



MCW Office of Research Standard Operating Procedure

ADVERTISEMENTS

Unit: Human Research Protections Program (HRPP), Office of Research

Applies to: MCW/FH Faculty and Staff involved in human research

PURPOSE:

Advertisements used to recruit subjects issued to the public regarding Medical College of Wisconsin or Froedtert Hospital project activities will be reviewed and approved by the MCW/FH Institutional Review Board (IRB) as part of the initial review or via amendment.

The MCW/FH IRB will review the information contained in the advertisement and the mode of its communication to ensure that the documents are not coercive, unduly influential, and do not state or imply a certainty of favorable outcome or other benefits beyond what is outlined in the informed consent document and the protocol. The MCW/FH IRB will review the print 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 MCW/FH IRB will review the final audio/videotape prior to use.

DEFINITIONS:

Recruitment - seeking individuals to enroll or participate in a project

Advertising - a public announcement usually by a printed notice or voice or data broadcast that describes a project including contact information. Typically this is used for recruitment purposes for a project.

Coercion – the use of force or intimidation to persuade someone to do something which they are unwilling to do.

Undue Influence - (as a term in jurisprudence) is an equitable doctrine that involves one person taking advantage of a position of power over another person. It is where free will to bargain is not possible.

Final Format – an advertisement which has been prepared and is ready for print or to be used for recording. An advertisement which is in “final format” has:

- Identified the mode of advertisement, i.e. print flyer/poster, radio script, video script or web posting
- All text, font and style used is exactly how it will appear to potential subjects
- Incorporates all images to be used

PROCEDURE:

1. The MCW/FH IRB considers advertising for or soliciting subjects to be the start of the informed consent process and subject selection process. Advertisements must be reviewed and approved by the MCW/FH IRB as part of the eBridge submission for

initial review. When the Investigator decides after the initial approval to advertise for subjects or to change the advertisement, the advertising is considered an amendment to the ongoing project. The MCW/FH 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.

2. An Investigator must obtain MCW/FH IRB approval for all television, radio, videotape or print advertisements, electronic (including email) solicitations, Internet websites, and other recruitment methods and materials intended for the recruitment of prospective subjects. All methods of advertisement require approval from the MCW/FH 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 Public Affairs Office regarding the use and content of new stories and media releases at <http://www.mcw.edu/publicaffairs.htm>

3. When advertising is to be used, the MCW/FH 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 MCW/FH 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 MCW/FH IRB must review the final audio or video tape prior to use. After an advertisement or press release has been approved by an MCW/FH IRB, it must also be submitted to the MCW Public Affairs Office for review and approval.**

The MCW/FH IRB can review and approve the wording of the advertisement prior to taping to avoid the necessity of re-taping because of inappropriate wording. The review of the final taped message prepared from MCW/FH IRB-approved text may be accomplished through expedited review of an amendment.

Content of Advertisements

1. When preparing an advertisement, website 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 this procedure.
2. Advertisements used to recruit subjects should be limited to the information the potential subjects need to determine their eligibility and interest. **When appropriately worded, the following items may be included in advertisements:**
 - The name and address of the PI or the facility where the project will be conducted
 - The purpose of the project unless otherwise justified
 - The criteria that will be used to determine eligibility for the project

- 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.
 - Use of the term “free” in reference to treatment or procedures.
 - Use of bold or enlarged print or other means to emphasize payment or the amount to be paid.
 - Use of exculpatory language, or asking subjects to give up legal rights
 - Claims that the subject will receive therapeutic benefit from participation in the project.
 - The use of any inappropriate pictures or images that would be inconsistent with equitable subject recruitment.
 - Offers of compensation from a sponsor that would involve a coupon good for a discount on the purchase price of the product once it had been approved for marketing.
 - Exhibition of the ad in venues which are not in line with the project’s purpose or intent.

Receptionist Scripts

1. The first contact prospective subjects make is often with an individual who follows a script to determine basic eligibility for the specific project. The MCW/FH IRB must review the procedures and script/list of talking points to assure that they adequately protect the rights and welfare of the prospective subjects. The MCW/FH IRB must have assurance that any information collected about prospective subjects will be appropriately handled.

Internet Recruitment

1. All uses of internet recruitment should be described in the eBridge SmartForm. Investigators should utilize the information under “Content for Advertisements” in this procedure with regard to acceptable wording or content.
2. The content of websites, web postings and/or various internet recruitment practices must be reviewed and approved prior to posting. Exceptions to this content review are limited to the following:
 - the National Cancer Institute's cancer clinical trial listing (PDQ),
 - the government-sponsored AIDS Clinical Trials Information Service (ACTIS), and
 - Clinicaltrials.gov, and
 - Froedtert Hospital website, Clinical Trials on the MCW/Froedtert Campus.

Review by MCW Public Affairs Office

1. After an advertisement or press release has been approved by an MCW/FH IRB, it must be submitted to the MCW Public Affairs Office for review and approval as to such matters as fall within the jurisdiction of the MCW Public Affairs Office. Please reference the Public Affairs website at: <http://www.mcw.edu/publicaffairs.htm>

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

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