

SUBJECT POOLS, RECRUITMENT REGISTRIES & DATABASES IN RESEARCH

This guidance document is intended for researchers who are considering the creation and/or use of subject pools, recruitment registries and databases. Should you need additional assistance, please contact OPHS at 510-642-7461 or ophs@berkeley.edu.

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A. Introduction

Subject pools can be a useful tool for selecting and recruiting research participants. In general, maintaining a subject pool at UC Berkeley does not require review by the Committee for Protection of Human Subjects (CPHS) or Office for the Protection of Human Subjects (OPHS) if activities are limited to: (1) informing prospective subjects about the availability of the research; (2) providing prospective subjects with information about the research; (3) providing prospective subjects with information about contacting investigators for information or enrollment; and/or (4) seeking or obtaining the prospective subjects' permission for investigators to contact them. These activities do not constitute engagement in human subjects research as explained in the Part III, B, (4) of the Department of Health and Human Services, Office for Human Research Protections (OHRP) [Guidance on Engagement of Institutions in Human Subjects Research](#). However, subject pools come in different shapes and sizes and researchers who are thinking about establishing such a resource should be aware that CPHS review may be required if activities are not limited to those listed above.

It is also important to note that each human subjects research protocol which will make use of a subject pool for recruitment must be submitted to CPHS/OPHS for review before an investigator may initiate contact with potential subjects.

B. Definitions

1. ***Subject Pool:*** An aggregation of people from which research participants may be recruited.
2. ***Recruitment Registry:*** An organization that collects and maintains contact information from individuals who have agreed to join an established subject pool in order to receive information about available research.
3. ***Recruitment Database:*** An organization that collects and maintains contact information, as well as health, demographic, and/or screening data, from individuals who have agreed to join an established subject pool in order to receive information about available research. The subject pool

data may also be used to determine eligibility for future invitation to participate in research and included in the evaluation of study outcomes.

4. ***Student Subject Pool:*** A subject pool that is typically comprised of undergraduate students enrolled in particular courses requiring, as part of the curriculum, research experience either through participation in one or more research projects, or an alternative assignment in lieu of participation in research.

C. Considerations for Recruitment Registries

Maintaining a recruitment registry does not constitute engagement in human subjects research because the registry's activities involve *only* providing prospective subjects with information about the research and enrollment, and/or obtaining the permission of the prospective subjects for investigators to contact them. Thus, CPHS review is not required for recruitment registries. However, before study specific information is provided to individuals who have joined the registry, the research protocol must first receive CPHS/OPHS review and approval.

Example:

The Tiddler Participant Pool (TPP) is a recruitment registry for the Tiddlywinks Institute of Child Development. The TPP is looking for families who are interested in helping the institute's researchers learn more about how children grow and interact with their surroundings. The registry collects the names, email, addresses and phone numbers of parents who would like to receive information about participation in specific child development research studies and sends them this information as it becomes available. *Creating this registry does not require CPHS review and approval.*

D. Considerations for Recruitment Databases

CPHS review is required for maintaining a recruitment database due to the collection of preliminary data, such as health, demographic, and/or screening information, from individuals who have agreed to join a subject pool. This information is generally used to determine eligibility for future invitation to participate in research and included in the evaluation of study outcomes. Therefore, this activity therefore constitutes engagement in research with human subjects.

Example:

The Fog City Center for Aging Fashionistas conducts research on fashion among San Francisco Bay Area seniors. The center's Maturing In Stylish Threads (MIST) subject pool reaches out to seniors in the city with the explicit purpose of building their recruitment database. This database is comprised of people who have agreed to be contacted with invitations to participate in fashion-related studies. These individuals are asked to provide names, email, addresses and phone numbers and to complete a brief screening questionnaire. *Creating this database requires CPHS review because of the use of a screening tool.*

See section F. CPHS Review of Student Subject Pools and Recruitment Databases

E. Considerations for Student Subject Pools

CPHS review is required for student subject pools that meet the definition of a recruitment database. The committee considers UCB students to be a potentially vulnerable population, as their grades are or may be dependent on those investigators recruiting them for research, and the CPHS will thus closely examine

research that requests the recruitment of students. Student subject pools must meet the following conditions in order to ensure that the student subjects voluntarily choose to participate:

