2. When an Investigator decides after initial approval to advertise for subjects or to change the advertisement, the revised advertising should be submitted as an amendment to the ongoing project.
3. The IRB reviews the advertising to assure that it is not coercive and does not promise a certainty of cure beyond what is outlined in the consent and the protocol. This is especially critical when a project may involve subjects who are likely to be vulnerable to undue influence.
4. Investigators must obtain IRB approval for all television, radio, video or print advertisements, electronic (including email and social media) solicitations, websites, and other recruitment methods and materials intended for the recruitment of prospective subjects. All methods of advertisement require approval from the IRB prior to their use.
    a. The following examples do not qualify as an advertisement:
        Communications intended only to be seen or heard by health professionals, such as “dear doctor” letters and doctor-to-doctor letters;
        News stories, as long as they are not intended for recruitment purposes (e.g. including phone number at the end to contact for more information to participate in a particular project, full details of inclusion/exclusion criteria of a particular project, etc.); and
        Publicity intended for other audiences (e.g., media releases regarding types of services available or offered by a particular clinic, institute or physician).

    Contact the MCW Office of Communications regarding the use and content of news stories and media releases.

5. When advertising is to be used, the IRB must review the information contained in the advertisement and the mode of its communication to determine that the document for recruiting subjects is not coercive and does not state or imply a certainty of favorable outcome or other benefits beyond what is outlined in the consent document and the protocol. **The IRB must review the printed advertisements in final format to evaluate the relative size of type used and other visual effects**. **When advertisements are to be taped for broadcast, the IRB must review the final audio or video tape prior to use. After an advertisement or press release has been approved by an IRB, it must also be submitted to the MCW Office of Communications for review and approval.**

The IRB can review and approve the wording of an advertisement prior to recording to avoid the necessity of rework because of inappropriate wording. The review of the recorded message prepared from IRB-approved text may be accomplished through expedited review of an amendment.

<u>Content of Advertisements</u>

1. When preparing an advertisement, social media posting or approach letter to be used to recruit potential subjects to their project, Investigators should ensure the content of the advertisement is appropriate and consistent with institutional and IRB p1 Tcnenvestigato41.6393 -me Tc-.3seD.i7yTc-.31.3seD.i6frecording tp1Tc-.0civeertisepproach lettcert

A brief summary of participation benefits, if appropriate
Time or other commitment required of the subject
Location of the project and the person to contact for additional information

3. Advertisements used to recruit subjects should **NOT** include the following:
   Claims of safety, effectiveness, equivalence or superiority in reference to the drug, device or procedure under investigation.
   Use of the terms “new” or “exciting” in reference to a drug or device without explaining that the test article is investigational.

REFERENCES:
21 CFR 56.107(a)
21 CFR 56.111(a)(3)
21 CFR 56.111(b)
21 CFR 50.20
21 CFR 50.25
21 CFR 812.20(b)(11)
Food and Drug Administration (FDA) Information Sheets: “Recruiting Study Subjects,” 1998 Update

SUPPORTING DOCUMENTS:
IRB SOP: Recruitment Methods and Compensation

Effective Date:	07/01/2023
Version number:	4.0
Previous Version/date:	3.0, 06/07/2013
Responsible Office:	HRPP Office
Approval Date:	05/29/2023

Approved By
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