

Overview

Federal regulations require the IRB to ensure that appropriate safeguards exist to protect the rights and welfare of research subjects. In fulfilling these responsibilities, the RU IRB is expected to review all the research documents and activities that bear directly on the rights and welfare of the subjects of proposed research. The RU IRB considers the recruitment process as the start of the informed consent process and treats the review of recruitment materials as part of this process. The protocol, the consent document, all television, radio, videotape or print advertisements, e-mail solicitations, Internet websites, and other recruitment methods and materials intended for the recruitment of prospective research participants and, for studies conducted under the FDA Investigational New Drug (IND) regulations, the investigator's brochure, are examples of documents that the IRB should review. The IRB should also review the methods and materials that investigators propose to use to recruit subjects.

The following materials are not considered advertisement materials:

- Communications intended to be seen or heard by health professionals, such as "dear doctor" letters and doctor-to-doctor letters (even when soliciting for study subjects);
- News stories;
- Publicity intended for other audiences, such as financial page advertisements directed toward prospective investors.

Since the RU IRB considers the recruitment process as the beginning of the consent process, all recruitment materials and methods must be submitted as part of the initial review process (see Standard II-2.C). However, if the investigator decides after the initial approval of the research protocol to advertise for subjects or wishes to change the advertisement, then this is considered an amendment to the research protocol and is reviewed as such.

Is IRB review of clinical trial listings required?

IRB review and approval of listings of clinical trials on the internet would provide no additional safeguard and is not required when the system format limits the information provided to basic trial information, such as: the title; purpose of the study; protocol summary; basic eligibility criteria; study site location(s); and how to contact the site for further information. Examples of clinical trial listing services that do not require prospective IRB approval include the National Cancer Institute's cancer clinical trial listing (PDQ) and the government-sponsored AIDS Clinical Trials Information Service (ACTIS). However, when the opportunity to add additional descriptive information is not

precluded by the data base system, IRB review and approval may assure that the additional information does not promise or imply a certainty of cure or other benefit beyond what is contained in the protocol and the informed consent document.

The following sections describe the principles that the RU IRB uses to evaluate proposed recruitment procedures.

- A) [Equitable selection of participants](#)
- B) [Permissible recruitment practices](#)
- C) [Review of recruitment methods, advertising and payment arrangements](#)

REFERENCES

Amdur, R. *The Institutional Review Board Member Handbook*. Sudbury MA: Jones and Bartlett Publishers, Chapter 3-3. Advertisements for Research.; 3-4, Denying Subjects Access to Research Results; 3-5, Paying Research Subjects.

FDA information sheet (1998 rev.) [Recruiting Study Subjects](#).

A. Equitable selection

The IRB reviews proposed recruitment methods to determine whether they allow for fair and equitable distribution of the burden and benefits of research. To a reasonable extent, members of all populations who will benefit from the research should have an opportunity (and burden) to participate as subjects. The IRB should keep the following points in mind when reviewing recruitment materials.

- If the study is to be generalized to “all people”, then recruitment materials and methods should not target one group of people (for example both males and females should be targeted). The IRB should take into consideration the purpose of the research when making this assessment;
- Investigators should not recruit subjects solely because they are easily available, are in a compromised position, or their circumstances are easy to manipulate;
- The advertising should not be unduly coercive and should not promise a certainty of cure/treatment 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 and are in a dependent relationship to the investigator, for example, students, patients or employees.

REFERENCES:

AAHRPP II-5.A. The RRU has and follows written policies and procedures to evaluate the equitable selection of participants from various populations and sub-populations, where applicable, and considers whether inclusion and exclusion criteria impose fair and equitable burdens and benefits.

B. Permissible recruitment practices

The IRB follows the guidelines in the [FDA information sheet](#) (rev. 1998) to be sure that advertising fairly represents the research and provides a basis for an informed decision about possible participation.

According to these guidelines, adequately informative advertisements include the following details:

- Name and address of the investigator or the research facility
- The condition that is under study, or the purposes of the research
- Inclusion and exclusion criteria in summary form
- Brief list of procedures involved
- Time commitment required
- Compensation or reimbursement, if any
- Location of research, and contact person for further information.

What are some of the recruitment methods and materials that are not acceptable?

The IRB reviews the recruitment methods and materials to ensure that the research is fairly represented and the following items do not appear in any recruitment materials:

- Advertisements should not emphasize monetary compensation
- They should not use catchy words like “free” or “exciting”
- They should be clear that research participation is what is being solicited, and not create the impression of a proven procedure
- They should not be misleading about the purpose of the research, though they may describe it in accurate general terms.
- No claims should be made, either explicitly or implicitly, that the drug, biologic or device is safe or effective for the purposes under investigation, or that the test article is known to be equivalent or superior to any other drug, biologic or device.
- Advertising for recruitment into investigational drug, biologic or device studies should not use terms such as "new treatment," "new medication" or "new drug" without explaining that the test article is investigational. A phrase such as "receive new treatments" leads study subjects to believe they will be receiving newly improved products of proven worth.
- Advertisements should not promise "free medical treatment," when the intent is only to say subjects will not be charged for taking part in the investigation.
- Similarly, advertisements should not overly emphasize the potential benefits of receiving psychological treatment as a part of participation in the research.

