CHAPTER #5

IRB Review and Approval process

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CHAPTER #5: IRB Review and Approval

5.1 IRB SOPs and the Investigator Manual


The UC Davis IRB is an administrative body established to protect the rights and welfare of human research subjects recruited to participate in research studies conducted under the auspices of the University of California, Davis. The role of the IRB is to review and to make decisions on all research involving human subjects at UC Davis.

Types of regulatory review for research activities

Submitted research activities may fall into one of the following four regulatory classifications:

- **Not “Human Research”:** Activities must meet the organizational definition of “Human Research” to fall under IRB oversight. Activities that do not meet this definition are not subject to IRB oversight or review. Review the IRB “WORKSHEET: Human Research (HRP-310)” [http://research.ucdavis.edu/policiescompliance/irb-admin/researchers/irb-forms/](http://research.ucdavis.edu/policiescompliance/irb-admin/researchers/irb-forms/) for reference. Contact the IRB Office in cases where it is unclear whether an activity is Human Research.

- **Exempt:** Certain categories of Human Research may be exempt from regulation but require IRB review. It is the responsibility of the organization, not the investigator, to determine whether Human Research is exempt from IRB review. Review the IRB Administration’s “WORKSHEET: Exemption Determination (HRP-312)” for reference on the categories of research that may be exempt.

- **Review Using the Expedited Procedure:** Certain categories of non-exempt Human Research may qualify for review using the expedited procedure, meaning that the project may be approved by a single designated IRB reviewer, rather than the convened board. Review the IRB Administration’s “WORKSHEET: Eligibility for Review Using the Expedited Procedure (HRP-313)” for reference on the categories of research that may be reviewed using the expedited procedure.

- **Review by the Convened IRB:** Non-Exempt Human Research that does not qualify for review using the expedited procedure must be reviewed by the convened IRB.

Criteria for IRB Approval

In order to evaluate and potentially approve human subjects research, the UC Davis IRB must review the protocol and determine that all of the federal requirements for approval, as outlined in 45 CFR 46.111(a)(1-7)(b), are satisfied. The criteria for IRB approval can be found in the “WORKSHEET: Criteria for Approval and Additional Considerations (HRP-314)” for non-exempt Human Research. The worksheet references other checklists that might be relevant. All checklists and worksheets can be found on the IRB web site.
What are the decisions the IRB can make when reviewing proposed research?

The IRB may approve research, require modifications to the research to secure approval, table research, or disapprove research:

- **Approval:** Made when all criteria for approval are met. See “Criteria for IRB Approval” above.
- **Modifications Required to Secure Approval:** Made when IRB members require specific modifications to the research before approval can be finalized.
- **Deferred:** Made when the IRB determines that the board is unable to approve research and the IRB suggests modifications the might make the research approvable. When making this motion, the IRB describes its reasons for this decision, describes modifications that might make the research approvable, and gives the investigator an opportunity to respond to the IRB in person or in writing.
- **Tabled:** Made when the IRB cannot approve the research at a meeting for reasons unrelated to the research, such as loss of quorum. When taking this action, the IRB automatically schedules the research for review at the next meeting.
- **Disapproval:** Made when the IRB determines that it is unable to approve research and the IRB cannot describe modifications the might make the research approvable. When making this motion, the IRB describes its reasons for this decision and gives the investigator an opportunity to respond to the IRB in person or in writing.

### 5.2 Prepare IRB Packet

#### Initial Review Application

The UC Davis IRB Administration uses an online application (IRBNet) to capture relevant information required to make a determination on research protocols during initial review. The on-line IRBNet form replaces the standard paper protocols submitted in the past to the IRB. The form was designed to use its “SmartForm” capabilities to the fullest by using the information you provide to determine whether additional information is needed. Based on how you answer a question, the form may or may not request additional information. For example: under the “Vulnerable Participants” section, if you answer “none of the above” the form will not ask you to complete any of the next 11 sections.

#### Conflict of Interest Disclosure

The Public Health Service (PHS) regulations include new requirements for mandatory and ongoing education and training. All investigators who are engaged in any research funded by PHS agencies (including NIH) and sponsors who have adopted the PHS rules as of August 24, 2012 must complete this training prior to the receipt of any new funds from the covered entity via a Notice of Award. All investigators who will engage in research funded by a covered entity must complete the training prior to engaging in the research following receipt of funds via a Notice of Award.

Provide evaluation of any related financial Interest for study personnel (you will need to submit the determination from the Conflict of Interest Committee (COIC) regarding conflict management if a conflict of interest does exist) (see section 4.2.2).
For training registration see the Research Compliance & Integrity Office website http://research.ucdavis.edu/policiescompliance/coi/

Written materials meant to be seen or heard by subjects

Note: The initial application review form will instruct you at the end of completion which documents required to be submitted with the application for review.

- Evaluation instruments and surveys
- Advertisements (printed, audio, and video)
- Recruitment materials and scripts
- Consent Documents
- If consent will not be documented in writing, a script of information to be provided orally to subjects
- Foreign language versions of the above

Consider accessing Protected Health Information (PHI) for feasibility purposes you can apply for access to the PHI under the “review preparatory to research” portion of HIPAA (see Chapter 8 of this Guidebook).

