Recruitment Guidelines

Castle IRB Guidance

Introduction

Recruitment methods and materials used in human subjects research are considered part of the consent process and must be submitted for IRB review and approval prior to their use. Recruitment materials can be part of the initial IRB submission or submitted later as part of a modification (amendment).

Participants may be recruited through a variety of methods, including but not limited to current patients/clients, through referrals, through direct solicitation, and/or through advertisements. Investigators should be aware of applicable guidelines, such as the FDA "Recruiting Study Subjects" Information Sheet when preparing recruitment methods and materials.

What to submit

Direct advertising that is intended to be seen or heard by prospective participants to solicit them to take part in a study should be submitted to the IRB. Direct advertising includes, but is not limited to:

- Website
- Radio
- Phone Scripts
- Social Media
- Podcast Script
- Television
- Post Cards
- Print Advertisements
- Email
- Direct Patient Letters
- Posters
- Flyers

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Recruitment materials **should** include the following information as appropriate:

- ☑ Brief description of the study (i.e., purpose).
- ☑ That the study is research (clinical studies should not say it is for “treatment”).
- ☑ Age restrictions or other qualifications for eligibility.
- ☑ Time commitment.
- ☑ Compensation (if any is offered – but without overemphasizing by such means as larger or bold type).
- ☑ Name and address of the investigator or center doing the research.
- ☑ Location of the research and name of the person to contact for further information.
  - They should be someone who is knowledgeable about the study, not just a general telephone operator.

Recruitment materials **should not** include:

- ☒ State or imply a certainty of favorable outcomes or other benefits beyond what is outlined in the consent document and the protocol
- ☒ Promise of “free treatment” when the intent is only to say participants will not be charged for taking part in the investigation
- ☒ Claims, either explicitly or implicitly, about the drug, biologic, or device under investigation that are inconsistent with FDA labeling
- ☒ Exculpatory language.
- ☒ Use the terms such as “new treatment,” “new medication” or “new drug” without explaining that the article is investigational.
- ☒ Information regarding compensation for participation in a trial offered by a sponsor to include a coupon good for a discount on the purchase price of the product once it has been approved for marketing

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IRB Review

Federal agencies expect IRBs to review advertisements to ensure that they are not unduly influential and do not promise a certainty of cure beyond what is outlined in the consent and the protocol. This is especially critical when a study may involve subjects who are likely to be vulnerable to undue influence.

Offering or accepting a finder's fee for identification and referral of participants is not permitted because of the potential for coercion of participants or conflict of interest on the part of the individual making the referral. Paying or accepting a recruitment bonus or other incentive tied to the timing or rate of enrollment or number of enrolled participants is also not permitted.

Submissions to the IRB could include recruitment scripts as well as materials.

For content to be used in social media postings and websites, copy can be provided with sample images that will be used and a marketing plan that specifies what platforms will be used (e.g., social media, webpages, etc.).

Exact screenshots of social media posts are **not required** to be submitted.

When possible, website URLs should be provided to enable review and monitoring.