- Individuals named as a contact person in the informed consent and recruitment materials for research
- Faculty Advisors/Faculty Sponsors
What are the education requirements at UC Davis?

Investigators and staff involved in research that poses no more than minimal risk to subjects:

- **CITI Basic Human Research Protections Training** (https://about.citiprogram.org/en/homepage/)

  OR

- **NIH Program Protecting Human Research Participants course (PHRP)** (https://phrp.nihtraining.com/users/login.php)

Investigators and staff involved in research that poses more than minimal risk to subjects:

- **CITI Basic Human Research Protections Training**.
  - Biomedical Research Course
  - Social and Behavioral Research Course
Check Training:
http://research.ucdavis.edu/policiescompliance/irb-admin/outreach/citi/

Required CITI Education

Verify CITI Training Status (PDF)

Requirements

Investigators, staff, and faculty advisors are required to complete human subject research protection training prior to engaging in research activities. Training should be completed before submitting an application for IRB review when initiating a new study, or prior to engaging in research activities, including access and analysis of private identifiable data, when joining an active research project. It is the responsibility of the Principal Investigator to ensure all research staff have completed all necessary training before engaging in research activities. The following personnel must complete training:
About the GCP Training:

Investigators and staff involved in a clinical investigation or an NIH-funded clinical trial are required to take GCP training.

- **CITI GCP** training is required if the research is a *clinical investigation* under FDA jurisdiction. You must complete:
  - CITI GCP for Clinical Trials with Investigational Drugs and Biologics (ICH Focus); or
  - CITI GCP for Clinical Trials with Investigational Medical Devices.

- **NIH GCP** course can be completed for NIH-funded clinical trials that are not “clinical investigations” subject to FDA. Investigators have the option of taking the CITI GCP or the NIH GCP if the trial is not a clinical investigation. If you are involved in the conduct of an NIH funded clinical trial, you are required to be trained in GCP. If you fail to maintain the training, you may lose funding.

NOTE: The NIH GCP course is available in LMS
What is CIRTification?

CIRTification (http://www.ccts.uic.edu/content/downloads-videos) human research protection training can be completed to satisfy the training requirement when the following conditions are satisfied:

- The researchers are not affiliated with a domestic institution, including UC Davis;
- The research involves only minimal risk;
- The training is conducted by a facilitator experienced in human research protections who has completed the basic CITI course for investigators and has current CITI certification or is otherwise approved by IRB;
- The facilitator and research personnel receiving training attend the entire training session and sign the CIRTification Completion Log;
- The facilitator signs the attestation on the CIRTification Completion Log; and
- The PI maintains a copy of the CIRTification Completion Log.
How long is the training certificate valid?

Training is valid for a three-year period. Investigators and staff must renew their training certification before it expires by taking either a refresher course or retaking the full course. Members of the research team who have not completed human subject research protection training may not take part in aspects of the research that involve human subjects or their private identifiable data.
Other Types of Training:

• **New Submitter Training**
  check the IRB website for dates
  (http://research.ucdavis.edu/policiescompliance/irb-admin/outreach/upcoming-training/)

• **Department/group requested training**

• **Topic focused training required by the IRB committees**
IRBNet
IRBNet – Where Do I Start?

https://www.irbnet.org

- Linking CITI Training
- Sharing Studies
- Forms and Instructions
- Communication: Project Mail
- Roles: PI vs CRC
- Approved Documents
Navigate the IRB Website
(Investigator’s Manual, SOPs, Forms, Checklists)
IRB Administration Website
http://research.ucdavis.edu/policiescompliance/irb-admin/

IRB Administration
The Institutional Review Board (IRB) Administration is committed to following the federal regulations to protect the rights and welfare of human subjects involved in research conducted under the auspices of the University of California, Davis.

Quick Links for Researchers
Does My Project Need IRB Review
How to Submit to the IRB
Go to IRBNet.org
Forms and Templates
Policies, Procedures and Regulations
Education, Training, CITI
Multisite Reliance Agreements
MORE...