If you use identified patient information for recruitment purposes you must describe in your online initial review application how the PHI will be obtained. You also need to submit the recruitment materials specifically designed for this cohort to the IRB for review and approval.

Informed Consent

Create an Informed Consent Document - Use the “TEMPLATE CONSENT DOCUMENT” [HRP-502]] found within IRBNet under the “Forms and Templates” section.

- If consent will not be documented in writing, a script of information to be provided orally to subjects
- Foreign language versions of the above (if applicable), should be submitted as a modification to the IRB after initial approval.

Please be sure that you use the current consent template as the standard UC Davis boilerplate language and formats are updated frequently. When receiving a consent form from industry sponsors, you will need to incorporate the information into our UCD standard consent format. The person creating the consent must incorporate all required information from the sponsor consent into the UC Davis standard consent. In most cases, the UC Davis version of the consent form must be approved by the sponsor prior to IRB submission. The UC Davis IRB has final jurisdiction over what information is contained in the informed consent.
Common Mistakes in Informed Consent

1. Incomplete and/or inconsistent information
2. Language is too complex
3. Recruitment and consent process is not well explained
4. “De-identified” not a meaningful term by itself
5. Standard of care procedures vs research procedures are not clearly described
6. Use of exculpatory language

Helpful Hint: Consent versus Clinical Trial Agreement (Contract)

Some industry sponsors desire to include information into the consent form that should be a part of a Clinical Trial Agreement. The table below shows significant differences between Consent and Contract. Please keep this in mind when converting Sponsor Consents into UC Davis templates.

<table>
<thead>
<tr>
<th>The Consent Form</th>
<th>The Clinical Trial Agreement (Contract)</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Is not a contract for exchange of services for payment, but an acknowledgement</td>
<td>• Is a contract for services by the University in exchange for payment: required only when we are being paid by a Sponsor to conduct a trial</td>
</tr>
<tr>
<td>• It is between the University and the patient/subject</td>
<td>• It is between the University and the Sponsor (the PI and the study subjects are not parties to the contract)</td>
</tr>
<tr>
<td>• Necessary for regulatory compliance purposes</td>
<td>• It is necessary to cover the legal risks between the parties in exchanging services for payment</td>
</tr>
<tr>
<td>• Project specific</td>
<td>• May be a template or master and not project specific</td>
</tr>
</tbody>
</table>

Administrative Approvals Form [HRP-226]

This form is signed by the individuals listed in the form, including the Department Chair of the PI’s home Department. For School of Nursing studies, the Dean’s signature is also required, and for student principle investigators [e.g., graduate students] the Faculty Advisor’s signature is required. Electronic signatures are accepted.

5.3 Submit Required Documents to IRB

5.3.1 Submitting your materials to the IRB via IRBNet

The IRB Administration has adopted the IRBNet suite of tools, accessible via the internet, bringing electronic protocol management, online submission and many other important research oversight features to the University of California, Davis, research community: https://www.irbnet.org/release/index.html
IRBNet brings a robust set of electronic tools supporting the management, submission, review and oversight of our research protocols. Some of IRBNet’s many features include an online initial application, electronic document management, web-based protocol sharing and collaboration, automatic notifications, electronic submissions and reviews, integrated training and credential management, and important audit capabilities including electronic revision histories, electronic signatures and event tracking.

For more information, please see: http://research.ucdavis.edu/policiescompliance/irb-admin/researchers/irb-forms/

The IRB requires that each document is submitted as a separate file in order to facilitate administrative processing. Submissions incorporating multiple documents as a single PDF or Word document will be returned for splitting into separate documents. Missing documents can cause delays in the review and approval of your submission. If you have more than one consent form, advertisement, survey, etc., include a one to two word identifier in the footer of the document to easily distinguish the documents of the same type from each other. Document files should be named such that they are easily identifiable.

If you inadvertently submitted an incomplete package of materials, please immediately email IRBadmin@ucdmc.ucdavis.edu.

5.4 IRB Comments and Decision

The IRB will provide you with a written decision indicating that the IRB has approved the Human Research, or requires modifications to secure approval, or has disapproved the Human Research.

- **If the IRB has approved the Human Research:** The Human Research may commence once all other organizational approvals have been met. IRB approval is usually valid for a specific period of time and has an expiration date which is noted in the approval letter.

- **If the IRB requires modifications to secure approval and you accept the modifications:** Make the requested modifications and submit them to the IRB. If all requested modifications are made, the IRB will issue a final approval. Research cannot commence until this final approval is received. If you do not accept the modifications, write up your response and submit it to the IRB (refer to HRP-213).

- **If the IRB defers the Human Research:** The IRB will provide a statement of the reasons for deferral and suggestions to make the study approvable, and give you an opportunity to respond in writing. In most cases if the IRB’s reasons for the deferral are addressed in a modification, the Human Research can be approved.

- **If the IRB disapproves the Human Research:** The IRB will provide a statement of the reasons for disapproval and give you an opportunity to respond in writing.

In all cases, you have the right to address your concerns to the IRB directly at an IRB meeting.

5.5 File Approvals into Regulatory Study Binder

See Chapter 10 for documentation maintenance.