

Title: Subject Pools

SOP # 8

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Subject: Human Subjects Research with Subject Pools

I. Introduction

Upholding the Belmont Report principle of respect for persons requires recruitment procedures that ensure the voluntary participation of the subject. The UC Merced IRB is responsible for the review of all procedures to recruit subjects to participate in research, in order to ensure that materials provided to and/or communications with potential subjects will ensure subjects' voluntary participation in the research. Instructors are strongly discouraged from directly recruiting subjects they teach or supervise or selecting subjects on such basis. Comparable alternatives must be provided in lieu of participation in research.

Although each individual research project must receive prospective IRB approval or certification of exemption from IRB review before an investigator may initiate contact with potential subjects, the UC Merced IRB also prospectively reviews and approves methods of subject recruitment which are intended to recruit subjects to participate in multiple studies, including studies which have not yet been developed and submitted for IRB review.

IRB review and approval is therefore required for all proposals with the intention to maintain potential subjects' contact information for the purpose of inviting participation in future research.

II. Definitions

A. Subject pool: Also known as "participant pool."

B. Registry: Subject pools which retain screening information from potential subjects in order to determine eligibility for future invitation to participate in research may be considered to be functioning as a "registry."

C. Student subject pools: Student subject pools are usually comprised of undergraduate students enrolled in particular courses requiring participation in one or more research projects. Departments provide students with incentives (usually extra credit) to participate in the subject pool. The UC Merced IRB reviews all human subjects research projects which propose to recruit from the subject pool.

III. Materials to be reviewed

Investigators or departments who intend to maintain a student or non-student subject pool in order to invite their participation in future research studies must submit an application

to the UC Merced IRB to obtain IRB review and approval for the continued maintenance of potential subjects' contact information and re-contact to invite participation in future research studies.

The IRB application using the appropriate IRB forms should specify the following:

- A. How current members of the subject pool were previously identified, and how future members of the subject pool will be identified. In addition, it should outline the methods by which members of the subject pool will be re-contacted and invited to participate in future research.
- B. In general, the types of research which potential subjects will be invited to participate in.
- C. In specific detail the procedures for confidentially maintaining potential subjects' contact information.
- D. Copies of any sample recruitment materials and newsletters to be provided to members of the subject pool.

IV. Additional Considerations for Registries or Databases that Retain Screening Information about Subjects

All recruitment and screening procedures are part of the IRB review of research proposals. Although screening activities do not necessarily result in data that are used to evaluate study outcomes, such procedures must be reviewed by the IRB during consideration of the protocol in order to ensure appropriate consent is obtained, when required, and so that all potential risks to subjects may be evaluated. Investigators who wish to retain screening information from subjects who are determined to be ineligible in order to recruit subjects for other research studies must also obtain prospective IRB review and approval for the registry or database of information to be developed for future use.

Investigators should also include the following:

- A. A description of the process of obtaining subjects' informed consent to retain information collected during screening procedures for the purpose of inviting participation in future research studies for which they are determined to be eligible.
- B. Copies of the consent script or consent form to be used to obtain subjects' consent to retain screening information for the purpose of inviting participation in future research studies. The IRB will approve an oral consent process and the use of a consent script for the retention of the screening information only if sufficient justification is provided to support a waiver of the requirement for subjects' signed informed consent in accordance with 45 CFR 46.117(c).
- C. A& B do not preclude the requirement for project specific informed consent of the research participant.

V. Additional Considerations for Student Subject Pools

The UC Merced IRB considers UC Merced students a vulnerable population (perceived or actual), and will closely examine research that requests the recruitment of students, as their grades are dependent on those investigators recruiting them for research. The IRB requires that investigators use recruitment procedures that minimize the possibility of coercion or undue influence when recruiting students to participate in subject pools. Student subject pools must therefore meet the following conditions in order to ensure that the student subjects voluntarily choose to participate:

- A. Students' participation in each project must be entirely voluntary; instructors cannot mandate or require student participation.
- B. Stipulations must be built into the research to assure students that their participation is strictly voluntary and that they may withdraw their participation at any time without penalty.
- C. When research participation is introduced as a part of class curriculum, students must not be penalized for a decision not to participate in research. Therefore, comparable alternative assignments must be offered to students, and such assignments must not be graded, but rather counted as "complete" or "incomplete", in the same manner that participation in research would be.
- D. When extra class credit is offered in exchange for participation, the investigator must provide alternate means of earning equivalent extra credit for an equivalent commitment of time and effort.
- E. The research must not bestow upon participating UC Merced student subjects any competitive academic or occupational advantage over other UC Merced students who do not volunteer, and the researchers must not impose any academic or occupational penalty on those UC Merced students who do not volunteer.
- F. Reimbursement for participation must not jeopardize subject confidentiality or anonymity which is otherwise maintained through the individual project's IRB-approved procedures.
- G. Each individual research project must be determined to be exempt or reviewed and approved by the IRB prior to use of the student subject pool. While the UC Merced subject pool will have extant IRB approval, each individual investigator must gain separate approval for research projects proposing to use the student subject pool.

Regulations:

45 CFR 46.117(c)

References:

45 CFR 46

The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, The Belmont Report - Ethical Principles and Guidelines for the Protection of Human Subjects of Research, April 18, 1979.

<http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.htm>