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POLICY AND GUIDELINES FOR ADVERTISING AND PAYMENTS TO SUBJECTS (SUBJECT RECRUITMENT MATERIALS)

POLICY

The FDA and DHHS consider advertising (subject recruitment) to be the first component in the informed consent process. Therefore, the Wright State University Institutional Review Board (WSU 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

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 WSU 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 WSU.

All advertisements must define their mode of communication and:

- Be written in simple language (6-8th grade reading level).
- Include the IRB Study 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.
- A claim that the purpose of the study is to provide any sort of therapy, treatment or cure.
- Use of the term "new" in reference to a drug or device without explaining that the test article is investigational. In addition, the term "investigational drug" should be used instead of "medication" or "medicine".
- 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.
- Exclamation points
- Use of exculpatory language.
- A statement or an implication of IRB or other WSU 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 WSU 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 by the investigator to the WSU IRB as part of new protocol submissions and continuing review submissions. Any advertisements on protocols involving WSU faculty or students as investigators must also be approved by the Chairperson or Dean of the investigator's department. An advertisement must be resubmitted to the WSU IRB for approval when any revisions are made to the IRB -approved version of the advertisement. If an advertisement is added after the initial approval process, that advertisement must be approved through submission of a request for amendment. In addition, investigators must re-submit any changes in an advertisement for approval through a request for amendment before instituting the changes.

Internet Postings – Clinical Trial Websites

OHRP draft 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, IRB review/approval for brief internet postings on clinical trial sites 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 WSU 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 WSU 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.

Internet Postings – Websites other than Clinical Trial Websites (e.g. social media)

Social media and online communities provide powerful tools for recruiting participants. In addition, social media postings are likely to be available to a broad audience and for an indefinite period of time. Thus, postings on social media are required to meet the requirements described above and undergo the same prospective IRB review as any other advertisement for recruitment.

Online advertising raises particular concerns when it relates to minors. If the advertisement will be accessible to minors, there needs to be age-verification tools in place to ensure that minors do not access research that has not been approved for minors. If the advertisement directs potential subjects to further interaction with the investigator this may not be an issue. However, if the advertisement directs the potential subject to an online-survey or online-research site then minors may inappropriately access the site. There are age verification software products available, which may be of use to researchers. Verification of age can take place through less formal fact-checking embedded in the research instruments (for instance , cross - validating multiple age and birthdate questions). Researchers may choose to advertise only on sites that are age - limited to begin with. Since it may be difficult to guarantee that children won't access research, some research may not be appropriate for social media.

REFERENCES

Applicable regulations:

45 CFR 46.11 1(a)(3)
21 CFR 56.11 1(a)(3)