	University of Puerto Rico Medical Sciences Campus Human Research Subjects Protection Office	Effective: 9/1/2008
		Rev. 07/01/2014

ADVERTISEMENTS

Purpose:

To define the procedure for submission of advertisements for IRB review and approval.

Sources:

OHRP Guidance on Written IRB Procedures
45 CFR 46.111 (a) (3)
21 CFR 56.111 (a) (3)

Applicability:

Investigators, students, IRB members and IRB staff

Background:

The FDA and DHHS consider advertising (subject recruitment) to be the first component in the informed consent process. Therefore, the Institutional Review Board (IRB) must review and approve recruitment methods and content of the materials to ensure adequate subject protection. The IRB must review the information contained in all advertisements and the mode of their communication. Advertisements cannot be displayed or put to use until the IRB has approved the final copy of printed ads, the final version of audio/video tape recorded, and final version of electronic media advertisements. As an additional layer of review,

the MSC Press Office must approve advertising style and format. Federal regulations require that the institutional human research protection program and investigators protect potential and current research subjects from coercion or undue influence, and this requirement underpins IRB advertising guidelines. Federal regulations also require investigators to use fair and equitable recruitment practices. OHRP guidance states that IRBs, in their review of all advertising/recruitment materials, should pay particular attention to risk and potential benefit information to ensure it is presented in a balanced and fair manner. The information presented should not mislead, for example, by promising benefits or implying a benefit beyond that potentially provided by the research. The IRB will assess the types of incentives, if any, that are being offered to prospective subjects. Monetary and nonmonetary incentives (e.g., access to services or programs) can create undue influence on a potential subject's decision about research participation. The IRB will ensure that participation is voluntary, and that incentives for participation are not so great that they compromise a prospective subject's assessment of the risks or affect the voluntariness of his or her choices.

Policies:

All advertisement related to research with human subjects require IRB approval before publication in any media and/or form. It must be written in simple language (6th grade reading level). Include the IRB Approval Stamp in the lower right hand corner of the ad. Use of cohesive and/or intimidating language is not permitted in advertisements.

Procedures:

(1) Protocols that require the use of advertisement for recruitment of research participants have to include evidence of approval of the advertisement by the MSC Press Office in the IRBWISE system. Ads are submitted electronically by the investigator through the e-IRB system as part of new protocol submissions and continuing review submissions.

(2) An ad must be re-submitted to the IRB for approval when any revisions are made to the IRB approved version of the ad. Investigators must re-submit an ad that has been changed, using the amendment process in the IRBWISE system.

(3) For approved studies that did not included the advertisement with the original documentation evaluated and approved by the IRB, the request for advertisement approval has to be submitted as an amendment to the approved protocol.

(4) The Advertisement Submission Form found at the IRB website (Comunicado de Prensa) has to be filled out for each advertisement and must be submitted to the MSC Press Office for their evaluation and approval prior to consideration by the IRB. All ads must have IRB approval in addition to approval from the MSC Press Office before being exhibited.

(5) If the study requires the use of consent and/or assent forms both in Spanish and English, announcements on both languages are required to be approved by both the MSC Press Office and the IRB.

(6) The following **may be** included in the advertisement:

(a) A straightforward description of potential benefits to study participation. Do not overstate.
(b) A brief list of procedures involved.

(c) The time or other commitment required (number of visits, duration of study, etc.).

(d) Any compensation or reimbursement

(e) Advertisements may state that subjects will be paid but should not use bold or enlarged print or other means to emphasize payment or the amount to be paid.

(f) Do not refer to payment in the header of the ad.

(7) The following **MUST** be included in the advertisement:

(a) The condition under study and/or the purpose of the research, described clearly and concisely.

(b) Clearly state that the project is research and includes the use of an investigational drug or device, if applicable.

(c) The key eligibility criteria.

(d) The location where the research will be conducted and the contact (name and phone/address) for further information.

(8) The following **<u>may NOT</u>** be included in the advertisement:

(a) Claims of safety, effectiveness, equivalence or superiority in reference to the drug, device or procedure under investigation. Use of the term "new" in reference to a drug or device without explaining that the test article is investigational.

(b) 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.

(c) Use of exculpatory language.

(d) Claims that the subject will receive therapeutic benefit from participation in the study.

(e) The use of any inappropriate pictures or images that would be inconsistent with IRB policies on equitable subject recruitment.

(f) Offers of compensation from a sponsor that would involve a coupon good for discount on the purchase price of the product once it had been approved for marketing.

(g) Exhibition of the ad in inappropriate venues.

(9) Distribution of ads within the MSC, Puerto Rico Medical Center and University Hospitals.

After IRB approval ads can be posted on the MSCTV network, MSC website and can be placed in designated areas with corresponding management approval. It is the PI's (or his/her designee's) responsibility to coordinate placing posters, flyers and brochures in designated areas with the applicable manager and remove ads at appropriate times.

To advertise on the MSCTV network, the PI should contact the CATA

Office electronically, by phone or in person (2) weeks prior to air date. CATA Office staff will load and run the ad on the MSCTV network for an agreed upon period of time. For internet posting on the MSC website, the PI must contact the Systems Information Office.