207.1 Equitable Selection

Guidance and information is made available to Principal Investigators (PIs) and research support staff to assist them in creating recruitment materials and participant selection procedures that are fair and equitable. Guidance and information can be found here:

- GUIDE 619: Recruitment Guidelines
- TMP 475: Model Recruitment Flyer

Investigators shall provide detailed information on how participants will be identified and recruited in response to questions in the Research Application. This information shall include a description of the target study population (including age range, gender, and ethnic background), the inclusion and exclusion criteria and whether compensation for participation will be offered. Additionally, Investigators are required to justify the inclusion of targeted persons (e.g., healthy participants, students or participants with certain medical conditions).

In determining if the selection and recruitment of participants is equitable, the IRB takes into consideration the purpose of the research, the setting in which the research will be conducted, whether potential participants will be vulnerable to coercion or undue influence, the selection criteria, participant recruitment and enrollment procedures, and the influence of compensation to participants. The IRB also reviews whether the study imposes fair and equitable burdens and benefits – such that one group of persons does not disproportionately receive the benefits compared to another group assuming only the risks.

The HSP staff and IRB members review this information and confirm the recruitment and selection methodologies are fair and equitable. If the methodologies for recruitment and selection are not fair and equitable, the Investigator will be asked to revise the recruitment and enrollment plan accordingly, as a condition for approval.

Vulnerable Participants

Investigators must provide justification for involving participants belonging to a vulnerable population, such as children, prisoners, pregnant women, persons of disadvantaged social and economic status, persons with diminished decision-making capacity and homeless people. There must be substantial rationale provided in the research plan on the decision to involve a vulnerable population and why a less vulnerable population would not serve the purpose of the research.

When vulnerable populations are used for enrollment, the IRB assesses the additional safeguards proposed by the Investigator to minimize the possible risks and harm to these populations. Though pregnant women are considered vulnerable participants, women of reproductive age shall not be arbitrarily excluded from participation in research. If such women are excluded, the Investigator must provide a rationale for this decision.
Non-English Speaking Participants

Non-English speaking participants shall not be excluded from research due solely to language barriers. The IRB encourages the inclusion of non-English speaking participants and permits such individuals to be enrolled via informed consent in their primary language or the use of the short form consent process consistent with 45 C.F.R. § 46.117(b)(2) and 21 C.F.R. § 50.27(b)(2). See Section 209 on Informed Consent.

207.2 Review of Recruitment Plan, Advertisements and Compensation

Recruitment Plan

The research plan must include a description on all methods of recruitment proposed on a project, including how participants will be identified for recruitment. Guidance on recruitment is available on the Human Studies Program website, as well as sample recruitment materials (e.g., flyers, recruitment script).

Advertisements

The use of advertisements initiates the informed consent process, and, consistent with the consent process, the IRB reviews those materials for coercion and undue influence during recruitment. The Investigator will be asked to revise the advertisement materials accordingly, as a condition for approval, if the submitted materials are found to be coercive or pose undue influence.

Mode of advertisement (flyers, radio, newspaper, or internet), and information contained in the advertisement must be reviewed and approved by the IRB before use. As appropriate, information on where the advertisement material will be posted and/or the specific vehicle of advertisement (i.e., blog, Facebook, type of magazine) may also be reviewed by the IRB before approval.

- **Printed advertisement**: The IRB reviews the final copy. If posting on the internet or newspaper, the IRB may request to receive the copy within its planned placement (i.e., screenshot), when appropriate.
- **Audio and video advertisement**: The IRB may review and approve the script prior to taping to avoid the chance of re-taping due to inappropriate wording. The IRB reviews the final version of the advertisement.

See:
- Guidance on Recruitment, **GUIDE 619: Recruitment Guidance**
- **GUIDE 620: Advertisements Appropriate Language for Recruitment Material**
- **TMP 475: Model Recruitment Flyer**

Compensation

Compensation, defined as remuneration in the form of cash, gift cards, extra credit, etc., intended to compensate human participants for their time and effort, must be reasonable in relation to the level of
effort required to participate in the research. Financial or other forms of compensation are not considered a benefit from research participation, and therefore cannot be described as a benefit of participating in the research in the consent form. The UH IRB does not permit the use of the term “payment” for compensating participants for their time and effort in the research, since participation in research is voluntary. Instead, “compensation” is often the label used in lieu of “payment.”

Although financial compensation can be perceived as an incentive to a participant, it will not be used in the IRB’s analysis of the risks and benefits of a study. For review of non-exempt research, the reviewer or convened IRB evaluates the amount and the form of compensation to ensure that it is:
- Not coercive nor poses undue influence; and
- Equitable in distribution.

If research involves multiple visits in which compensation is given, compensation shall be prorated throughout the duration of the study to provide partial payment to persons who withdraw before completing the entire study. The Investigator shall also take into consideration how participants shall be compensated if certain procedures within a given visit are not completed, either as a result of the Researchers’ determination or the participant’s choice.

All information regarding compensation for participation, including the amount and the schedule of remuneration, must be included in the informed consent.

Lotteries

The UH IRB prohibits lotteries, or other types of chance-based drawings. This is because lotteries or other types of chance-based drawings do not compensate each research participant equally for their involvement and, thus, are not equitable in distribution. Such activities may also pose undue influence in inducing participation.

Referral Payments

The UH IRB may allow finder's fees or referral fees that are made in exchange for referrals of prospective participants. Approval is made on a case-by-case basis. Referral fees may be allowed for research in which recruiting potential participants qualified for the research may be difficult or unreliable through more traditional means.

However, the UH IRB prohibits bonus payments to those referring participants that are designed to accelerate recruitment by tying payment to the rate or timing of enrollment.