

Guidance -

Recruitment with Vulnerable Participants

When a research study includes recruitment for involvement of any vulnerable populations, additional safeguards must be followed. Below is some guidance information for researchers and their staff.

The PI must consider the following elements:

- Purposes of the research
- Research environment
- Recruitment methods and materials
- Payment arrangements
- Timing of the consent process
- Inclusion/exclusion criteria
- Whether participants may be susceptible to coercion or undue influence
- Whether a population that stands no chance of benefiting is being selected to assume the risk.

Recruiting special subject populations

Vulnerable participants:

- Provide a rationale for involvement of vulnerable subjects, such as children, prisoners, pregnant women, economically and educationally disadvantaged, decisionally impaired, and homeless people, and
- Address why a less vulnerable population would not serve as well.

Children:

- Explain whether enrollment is limited to children. Research that limits enrollment to children is generally not appropriate unless
 - (i) the condition or disease is limited to children, **or**
 - (ii) the research seeks to obtain information on a test article or procedure that previously had been studied only in adults.

Members of minority groups:

- Explain whether the research holds out the prospect of benefit to individual subjects or the groups to which they belong, and
- How non-English speaking participants will be consented.

Geisinger employees or students:

- Explain how they will be protected from coercion and undue influence, and
- What alternatives to participation exist.

Excluding women and certain other types of participants

Explain whether it is justified by:

- Physiology, e.g. treatment for prostate cancer;
- Cultural prohibitions, e.g. one-to-one interviews of women in a situation where that might be construed as morally unacceptable;

- Childbearing potential, when women are not able to use reliable birth control methods for religious or other reasons and might have to be excluded from early Phase I studies of toxic chemical agents;
- Other reasons to be considered by the IRB.

Advertisements see Guidance Advertisements: Appropriate Language for Recruitment Material

Payment to participants

When proposing payment, there must be justification to:

- Substantiate that proposed payments are reasonable and commensurate with the expected contributions of the subject;
- State the terms of the subject participation agreement and the amount of payment in the informed consent form; and
- Substantiate that subject payments are fair and appropriate, and that they do not constitute (or appear to constitute) undue pressure on the subject to volunteer for the research study.

Recruitment material to submit for IRB review

- ***Audio and video tape:*** The IRB may review and approve the wording prior to taping in order to preclude re-taping due to inappropriate wording, with expedited review of final broadcast-ready tape.
- ***Printed advertisement:*** The IRB will review the final copy to evaluate visual effects of materials.
- ***Telephone:*** The IRB will review the phone scripts to determine whether the information collected constitutes the minimum necessary to establish basic eligibility for the specific study.
- ***Internet and web postings:*** The IRB will review the final draft to evaluate wording and visual effects. No review is necessary if the recruitment material only lists basic information such as: Title; Purpose of research; Protocol summary; Basic eligibility criteria; Research site location; Contact information.

Not allowed

The following activities are examined carefully and generally not allowed:

- Payment *from* research participants
- Compensation for participation in the form of a coupon for a discount on the test article to be used after the product has been approved for marketing.
- “Cold-calling” of potential research participants (i.e., unrelated party initiating telephone contact based on knowledge of confidential information), unless the following preferred methods are unavailable and good reason exists:
 - Patients of a particular clinic, physician or other caregiver only after the patient’s physician or caregiver has previously notified the potential research participant (or parent or legal representative) and obtained approval for such contact.
 - Members of a program based in the community, workplace, school, trade or union only after a program representative has previously notified the potential research participant (or parent or legal representative) and obtained approval for such contact.
- Exculpatory language through which the participant or participant’s LAR is made to waive or appear to waive any of the participant’s legal rights, or releases or appears to

release the investigator , the sponsor, the institution or its agents from liability for negligence.

References

- Geisinger HRPP Handbook Section 10: Participant Recruitment and Selection
- [45 CFR 46.111\(a\)\(3\), 45 CFR 46.116](#)
- [OHRP Guidance on Written IRB Procedures](#)
- [OHRP Compliance Activities: Common Findings and Guidance #3, #45 and #65](#)
- [21 CFR 50.20, 21 CFR 56.111\(a\)\(3\)](#)
- FDA Information Sheets: [FAQs: Informed Consent Document Content](#), FAQs: IRB Organization, A Guide to Informed Consent, Recruiting Study Subjects, Payment to Research Subjects