- The research must not bestow upon participating UCB student subjects any competitive academic or occupational advantage over other students who do not participate.
- Reimbursement for participation must not jeopardize subject confidentiality or anonymity that is otherwise maintained through the individual project's CPHS approved procedures.
- Student participation must be entirely voluntary; instructors, research lab supervisors or faculty advisors cannot require students to participate in a particular study.
- When research participation is introduced as a part of class curriculum, alternative, equivalent assignments must be offered to students. Such assignments must be agreed to by the course instructor before the protocol is submitted for review and, rather than being graded, these assignments must count as "complete" or "incomplete."
- When course credit is offered in exchange for participation, alternate means of earning equivalent credit for an equivalent commitment of time and effort must be provided to the students.
- If a student does not show up for a scheduled experiment, federal regulations do not permit the student to be penalized (e.g. deduct credits previously earned by the student for taking part in other studies, or increase the number of credits that the student would have to earn in order to receive an equivalent amount of course credit). Students must be free to choose not to take part in research at anytime prior to the start of their involvement. For more information on this topic, see section G. Dealing with No-Shows.

F. CPHS Review of Student Subject Pools and Recruitment Databases

As mentioned above, investigators or departments who intend to create and maintain a student subject pool or recruitment database must submit an application to CPHS for review and approval. The protocol should include the following information:

- Specification of how members of the subject pool are identified. Methods by which members of the subject pool will be re-contacted and invited to participate in future research should also be outlined.
- General description of the types of research in which potential subjects will be invited to take part.
- Description of the process for obtaining informed consent to retain information collected during screening procedures for the purpose of inviting participation in future research studies.
- Description of the data elements that will be collected during the screening process.
- Copies of the document to be used to obtain subjects' consent for retention of screening information for the purpose of inviting participation in future research studies. The CPHS may approve an oral consent process and use of a consent script for the retention of screening information if there is sufficient justification to support a waiver of the requirement for documented (signed) consent.

It is important to note that some first year college students will be under the age of 18 and are legally considered to be minors. If minors will be included in the subject pool, the matter of child assent and parent permission must be addressed in the study protocol. Alternatively, the CPHS will consider requests to waive parent permission for the inclusion of college students who are minors.

See [CPHS Informed Consent Guidelines](#) and [CPHS Guidelines on Research Involving Children](#).

- Detailed description of the procedures for confidentially maintaining potential subjects' contact (and screening) information.
- Copies of recruitment materials, email messages, websites, flyers, newsletters or any other means by which potential subjects will be recruited for enrollment in the pool or database.

G. Dealing With No-Shows

No-shows, people who agree to participate in research and then fail to appear for a scheduled appointment without notifying investigators in advance, can be disruptive to conducting research. As such, it makes sense that investigators would want to develop strategies to discourage this behavior and encourage participation. It is, however, essential to ensure that these strategies do not undermine the voluntary nature of participation in the research. Subjects must be free to refuse to participate in a research study or discontinue participation at any time without penalty or loss of benefits to which they are otherwise entitled (45 CFR 46.116(8)(a)).

An approach frequently used to minimize no-shows is exclusion from the subject pool, or from participation in future research, of individuals who fail to show up for an appointment a certain number of times. This approach is only acceptable if participation in future research is not tied to a benefit to which the individual would otherwise be entitled. It is not appropriate for a subject pool of students who need to participate in research for course credit and for whom an alternative activity to fulfill the requirement is not available. In this instance, preventing a student from participating in future research would also prevent him or her from obtaining course credit, a benefit that the student would receive otherwise.

On January 10, 2010, OHRP issued a letter to a commercial company, which provides a web-based system for managing student subject pools, clarifying that deducting previously earned course credit for students who fail to show up for scheduled appointments with investigators without cancelling by a specified deadline is prohibited under 45 CFR 46.116(8)(a). The letter also provided examples of acceptable approaches for encouraging student participation, as follow:

- 1) Students who fail to show up for an appointment they scheduled could have a decrease in the number of credits that can be earned through participation in research for a particular course, provided such students can still earn the same maximum number of credits by substituting an alternative non-research activity that involves a comparable amount of time and effort. For example, if there is an alternative activity to earn research credits, students could be required to earn their credits with the alternative activity.
- 2) Students who show up for an appointment could be awarded some form of extra credit. For example, a subject pool that requires participation in 4 studies could award one credit to students who showed up for their first 3 studies, thus providing a reward rather than a penalty.