Quick Links for Participants
Things You Should Know
Your Rights as a Research Subject
Research at the UC Davis Health System
Let’s Navigate the Website:

- **Investigator’s Manual – HRP-103**
  

- **SOPs**
  

- **Forms, Checklists and Worksheets**
  
Research Personnel List
Research Personnel List

• When to submit changes to the IRB
  - Change in PI, co-PI or Faculty Advisor
  - At continuing review for all other research personnel
  - If an outside investigator joins the study and they don’t have an IRB (with an Individual Investigator Agreement)

• What forms to use
  - Modification Form HRP-213
  - Administrative Approval (HRP-226) – **PI Change**
  - All documents that have the PI’s name (i.e. protocol, consent, flyer) – **PI Change**
  - (HRP-215 if no Initial Review Application)
  - IRBNet – Project Overview **Edit** – **PI Change**
  - Initial Review Application
Recruitment of Subjects
The ethical identification, initial contact, screening and recruitment of potential human subjects form the foundation of the informed consent process.
Ethical Concerns:

- **Equitable selection of participants**: equitable and appropriate for the study

- **Respect for privacy**: Respect an individual’s reasonable expectations for privacy.

- **Voluntariness**: The study is introduced in a way that allows subjects ample time to consider participation, with no undue pressure
Ethical Concerns:

- **Unbiased presentation:** information is accurate, balanced, and free of any misleading emphases that make the study excessively attractive.

- **The “Therapeutic Misconception:”** the recruitment strategy minimizes the potential for misconception.
Ethical Concerns:

- **Students** may feel obliged to participate in a researcher’s study if that researcher is also their instructor.

- **Patients** may prefer that someone involved in their care contact them about research, but they may find it hard to say “no” to a care provider.

- **Clinicians** may find their clinical judgment in conflict with a desire to enroll patients in their studies.
Acceptable Methods of Recruitment


- Advertisements, flyers, information sheets, notices or media are used to recruit (see worksheet HRP- 315) – the IRB must review and approve the text when it’s study specific.

- Direct recruitment of potential study - considerable care taken so that the person contacted does not feel pressured to participate
  - in person
  - on the phone
  - on the internet

- Medical records review: Study investigators request a Waiver of Consent/HIPAA Authorization for recruitment
• **Cold Calling** - Contact the IRB to obtain template scripts for this type of recruitment

• **Do not Call List** – Contact Kate Marusina’s office to access this list
Unacceptable Recruitment Methods:

- **Direct Recruitment by Study Sponsors**: Sponsors may not directly contact prospective subjects based on information from UCD researchers. However, UCD does permit researchers to be part of a national or local multi-site study which may include a national or local advertising campaign by the study sponsor to recruit.

- **Use of Incentives and Referral Fees**: Per-subject incentive payments or referral fees are not permitted. Such payments may encourage recruiters to put inappropriate pressure on prospective subjects and are illegal in California. Lump-sum payments not tied to the number of subjects referred or enrolled may be allowed in particular studies. Investigators should include all information about incentives and/or referral fees in the recruitment section of the IRBNet submission.
Typical Issues with Investigator Initiated Research
Typical issues with investigator initiated research

Make sure your study is complete before you click SUBMIT

Inconsistent information among study documents

Appropriate Safeguards for Inclusion of Vulnerable Populations
• Children, Cognitively Impaired Adults, Students, Etc.

Consent Forms
• Elements of Consent 21CFR 50.25
• Formatting, Font, Lay Language, Spelling Errors, Grammatical Errors
• Risks
• Template Language

Protocol
• Protocol does not define the research taking place
• Adequate Monitoring

Waivers
• Justification for Waivers are not provided. Being minimal risk is not a justification
• You must address the “impracticability” of obtaining the consent.

The CTSC offers services for Investigator Initiated Research. Please contact them for more information.
Reportable New Information
REPORTABLE NEW INFORMATION

Reference Materials

- HRP-214: Reportable New Information
- Serious Adverse Event Reporting Flowchart
- HRP-212: Continuing Review Progress Report
INVESTIGATOR BROCHURES

When to Submit

- You’ve received a new investigator brochure for the investigational drug used in your study today. The sponsor indicates the risk/benefit ratio has not changed with the new version, and they will not be updating the consent form.

Should this be reported to the IRB?

Why?
SERIOUS ADVERSE EVENT (SAE) REPORTING FLOW CHART – What to report to the IRB

You’ve received a serious adverse event report today. What do you do?

Review the report to determine whether the event is considered SERIOUS

**DEFINITION:** An event is considered “serious” if it meets any of the following criteria:
- Results in death
- Is life-threatening (places the subject at immediate risk of death from the event)
- Results in inpatient hospitalization or prolongation of existing hospitalization
- Results in congenital anomaly/birth defect
- Results in persistent or significant disability/incapacity
- May jeopardize the subject’s health, and may require medical, counseling, or surgical intervention to prevent any of the above
- Results in criminal or civil liability, or damaging to the subject’s financial standing, employability, or reputation.

