



## **POLICY AND GUIDELINES FOR ADVERTISING (SUBJECT RECRUITMENT MATERIALS)**

9/22/2008

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 ads and the final version of audio/video tape recorded advertisements. As an additional layer of review, the Office of Creative Services 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 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 subjects to participate in research studies at DUHS.

### **All advertisements must:**

- Be written in simple 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.).
- Any compensation or reimbursement.

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. Do not refer to payment in the header of the ad.

- 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.
- 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.
- 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 ad in inappropriate venues.

Ads are submitted electronically by the investigator through the e-IRB system as part of new protocol submissions and continuing review submissions. An ad must be re-submitted to the DUHS 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 e-IRB system.

If submitting ads on paper to the IRB, for studies that have not yet been converted to the e-IRB, the investigator must complete the (paper) **Advertisement Submission Form** found at the DUHS IRB website. All ads must have DUHS IRB approval in addition to approval from the Office of Creative Services before being exhibited.

**Distribution of Ads Within Duke University Medical Center and Hospital**

After IRB approval and approval by the Office of Creative Services, research ads can be posted on the DukeTV network, dukehealth.org, dukehealthline, and in the INSIDE publication. Research posters, flyers and brochures can be placed in designated areas within PDC 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.**

To advertise on the DukeTV network, the PI should contact the Duke Hospital Communications Office at 681-6930 with the following required information electronically or in person (2) weeks prior to air date:

- Related artwork
- Duration of ad
- Contact name/number (Only the contact name may change, discontinue or proof ad)

The Duke Hospital Communications Office staff will load and run the research solicitation on the DukeTV network for an agreed upon period of time.

For posting on dukehealth.org, dukehealthline or INSIDE, the PI must contact the Office of Creative Services at 419-3270. 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 remove ads at appropriate times.

### **Internet Postings**

OHRP guidance on internet website advertising, issued September 20, 2005, may be found at: <http://www.hhs.gov/ohrp/policy/clinicaltrials.html>. FDA guidance on advertisements and recruiting study subjects may be found at: <http://www.fda.gov/oc/ohrt/irbs/toc4.html#recruiting> (FDA Information Sheets, Guidance for IRBs and Clinical Investigators, 1998 Update). This Guidance also addresses the question of internet postings and IRB review:

*'IRB review and approval of listings of clinical trials on the internet would provide no additional safeguard and is not required when the system format limits the information provided to basic trial information, such as: the title; purpose of the study; protocol summary; basic eligibility criteria; study site location(s); and how to contact the site for further information. Examples of clinical trial listing services that do not require prospective IRB approval include the National Cancer Institute's cancer clinical trial listing (PDQ) and the government-sponsored AIDS Clinical Trials Information Service (ACTIS). However, when the opportunity to add additional descriptive information is not precluded by the data base system, IRB review and approval may assure that the additional information does not promise or imply a certainty of cure or other benefit beyond what is contained in the protocol and the informed consent document.'*

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

- 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 his or her 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 amfAR clinical trial directory listings, 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(a)(3)

21 CFR 56.111(a)(3)