University of California, Merced

Title: IRB Review Process – Initial Review
SOP # 6
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Subject: Initial Review Process

Policy
Federal regulations require that in conducting the initial review of proposed research, IRBs obtain information in sufficient detail to make the determinations required under 45 CFR 46.111 (or 21 CFR 56.111 for FDA-regulated research) regarding risks, potential benefits, informed consent, and safeguards for human subjects.

UCM investigators who conduct research involving human subjects are required to submit an application describing their proposed research to the UCM IRB, in order to obtain prospective IRB review and approval or Certification of Exemption from IRB review prior to initiating any research activities. No intervention or interaction with human subjects in research, including recruitment, and no collection of data about or samples from human subjects may begin until an investigator's application to conduct human subjects research has received UCM IRB approval or certification of exemption.

The receipt of a complete protocol is the first step in IRB review. Deadlines, ancillary reviews, and signature requirements need to be carefully considered and planned in advance. At the time protocol materials are received, all documents will be examined for compliance with submission requirements. The IRB administrative staff also will perform a preliminary review of the protocol and may question the Principal Investigator directly on any concern before the actual IRB review. The Investigator must respond to the comments before the protocol is distributed and reviewed by the IRB. To ensure a thorough and complete review, the Principal Investigator should address the following points in his/her IRB application:

1. The full protocol or a protocol summary, developed by the Principal Investigator.

2. Sponsor/company protocol and Investigator Brochure (if one exists), if the study involves an investigational drug or device. Results of previous animal and human studies which are summarized in the Investigator's Brochure.

3. Grant application, if federal sponsorship is proposed.

4. Proposed informed consent documents.

5. Recruitment materials, including advertisements intended to be seen or heard by potential participants.

6. Participant enrollment procedures.

7. Selection of participants.

8. Provisions to protect the privacy of participants.

9. Provisions to maintain the confidentiality of data.

10. Additional safeguards to protect the rights and welfare of participants who are likely to be vulnerable to coercion and undue influence.

All IRB members will receive the same documents for full committee review. However, since the IRB uses a primary/secondary review system, items 2 and 3 above will only be provided to the IRB Chair, primary and secondary reviewers. In cases of expedited review, the IRB Reviewer will receive all documents for review. The regulations specify criteria for IRB review and approval (see IRB Policy "Criteria for Approval"). IRB members must apply these criteria during the review process and have appropriate knowledge and understanding of the regulations.

A tool to assist IRB members in performing an in-depth and thorough review is the *IRB Review Evaluation Form*. The form is divided into sections and each section addresses the specific criteria for IRB approval, as specified in the regulations. Additional space is provided so that IRB members can pose questions to investigators. This form also helps the IRB Administration staff to document comments, prepare minutes, and report the IRB findings back to the Principal Investigator after IRB review. The form is also a quality-control mechanism that ensures that reviewers have considered all of the regulatory and institutional criteria for review and approval; it encourages and provides a level of consistency in the IRB review process and it serves as written documentation that the IRB review process occurred.