Bluebonnet Ethical Review

RECRUITMENT MATERIALS GUIDELINES

Recruitment material must be consistent with the IRB-approved protocol and ICF. In addition to following the requirements outlined in this document, the IRB requires that recruitment material follow the FDA Information Sheet on Recruiting Study Subjects.

RECRUITMENT/SUBJECT FACING MATERIALS

Recruitment material and any modifications made to the content or presentation of approved recruitment material must be approved by the IRB prior to its use. While the IRB reviews scripts for audio and video recruitment materials, the final audio and/or video version must also be submitted to the IRB for review.

Bluebonnet only requires materials intended to **recruit** study subjects and materials that support their ability to continue participation in a study such as direct advertising or screening scripts.
***Note**: Clinical trial listings, such as those seen on clinicaltrials.gov are not considered recruitment materials by the IRB.

Examples of advertisement include, but are not limited to the following;

- Newspaper advertisement
- TV/Radio advertisement
- Bulletin board or billboards
- Internet advertisement
- Posters and Flyers
- Telephone screening scripts

To expedite the IRB review/approval process, please submit these materials electronically as MS Word files. This allows Bluebonnet to make any necessary revisions to the materials to be able to grant approval.

Print advertisements must be submitted in final format (free of typographical, grammatical, and spelling errors) and include any **graphics** that are used.
***Note**: any graphics used in any forms of advertisement must be approved by the IRB

The following materials can be submitted as "Sets". The content can include up to 25 items before considered another set:

- Website tag lines
- Company website content
- Text messages
- Banner ads such as Facebook, google, etc.
- Multiple pictures/graphics to be used in all advertisement

Note: Any other ads submitted as "sets" will be separated and reviewed individually.

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Recruitment material should be limited to the information a prospective subject need to determine their eligibility and interest in the research, such as:

- The name, address and phone number of the investigator and/or research site.
- The condition under study and/or the purpose of the research.
- The criteria to be used to determine a subject's eligibility.
- A brief list of study participation benefits, if any, and the risks for participating in a research study.
- A description of any benefits of the study must be balanced with the risks of the study.
- The amount of time or other commitment required of the subjects in the study.
- The location of the research site and the name of the person or office a potential subject can call to obtain additional information.

Bluebonnet IRB requires that recruitment materials must:

- Clearly indicates this is research (use of the following words: research, study, clinical trial or trial). If not, then the word 'research' must be added.
- Ensure the font size is appropriate and does not add extra emphasis on payment

Bluebonnet IRB requires that recruitment materials must **NOT**:

- Include coercive or exculpatory language.
- List compensation as a benefit.
    - **Note**: FDA prohibits labeling compensation as a benefit.
- State or imply a certainty or favorable outcome or other benefits beyond what is outlined in the consent document and the protocol.
- Claim that the study drug or device is safe or effective for the purposes under investigation or that it is equivalent or superior to any other drug or device.
- Use terms as "earn money" or "make money" as it implies this is a job
- Use terms such as "**new** treatment/drug/medication" without also stating that it is investigational.
- Refer to the study drug as "approved medication" or imply that the study drug is approved.
    - **Note:** This does not apply for studies that do not involve a drug or involves only marketed drugs.
- Promise "free medical treatment". Procedures may be listed and identified as "free of charge" or the material may say "free medical exams" but not "free treatment."

The IRB understands materials may be resized for different applications (e.g. 4x6, 5x7, 8x10). The IRB does **NOT** require the individual submission of the variations so long as changes to the font size are consistently applied across each variation.

When submitting a subject diary (or something similar) consider submitting a placeholder (i.e. Week <x> Diary) instead of submitting the individual items that include each variation of the diary (i.e. Week 1 Diary, Week 2 Diary, etc.) when all the content is the same except the title/header of the document.

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SCREENING SCRIPTS/ONLINE SCREENERS

The first contact prospective study subjects make is often with a study staff member who follows a script to determine basic eligibility for the specific study, or by answering an online study screener. The IRB must ensure the procedures followed adequately protect the rights and welfare of the prospective subjects. In some cases, these screeners gather personal and sensitive information about the individual. Researchers must provide assurance that the information will be appropriately handled. A simple statement such as "confidentiality will be maintained" does not adequately inform the IRB of the procedures that will be used.

If sensitive information is being asked (e.g. depression, anxiety disorder, sexual dysfunction, alcoholism, HIV, hepatitis, etc.), ensure that the subject is not asked to elaborate. These types of questions should be limited to Yes/No answers.

If the questions are asking for elaboration, ensure the following information is included:

- A description of the training that screeners have received to handle a potential participant who might become disturbed by talking about these issues
- A description of the measures in place to care for a disturbed participant (e.g., counseling, referrals, keeping the caller on the line and calling 911, etc.)

AUDIO/VIDEO

Bluebonnet recommends the IRB review and approve all audio/video scripts prior to the production of the final recording. Submitting scripts prior to production ensures the submitted script follows regulatory requirements, preventing costly post-production revisions that may result from the IRB requested revisions.

Scripts should include descriptions of the text, photos and logos displayed on screen and identify any changes in the text font or color. This will help to ensure that there are no inappropriate images used or overemphasis placed on certain text, such as compensation.

PAYMENT & REIMBURSEMENT TO SUBJECTS

Paying research subjects in exchange for their participation is a common and, in general, acceptable practice. Payment to research subjects for participation in studies is not considered a benefit that would be part of the weighing of benefits or risks; it is a recruitment incentive. Reimbursement for travel expenses to and from the clinical trial site and associated costs such as airfare, parking, and lodging is not considered to raise issues regarding undue influence. Payment for participation in research should be just and fair. However, compensation may not be emphasized by such means as larger or bold type or vocal emphasis (for audio ads). 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.

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GENERIC RECRUITMENT/SUBJECT MATERIALS

Generic materials are typically used for general recruitment and are not tied to any specific protocol or study. These types of materials cannot include any protocol specific information and could be used for any type of study, without the need for protocol specific information.