Creighton UNIVERSITY
Institutional Review Board

IRB Requirements for Recruitment Materials

Why do my recruitment materials require IRB review?
Federal regulators consider advertising for study subjects to be the start of the informed consent and subject selection processes. IRB review and approval of recruitment materials is therefore required.

Which recruitment materials require IRB review?

IRB review required	Emails; Posters and flyers; Social media posts; Newsletters; Electronic, television, and/or radio ads; Any direct advertisements developed by the investigator, staff, or external sponsor.
IRB review not required	Dear Doctor letters; Doctor-to-doctor letters; Press releases; News stories; Posts to clinical trials listing services or financial pages.

When should recruitment materials be submitted to the IRB?
Ideally, recruitment materials should be reviewed and approved by the IRB as part of the initial submission package. Changes to recruitment materials and new recruitment materials may be submitted later as a modification to the study. Regardless of whether recruitment materials are included with the initial submission or later in a modification, recruitment materials cannot be used prior to IRB review and approval.

Phone scripts and other screeners
Phone calls to prospective study participants are considered recruitment activities. IRB review and approval of recruitment scripts and other screeners are required.

What may I include in my recruitment materials?

Required Content

- Name and contact information for the investigator
- Information identifying Creighton University as the research institution
- Clear statement that the activity is research
- Purpose of the research

Permitted Content

- Criteria that will be used to determine study eligibility
- Brief list of participation benefits, if any (for example, a no-cost health examination)
- Time or other commitment requirements of the participant
- Person or office to contact for additional information

Prohibited Content

- Statements implying a certainty of a favorable outcome or other benefits beyond those described in the consent document and the protocol
- Claims, explicit or implicit, that the intervention is safe or effective for the purposed under investigation, or that the test article is known to be equivalent or superior to other interventions off-study
- Promises of “free treatment” regardless of whether the study treatment will be provided without charge.
    - The IRB will accept “at no cost”
- Exculpatory language
- More than one reference to compensation per advertisement
- Stated amount of compensation for participation or indication that compensation is available in any font, font size, or manner that is intended to draw attention to the value or availability of compensation.
- Phrases such as “new medication” or “new drug” without a disclaimer such as “study” or “investigational” before the words “medication” or “drug”
- Claims, either explicit or implicit, about the drug, biological, or device under investigation that are inconsistent with FDA labeling
- Any language not approved by the IRB (for example, unapproved introductory or reminder text)