- **NO** Do not submit to the IRB
- **YES**

Review the report to determine whether the event is considered UNEXPECTED

**DEFINITION:** An event is considered “unexpected” when it’s specificity or severity are inconsistent with risk information previously reviewed and approved by the IRB in terms of nature, severity, frequency, and characteristics of the study population. These approved documents include:
- Sponsor or local protocol
- Consent Form
- Investigator Brochure
- Package Insert
- Device Information

- **NO** Do not submit to the IRB
- **YES**

Review the report to determine whether the event is considered PROBABLY RELATED

**DEFINITION:** An event is considered “probably related” to the research procedures if, in the opinion of the investigator and/or the sponsor (the sponsor’s assessment supersedes the investigator’s), the research procedures more likely than not (greater than 50% likely), caused the harm. Terms not considered probably related:
- Cannot be ruled out
- Possibly related
- May be related
- Casual relationship

- **NO** Do not submit to the IRB
- **YES** Submit to the IRB
SERIOUS ADVERSE EVENTS

Flowchart – When to Submit SAE Reports to the IRB

- You’ve received a MedWatch report of an event that occurred at another site. A subject experienced a heart attack and was admitted to the hospital. Study drug was stopped, and the subject later died. Heart attack is not a listed side effect in the investigator brochure. The site PI felt the event was related to study participation. The sponsor did not agree, but determined the casualty could not be ruled out.

Should this be reported to the IRB?

Why?
The investigator assessed the event of sinus thrombosis as grade 3 (severe) in intensity, a serious adverse event (SAE) due to being a medically significant event, related to [redacted], [redacted], and [redacted], and not related to leukapheresis.

Sponsor independently assesses the event of Grade 3 Sinus Thrombosis as NOT related to the administration of [redacted]. Sinus thrombosis is not an expected event with the use of [redacted].

A review of the database of all subjects treated with [redacted] to date revealed no cases of suspected or documented central sinus venous thrombosis (CVT).
SERIOUS ADVERSE EVENTS

Flowchart – When to Submit SAE Reports to the IRB

• You’ve received a follow-up report from the sponsor related to an event that was submitted to the IRB, and acknowledged. The initial report indicated the event was serious, unexpected, and possibly related to study treatment, as determined by the sponsor. The follow-up report includes additional lab results that were not previously available, but does not change the initial determination by the sponsor.

Should this be reported to the IRB?

Why?
SERIOUS ADVERSE EVENTS

Flowchart – When to Submit SAE Reports to the IRB

- You’ve received a notification from your PI that a subject on their study died today.

What do you do?
UNANTICIPATED ADVERSE DEVICE EFFECT

Device Malfunction

- You received a report from the sponsor of your study that a subject at another site experienced an adverse event. The report indicated that the device housing was cracked and required explantation. The damage was noted during the two month assessment. Cracked housing is not listed as an expected event in the investigational plan.

Should this be reported to the IRB?

Why?
NEW SAFETY OR RISK INFORMATION

Protocol Clarification Letter

- You received a letter from the sponsor clarifying one of the exclusion criteria on a study of an investigational drug. The approved protocol states female patients are not eligible if they do not agree to using a highly effective form of contraception. The effects of the study drug on a human fetus during pregnancy are unknown, though animal studies have shown negative side effects. Patient options are an IUD, an implanted progestin secreting device, or abstinence. Subjects who have had a hysterectomy do not need to be on a highly effective form of birth control. The letter indicates that female patients who have had a hysterectomy do not need to using a highly effective form of birth control, and are eligible to participate. The sponsor will be providing sites with an updated protocol that includes this information within 60 days.

When should this be reported to the IRB?

Why?
AUDIT REPORTS

When to Report

• The sponsor monitor conducted an audit of your site. They did not identify any deficiencies, and provided a letter congratulating you on a successful site visit.

Should this be reported to the IRB?

