

Policies and Procedures

SECTION: Human Research Protection Program	NUMBER: 113	
CHAPTER: Institutional Review Board	ISSUED: 2/2000	REVISED/REVIEWED: 9/2004; 6/2006; 8/2009; 11/2013
POLICY: Recruiting Research Subjects	PAGE 1 OF 7	

1. PURPOSE

This policy defines the standards and parameters for the recruitment of research study subjects for biomedical, behavioral, and social science research.

2. POLICY

The IRB is responsible for ensuring the equitable selection of research subjects. In fulfilling this responsibility, the IRB shall review the methods that investigators use to recruit subjects.

3. ADVERTISING FOR RESEARCH SUBJECTS

- 3.1. When advertising is to be used to recruit research subjects, the IRB shall first review the information contained in the advertisement and the mode of its communication to determine whether the procedure for recruiting subjects affords adequate protection. The following are **not** included in this requirement for IRB review:
 - 3.1.1. Communications intended to be seen or heard by other health professionals, such as “dear doctor” letters and doctor-to-doctor letters
 - 3.1.2. News stories
 - 3.1.3. Publicity intended for other audiences, such as financial page advertisements directed toward prospective investors
- 3.2. Advertisements used to recruit subjects should be seen as an extension of the informed consent and subject selection processes. IRB review is necessary to ensure that the information is not misleading to subjects, especially when a study will involve persons who have acute or severe physical or mental illness or persons who are economically or educationally disadvantaged.
- 3.3. All advertising material shall be submitted in their final form and shall receive IRB approval prior to use. These include but are not limited to:
 - 3.3.1. Advertising flyers
 - 3.3.2. Letters to individuals

Policies and Procedures

SECTION: Human Research Protection Program	NUMBER: 113	
CHAPTER: Institutional Review Board	ISSUED: 2/2000	REVISED/REVIEWED: 9/2004; 6/2006; 8/2009; 11/2013
POLICY: Recruiting Research Subjects	PAGE 2 OF 7	

- 3.3.3. Recruitment brochures
 - 3.3.4. Billboards
 - 3.3.5. Web sites
 - 3.3.6. Social media
 - 3.3.7. Final television advertisements (CD or DVD) or final radio advertisements (CD or script)
 - 3.3.8. Any recruitment material directed at potential subjects
- 3.4. Generally, any advertisement to recruit subjects should be limited to:
- 3.4.1. The name and address of the clinical investigator
 - 3.4.2. The purpose of the research and, in summary form, the eligibility criteria that will be used to admit subjects into the study
 - 3.4.3. A straightforward and truthful description of the benefits (e.g., compensation or free treatment) to the subject for participation in the study
 - 3.4.4. Time or other commitment required of subjects
 - 3.4.5. The location of the research and the person to contact for further information
- 3.5. No claims shall be made, either explicitly or implicitly, that the investigational drug or device is safe or effective for the purposes under investigation, or that the drug or device is in any way equivalent or superior to any other drug or device. Such representation would not only be misleading to subjects, it would also be a violation of the FDA's regulations concerning the promotion of investigational drugs and investigational devices. Terms such as "new treatment," "new medication," or "new drug" should not be used without explaining that the test article is investigational.
- 3.6. The advertisement should not promise "free medical treatment" when the intent is only to say that subjects will not be charged for participation in the research

Policies and Procedures

SECTION: Human Research Protection Program	NUMBER: 113	
CHAPTER: Institutional Review Board	ISSUED: 2/2000	REVISED/REVIEWED: 9/2004; 6/2006; 8/2009; 11/2013
POLICY: Recruiting Research Subjects	PAGE 3 OF 7	

project. To avoid conveying the impression that benefits are payments, references to subject benefits in advertisements shall not use the term “payments.” The advertisement may include the amount of the stipend, but the stipend amount shall not be in larger font than the rest of the text and it shall not be in bold.

