

University of Cincinnati

A Principal Investigator's Guide to Recruitment and Study Related Materials

The UC IRB reviews recruitment and study-related materials according to federal regulations [both Department of Health and Human Services (DHHS) and Food and Drug Administration (FDA)], International Conference on Harmonization (ICH) Guidelines (if applicable) and the Board's policies and procedures. These regulations and guidelines require that Institutional Review Boards (IRBs) make sure that the selection of participants for a study is equitable. The IRB is required to ensure that appropriate safeguards exist to protect the rights and welfare of research participants [21 CFR 56.107 (a) and 56.111]. Each protocol submitted to the UC IRB must explain how participants will be identified and recruited for each study. The IRB must consider how the investigator proposes to approach those individuals. Any approach to participants must be non-coercive and potential participants must voluntarily participate in the recruitment process. Participant's privacy must be respected and protected.

General Recruitment

Advertisements, recruitment materials and study-related materials are an extension of the informed consent process. Recruitment of participants into a study may not begin before IRB approval.

The IRB should review the methods and materials that investigators propose to use to recruit participants. The following are examples of **recruitment materials/methods** for human research studies. All recruitment methods must be described in the protocol application.

- Media advertisements- *Radio script/Commercial television
 - Subject/patient letters and emails
 - Website advertisements-
 - Phone-screen scripts
 - Newsletters and flyers/posters/handouts/brochures
 - Pre-screening scripts
 - Generic pre-screening informed consent documents (ICDs)
 - Doctor to Doctor letters related to recruitment, referral and/or retention of study participants
- *it is recommended that scripts are reviewed and approved prior to production of audio/video materials. All recruitment medial must be approved before advertising begins.***

The IRB is expected to review all the research documents and activities that bear directly on the rights and welfare of the participants of proposed research. **Study-related materials** include but are not limited to:

- Diaries
- Subject instructions
- Questionnaires

Recruitment and Study-Related Materials Guidelines

Recruitment and study-related materials must not be coercive and must not promise a benefit beyond what is outlined in the consent and the protocol. The recruitment materials must direct potential participants to proper personnel for further information. This is especially critical when a research study may involve participants who are likely to be vulnerable to undue influence [21 CFR 50.20, 50.25, 50.111(a)(3), 56.111(b) and 812.20(b)(11).]

Recruitment materials should contain the following information:

- A statement that the study involves **“research study”** (instead of trial or clinical trial);
- The name and location of the institution and center/department conducting the research;
- The name of the PI or department if appropriate;
- Statement or condition under study and brief description of the purpose of the research study, e.g., “an investigational drug to determine if it may improve (condition)”; “An investigational drug is one that is not approved by the United States Food and Drug Administration (FDA).”;
- Use “investigational” or “experimental” wherever appropriate;
- A brief list of the procedures involved- “study-related” procedures include...”;
- A brief summary of the eligibility criteria;
- A statement of the approximate time commitment required, if appropriate;
- A brief description of the compensation/reimbursement- “compensation for time and travel”;
- Contact information for further information, with telephone number;

Language in recruitment and study-related materials must be understood by potential participants. Use lay language that a lay person would be able to understand.

Recruitment materials should NOT include:

- Any language that would contribute to therapeutic misconception (research participant’s belief that enrolling in the study will contribute to therapeutic benefit)

An example of this would be the use of “patient” instead of “participant” or “clinical trial” instead of “research study”;

- Claims about the efficacy, safety, or superiority of investigational agents (drug, device or biologic) that is inconsistent with the FDA labeling, [or the security of confidential information and/or proprietary information];
- Enticing or inducing terms such as “free”, “new”, “exciting”, “opportunity”, “limited opportunity”, “you deserve to feel better”;
- Inducing phrases such as “limited enrollment,” “call today” or “study ends soon”
- Exculpatory language through which the participant waives or appears to waive any legal rights, or release the investigators, the institution or its agents from liability for negligence;
- Overemphasis on compensation, should not emphasize the amount paid by such means as larger or bold type or font. If the payments will be prorated, the ad should make this clear. For example, instead of stating “\$300 compensation,” the ad should state that participants will receive \$50 for each of six completed visits.
- Links to sites/resources that are not IRB approved
- Any overemphasis on specific parts of the advertisement (i.e., underlining, bold, italics, all caps, color font, etc.).