Why?
Corrective and Preventive Action Plans (CAPA)

- What was the error?
- Who was responsible (only use job titles)?
- How and why did it occur (what was the root cause)?
- Develop corrective actions.
- Develop preventive actions.
- Document training of all stakeholders.
- Evaluate the effect of the actions.
Breach of Confidentiality

- You (a coordinator) are conducting an internal review of your research files, and realize that while the signed consent form is present, the HIPAA Authorization is missing for Subject 0012. A week after the subject was enrolled, your colleague (another coordinator) went into the medical record and collected several data points, and included the information in a spreadsheet that will be used for data analysis when enrollment closes next year.

What do you do?

What is the CAPA?
NON-COMPLIANCE

Out of Window

• You are meeting with Subject 0043 in 20 minutes to complete visit 4. As you’re going through the research binder that includes all of their information, signed forms, and test results, you notice the lipid panel results that are usually required during visit 3 are missing.

What do you do?

What is the CAPA?
NON-COMPLIANCE

Regulations

- You received a new investigator brochure for the investigational drug used in your study two months ago. The sponsor indicated the risk/benefit ratio has not changed with the new version and they will not be updating the consent form, so you decided to wait until you received the next protocol amendment to submit to the IRB. You received an updated protocol today, and submitted a modification that also included the revised IB from two months ago. The IRB contacted you and stated they identified a new risk in the brochure: abnormal heart rhythm. This risk is not described in the currently approved consent form, so the revised IB will need to be reviewed by the full board. The IRB also requested an RNI to address the late submission of the IB. You note that you enrolled three subjects since the IB was received. It looks like these subjects did not sign a consent document that is compliant with the requirement for a description of all foreseeable risks.

What is the CAPA?
NON-COMPLIANCE

Over Enrollment

- Research Compliance and Integrity has completed an audit of your investigator-initiated study, and identified deficiencies in the enrollment numbers. The enrollment numbers were not calculated correctly throughout the year, and the UC Davis investigator over-enrolled by 2 subjects.

What do you do?

What is your CAPA?
NON-COMPLIANCE

Study Expiration (Late Submission)

- You just realized one of your studies expires in two weeks.

  What do you do?

  What is your CAPA?
SUBJECT COMPLAINTS

What do you do?

You received a call from a potential subject because he is unable to receive a copy of an assessment that will be used in one of your studies to see if it is able to identify whether an individual has early Alzheimer’s Disease (AD). The subject believes the PI of this study promised him he would receive a copy of the assessment results, because the UCD investigator stated the subject’s neurologist would probably not ask him to repeat the assessment exam. The consent form and protocol both indicate subjects will not be given a copy of this assessment. The rationale for not providing a copy of the assessment results is that the assessment procedure experimental, and is not currently used as a standard of care method to diagnose early AD. When the potential subject noted the language in the consent form, he emailed the investigator prior to his first clinic visit, requesting clarification as to whether he would receive a copy of the assessment results. He stated that he is a physician and wants a copy of the assessment to show his neurologist during his next visit. The investigator replied that he would not receive a copy of the results. Now the potential subject is calling back to complain. The UCD PI is out of the office for the next two days.

What do you do?
“OTHER” INFORMATION

**Catch-All**

- Sponsor requires submission of a letter or report
- Status of the study changes
- Contact the IRB with questions about whether something needs to be submitted within the required time frames
COMPLETING THE RNI FORM

HRP-214: Reportable New Information

• Make sure you submit within the required time frames:
  • 5 business days for safety related events/information
  • 10 business days for all other events/information

• Ensure the form is complete and accurate:
  • Date you became aware of the information
  • Total number of subjects enrolled
  • If subjects are receiving interventions/interactions
  • If the study is open to enrollment
  • Whether the event/information will result in a change to the documents
    (protocol, consent form, advertisements, surveys, etc.)
COMPLETING THE RNI FORM

HRP-214: Reportable New Information

- For SAEs, include the following in the “Description of Information” section:
  - Did the event occur at UCD or another site?
  - Indicate whether the event was serious, unexpected, and probably related (if not, indicate why the report is being submitted)

- For non-compliance/deviations, be sure to include the corrective and preventive action plan (CAPA)
RNI DETERMINATIONS

Levels of Review and Determinations

**Expedited**
(Non-Committee Review)

- Acknowledged (none of the above)
- Non-Compliance

**Full Board**

- Acknowledged (none of the above)
- Non-Compliance
- Serious and/or Continuing Non-Compliance
- Suspension or Termination
- Unanticipated Problem involving Risks to Subjects or Others
Subject Does Not Meet Inclusion Criteria

Your PI informs you that they have a potential subject they want to enroll in their study. You pull up the protocol and review the inclusion criteria with the PI, and the patient does not meet the platelet requirement, which states the patient must have normal organ and marrow function as defined by platelets greater than or equal to 100,000/mcL. The patient has a platelet count of 99,000/mcL. The PI contacts the sponsor, and the sponsor approves the enrollment of the subject.