3.7. Advertisements shall not be directed to minors. Advertisements intended to recruit minor subjects shall be directed to minors’ parents or guardians and shall be sent to the IRB office for review.

3.8. All IRB-approved advertisements posted outside of the University shall be in accordance with [Public Relations Graphics Standards](#). When developing complex advertising media, investigators shall contact the Public Relations department to assist in development to ensure consistency with the Creighton branding.

3.9. Principal Investigators who post any IRB-approved advertisements shall also gain approval from the department, institution, or business where they post the advertisement.

4. RECRUITMENT OF INDIVIDUAL SUBJECTS THROUGH THIRD-PARTY CONTACTS

4.1. Investigators shall specify how they will identify and recruit research participants.

4.2. When appropriate, the names of third-party agencies and organizations from which participants will be identified and recruited should be disclosed, and a letter of cooperation from an authorized representative (e.g., non-Creighton physician, agency director, school principal) should be provided.

4.3. Investigators should not ask agencies or organizations to provide the names of potential participants or release private information about them.

4.4. Agencies or organizations should be asked to contact individuals to obtain their permission for investigators to be given their names, to distribute a letter or flyer describing the research and inviting persons to contact the investigators if they are interested in participating, or to arrange for investigators to explain the research at a meeting at which volunteers will be sought.

Policies and Procedures

SECTION: Human Research Protection Program	NUMBER: 113	
CHAPTER: Institutional Review Board	ISSUED: 2/2000	REVISED/REVIEWED: 9/2004; 6/2006; 8/2009; 11/2013
POLICY: Recruiting Research Subjects	PAGE 4 OF 7	

- 4.5. Investigators shall ensure that anyone in a position of authority at an agency or organization does not exert pressure on persons to participate in the research.
- 4.6. Recruitment letters or flyers shall be submitted to the IRB and shall contain a brief description of the research, contact information for the investigators, and any benefits provided for people to participate. Letters or flyers should not exaggerate the benefits of participation in the research.

5. DATABASE RECRUITMENT

5.1. Internal

- 5.1.1. Researchers may access their own research database from prior studies or access their clinical records to identify potential subjects. Researchers may access another Creighton University department's clinical records if they have the approval of that department's Chair or designee for the purpose of identifying potential subjects. In this latter instance, IRB-approved recruiting material (e.g., letters, phone scripts, etc.) should be used under the name of the potential subject's clinician or department, not the researcher.

5.2. External

- 5.2.1. Researchers may recruit using external databases legally purchased or otherwise legally obtained from third parties (e.g., public data repositories, vendors, or other non-HIPAA covered entities). Scripts or other recruiting materials shall receive IRB review and approval prior to use. Recruitment through covered entities shall comply with HIPAA standards.

6. PEDIGREE AND FAMILY STUDIES

- 6.1. Investigators shall specify how they will identify and recruit research participants. A study that identifies and recruits family members can pose challenges for ensuring that recruitment is free of coercion; the investigator is expected to minimize potential coercion to all family members. The following methods may be used:
- 6.1.1. Use the individual being studied (proband) as the point of contact for recruiting other family members

Policies and Procedures

SECTION: Human Research Protection Program	NUMBER: 113	
CHAPTER: Institutional Review Board	ISSUED: 2/2000	REVISED/REVIEWED: 9/2004; 6/2006; 8/2009; 11/2013
POLICY: Recruiting Research Subjects	PAGE 5 OF 7	

- 6.1.2. Recruit directly by the investigator through letters or telephone calls to individuals whose identity is supplied by the proband
- 6.1.3. Recruit participants through support groups or lay organizations
- 6.1.4. Contact individuals through their personal physicians

