

Guidelines for Human Subject Recruitment

Recruitment Issues

from Institutional Review Board Member Handbook

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The recruitment of subjects, which is considered the start of the consent/assent process, and the feasibility of recruiting must be considered and planned before initiation of a study and must continue throughout the study. For this reason, the IRB must review the methods, materials, procedures, and tools used to recruit potential research subjects before they are implemented. Some of the more commonly used tools of recruitment include direct advertising (flyers, posters, press releases, brochures), media advertisements (newspaper, TV, radio, websites), recruitment letters, review of medical charts and computerized databases, and presentations at community meeting places.

A 1998 update of the FDA information sheet *Recruiting Study subjects* presents guidelines for the format of study advertisement:

- Name and address of the investigator and/or research facility/institution
- Condition under study and/or purpose of research
- Inclusion exclusion criteria in summary form
- A brief list of procedures involved
- Time or other commitment required (number of visits, total duration during follow-up visits, etc)
- Compensation/reimbursement
- Location of research and contact person for further information

Flyers, Posters, and Brochures

Flyers, posters and brochures are often used to solicit potential research subjects. These types of advertisements are typically placed in strategic locations in the hope of targeting the population being studied. Some of these locations may include bulletin boards, professional offices/businesses, schools, public transportation (buses, subways, trains), and public areas such as restaurants. While it is mandatory to obtain IRB approval for use of such advertisements, it may also be necessary for an investigator to obtain approval from the various sites where the flyer, poster and/or brochure will be placed. This should also be done prior to posting or distribution of the ad, and evidence of this approval may be required by the IRB. Since these types of advertisements are visible tools of recruitment, they must present sufficient information that is accurate and balanced so that potential subjects are able to make an informed decision about possible participation. The decision to include compensation and/or reimbursement in the advertisement may be made on a case by case basis, depending on the study itself and the particular policies and guidelines of the IRB. Although compensation or reimbursement may factor into one's decision to participate in a study, it must be carefully thought out and worded appropriately so as not to coerce a subject to participate. The examples of acceptable and unacceptable research advertisements presented here will clarify these issues.

Advertisements for Research

The IRB must approve all plans for advertisement (including the actual posters, brochures, scripts for commercials, etc.) prior to their use. A 1998 update of the FDA information sheet: *Recruiting Study Subjects* presents guidelines for the format of study advertisement:

- Name and address of the investigator and/or research facility/institution
- Condition under study and/or purpose of research
- Inclusion/exclusion criteria in summary form
- A brief list of procedures involved
- Time or aother commitment required (number of visits, total duration during follow-up visits, etc.)
- Compensation/reimbursement
- Location of research and contact person for further information

Additional guidelines include the following:

- Advertisements should not emphasize monetary compensation
- Advertisements should not use catch words like "free" or "exciting"
- Advertisements should be very clear that research participation is what is being solicited
- Advertisements should not be misleading about the purpose of the research

Example 1 presents an advertisement that should not be approved by the IRB.

***Lose Weight Fast and Receive Cash!!
Join an Exciting Weight Loss Study***

- Are you a teenager?
- Are you fat and want to lose weight?

If you answered YES to these questions, you may qualify to participate in a weight loss study.

You will receive a free medical evaluation and participate in a cutting-edge nutrition program. You will also receive \$\$\$ money \$\$\$ and parking vouchers. No medications will be given.

Call (810) xxx-xxxx for more information

Reasons why the above advertisement would not be approved:

- *Monetary compensation is emphasized*
- *Catch words such as “exciting,” “fast,” “cutting-edge,” and “free” are used*
- *The ages for eligibility are not specified*
- *The purpose of the study is not specified*
- *There is no mention that this study is “research”*
- *Terms such as “fat” may be insulting*
- *The name of the contact person is not included*
- *The study location is not included*
- *The purpose of the advertisement is misleading*

Example 2 presents an advertisement that meets the basic guidelines for IRB approval:

Weight Loss Prevention and Diabetes Study

Be part of an important nutrition research study

- Are you between 13 and 21 years of age?
- Do you want to change your eating habits in order to lose weight?
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If you answered YES to these questions, you may be eligible to participate in a nutrition research study.

The purpose of this research study is to compare the effectiveness of different diets in preventing Type II diabetes. Benefits include a comprehensive medical evaluation and individual nutrition program. Participants will receive an incentive payment and a voucher for free parking. No medications will be given.

*Both adolescents (13 - 17 years of age) and adults (18 - 21 years of age) are eligible to participate.
This study is being conducted at Central Hospital, 1234 Main St., Any City, USA*

Please call Beth Woods at (810) xxx-xxxx for more information

Reasons why the above advertisement would be approved:

- *The approach is straightforward and honest*
- *The type of research is specified*
- *The ages for eligibility are included*
- *The purpose is clearly stated*
- *The benefits are included*
- *The contact person’s name is included*
- *The institution is identified*