Guidance – Advertisements Appropriate Language for Recruitment Material

Using Standard Recruitment Methodologies (posters, letters, flyers, etc.)

All recruitment plans and materials require IRB review and approval to ensure that the information is accurate, non-coercive and does not unfairly bias subjects to participate or induce researchers to recruit subjects who do not meet enrollment criteria. Most agree that basic descriptive information may be posted to the web without IRB review and approval. Basic information includes:

- Study title
- Study summary (purpose)
- Name of investigator
- Basic eligibility criteria
- Brief list of benefits
- Time or other commitment required of participants
- Study site location(s) (facility)
- How to contact study site for further information

When information posted on a clinical trial website goes beyond directory listings with basic descriptive facts and includes additional information, such as following, then it would be considered part of the informed consent process and therefore requires IRB review and approval.

- ✓ descriptions of clinical trial risks and potential benefits
- ✓ solicitation of identifiable information

The purpose of the IRB review and approval is to ensure that the advertisement does not imply a certainty of favorable outcome or other benefits beyond those outlined in the consent document and the protocol. Research advertisements must be reviewed by the Corporate Communications Department prior to submission and review by the IRB. This includes material using Geisinger name or logos.

When submitting advertisements and other recruitment material(s), consider the following:

1. **No claims should be made, either explicitly or implicitly, that the drug, biologic or device is safe or effective for the purposes under investigation, or that the test article is known to be equivalent or superior to any other drug, biologic or device.**

   Such representation would not only be misleading to subjects but would also be a violation of the FDA's regulations concerning the promotion of investigational drugs [21CFR 312.7(a)] and of investigational devices [21 CFR 812.7(d)].

2. Advertising for recruitment into investigational drug, biologic or device studies **should not use terms such as "new treatment," "new medication" or "new drug" without explaining that the test article is investigational.**

A phrase such as "receive new treatments" leads study subjects to believe they will be receiving newly improved products of proven worth.

3. **Advertisements should not promise "free medical treatment," when the intent is only to say subjects will not be charged for taking part in the investigation. Advertisements may state that subjects will be paid, but should not emphasize the payment or the amount to be paid, by such means as larger or bold type.**

4. **Generally, advertisements to recruit subjects should be limited to the information the prospective subjects need to determine their eligibility and interest.**

When appropriate, the following items may be included in advertisements:

a. The name, phone number and address of the investigator and/or research facility;
b. Where an email address is included, it should be the institutional email address, e.g., "xxx@geisinger.edu", (not Gmail, etc.).
c. The condition under study and/or the purpose of the research;
d. In summary form, the criteria that will be used to determine eligibility for the study;
e. A brief list of participation benefits, if any (e.g., a no-cost health examination);
f. The time or other commitment required of the subjects; and
g. The location of the research and the person or office to contact for further information.
h. For general information about participant rights, contact 1-570-271-8663.

Using Social Media (including websites) for Recruitment

The Geisinger IRB understands the powerful potential of using social media to contact and inform potential research subjects, but there are risks. The IRB must review each use and all materials intended and designed for potential research subjects and use of social media on a case-by-case basis and evaluate the plan for recruitment as in any other protocol.

- Social media sites cannot provide absolute anonymity, confidentiality, or privacy
    - Researchers must understand privacy provisions of the site and be able to provide details to IRB and potential study subjects
- Submission must include detailed privacy and data security plans, including:
    - How the data is transmitted
    - How the data is maintained
- Is information created to only educate patients about a topic or being used to assist with study recruitment?

In the case of social networking or search site advertisements:

- a summary sheet of the sites summary sheet arrangement,
- copy of any other linked websites
- address how privacy will be maintained if information from users will be collected through the interaction on a social networking site

IRB Review of Recruitment Materials

Geisinger IRB requires researchers to submit the following materials/information for review and approval:

- Copies of all advertisement materials used to recruit subjects, including but not limited to:
    - Flyers
    - Copy of printed ads
        - Newspapers
        - Posters
        - Brochures
    - Copy of videos, radio, and audio tape presentations (scripts must be provided)
    - Screen shots website listing
    - Copy of recruitment e-mail or letter (doctor-to-patient, doctor to doctor, etc.)
    - Questionnaires
    - Diaries
    - Telephone script

The following details must be included in the submission to the IRB:

- The information in the advertisement
- The mode of communication

Questions should be directed to the IRB staff at 570-271-8663.

References:

45CFR46.111(a)(3)
21CFR56.111(a)(3)
OHRP Guidance on IRB Review of Clinical Trial Websites
FDA Guidance for IRBs and Clinical Investigators - 1998 Updated