

**Guidance and Procedures Number: 28**  
**Title: Subject Pools and Recruitment Databases**  
**Date of Last Revision: March 6, 2009**

## I. Introduction

Upholding the Belmont Report principle of respect for persons requires recruitment procedures that ensure the voluntary participation of the subject. The UCLA 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.

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 UCLA 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. **Recruitment Databases:** Databases that include health or demographic information and are developed for the purpose of identifying and recruiting potential research subjects.
- C. **Registry:** Subject pools and recruitment databases 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."
- D. **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 UCLA IRB reviews all human subjects research projects which propose to recruit from the subject pool. Instructors are strongly discouraged from recruiting subjects they directly supervise or selecting subjects on such basis. Alternatives must be provided in lieu of participation in research (see V(C)).

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

The application should include the following:

- A. Cover letter
- B. HS-1 application form; including the following information:
  - 1. Specify (a) how current members of the subject pool were previously identified, and (b) how future members of the subject pool will be identified. In addition, outline the methods by which members of the subject pool will be re-contacted and invited to participate in future research
  - 2. Describe *in general* the types of research which potential subjects will be invited to complete.
  - 3. Describe *in specific detail* the procedures for confidentially maintaining potential subjects' contact information.
  - 4. Indicate "not applicable" for those sections of the HS-1 application that request information that will be required for each individual research project which proposes to recruit subjects using the subject pool.
- C. Copies of 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 recruitment purposes.

In addition to the materials outlined in Section III (A) and (B)(1-3) above, investigators should also include the following:

1. Section IV-23-26 should describe 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.
2. 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).

## **V. Additional Considerations for Student Subject Pools**

The UCLA IRB considers UCLA students a vulnerable population, 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<sup>1</sup> 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:

1. Students' participation must be entirely voluntary; instructors cannot mandate or require student participation.
2. Measures must be built into the research to assure students that their participation is strictly voluntary and that they may withdraw their participation at anytime without penalty.
3. 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, 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.
4. 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.
5. The research must not bestow upon participating UCLA student subjects any competitive academic or occupational advantage over other UCLA students who do not volunteer, and the researchers must not impose any academic or occupational penalty on those UCLA students who do not volunteer.
6. Reimbursement for participation must not jeopardize subject confidentiality or anonymity which is otherwise maintained through the individual project's IRB-approved procedures.

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<sup>1</sup> The Department of Health and Human Services, National Institutes of Health, Office for Protection from Research Risks (OPRR) guidebook "1993 Protecting Human Research Subjects", Chapter III.

**Regulations:**

45 CFR 46.117(c)

**References:**

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>

U.S. Office for Human Research Protections' (OHRP, formerly OPRR) *Protecting Human Research Subjects Guidebook (1993)*.