

## 6 Selection & Recruitment of Subjects

### SELECTION OF SUBJECTS

Distributive justice, the third principle of The Belmont Report (See *Chapter 1, "Introduction: The Foundation of 45 CFR 46: The Belmont Report"*) requires the fair selection of subjects and the equitable distribution of the risks and benefits of research. The systematic selection of subjects because of easy availability, their compromised position, or because of social, racial, sexual, economic or cultural biases institutionalized in society results in an uneven distribution of the benefits and the burdens of research. The Sunrise Health Institutional Review Board (SHIRB) will closely examine research that requests the recruitment of subjects solely due to their easy availability, compromised position, or susceptibility to manipulation. For example, students, patients, or laboratory employees are compromised to the extent that their grades, access to health care, or jobs are dependent on those investigators recruiting them for research. The protocol should clearly articulate how the recruitment will avoid the appearance of coercion when selecting subjects who are in a dependent relationship to the investigator. (Please see *Chapter 8, "Special Classes of Research Subjects: Students and Employees,"* for more information.)

In order to allow for the fair and equitable distribution of the burden of research and to ensure that certain populations, such as prisoners or patients in mental institutions, were not recruited solely because of their easy availability, the National Commission for the Protection of Human Subjects recommended a hierarchy of preference in the selection of subjects for research: adults before children; competent individuals before incompetent individuals; and non-institutionalized persons before institutionalized persons. To adequately assess the risks and benefits of participation in research, the SHIRB requires accurate information regarding the number of subjects to be recruited and tested. In addition, the SHIRB will closely examine the characteristics of the subject population, such as age, gender, and population diversity outlined in the protocol and the procedures for identifying and recruiting subjects.

The mandate for the equitable distribution of the risks and benefits of participation in research to include women and minorities was addressed by the NIH, in the Outreach Notebook for the NIH Guidelines on Inclusion of Women and Minorities as Subjects in Clinical Research, published in 1994 (Please see Appendix 8, for more information). The guidelines indicate that researchers should include minorities and women in study populations, "so that the research findings can be of benefit to all persons at risk of the disease, disorder, or condition under study." The SHIRB will ask for a clear and compelling justification if women and/or minorities are not appropriately represented or are excluded from the research. (Please see *Chapter 8, "Special Classes of Research Subjects: Women; Minorities,"* for more information.) In order to ensure that the burdens of research are evenly distributed, the SHIRB is required to consider more than the risks associated with the research procedures. The SHIRB will also consider the impact participating in research poses on the daily life of the potential subject. For example, the Committee will consider reimbursement of subjects for inconvenience posed by the research, such as: the time required to take part; travel involved and/or parking costs; restrictions on diet or other activities; etc. Investigators should include provisions in the protocol for addressing these concerns, especially for research that poses little or no direct benefit for the subjects.

### RECRUITMENT OF SUBJECTS

Recruitment is the dialogue that takes place between an investigator and a potential subject prior to the initiation of the consent process. In some ways, recruitment is the introduction to the consent process. Recruitment may take the form of a flyer, a newspaper advertisement etc., or a verbal exchange between an investigator and a potential subject. Investigators that are responsible for both the primary care of a patient/client and wish to consider enrolling the patient/client into a research project should carefully differentiate for the patient/client the alternatives and options of participating in the research without undue prejudice or pressure. Respect for potential subjects begins with recruitment procedures that ensure the voluntary participation of the subject. Potential subjects should not feel coerced into participating in research, nor must they fear the loss of some benefit to which they are otherwise entitled if they choose not to participate. A person in authority, such as a teacher recruiting students or a physician recruiting patients, should take special precautions to ensure that a potential subject's decision to participate in research is not based on subtle pressures such as grades or a fear of loss of benefits, like medical treatment. Investigators proposing to recruit their students or patients as research subjects should justify in the protocol the necessity for the inclusion of the dependent subject. In addition, the SHIRB will closely scrutinize the precautions in place to prevent the appearance of coercion in the recruitment of the subjects. Investigators build a strong foundation for ethical research by ensuring and preserving the privacy and confidentiality of potential research subjects. In order to avoid a breach of the potential subject's privacy, investigators should not ask institutions, or their employees such as physicians or case workers to directly identify potential subjects for a research study. Instead, an investigator should ask the physician, case worker, etc., to first approach potential subjects (or their parent/guardian, as appropriate) and inform them of the research. A potential subject's privacy and confidentiality may be compromised simply by being identified as a potential subject in a study (for example, of cancer, AIDS, schizophrenia, or sexual deviance) or by identifying a patient/client's disorder to an investigator for the purposes of recruitment into research without the patient's consent. An investigator should not ask institutions or individuals to release records or anecdotal information either for the purposes of identifying potential subjects or for examination by the investigator, unless the information is in the public domain. For example:

