

DEPARTMENT: INSTITUTIONAL REVIEW BOARD
POLICY NUMBER 029
SECTION: GENERAL IRB POLICIES
REVIEW RESPONSIBILITY: IRB
EFFECTIVE DATE: AUGUST 13, 2003
REVISION DATE:
LAW IMPLEMENTED: 45 CFR 46.103

SUBJECT: Recruitment of Subjects

1. The IRB must ensure that appropriate safeguards exist to protect the rights and welfare of research subjects. In fulfilling these responsibilities, the IRB must review the methods and materials that investigators propose to use to recruit subjects. For example, the Investigator must obtain IRB approval for all television, radio, videotape, or print advertisements, email solicitations, Internet websites, and other recruitment methods and materials.
2. Advertising or soliciting for study subjects is part of the informed consent and subject selection process. Thus, advertisements must be reviewed and approved by the IRB as part of the package for initial review. When the Investigator decides after the initial approval to advertise for subjects or to change the advertisement, the advertising is considered an amendment to the ongoing study. The IRB will review the advertisement to assure that it is not unduly coercive and does not promise a certainty of cure or other benefits beyond what is outlined in the consent and the protocol. This is especially critical when a study may involve subjects who are likely to be vulnerable to undue influence.
3. The IRB must review the information contained in an advertisement and the mode of communication. The IRB must review the final copy of printed advertisements to evaluate the relative size of type used and other visual effects. When advertisements are to be taped for broadcast, the IRB must review the final audio/video tape.
4. Any advertisement to recruit subjects should be limited to the information the prospective subjects need to determine their eligibility and interest. Advertising materials should not include the following:
 - a) claims, either explicitly or implicitly that the drug, biologic, device or other type of intervention is safe or effective for the purposes under investigation;
 - b) claims, either explicitly or implicitly, that the test article is known to be equivalent or superior to any other drug, biologic, device or intervention.
 - c) terms such as “new treatment”, “new medication” or “new drug” without explaining that the test article is investigational;
 - d) promises of “free medical treatment”, when the intent is only to say that subjects will not be charged for taking part in the investigation.

5. Receptionist Scripts. The first contact prospective study subjects make is often with a receptionist who follows a script to determine basic eligibility for the specific study. The IRB must review the script and procedures to ensure protection of rights and welfare of prospective subjects, and that any information collected about prospective subjects will be appropriately handled.
6. Student Subjects. The IRB has oversight of the use of students as subjects in research. The IRB must ensure that the consent for participation is sought only under circumstances which minimize the possibility of coercion or undue influence, and that genuinely equivalent alternatives to participation are available (i.e. term papers).
7. Inclusion of Women, Children, and Minorities. The inclusion of both women and men and of minorities in research is important, both to ensure that they receive an appropriate share of the benefits of research and that they do not bear a disproportionate burden. Moreover, for purposes of generalizing research results, investigators must include the widest possible range of population groups.
8. NIH supported investigators must provide to the IRB details of the proposed involvement of humans in their research protocols, including the characteristics of the subject population, anticipated numbers, age ranges, and health statuses. The proposed research should specify the gender and racial/ethnic composition of the subject population, as well as criteria for inclusion or exclusion of any subpopulation. If ethnic, racial, and gender estimates and continuing review numbers are not included in the background data for a protocol, the investigators must provide a clear rationale for exclusion of this information.