

Guidance for Recruitment and Study-Related Materials

Advertising for the recruitment of research subjects is considered the beginning of the informed consent process. Accordingly, the recruitment of study subjects is considered a research activity. The United States Food and Drug Administration ("FDA") requires that an Institutional Review Board ("IRB") review and have authority to approve, require modification to, or disapprove all research activities covered by 21 CFR 56.109(a). Before any Recruitment and Study-Related Materials are seen or heard by prospective or current subjects, the IRB must review and approve or acknowledge them. Schulman Associates IRB ("Schulman" or the "Board") reviews Recruitment and Study-Related Materials according to FDA guidelines (FDA Information Sheets), International Conference on Harmonization ("ICH") Guidelines and the Board's standard operating procedures ("SOPs"). **Recruitment Materials** include, but are not limited to: media advertisements, subject/patient letters, website advertisements, phone-screen scripts, newsletters, pre-screening scripts, and generic pre-screening informed consent documents ("ICDs"). Schulman also requires review of "Doctor to Doctor" letters related to the recruitment, referral and/or retention of study subjects. **Study-Related Materials** include, but are not limited to: diaries, subject instructions, and questionnaires.

Recruitment and Study-Related Materials Content Guidelines

Generally, Recruitment Material should be limited to the following information:

- A statement that the study involves research;
- The condition being studied and/or the purpose of the research, e.g., "an investigational drug to determine if it may improve (condition)";
- A summary of eligibility (inclusion/exclusion) criteria;
- A list of potential benefits, if any, such as study-related examinations and laboratory testing (payment to subjects for participation in studies may be included but should not be included as a "benefit"); and
- Location of the research site and the contact information.

Unacceptable content for Recruitment Material:

- Implied or express claim(s) that the drug, biologic or device is safe or effective for the purposes under investigation or that the study product is equivalent or superior to any other drug, biologic or device;
- Implied or express claim(s) that the study product will improve or cure a medical condition;
- References to "free" medical treatment (must be "study-related");
- References to physical examinations or other study procedures unless preceded by the words "study-related";
- Emphasis on subject compensation (e.g., bold, underlined, italicized or large font);
- Implied or express statement that an investigational study product is FDA approved;
- Statement that an investigational drug, biologic or device is "new" ("new treatment," "new medication," or "new drug") without explaining that the study product is investigational or experimental;
- Misleading mottos or logos such as "Tomorrow's new drugs today";
- Duplicative use of words such as "free" or "at no cost";
- Dollar compensation amounts for studies involving children (but may state that there will be "compensation for time and travel");
- Referral fees (finders' fees) offered to referring physicians or subjects based on enrollment and/or retention;
- Words leading to therapeutic misconception, such as "patient" instead of "subject" or "study participant";
- Exculpatory language through which the subject waives or appears to waive any legal rights, or releases or appears to release the investigators, the institution or its agents from liability for negligence; and
- Advertisements that make claims, either explicitly or implicitly, about the drug, biologic or device under investigation that is inconsistent with FDA labeling.

Additional considerations: As with the ICD, language in Recruitment and Study-Related Material must be understood by potential subjects; that is, it must be in language that a lay person would be able to understand. In addition:

- Use "investigational" or "experimental" wherever appropriate;
- Use "research study" instead of "clinical trial";
- If using "placebo," explain that this is an inactive substance or "a look-alike pill" that contains no active medication; and
- When describing 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..." as seen in the Schulman approved ICD.

Radio and Television Scripts

Schulman recommends that all radio and television scripts undergo review and approval by the Board prior to the production of the recording. Submitting the scripts prior to the production of the audio/video ensures that the submitted script follows FDA Guidelines and the Board's SOPs and attempts to prevent costly post-production revisions to radio/television recordings that may result from Schulman-requested changes. Television scripts should include a description of the text, photos, and logos that will be displayed on screen, as well as identify any differences or changes in the font or color of the text. The necessity of this request is to ensure that there are no inappropriate images used or overemphasis placed on compensation or specific text, such as "Free Medication."