*Ms. Smith is diagnosed with emphysema by Dr. Jones. Dr. Jones has not yet informed Ms. Smith about her disease. Dr. Brown is conducting research on emphysema. Dr. Brown asks Dr. Jones for the names and telephone numbers of all patients with emphysema. Dr. Brown contacts Ms. Smith to recruit her for his emphysema study. Ms. Smith is shocked not only that Dr. Brown has her name and personal medical information but that she has learned of her emphysema from someone she does not know. Dr. Jones has breached Ms. Smith's confidentiality by giving her name without permission to Dr. Brown.*

*Dr. Brown has breached Ms. Smith's privacy by contacting Ms. Smith without her permission. Oftentimes, in order to protect the privacy of the potential subject and decrease any appearance of coercion, the Committee will request the use of a flyer or a contact letter posted in the waiting room or the lobby of the facility to inform potential subjects about the research. The flyers or post-cards, etc., would include a description of the study and a telephone number for potential subjects to call if they are interested. Through this process, investigators avoid the appearance of coercion in the initial recruitment stage, while potential subjects maintain their privacy by initiating contact with the investigator.*

***Recruitment tools:***

A recruitment tool informs potential subjects of a research activity and provides them with an opportunity to contact the researcher. A recruitment tool may include but is not limited to post-cards, flyers, advertisements, press releases, brochures, and postings on the internet. Investigators are encouraged to use the following guidelines when developing recruitment tools:

- Information should not be misleading to subjects, especially when a study involves vulnerable populations;
- Include the name, affiliation, and address of the investigator;
- the purpose of the research;
- the eligibility criteria for participating;
- an honest and direct description of the risks and benefits of the study;
- whom to contact for further information;
- no claim should be made as to the superiority, safety, or effectiveness of drugs or devices used in research.

***NOTE: All recruitment materials are required to have SHIRB review and approval***

**NOTE:** When recruiting subjects from another institution, investigators are required to gain approval from that institution's Institutional Review Board (IRB). If the institution does not have an IRB, investigators are required to obtain a letter of compliance on the facility's letterhead with a statement that the agency/institution will "review, abide by, and comply with the procedures approved by the Sunrise Health IRB."

**Payment for Participating in Research**

The nature, amount and method of payment or other remuneration should not constitute undue inducement to take part (i.e., the payment alone should not serve as sufficient inducement for the subject to volunteer). Investigators should consider reimbursement for the inconvenience posed to subjects or other costs to subjects resulting from participating in the research, such as: parking fees, travel, lost time from work, baby-sitters, etc. Since subjects reserve the right to withdraw their participation from the research without prejudice, payment to subjects should be prorated, i.e., partial participation in a research activity would obligate partial payment. The SHIRB will review both the amount of the payment and the proposed method of disbursement to ensure that neither includes problems of coercion or undue influence.

**Recruitment of Children**

The ethical requirement of respect for persons, as outlined in The Belmont Report, applies to children as well as adults. Children, however, are in a dependent relationship to adults and easily manipulated in an academic or clinical setting. A child's dependent relationship entitles them to extra protections and are thus considered a "vulnerable subject population" (Please see *Chapter 8, "Special Classes of Subject Populations: Children"* for more information) Investigators should take every precaution to insure that a child's decision to participate in research is both voluntary and free from coercion. A child's refusal to participate should not be met with a negative response or punishment.

The SHIRB strongly recommends that investigators address the following when submitting applications that include the recruitment of children: 1. investigators should acknowledge and create a mechanism for addressing and minimizing the coercion implicit in requests to participate from parents, teachers, or other adult authorities, such as the investigator or the research staff; 2. investigators should make provisions to minimize the fear of ridicule, social pressure, or peer pressure to participate; 3. incentives or rewards for participating may be used but should not be so valuable, within the value system of the child, as to sway their legitimate reluctance to take part.

**Permission of the School:**

School officials and/or teachers do not have the authority to give consent for children to participate in research. Only a parent or guardian may allow a child, with the child's assent, to participate in research. The SHIRB requires submission of proof of approval of the school district prior to allowing investigators to contact, recruit, or enroll children into a study. Investigators should contact school district officials regarding the appropriate procedures for obtaining permission to conduct research in individual schools.