

Series 501 Recruitment of Prospective Subjects | Institutional Review Board

The Institutional Review Board from Series 501 of Recruitment of Prospective Subjects

I. Recruitment Generally

Recruitment is the process and associated documentation that permits the targeted population to learn about a research study. Recruitment is considered to be the start of the informed consent process. It represents the beginning of the exchange of meaningful information with a participant, during which the prospective participant is formulating their decision of whether or not to enroll in a research project.

In order to approve a human subjects research project, the IRB is required to find and document that selection of subjects is equitable, in line with requirements of the *Belmont Report* and 45 C.F.R. 46. Equitable selection of subjects necessarily encompasses recruitment processes and materials, and so this process and its associated documentation must be reviewed and approved by the IRB.

II. Equitable Selection

To gain IRB approval, all studies must have a recruitment structure in place that ensures equitable selection of subjects. As a result, recruitment processes and documents will be closely examined during the review process. Equitable selection of subjects means that the research is structured in a manner that ensures that the benefits and burdens of research participation are fairly distributed among those who are likely to be impacted by the study's findings and outcomes. It also means ensuring protections for those who might already bear disproportionate social, financial, or health burdens, and from time to time, ensuring distributive justice rather than equity.

IRB members examine the following factors in determining whether subject selection is equitable:

- The purposes of the research, to ensure targeted participants are appropriate for the problem or issue under study.
- The setting in which the research will be conducted, to ensure it does not unjustly target already-burdened populations or unjustly deprive participants that should be presented with the research opportunity.
- Whether prospective participants will be vulnerable to coercion or undue influence.
- The inclusion and exclusion criteria
- Whether any protected class is being unjustly targeted or unjustly excluded under USU's antidiscrimination policies.
- Participant recruitment and enrollment procedures.
- The influence of payments to participants.

In order to adequately examine those factors, researchers must provide, as a part of their protocol submissions:

- The information contained in the recruitment materials.
- The method and frequency of recruitment communications.
- The final copies of all materials that will be used to share information about the study in a manner that is likely to result in enrollment into the study.
- Any compensation structures that will be utilized.
- The final audio or video recorded recruitment materials.

III. Equitable Selection & Vulnerable Populations

Research conducted with individuals with limited, questionable, or fluctuating decision making capacity must be designed in such a way as to provide additional protections to these populations. Conducting research involving participants who cannot consent to enroll because of a physical or psychological condition is vital to the expansion of knowledge that can benefit the lives of those and similarly situation individuals, and this kind of research must be designed with care. Participants who cannot consent to enrollment in research due to a legal deficiency deserve additional protections. In all cases, these populations should be targeted for research participation when they are necessary to the design of the research and are among the population that stands to benefit from the outcomes of the research.

IV. Technical Requirements

In addition to the general requirements that recruitment practices ensure equitable selection of subjects, there are some technical requirements that must be in place for applicable recruitment materials and practices:

- The purpose of the research, or why participants are being sought;
- Contact information for a person on the study team who can answer questions about the research or register complaints about the recruitment process;
- Contact information for the PI, if different from the person above;
- The protocol number and reference to Utah State University's IRB;
- The basic information a prospective participant would need to know to determine eligibility (such as inclusion/exclusion criteria);
- The basic information a prospective participant would need to know to determine interest (such as the location of the research, the compensation, and the time commitment); and
- A reasonable expectation that the recruitment processes outlined will result in participant accrual rates necessary to achieve study aims.

V. Recruitment Prohibitions

To ensure equitable and informative recruitment practices, certain aspects of recruitment are not permitted in human subjects research at Utah State University. Recruitment prohibitions include:

- Emphasis on compensation relative to the rest of the information about study participation;
- Any statement that implies or explicitly states favorable outcomes or benefits beyond that which is included in the protocol and the informed consent documents;
- Any exculpatory language appearing to waive any legal rights;
- Conflation of "free" services or items with a lack of a charge or cost for study participation;
- Conflation of compensation with benefits;
- Any circumstances which do not permit a prospective participant adequate time and space to decide whether to participate in the research;
- Any circumstances or practices that are violations of privacy;
- Any circumstances which do not minimize the possibility of coercion or undue influence.

Finder's fees or enrollment bonuses are generally discouraged, as they typically involve people who actively recruit into a study and are thus acting as investigators but who are not trained and listed on a protocol as investigators, and because their incentives are often not in alignment with the requirement that prospective participants have adequate time and space to make decisions about whether to engage with the research. However, in some circumstances (such as participant panel services that actively recruit into panels, but take a less active approach to recruiting panelists into particular studies), these types of recruitment situations are allowable. The circumstances of recruitment, payment, and informed consent must be closely examined before these kinds of recruitment structures are permitted.