Additional Considerations:

- Recruitment and study-related material must be in lay language or understood by potential participants;
- Use “research study” instead of “clinical trial” or “trial”;
- Use the phrase “at no cost” in place of “free”
- If using a placebo explain that this is an inactive substance or a “look-alike pill” that contains no active ingredient;
- When describing the study purpose (e.g., “...a research study of an investigational drug...”), include “to determine if it helps...,” “to determine if it improves...,” or to see if it” Use the UC IRB approved ICD as a guide.



EXAMPLE

Volunteers Needed for a Research Study

“Improving muscle tone and balance for older adults”

The study is open to adults 50 years and older.

The purpose of the research study is to compare the effect of two different exercise programs on muscle tone and balance.

Participation involves light to moderate exercise during 12 study visits over a 6 week period.

Time commitment: Each study visit will last approximately 1 hour.

Participants will receive study related physical fitness tests and may see improved muscle tone and balance.

Participants will be reimbursed for time and travel. Up to \$XXX or \$XX for each study visit.

The research will be conducted at the University of Cincinnati.

For additional information, please contact Jennifer HXXXX at 513- XXX-XXXX or email Jennifer at: xxxxxx.xxx@xxxxx

Principal Investigator: Dr. Sxxxxx Dxxxx, Ph.D.

University of Cincinnati, Allied Health Sciences

EXAMPLE



Type I Diabetics Needed for a Research Study

“Improving blood glucose control in diabetic adults”

The research study is open to Type I insulin dependent adults 18 years and older.

The purpose of this research study is to determine the effectiveness and safety of an investigational study drug (not approved by the United States Food and Drug Administration) combined with your normal insulin regimen and will be compared to your normal insulin regimen plus placebo (an inactive substance).

Time commitment: The study will last 12 months and involve 13 study visits. Each visit lasts approximately 1 hour.

Eligible participants will receive study related physical examinations, laboratory tests at no cost.

Participants will be compensation for time and travel. Up to \$XXX or \$XX for each study visit.

The research will be conducted at the University of Cincinnati’s Allied Health.

For additional information, please contact Jennifer HXXXX at 513- XXX-XXXX or email Jennifer at: xxxxxx.xxx@xxxxx.

University Hospital, Endocrinology and Diabetes Clinic

Radio and Television Scripts

The UC IRB recommends that all radio and television scripts undergo review and approval prior to the production of the recording. Submitted scripts prior to the production of the audio/video script ensures the submitted script follows FDA Guidelines and the Board's SOPs and attempts to prevent costly post-production revisions to radio/television recordings.

Television scripts should include a description of the text, photos, and logos that will be displayed on screen, as well as any differences in the font or color of the text. This is to ensure that there are no inappropriate images used or overemphasis placed on compensation or specific text, such as "Free medication".

The IRB review of final taped message prepared from IRB-approved text may be accomplished through expedited procedures.

Telephone Screen

The following recommendations are from the *1998 Update Food and Drug Administration Information Sheets- Guidance for Institutional Review Boards and Clinical Investigators*.

Often the first contact prospective participants make is often with a receptionist or professional clinical study screener/recruiter who follows a script to determine basic eligibility for a study. The IRB should assure the procedures followed adequately protect the rights and welfare of the prospective participants. The IRB should be made aware of the **procedures used** to maintain confidentiality. Confidentiality disclosures should be made available to the caller. In addition callers should be made aware of the following:

1. The purpose of the phone screen
2. The type of information that will be requested during the phone screen and who will have access to that information;
3. The caller's permission to go forward with the phone screen questions
4. Explain to the caller what will be done with the personal information if the caller ends the interview or simply hangs up;
5. If the caller does not qualify for the study that is the focus of the phone screen, request the caller's permission to use the information obtained from the phone screen to contact him/her on other studies.

Consider the following:

What happens to the personal information if the caller ends the interview or simply hangs up

Is the data sold to a marketing company? Are the names sold to others?

Are names of non-eligibles maintained in case they would qualify for another study?

Are paper copies shredded or electronic files saved in encrypted password protected servers?

"The acceptability of these procedures would depend on the sensitivity of the data gathered, including personal, medical and financial."

The IRB recommends the following script to be used in conjunction with your telephone script:

Opening: "In order to determine if you qualify for this research study, we are going to ask you some confidential questions about your health history and present condition. You are free to answer only those questions you feel comfortable with answering."

Do we have your permission to proceed?

Closing: Based on the information you have given us, it appears that you do not qualify for this research study. With your permission we will keep this information about your health on file for your possible qualification in a future research study. _____Yes _____No

Do we have your permission to retain in our files the information we collected in this telephone conversation? _____Yes _____No*?

*If no, we will destroy this information at the conclusion of this call.