

8.0 Selection and Recruitment of Subjects

- I. Defining the appropriate group of subjects for a research project involves a variety of factors - requirements of scientific design, susceptibility to risk, likelihood of benefit, practicability, and considerations of fairness. To that end, the HSC shall make a specific determination that the selection of subjects is equitable.
- II. The HSC reviews the proposed study population to determine that subject selection is equitable and that additional safeguards are taken to protect subjects that may be vulnerable to coercion or undue influence.
- III. Investigators will provide relevant characteristics of the target population in the HSC application. Relevant characteristics may include age, gender, ethnicity and health status. Investigators will identify any vulnerable populations targeted for study participation. Investigators will describe measures to ensure that subject selection is equitable and that all relevant groups have access to the study.
- IV. Investigators may not exert undue pressure on potential subjects during the recruitment process. The investigator must ensure that subjects be given sufficient time to consider the decision to enroll in a research study. All reasonable steps must be taken to ensure that the recruitment method or material does not state or imply a guarantee of favorable outcome or other benefits beyond what is outlined in the consent document and the protocol.

8.1 HSC Review of Recruitment Materials and Selection of Subjects

- I. The HSC will review recruitment materials in making its determination that the selection of subjects is equitable. If available, investigators should include proposed recruitment materials in the initial application. If the investigator decides to advertise after study approval, the advertising would be considered an amendment to the ongoing study.
- II. The HSC reviews the information contained in the recruitment materials and the mode of its communication.
- III. Recruitment materials include, but are not limited to, the following:
 - A. flyers,
 - B. recruitment letters,
 - C. websites,
 - D. newspaper ads, and
 - E. television and radio commercials.

- IV. When advertisements can be easily compared to the approved protocol and consent form, the materials may be reviewed on an expedited basis by the HSC chair or other experienced member. If the reviewer has concerns about the appropriateness of the advertising, the materials will be reviewed at a convened meeting.
- V. In its review of selection of subject, the HSC will consider means for reducing the pressures on certain classes of subjects to participate in research. For example, patients should be reassured during the consent process that no benefits to which they are otherwise entitled, and no care or concern on the part of the health care providers, will be jeopardized by a decision not to participate in research. In cases where the principal investigator is the potential subject's physician, the HSC might find it preferable for someone other than the physician-investigator to discuss participation with the potential subject or to solicit the patient's consent. In other cases, the possibility of pressure may be reduced by consulting beforehand with representatives of the proposed subject group.
- VI. The informed consent process begins when the subject is first contacted about the possibility of participation. Therefore, the HSC must review advertising to ensure that the advertising:
 - A. Is not unduly coercive and does not promise a certainty of cure beyond what is outlined in the consent and the protocol.
 - B. Makes no claims, either explicitly or implicitly, that the drug, biologic, device or other research procedures are safe or effective for the purposes under investigation, or that the test article or other research procedures are known to be equivalent or superior to any other drug, biologic, device, or procedure.
 - C. Does not use terms such as "new treatment," "new medication" or "new drug" without explaining that the test article or the research procedures are investigational or experimental.
 - D. Does not promise "free medical treatment," when the intent is only to say subjects will not be charged for taking part in the investigation.
 - E. Does not emphasize the payment or the amount to be paid, by such means as larger or bold type, although it may state that subjects will be paid.
- VII. Advertisement to recruit subjects should be limited to the information the prospective subjects need to determine their eligibility and interest. When appropriately worded, the following items may be included in advertisements.
 - A. The name and address of the clinical investigator or research facility
 - B. The condition under study and the purpose of the research
 - C. In summary form, the criteria that will be used to determine eligibility for the study
 - D. A brief list of participation benefits, if any (e.g., a no-cost health examination)

- E. The time or other commitment required of the subjects
- F. The location of the research and the person or office to contact for further information.

8.2 Use of Medical Records for Recruitment

- I. Investigators who use medical records for subject selection and recruitment must meet HIPAA standards on the use of protected health information.
- II. If the investigator has an existing treatment relationship with the potential subject, then information from the medical records may be used to determine study eligibility without additional compliance requirements.
- III. Persons who do not have a treatment relationship with potential subjects may have access to medical records to determine eligibility under the following conditions:
 - A. The access must occur either with an authorization from the potential subject or an approved Partial Waiver of Authorization for Recruitment Purposes.
 - B. Once a potential subject has been identified, the initial contact to the potential subject must come from an individual or group who has an existing treatment relationship with the potential subject.

8.3 Payment of Research Subjects

- I. The HSC may approve payment to individuals who participate in research. The HSC reviews plans for study payments to determine that they are reasonable, equitable and do not represent coercion or undue influence.
- II. The HSC reviews the amount, schedule, and method of disbursement of all payments. The amount paid should be comparable to other research projects involving similar time, effort, and inconvenience.
- III. To avoid coercion, investigators may not make the entire payment contingent upon completion of the study. Credit for payments should accrue as the study progresses. The HSC may approve payment plans that include a small incentive for study completion, provided such payment would not unduly induce participants to stay in the study when they otherwise would have withdrawn.
- IV. For sponsored studies, compensation for participating in the study may not include a discount coupon on the purchase price of the product after it has been approved for marketing.

- V. All information concerning payment, including the amount and schedule of payment(s), must be present in the informed consent document.
- VI. The consent document will disclose the office(s) responsible for processing study payments and the nature of individually-identifiable information that will be disclosed to that office (such as the study title, name, address and Social Security Number) and any reporting of study payments that will be made to the Internal Revenue Service.

8.4 Enrollment Incentives to Investigators

- I. The HSC does not permit incentives or bonus payments to investigators or others solely to encourage recruitment of subjects into research studies.
- II. No payment of any type (cash, educational stipends, gift certificates, or anything else of value) may be made to an individual or department in exchange for referral or recruitment of a participant to a research study.
- III. All payments to investigators must be included in the study contract. If study sponsors propose to offer additional payments for enrollment after the contract is finalized, an amendment to the contract is required. Additional payment for enrollment must be tied directly to increased costs of enrollment activities (such as additional costs for clerical support, chart reviews or advertising or additional personnel costs to actively enroll subjects, evaluate eligibility or conduct follow-up visits). Bonus payments tied to the rate or timing of enrollment are disallowed.

References:

45 CFR 46.111
21 CFR 56.111
45 CFR 46.116
21 CFR 50.20, 25