



POLICY AND GUIDELINES FOR ADVERTISING (SUBJECT RECRUITMENT MATERIALS)

7/7/2021

The FDA and DHHS consider advertising (subject recruitment) to be the first component in the informed consent process. Therefore, the Duke University Health System Institutional Review Board (DUHS 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 and electronic ads and the final version of audio/video recorded advertisements. As an additional layer of review, the Duke Health Brand Center must approve advertising style and format of materials that use the Duke logo.

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 DUHS IRB advertising guidelines. Federal regulations also require investigators to use fair and equitable recruitment practices. The IRB has established the following requirements for advertisements seeking participants in research studies.

All advertisements must:

- Be written in plain language (6-8th grade reading level).
- Include the IRB Registry Number in the lower right hand corner of the ad in a small font size.

The following may be included in the advertisement:

- The name and address of the principal investigator.
- The condition under study and/or the purpose of the research, described clearly and concisely. Clearly state that the project is research and includes the use of an investigational drug or device, if applicable.
- The key eligibility criteria.
- A straightforward description of potential benefits to study participation. Do not overstate.
- A brief list of procedures involved.
- The time or other commitment required (number of visits, duration of study, etc.).
- Advertisements may state “You will be compensated for your study participation” but should not state the specific amount to be paid, or use bold or enlarged print or other means to emphasize compensation. Do not refer to compensation or payment in the header of the advertisement.

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

The following may NOT be included in the advertisement:

- 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.
- Claims, either explicit or implicit, about the drug, biologic, or device under investigation that are inconsistent with FDA labeling.
- Use of the term “free” in reference to treatment or procedures.
- Specific dollar amounts for compensation may not be mentioned.
- Use of bold or enlarged print or other means to emphasize compensation.
- Use of exculpatory language.
- A statement or an implication of IRB or other DUHS institutional endorsement of the study.
- Claims that the subject will receive therapeutic benefit from participation in the study.
- The use of any inappropriate pictures or images that would be inconsistent with DUHS IRB policies on 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 advertisement in inappropriate venues.

Advertisements are submitted by the investigator through iRIS as part of new protocol submissions and amendments. An advertisement must be re-submitted to the IRB for approval, via an amendment in iRIS, when any revisions are made to the IRB-approved version.

All advertisements must have DUHS IRB approval in addition to approval from the Duke Health Brand Center (if Duke logo is included) before being exhibited.

When reviewing FDA-regulated research, the IRB reviews advertising to ensure that advertisements do not make claims, either explicitly or implicitly, about the drug, biologic, or device under investigation that are inconsistent with FDA labeling.

Distribution of Ads Within Duke University Medical Center and Hospital

After IRB approval and approval by the Duke Health Brand Center, as applicable, research ads can be posted on Duke Health web sites and in internal Duke Health publications. Research posters, flyers and brochures can be placed in designated areas within health system clinics and clinical departments at Duke Hospital with department management approval. **Posters and flyers are prohibited on walls, lobbies, restrooms, stairwells, hallways, elevators and other general public areas.**

It is the PI's (or his/her designee's) responsibility to coordinate placing posters, flyers and brochures in designated areas with the applicable department/clinic manager. The Department Manager will advise the PI of designated locations for brochures, flyers and posters; ensure posters and flyers are not affixed to the walls, and brochures are placed in racks, and materials are removed at appropriate times.

Online Advertising

OHRP guidance on internet advertising, issued September 20, 2005, may be found at: <http://www.hhs.gov/ohrp/policy/clinicaltrials.html>

FDA Information Sheets, Guidance for IRBs and Clinical Investigators, Recruiting Study Subjects, issued January 1998, may be found at: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/recruiting-study-subjects>

In keeping with DHHS and FDA Guidance, the DUHS IRB has determined that IRB review/approval for brief internet advertisements is not necessary provided that the information is limited to:

- study title
- purpose of the study
- protocol summary
- basic eligibility criteria
- study site location(s), and
- how to contact the study site for further information.

When information posted on a clinical trial website goes beyond directory listings with the basic descriptive information given above, such information is considered part of the informed consent process and therefore requires IRB review and approval. Information exceeding such basic listing information includes descriptions of clinical trial risks and potential benefits, or solicitation of identifiable information from potential research subjects.

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 DUHS IRB, when reviewing clinical trial websites, also will assess the types of incentives, if any, that are being offered to prospective subjects. Monetary and non-monetary incentives (e.g., access to services or programs) can create undue influence on a potential subject's decision about research participation. The DUHS IRB will ensure that the clinical trial website makes clear that participation in a trial 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 their choices.

Some clinical trial websites ask viewers to answer questions regarding eligibility for a specific clinical trial. If identifiable private information is collected via the clinical trial website, the IRB will review plans for protecting the confidentiality of that information. The IRB will assess whether the website clearly explains how identifiable private information might be used.

Informed consent must be obtained for the collection of any identifiable private information about the respondent unless the IRB has determined that the informed consent requirement can be waived. Respondent authorization must also be obtained if protected health information is collected unless the IRB has determined that the authorization requirement can be waived.

Additional examples of clinical trial listing services that do not require prospective IRB approval include the National Institutes of Health (NIH) clinicaltrials.gov website, and the dukehealth.org website: <http://www.dukehealth.org/clinicaltrials> providing that the clinical trial information posted is of the limited nature described above.

REFERENCES

45 CFR 46.111
21 CFR 56.111

Previous Version Date(s): 9/22/2008, 6/27/2014, 3/4/2016