7. RECRUITMENT OF THE CREIGHTON UNIVERSITY COMMUNITY

- 7.1. Investigators should recognize that directly approaching their students or staff for the purposes of research participation may be considered coercive; it may be difficult for the prospective participant to refuse the investigator's request. The prospective participant also may believe that the investigator will look favorably upon them should they agree to participate in the research study. Therefore, investigators must carefully consider their ability to influence others when designing study recruitment methods.
- 7.2. The IRB shall determine on a case-by-case basis whether investigators may recruit faculty, staff, or students of the University community. Investigators shall take special steps to ensure that participation of Creighton University faculty, staff, or students in research is voluntary and free of coercion or pressure. The IRB discourages recruitment of participants by persons who have direct authority over the participant, and shall disapprove such research unless there is a clear rationale for recruiting such persons and participation is clearly voluntary. Investigators shall specify in the protocol how the recruitment method will eliminate possible coercion when recruiting these populations. For instance, such individuals may participate in research if they approach the research team and initiate enrollment on their own behalf. Participation in research shall not be made a condition of employment or continued employment at the University, or used to satisfy the requirements of any University disciplinary action.

8. SUBJECT STIPENDS

- 8.1. The IRB shall review and approve stipends offered to subjects to participate in research. Stipends may include monetary payment, gift cards, course credit, small gifts, toys or educational materials, and other items or services. Stipends shall not be of such an amount as to result in undue influence on an individual's decision to participate, especially in the case of persons who are economically disadvantaged. In addition, stipends shall not be provided on a schedule that results in coercion or undue influence on an individual's decision to continue

Policies and Procedures

SECTION: Human Research Protection Program	NUMBER: 113	
CHAPTER: Institutional Review Board	ISSUED: 2/2000	REVISED/REVIEWED: 9/2004; 6/2006; 8/2009; 11/2013
POLICY: Recruiting Research Subjects	PAGE 6 OF 7	

participation. That is, stipends shall not be withheld as a condition of an individual completing the research. If an individual withdraws early, the payments or stipends shall be prorated to reflect the time and inconvenience of the individual's participation up until that point. Completion bonuses shall not be allowed.

- 8.2. Payment to research participants shall be arranged in a way that minimizes potential violations of privacy. For example, investigators should try to avoid linking subjects to participation in sponsored research involving sensitive topics (e.g., HIV and AIDS, drug use).
- 8.3. The IRB prohibits lotteries for the payment of research participants for projects that are greater than minimal risk. However, for projects presenting little or no risk to a participant, the IRB may consider approval of drawings for small gifts (defined as having a cost less than \$500).
- 8.4. Students enrolled in Creighton University courses may be offered extra credit to participate in research projects under the following conditions:
 - 8.4.1. The research has been approved by the chairperson of the department in which the course is offered;
 - 8.4.2. Students derive some benefit from participation in the research (e.g., learning about the nature of research);
 - 8.4.3. Students are offered an alternative assignment of a non-research nature that entails a comparable investment of time as the research;
 - 8.4.4. Students who participate in part but not all of the research are offered partial credit for participation according to the amount of time spent (an alternative assignment comparable in time must be offered to enable students to receive full credit); and
 - 8.4.5. Whenever possible, the instructor of these courses should not know the identities of students who participate in research projects for credit.
- 8.5. Compensation for participation in research is not considered to be a benefit of the research and shall not be reported as such on the IRB application or on the consent/permission/assent form. Stipends are considered compensation for the participants' extra time and the inconvenience of becoming a research subject.

Policies and Procedures

SECTION: Human Research Protection Program	NUMBER: 113	
CHAPTER: Institutional Review Board	ISSUED: 2/2000	REVISED/REVIEWED: 9/2004; 6/2006; 8/2009; 11/2013
POLICY: Recruiting Research Subjects	PAGE 7 OF 7	

9. FINDER'S FEES

- 9.1. Finder's fees and other financial incentives paid by a sponsor or by an investigator to others related to the recruitment of research subjects are considered unethical by the Creighton University IRB and are thus prohibited. No one shall receive any incentive for the purpose of encouraging individuals to participate in research. The IRB shall not approve research proposals that involve such payments.