Telephone Screen

A Telephone Screen Guidance Document is available on our forms page at sairb.com/forms under the Recruitment/Study-Related Materials section.

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Submissions

Recruitment and Study-Related Materials can be submitted via e-mail, fax or the Secure eSubmission at sairb.com/eSubmission. Recruitment and Study-Related Materials must be submitted in final format (written scripts as they will be broadcast or printed material as they will be given to potential/current subjects), and must not include any tracked or handwritten changes. The materials must be accompanied by Schulman's most recent version of the Recruitment/Study-Related Material(s) Submission Form, which can be found on our forms page at sairb.com/forms. When completing the form, be sure to indicate each item being submitted.

If any text or graphic in the material being submitted has been previously reviewed or approved/acknowledged by Schulman in any manner for any study, current or past, indicate this on the form and include a copy of the prior reviewed material(s) with the submission. This will help reduce inconsistencies and quickens the turnaround time of submissions.

The standard turnaround time for review of Recruitment and Study-Related Materials is approximately two (2) business days. Recruitment and Study-Related Material submissions received after 3:00 PM EST will be processed the next business day. The Board Reviewer may approve, acknowledge, or request changes to the submitted materials. The first page of each item submitted will be stamped according to the Board Reviewer's decision, and will be returned to the current contact for the submitting site, sponsor and/or CRO/SMO. Requested revisions must be made and resubmitted for review within three (3) weeks. In circumstances where the requested revisions are not made within this time frame, the item(s) will be billed according to the current Schulman Fee Schedule. If an item cannot be approved by expedited review or the requested revisions are not acceptable to the submitting party, the Board Reviewer may take it to the full Board for a decision.

Translated Materials

When submitting translated materials, you must include a copy of the stamped-approved/acknowledged English item. The submission must also include a certificate of translation or statement of attestation by a certified translator. For more information regarding translations please review [Guidance for Enrolling Non-English Speaking Subjects and Obtaining Translated Study Documents](#).

Compensation, Gifts and Subject Programs

Compensation

Subject compensation for participation is evaluated by the Board on a site-by-site basis according to the schedule of events outlined in the protocol. Please review the schedule of events outlined in the protocol before submitting compensation amounts. Compensation must be indicated on the Research Site Submission Form in order for the site submission to be reviewed by the Board. To submit a request to change the subject compensation amounts, complete the Revised ICD Form, which can be found on our forms page at sairb.com/forms. A copy of the current Schulman approved ICD with handwritten changes or an electronic copy of the ICD in track changes mode must be included with this form.

Guidelines for subject compensation for participation:

- Compensation must be described in the ICD;
- Compensation should be based on time and inconvenience to the subject (not risks and procedures);
- Compensation should be equal for all subjects (an investigator may request, in writing, supplemental compensation for a subject with special circumstances);
- Compensation should be prorated across study visits and not contingent on completion of the entire study;
- Completion bonuses should not exceed 15% of the total subject compensation;
- For studies involving children, allocate compensation to both the parent/guardian and the participating child when possible; and
- Raffles and coupons for a discount on the purchase price of the study product are not permitted as a form of compensation.

Gifts

Gifts to subjects are not considered compensation and should not be tied to compliance or advertised verbally or in writing. When submitting gifts for review, a photograph of each gift and the estimated value of each gift should be included. Gifts should be submitted to the Recruitment Team using the Recruitment/Study-Related Material(s) Submission Form.

Subject Programs

Reward, appreciation and retention programs ("subject programs") are evaluated by the full Board on a case-by-case basis. Subject programs should be submitted to the Recruitment Team using the Recruitment/Study-Related Material(s) Submission Form. When submitting subject programs for review, you must include photographs of any items to be used, their estimated values and a schedule/plan for providing the items to subjects.

If you have additional questions not addressed in this guidance, please contact Schulman at 513-761-4100.