Title: Criteria for Approval
SOP # 12
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Subject: Criteria for Approval of a Human Subjects Research Study

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Policy:
In order to approve human subjects research, the UC Merced IRB must determine that all of the requirements for approval are satisfied, as outlined in 45 CFR 46.111(a)(1-7)(b).

Procedures:

I. Criteria for Approval
The IRB will approve a research protocol only if the following criteria for approval are satisfied:

• risks to subjects are minimized;

• risks to subjects are reasonable in relation to anticipated benefits;

• selection of subjects is equitable;

• informed consent is adequate and appropriately documented;

• where appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects;

• where appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data; and

• appropriate safeguards have been included to protect vulnerable subjects (i.e., children, prisoners, and pregnant women in accordance with 45 CFR 46 Subparts B, C, and D.

A. Risks to Subjects Are Minimized

1. Risks to subjects are minimized by using procedures which are consistent with suitable research design and which do not unnecessarily expose subjects to risk, and whenever appropriate, by using procedures already performed on the subjects for diagnostic or treatment purposes.

2. Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result.

3. Selection of subjects is equitable.

4. Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by 46.116.

5. Informed consent will be appropriately documented, in accordance with, and to the extent required by federal and institutional policies.

6. When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.

7. When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

B. Vulnerable Populations

1. When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.

C. Assessing Suitable Study Design

A human research study should be well-designed according to proper scientific principles and be preceded by adequate laboratory and/or animal studies. A study which will not yield valuable data is unacceptable.

The UC Merced IRB shall consider the following points when assessing suitable study design:

1. Has the rationale and basis for the study hypothesis been provided in the background information?

2. Is the scientific design adequate to answer the research questions posed?

3. Is the sample size (number of subjects) adequate?

4. Is the method proposed for selecting and assigning subjects to treatment groups unbiased?

5. Are the study endpoints and methods of data analysis appropriate for the study?

D. Assessing Risks and Anticipated Benefits, If Any to Subjects

The UC Merced IRB shall conduct a risk/benefit analysis. The UC Merced IRB will ensure that risks to all subjects are minimized and are reasonable when compared to the benefits of participating in the research study or the knowledge that will be gained from participation in the study. The IRB shall carefully assess each risk and benefit to the study to determine if the benefits outweigh the risks and therefore justify the use of human subjects.

E. Assessing Equitable Selection of Subjects

While studies of a captive group of subjects, such as students, laboratory personnel, and hospitalized patients may be useful and desirable and can be conducted in an ethical fashion, a scrupulous effort must be made to preserve the individual’s rights because of the possibility of coercion.

Studies of volunteers in the investigator's own department or who are the investigator's students should be avoided and will usually be disapproved by the UC Davis IRB because of the subtle coercive factors that could be present in even the most harmonious situations.

The UC Merced IRB shall consider the following points when assessing equitable selection of subjects:

1. Does the nature of the research require or justify using the proposed study population?

2. Will the solicitation of subjects avoid placing a disproportionate share of the risks and discomfort as well as inconvenience of the research on any single group of individuals?

3. Are women of childbearing potential eligible for participation or, if not eligible, has their exclusion been justified?

4. Has the selection process overprotected potential subjects who are considered vulnerable so that they are denied opportunities to participate in research?

5. Are any payments to subjects reasonable, based upon the complexities and inconveniences of the study and the particular subject population?

In making this assessment, the IRB takes into account the purposes of the research and the setting in which the research will be conducted and is particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons [45 CFR 46.111(3)].

F. Assessing Methods for Obtaining Informed Consent of Subjects or Legal Representatives

Communication between subject and investigator should embody aspects similar to those in a good patient-doctor relationship. The discussion with the potential participant by the principal investigator or co-investigator should include the purpose of the research, the procedures to be followed, and the discomforts, risks and possible benefits, if any. The signing of the consent document should signify that a thorough discussion has taken place and will continue to take place during the conduct of the study.

G. Assessing Privacy and Confidentiality Protections

During the course of a study, the highest standards should be maintained with regard to the privacy and confidentiality of information, including interviews, photographs, and other records concerning the subject. Although more investigators and staff may be involved in the conduct of a study than might occur in the usual course of treatment of a patient, confidentiality standards should not be relaxed.

References:

45 CFR 46.111
45 CFR 46.116
45 CFR 46.117
45 CFR 46 Subparts B, C, and D
21 CFR 50 Subparts A, B, and D
21 CFR 56.111