What do you do?
Conflict of Interest
Investigators and research staff must report RFIs to the IRB at initial review and within 30 days of acquiring a new RFI or receipt of additional unreported income from the same entity. A complete description of the RFI must be provided. The description must include:

- The nature of the RFI;
- The relationship of the RFI to the study
- The amount of income (including travel expenses) received, if any;
- A description of the services performed, if any;
- The value of any equity interest in the sponsor and sponsor competitor;
- The position title, if the RFI involves employment;

Investigators may satisfy this requirement by uploading a narrative description of the RFI or submitting the COIC Forms 700-U, 800 and the Supplemental Form.

If additional, related income is expected before the study expires, Investigators may report the amount of the expected income in the description to avoid having to submit additional modifications when the additional income is received. However, if the income exceeds the amount included in the report, investigators must submit a modification and report the additional income.

http://research.ucdavis.edu/policiescompliance/irb-admin/researchers/conflicts-of-interest/
Question:
I already reported to the Conflict of Interest Committee (COIC) do I still need to report to the IRB?

Answer: YES! You always need to report to the IRB

The IRB is charged with oversight of COIs in human subjects research as part of its mandate to protect the rights and welfare of human subjects and the integrity of the research data.

Oversight of conflicts promotes transparency with research subjects (typically through disclosure in consent documents); supports the principle of equipoise among investigators and staff; avoids bias in subject recruitment and contributes to good study design.
Reliance: Single or Central IRB Review
Single or Central IRB (sIRB/cIRB) Review

What is a reliance?

- An agreement for one IRB to serve as the IRB of record for another participating site
  - Single IRB (sIRB)
  - Central IRB (cIRB)

- UC Davis may be the IRB of Record or rely on another IRB through an agreement
sIRB / cIRB

**IRB Authorization Agreement**

- Executed between IRBs
- May be for a specific study, a group of studies, all studies, or other on a case-by-case basis
- UC Davis IRB Reliance Team facilitates the execution of the agreements
sIRB / cIRB

Eligibility

- The minimum criteria:
  - human subjects research
  - Non-exempt (needs expedited or full board review)
  - UC Davis is engaged in the human subjects research

- Additional factors:
  - IRB expertise
  - Terms of the agreement
  - Local requirements/policies
sIRB / cIRB

Types

- MOU / Master Agreement
- IAA
- IIA
sIRB / cIRB

UC MOU and the Reliance Registry

- MOU allows reliance on a case-by-case basis
- UC Campuses and Lawrence Livermore National Lab
- Reliance Registry: Online tool to request, approve, and document reliance.

https://irbreliance.ucop.edu
sIRB / cIRB

UC Davis is Relying (non-UC Reliance Registry)

- Submit via IRBNet a Request to rely Cover Sheet with application documentation, such as:
  - HRP-226 Administrative Approvals
  - Protocol
  - Subject-facing materials
  - Ancillary approvals
  - IRB Approval
  - Other documents as requested
sIRB / cIRB

**UC Davis is the sIRB / cIRB**

- Consult the IRB early, such as during the grant writing process
  - Letter of IRB support
  - Budget for IRB Liaison and IRB fees
  - NIH: Plan for sIRB
- Consult the IRB prior submission to the IRB
  - Submission process
  - Different IRBNet #s for each site and the “CORE”
  - Full IRBNet access for Relying PIs
sIRB / cIRB

**Post Approval Submissions**

- Amendments
- Continuing Review
- Closures

[Diagram of process flow]
sIRB / cIRB

More Information

- Web page

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

- Email

HS-IRBreliance@ucdavis.edu

- Additional training

SOCRA – NIH Single IRB Mandate:
October 19, 2017; 12:00-1:00

CRC 2.0 – Reliance: TBD
Questions?
IRB Administration Website: http://research.ucdavis.edu/policiescompliance/irb-admin/

IRBNet: https://www.irbnet.org/

IRB Administration E-mail Contact: hs-irbeducation@ucdavis.edu

IRB Administration Phone Contact: 916-703-9151