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 or video tape. The IRB may review and approve the wording of the advertisement prior to taping to preclude re-taping because of inappropriate wording. The review of the final taped message prepared from

IRB-approved text may be accomplished through expedited approval procedures.

Should the IRB examine 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 procedures followed adequately to protect the rights and welfare of the prospective subjects. In some cases personal and sensitive information is gathered about the individual. The IRB should have assurance that the information will be appropriately handled.

What are some of the specific issues the IRB should review?

The IRB reviews the following issues to make sure they are adequately handled in order to protect the rights and welfare of possible research participants.

- What happens to personal information if the caller ends the interview or simply hangs up?
- Are the data gathered by a marketing company? If so, are names, etc. sold to others?
- Are names of non-eligible participants maintained in case they would qualify for another study?
- Are paper copies of records shredded or are readable copies put out as trash?

REFERENCES:

AAHRPP II-5.B. The RRU has and follows written policies and procedures describing permissible recruitment practices for proposed research.

FDA information sheet (1998 rev.) [Recruiting Study Subjects](#).

Sample subject recruiting guidelines (UCSF):

http://www.research.ucsf.edu/chr/chr_recruitment.htm

(last accessed 7/16/2003)

C. Review of recruitment methods, advertising and payment arrangements

The Rutgers University IRB reviews all plans for recruitment, advertisement and payment methods. The RU IRB does not take a position as to paying or not paying research subjects, but does review arrangements for remuneration in the context of the specific protocol, to ensure that they are fair, non-coercive, and appropriate.

The application for IRB review requires Investigators to attach any actual advertising materials such as posters, brochures, or scripts for commercials, with the application, before using them. The IRB follows the guidelines in the [FDA information sheet](#) (rev. 1998) to be sure that advertising fairly represents the research and provides a basis for an informed decision about possible participation.

The RU IRB considers the payment of research subjects as a recruitment incentive and not as a potential benefit of the study. The IRB requires that the amount and schedule of all payments be presented to the IRB at the time of initial review. The IRB reviews both the amount of payment and the proposed method and timing of disbursement to assure that neither are coercive nor present undue influence. When reviewing payment procedures of a study, the IRB keeps in mind the following guidelines:

- Any credit for payment 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 (or completed a phase of the study) had they not withdrawn. For example, in a study lasting only a few days, an IRB may find it permissible to allow a single payment date at the end of the study, even to subjects who had withdrawn before that date.
- While the entire payment should not be contingent upon completion of the entire study, payment of a small proportion as an incentive for completion of the study is acceptable to FDA, providing that such incentive is not coercive. The IRB should determine that the amount paid as a bonus for completion is reasonable and not so large as to unduly induce subjects to stay in the study when they would otherwise have withdrawn. All information concerning payment, including the amount and schedule of payment(s), should be set forth in the informed consent document.

What are RU policies regarding ‘finder’s fees’?

Sponsors may offer to pay Investigators or study personnel an additional fee to encourage participant recruitment efforts and the timely or accelerated opening of research studies. Also, physicians or other primary caregivers may be offered payments for identifying patients who may be eligible for study participation. In most cases, these additional “finder’s fees” are strictly prohibited by Federal regulations and promote the risk of serious ethical digressions. Although the RU IRB does not typically encounter such request due to the majority of the social-behavioral research it reviews, it is aware of the following guidelines:

- It is unacceptable to pay or to receive “finder’s fees” for referring eligible patients for research studies.
- It is unacceptable for Rutgers University employees or students to accept personal payments from sponsors or other researchers in exchange for accelerated recruitment or referrals of patients.
- It is unacceptable to accept bonus payments. Bonus payments are extra payments made to the investigator or research coordinators for newly enrolled subjects outside the negotiated budget.
- It is acceptable to receive compensation for recruitment and screening related activities that are unrelated to whether the participant ultimately enrolls in or completes the research study (such as advertising, administrative and personnel costs)
- It is acceptable to renegotiate an existing contract fee structure if the recruitment process is taking longer than anticipated and more time and resources must be expended in order to complete the study.

REFERENCE:

AAHRPP II-5.C. The RRU reviews proposed participant recruitment methods, advertising materials and participant payment arrangements, and permits them only if fair, honest and appropriate.

Amdur, R. *The Institutional Review Board Member Handbook*. Sudbury MA: Jones and Bartlett Publishers, Chapter 3-3. Advertisements for Research.

FDA information sheet (1998 rev.) [Recruiting Study Subjects](#).

FDA information sheet (1998 rev.) [Payment to Research Subject](#).

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