

Establishing/Utilizing Participant Pools

Definition: The Chapman IRB defines “subject pool” a.k.a., “participant pool” and “recruitment database” as a registry of individuals who are interested in participating in research and agree to be contacted for potential participation in a study. Subject pools do not include research data for the purpose of analysis; the sole purpose of the information about the prospective participants is for recruiting them to participate in a research study.

Researchers and the IRB share the responsibility for establishing a recruitment environment that adequately protects the rights and welfare of the prospective participants (Belmont Report; 45 CFR §46.111(a)(3)). This ethical and regulatory obligation requires consideration of the appropriate procedures for the initial identification, contact, and recruitment of potential participants. The recruitment process should demonstrate adequate respect for their dignity and autonomy while honoring and preserving any confidential information necessary to identify and contact potential participants while minimizing undue influence.

Generally, participant contact information acquired in a study would be destroyed at the end of the study. Maintaining participant information for the purpose of future recruitment must be approved by the IRB. Such information would be intentionally maintained for use as a prospective tool to recruit volunteers in order to conduct research. Maintenance of the subject pool will be led by a Chapman investigator who meets criteria for Principal Investigator Eligibility per [policy](#). In the case of full board/expedited review studies, unless informed consent is waived or documentation of consent is waived, participants will fill out a consent form agreeing that the research team may retain their information beyond the use of the current studies they are enrolled in, so that they can be contacted and invited to other studies. In the case of exempt studies, an informed consent form is not required; however, at minimum, an information sheet is needed.

Establishing a Subject Pool- Inviting individuals other than those already enrolled in actual studies, to join a subject pool or subject pool will require prior administrative IRB review. To request such IRB review, the PI must submit a Request to Establish a Subject Pool in Cayuse. Once approved, the subject pool may just be referenced by IRB# in the recruitment description of any study-specific IRB application which will be drawing from such subject pool, instead of explaining specifically in detail how recruitment will occur.

Since the stand-alone recruitment subject pool by itself is not yet “research”, such applications may be handled administratively by the IRB office. The approved IRB application for the recruitment database will undergo an administrative check-in at the third anniversary of IRB approval.

The researcher's plan for establishing a subject pool must include, at minimum, these details:

- A. Name of the subject pool (e.g., "ESI Recruiter", or "School of Communication Subject Pool")
- B. List of all information to be housed in the database
- C. Eligibility criteria for subject inclusion
- D. How individuals will be approached and invited to join the database

The IRB should be provided with all proposed methods to recruit to the database (e.g., tabling events, flyers, web postings, participants enrolled in studies). Standard recruitment methods would apply as documented in the IRB's [Guidance on Recruitment of Research Participants](#). Including information of individuals currently enrolled in studies is permissible only if such individuals have agreed to be contacted about further studies.

- E. Measures in place to maintain confidentiality of the data.

- a. Details should include:

- Training and qualifications of persons who will collect information for inclusion in the subject pool and/or be involved in the maintenance of such information
- Safeguards to prevent accidental or inappropriate release of information
- Methods used to organize and store information
- Procedures for releasing information to other investigators

- b. Examples of preserving confidentiality:

- A rigorous back-up method is recommended for database storage of especially sensitive data.
- Avoid portable media. If data will be backed up or downloaded on a portable computer or data drive, describe methods to secure data via password protection and other mechanisms.
- Passwords would be needed to access the database and/or limiting knowledge of the passwords to authorized persons(s).
- A coding system with the key to the code being stored in a separate location apart from the database. If the information must have identifiers, the IRB will require specific electronic protections, such as firewalls or passwords for access the database.
- Access to the key is provided to limited authorized individuals who are trained about the database and human research protections, including the preservation of confidentiality (i.e. CITI training).

- F. How the information in the pool will be kept current including how participants may request to be removed from the database
- G. Subsequent contact with participants of the database (i.e., how they will be contacted and at what frequency)
- H. Access to information in a Subject Recruitment Database or Pool
Database Administrators control access to the data contained in the participant recruitment database (or pool). Information would be released to CU researchers covered by the IRB-approved application for that particular study.

References:

[Establishing/Utilizing Subject Recruitment Databases IRB Guidance; University of Massachusetts Amherst; accessed 10Jul2024](#)

[Office for Human Research Protections \(OHRP\) Participant Brochure](#)

[Office for Human Research Protections \(OHRP\) Guidance on Research Involving Coded Private Information or Biological Specimens](#)

Revision history:

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