

## Recruitment and Study-Related Materials Guidance

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 (Study Materials) are seen or heard by prospective or current subjects, the IRB is required to review and approve or acknowledge them. Schulman 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, social media advertisements, online recruitment, phone-screen scripts, newsletters, pre-screening scripts, and generic pre-screening informed consents (ICs). 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, Study Materials should include, at minimum, the following information:**

- A statement that the study involves research (i.e. "research study" instead of "clinical trial")

**And may also include (as applicable):**

- The purpose of the study and eligibility criteria. 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..."
- Where applicable, the regulatory status of the drug or device (i.e. investigational, investigational use, or approved)
- A truthful description of benefits, if any, such as study-related examinations and laboratory testing (compensation should not be noted as a benefit)
- Compensation, if any
- Location of the research site and the contact information

**Unacceptable content for Study Materials:**

- 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, or that it will improve or cure at medical condition
- References to "free" medical treatment (needs to be "study-related")
- References to physical examinations or other study procedures unless preceded by the words "study-related"
- Emphasis on subject compensation (e.g., highlighting, 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"
- Referral fees (finders' fees) offered to referring physicians 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

**Additional considerations:** Study Materials must be at a reading level accessible to a lay person.

#### Online Recruitment

Schulman recommends that the same considerations that are taken for more traditional formats, such as a newspaper ad or other print ads, be taken when creating Study Materials in an online environment. For advertising venues that have character limitations, the ad should still reference a "research study"; if the study drug or device is referenced, the appropriate regulatory status be conveyed (i.e. investigational, investigational use, or approved).

#### Social Media

Many people have access to and frequently use social media platforms, and there is a wide range of experience levels and awareness of public visibility within these sites. Consideration should be given for how potential subjects will interact with the social media platform. Individuals may unknowingly share personal information regarding their health or study participation on these sites, believing the information is visible only to a limited audience such as the site staff. In reality, a comment/post may be visible to all users who have access to the platform. These interactions may affect subject privacy, potential disclosure of protected health information, and misconceptions regarding the investigational product's effectiveness. Additionally, if a subject discloses information about his/her personal experience with the study drug (or placebo), it could influence other subjects perceived response to the study drug and potentially skew study data. **The Board recommends** that commenting be disabled on platforms with this functionality; at a minimum, comments need to be closely monitored and removed if found to be inappropriate.

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### Audio and Video Scripts

Schulman recommends that all audio and video scripts be reviewed and approved by the Board prior to production of the recording. Submitting the scripts prior to the audio/video production ensures that the submitted script follows FDA Guidelines and the Board's SOPs and also may prevent costly post-production revisions that may result from Schulman-requested changes. Video 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. This helps 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](#) under the Recruitment/Study-Related Materials section.

## Compensation, Gifts and Subject Programs

### Compensation

It is permissible to list compensation for subject participation in Recruitment Material. Total compensation cannot be listed for studies that have a varying number of study visits, unless a range is specified. For more information about subject compensation, please refer to the FDA's Information Sheet "[Payment to Research Subjects: Guidance for Institutional Review Boards and Clinical Investigators.](#)"

Compensation for study participation can be fiscal or in material items. For example, a subject may be offered the opportunity to keep an iPad used in the study in place of or in combination with a fiscal stipend. In these instances, the value of the iPad is considered compensation, and subject to IRB review. Written and verbal advertisement and disclosure of this type of compensation in the Informed Consent Form and other subject material will be at the discretion of the Board.

### Gifts

Nominal gifts, (e.g., items used to thank subjects or given at community outreach events) with an estimated value of less than \$50 each that are not advertised verbally or in writing are not considered compensation and do not require IRB review. Since these items are not considered compensation, they should not be tied to study screening, enrollment or completion.

When submitting gifts for review, the estimated value of each gift should be included. For unique items, the Board may request additional information (i.e., photograph of the item) to assist with the review. Submit requests for review of gifts 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. Submit requests for review of subject programs to the Recruitment Team using the [Recruitment/Study-Related Material\(s\) Submission Form.](#) When submitting subject programs for review, include a schedule/plan for providing the items to subjects.

## Submissions

Study Materials can be submitted via e-mail, fax or secure [eSubmission](#) at [sairb.com/eSubmission](#). Study 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](#). 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.**

Schulman does not require IRB review or approval on subsequent versions of study documents when only the study dates change on materials including but not limited to Subject Study Calendars, Recruiting Scripts, and Subject Emails. Additionally, minor administrative changes to Study Materials that do not change the content, such as spelling corrections, changes to contact information, making minor revisions to the document identifier or version control in the headers or footers, do not require additional review by the Board.

Please visit Schulman's website for more information on Schulman's [submission process for recruitment and study-related materials.](#)

### Translated Materials

When submitting translated materials, 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.](#)

If you have additional questions you may contact Schulman at [Recruitment@sairb.com](mailto:Recruitment@sairb.com) or 513-761-4100.