Salus IRB

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GUIDANCE ON RECRUITMENT AND STUDY MATERIAL

GUIDANCE ON STUDY MATERIAL

This guidance is provided for Investigators to assist in their understanding of how study materials are reviewed by Salus IRB. Some examples of Study Material are:

- Device Manuals
- Phone Screening Logs
- Participant Diaries
- Questionnaires/Survey Instruments
- Newsletters not intended for recruitment
- House Rules
- Fine Accumulation Sheets
- Educational Material
- Package Inserts

Salus IRB considers "study material" to be components of the protocol and will typically review and acknowledge these items. However, if the study material contains study specific information, it will require IRB approval.

Study material that contains study specific information will be reviewed for approval to ensure that it is consistent with the information provided in the informed consent document and protocol. Some examples of Study Material that may contain these types of information are:

- Questionnaires
- Survey Instruments
- Dietary Instructions
- Participant Diaries (that may include more detail)

Questionnaires or surveys that collect detailed, sensitive information from the participant may have additional requirements. Examples of sensitive information are questions that;

- do not have simple yes or no answers
- collect details about drug, alcohol or sexual abuse
- collect details about HIV status
- collect details about suicidal thoughts, etc.

The Board may require additional counseling resources or verification of staff ability to handle participants who may be affected by such questions. These questions will also be reviewed to ensure that the information is limited to what is required by the protocol.

Study material must not;

- include coercive language or language that serves to persuade participants to interact in ways they would not conduct themselves if they were not participating in the research.
- persuade participants to disclose information they would not otherwise feel comfortable disclosing.
- include or appear to give unsubstantiated claims and/or medical advice about a disease, condition, or symptoms.

GUIDANCE ON RECRUITMENT MATERIAL AND METHODS

Salus IRB considers direct advertising for research participants to be the start of the informed consent process. Salus IRB reviews the content of all recruitment material and methods including advertisements intended to be seen or heard by prospective participants to solicit their participation, all proposed incentives for continued participation such as small gifts, and all payment arrangements to participants. Examples of Recruitment Material are:

- Print Ads
- Billboard Text
- Web page content
- Video scripts or Audio scripts
- Phone Screening scripts

Salus IRB does not require review and approval of generic recruitment material (does not reflect specific protocol information, such as inclusion/exclusion criteria, specific payment, etc.) However, upon client request, Salus IRB will review generic recruitment materials for approval.

When direct advertising is to be used, the Board reviews the text and the mode of its communication to determine that recruitment procedures are not misleading, inaccurate, or coercive and do not contain exculpatory language, or demonstrate undue influence.

The Board evaluates the plan for recruiting participants to ensure consistency with the inclusion and exclusion criteria, and the claims made in the recruitment material about the nature or potential benefits of the research. The recruitment methods should include a plan to reach a broad range of potential participants and not be targeted to an economically disadvantaged geographic area. Through their review, the Board ensures that the opportunity to participate in research is offered to all potentially eligible persons.

The Board considers the following criteria to judge the appropriateness of the advertisement material or methods. Recruitment material and methods shall not:

- state or imply a certainty of favorable outcome;
- state or imply benefits beyond what is outlined in the consent document and protocol;
- state or imply the safety or effectiveness of the investigational agent;
- state or imply that the test article is known to be superior to an approved drug, device or biological;
- state or imply claims about the test article that are inconsistent with FDA labeling, if regulated by the FDA
- use terms such as “new treatment”, “new medication”, “new drug” or “new program” without explaining that the article or program is investigational;
- promise free medical treatment when the intent is only to say participants will not be charged for taking part in the investigation;
- include the words “Press Release” or “For Immediate Release” to imply that the advertisement is a news article.
- offer coupons good for discounted purchase of the test article, once it has been approved

Advertisements may state that participants will be paid but should not include a guaranteed dollar amount or emphasize the payment or the amount to be paid, by stating it in larger or bold type.

In general, Salus IRB limits advertisements for recruitment to the information the prospective participants need to determine their eligibility and interest. When appropriately worded, the following items may be included in advertisements. It is not necessary for all of these criteria to be included:

- the name and address of the investigator and/or research facility;
- the purpose of the research; such as the condition or disease under study;
- in summary form, the criteria that will be used to determine eligibility for the study;
- a brief list of participation benefits, if any (e.g., a no-cost health examination);
- the time or other commitment required of the participants; and
- the location of the research and the person or office to contact for further information.

The Board reviews the final copy of printed advertisements to evaluate the relative size of font used and other visual effects such as large or bold print. When advertisements are to be taped for broadcast, the Board recommends that the investigator obtains Board approval of the text prior to taping, in order to avoid re-taping because of inappropriate wording. The Board reviews the final audio or video tape to ensure that there are no added visual affects and there is no emphasis or de-emphasis on certain wording. The review and approval of the final taped message prepared from IRB-approved text may be accomplished through expedited procedures.

Advertisements may be reviewed and approved via an expedited method if appropriate. An Investigator may not initiate recruitment by any methods prior to written IRB approval.

Additional information regarding Recruitment and Study material can be found at the following link; FDA, Science & Research, Recruiting Study Subjects.