

Chapter 14

RECRUITMENT AND SELECTION OF SUBJECTS

A. Advertisements

Defining the appropriate group of subjects for a research project involves:

- * Requirements of scientific design
- * Susceptibility to risk
- * Likelihood of benefit
- * Practicability
- * Considerations of fairness

Direct recruiting advertisements are seen as part of the informed consent and subject selection processes. IRB review is necessary to ensure that the information is not misleading to subjects. This is especially critical when a study may involve subjects who are likely to be vulnerable to undue influence.

The FDA believes that advertisements to recruit subjects should be limited to the information the prospective subjects need to determine their eligibility and interest.

Advertisements must include the following information:

1. the name, address and phone number of the investigator;
2. the purpose of the research and, in summary form, the eligibility criteria for subjects;
3. the location of the research;
4. if appropriate, a brief description of the procedures;
5. a description of the potential benefits;
6. the person to contact for further information;
7. amount of time or other commitment required of the subjects.

Notices related to inservices to hospital staff are not considered advertisements.

For drug or device studies, no claims may be made, either explicitly or implicitly, that the drug or device is safe or effective for the purposes under investigation or that the drug or device is in any way equivalent or superior to any other drug or device.

Advertisements that are easily compared to the consent form will be reviewed and approved by the IRB using expedited procedures. When the comparison is not obvious or other complicating issues are involved, the advertisement will be reviewed at a convened meeting.

B. Financial Incentive for Subject Participation in Research

It is not uncommon for subjects to be paid for their participation in research, especially in the early phases of investigational drug, biologic or device development. Payment to research subjects for participation in studies is not considered a benefit, it is a recruitment incentive. Financial incentives are often used when benefit to subjects is remote or non-existent. The amount and schedule of all payments should be presented to the IRB at the time of initial review.

All payments should accrue as the study progresses and not be contingent upon the subject completing the entire study. Unless it creates undue inconvenience or a coercive practice, payment to subjects who withdraw from the study may be made at the time they would have completed the study had they not withdrawn, or must be prorated accordingly.

While the entire payment should not be contingent upon completion of the study, payment of a small proportion as an incentive for completion of the study is acceptable, providing that such incentive is not coercive.

All information concerning payment, including the amount and schedule of payment(s), should be set forth in the informed consent document.

C. Screening Tests Prior to Study Enrollment

1. General Information

An investigator may discuss availability of studies and the possibility of entry into a study with a prospective subject without first obtaining consent. However, informed consent must be obtained prior to initiation of any screening procedures that are performed solely for the purpose of determining eligibility for research. When a doctor-patient relationship exists, prospective subjects may not realize that screening tests performed solely for research enrollment are not required for their medical care. Physician-investigators should take extra care to clarify with their patient-subjects why certain tests are being conducted.

2. Submission of Materials

You must submit a written outline of the screening procedure to be followed and how consent for screening will be obtained. The outline is limited to a description of the screening tests and to the reasons for performing the tests, including a brief summary description of the study in which they may be asked to participate.

3. IRB Review and Approval

Screening procedures for research eligibility are considered part of the subject selection and recruitment process and therefore require IRB review and approval. This approval may be obtained using expedited review if the screening test qualifies as a minimal risk procedure.

Unless the screening tests involve more than minimal risk or involve a procedure for which written consent is normally required outside the research context, the IRB may decide that prospective study subjects need not sign a consent document.

D. Equitable Selection of Subjects; Non-Discrimination

1. General Guidelines

Recruitment and selection of subjects must be equitable within the confines of the study. You may not *arbitrarily* exclude subjects on the basis of gender, race, national origin, religion, creed, education, or socioeconomic status. Investigators are required to justify any proposed involvement of hospital patients, other institutionalized persons, disproportionate numbers of racial or ethnic minorities, or persons at the lower end of the socioeconomic scale.

2. Recruitment of Women and Minorities

In March 1994, the National Institutes of Health (NIH) published Guidelines which address issues concerning the recruitment of women and minorities. There is a need to obtain critically important information to detect and account for significant differences between genders or racial and ethnic groups where they exist.

3. Economically Disadvantaged Subjects

a. Added Costs

The Board will be concerned if added costs are so great as to preclude participation by the economically disadvantaged.

b. Financial Remuneration, Reward or Reimbursement

Financial remuneration, reward, reimbursement for expenses, or other inducement for participation should not be so great as to be coercive to potential subjects.

E. Recruiting Patients of Clients

Physicians, psychologists, counselors, lawyers and others who have confidential relationships with patients or clients may not release their names without their express consent. You *may not* contact subjects without this consent.

F. Electronic Medical Records: Access and Use

This policy and form to be distributed at a later date.