



### **GUIDANCE ON STUDY MATERIAL**

This guidance is provided for Investigators to assist in their understanding of how study materials are reviewed by RCRC IRB. Study material is reviewed to ensure that it is consistent with the information provided in the informed consent document and protocol. Some examples of Study Material are:

- Device Manuals
- Phone Screening Logs
- Subject Diaries
- Questionnaires/Survey Instruments
- Newsletters
- Dietary Instructions
- House Rules
- Fine accumulation Sheets
- Study material is not stamped as "Reviewed" or "Approved"
- You will receive written notification that the material was reviewed.

RCRC IRB considers "study material" to be components of an already approved protocol. Once a protocol is approved, study material is reviewed and acknowledged to ensure that the information is consistent with the protocol and informed consent document (i.e. not an additional approval). Study material may also be reviewed simultaneously with the protocol.

Examples of material that is reviewed and acknowledged by RCRC IRB Chairs are: Participant Diaries, Questionnaires, Educational Material, Investigator Brochures, Device Manuals, and Package Inserts. These items are distinguished in the approval letter.

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.

Study material should not persuade participants to disclose information they would not otherwise feel comfortable disclosing.

All surveys must clearly state that participants do not have to answer all questions and reaffirm that the participant has the right to refuse to discontinue the survey at any time.

Study material shall not include or appear to give unsubstantiated claims and/or medical advice about a disease, condition, or symptoms.

### **GUIDANCE ON RECRUITMENT MATERIAL AND METHODS**

RCRC IRB considers direct advertising for research participants to be the start of the informed consent process. RCRC 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 Recruitment Material are: Print Ads; Billboard Text; Web page content; and Video scripts or Audio scripts

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 also evaluates the appropriateness of the atmosphere in which the recruitment activity will take place.

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. In making this assessment the Board considers the purposes of the research and the setting in which the research will be conducted and is particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, handicapped, or mentally disabled persons, or economically or educationally disadvantaged persons in accordance with [21 CFR 56.111].

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;
- use terms such as “new” treatment, medication, or drug;
- promise free medical treatment, medication, or medical exams 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.

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, RCRC IRB limit advertisements for recruit 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 clinical 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 clinical 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.