SOP 403: Recruitment Materials

Terms and Abbreviations

FDA: Food and Drug Administration; the division of Health and Human Services that oversees drugs, medical devices, and food.
IRB: Institutional Review Board
UWM: University of Wisconsin – Milwaukee

Overview

Recruitment is the first step in the consent process and requires IRB oversight.

Materials developed for the sole purpose of recruiting human participants for research activities must be reviewed and approved by the IRB. It is recommended that the materials include the UWM protocol number and IRB approval date.

The materials should be submitted with all formatting, pictures, etc. included. The IRB evaluates not only the written content, but the overall presentation for appropriateness and to ensure the recruitment material does not unduly promote compensation or promise benefit.

Details and Procedures

Submission Process
All recruitment materials must be submitted in an electronic format for the IRB's review and approval. This includes not only the traditional ads or flyers, but also all scripts for all in-person, phone, and email recruitment. To the extent possible, the submission should include the final, formatted version of all materials, including font color and sizes, pictures, and any other visual effects.

For audio or video recordings, researchers are required to submit the written text for review and approval. Once the wording has been finalized, it is recommended that an audio or video file also be submitted for review and for the IRB's records.

Copies of all approved recruitment materials will be stored in the study's file in the online submission system. Alterations to the approved recruitment materials must be submitted to the IRB as a protocol amendment before use.

Content of Recruitment Materials

The IRB reviews the recruitment material to ensure that it accurately reflects the study, does not include excessive emphasis on compensation, and does not promise a certainty of benefit 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.

Generally, materials to recruit subjects should be limited to the information the prospective participants need to determine their eligibility and interest. When appropriately worded, the following items may be included in recruitment materials. However, not all of the listed items are required for every study.

- the study title;
- the condition under study and/or the purpose of the research;
- basic eligibility criteria;
- a brief list of direct participation benefits, if any (e.g., a no-cost health examination);
- the time or other commitment required of the subjects;
- the name and contact information of the researcher
- for research occurring in a specific location, the location name and/or address where the research will occur; and
- the IRB study number and approval date.

To prevent undue influence, the following should not be included in recruitment materials:

- If an experimental drug or device is being studied, no claims should be made, either explicitly or implicitly, that it 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 or device.
- Recruitment for an experimental intervention should not use the term "new" without explaining that the intervention is investigational. A phrase such as "receive new treatments" leads study subjects to believe they will be receiving newly improved products of proven worth.
- Recruitment materials should not promise "free treatment," when the intent is only to say subjects will not be charged for taking part in the investigation.
- Recruitment materials may state that subjects will be paid, but should not emphasize the payment or the amount to be paid, by such means as larger or bold type.

Initial contact with participants

The first contact prospective study subjects make is often communication with a research team member to determine basic eligibility for the specific study. The IRB may ask to review full scripts for recruitment and screening conversations, particularly when the person conducting the discussions is relatively inexperienced in research (research assistants, community partners, etc.), or when studies involve sensitive topics or vulnerable populations.

The IRB must assure the procedures followed adequately protect the rights and welfare of the prospective subjects. In some cases, personal and sensitive information is gathered about the individual. The study submission should describe how this initial information will be handled.

- What happens to information collected from individuals who are ineligible? Is it kept, or destroyed? If kept, how long and where?
- Are paper copies of records shredded or are readable copies put out as trash?
- Are any other protections used to ensure the confidentiality of data collected at this stage?

The acceptability of the procedures depends on the sensitivity of the data being gathered.

References

FDA Information Sheet: Recruiting Study Subjects

Revision History

Version	Date	Summary of Changes
1	2 Jul 2020	Initial version