IRB *EasyEd™* - For IRB Members Volume 2 Number 1

**Topic: Review of Advertisements**

**Overview of the Topic**

*I was in a movie theater a few years ago watching the seemingly endless previews and advertisements when an ad for a research project caught my attention. During the entire 60 seconds of the ad, hundreds of green dollar signs floated across the screen - a coercive emphasis on momentary compensation. What IRB reviewed this, I thought, if any.* - PV

The recruitment of participants into research projects is key to the success of the research. One common way that researchers recruit participants is through advertising. OHRP guidance requires the IRB to review any recruitment materials, including advertisements intended to be seen or heard by potential subjects. The FDA offers much more extensive guidance on reviewing advertisement, and while this technically applies to FDA regulated research, the requirements provide important aspects that IRBs will find useful to apply to all research.

Some of the commonly used types of advertising includes flyers, posters, brochures, newspaper or magazine ads, television or radio ads, recruitment letters, and word-of-mouth recruiting. The high tech world of social media has provided additional methods of reaching potential participants including websites, emails, texts, Facebook, Twitter, Craig's List, and the like, presenting new opportunities as well as new challenges. Each of these various advertising methods presents different ethical issues for the IRB to consider, although most of the basics apply to all methods.

Your policies and procedures should describe the IRB review of advertisements and the mode of communication both by an expedited reviewer and the convened IRB. IRB applications should request any recruitment materials, including advertisements intended to be seen or heard by potential subjects. When reviewing advertisements the IRB or reviewers should consider the following:

1. Any advertisement to recruit subjects should be limited to the information the prospective subjects need to determine their eligibility and interest.
2. When appropriately worded, the following items may be included in advertisements: (*FDA Information Sheet – Recruiting Study Subjects – 10/18/2010*)
   a) The name and address of the investigator and/or research facility;
   b) The condition under study and/or the purpose of the research;
   c) In summary form, the criteria that will be used to determine eligibility for the study;
   d) A brief list of participation benefits, if any (e.g., a no-cost health examination);
   e) The time or other commitment required of the subjects; and
   f) The location of the research and the person or office to contact for further information.
3. The IRB should evaluate the relative size of type used in the ads and other visual effects for appropriateness.
4. Advertisements may state that subjects will be paid but not emphasize the payment or the amount to be paid, by such means as larger or bold type, or coercive visual effects (see first paragraph!).
5. The procedure for recruiting subjects must not be coercive nor state or imply a certainty of favorable outcome or other benefits beyond what is outlined in the consent document and the protocol.
6. The following requirements apply to FDA regulated research:
   a) No claims are made, either explicitly or implicitly, that a drug, biologic or device is safe or effective for the purposes under investigation.
   b) No claims are made that a test article is known to be equivalent or superior to any other drug, biologic or device.
   c) Terms such as "new treatment," "new medication" or "new drug" are not used without explaining that the test article is investigational.

The IRB may require changes to any advertisements and the researcher may go through several iterations of the ad. Remember that the IRB should review the <u>final</u> copy of any advertisements, including the final audio/video tape of advertisements that are taped for broadcast.

Regulations and guidance are struggling to keep up with ever-changing technology and the use of social media in research. None-the-less, the IRB must also review advertisements appearing on social media. If the researchers

establish a social network page to promote a study, then that page should be reviewed. Any blog, post, tweet, or text that contains study-specific direct advertising must be submitted for review. Of course, some social media advertising is passive, that is, simply electronic versions of printed materials that potential subjects may read and respond to. This passive advertising can be reviewed like any written materials. Electronic invitations that allow the recipient to open a website (e.g. hyperlink) must be presented to the IRB. The hyperlinks and connected web pages must be reviewed and approved.

Researchers may also directly contact potential subjects through emails, text, Facebook, or other social media methods. IRBs must review the text of this form of contact. In addition, IRBs should consider if opt-out language for any future contact be included. A unique characteristic of social media advertising is that there may be interactive communication between the researcher and potential subjects. The researcher should submit to the IRB a communication plan that outlines possible messages the researcher might desire to send in the course of an interactive discussion.

No social media site provides absolute anonymity, confidentiality, or privacy. It is up to the researcher to learn and understand the privacy and data security policies of the social media site to be used, including how the information is transmitted and maintained, and develop a protocol-specific data privacy and confidentiality plan. The researcher should be able to explain that information to both the IRB and the potential research subjects. Even if potential subjects are users of a given site, most people will not know the privacy and confidentiality policies of that site. Also, the IRB must recognize that many people have an expectation of privacy, even on public websites such as online support groups or social media sites restricted to friends. The IRB must consider the rights and welfare of these people even in this circumstance and ensure protections when appropriate.

Review and approval of advertisements is an often overlooked IRB function. The burgeoning use of social media in research recruiting has presented new challenges to the IRB and the need for flexible extension of requirements. Good policies and procedures and awareness by IRB members will enable the review of advertisements to be accomplished, and potential subjects fairly recruited and protected.

**Questions for the IRB to Consider**

Questions your IRB may ask about the review of advertisements:

1. Have all recruitment and advertising materials been submitted to the IRB for review?
2. Does the content and form of the advertisement meet all regulatory, institutional and IRB requirements?
3. Does the advertisement include any coercive language or visual practices?
4. When social media is used for recruiting, have all webpages and messages that will be seen by the potential subjects been accessed, reviewed and approved?
5. Has the IRB received, reviewed and approved the final version of any advertisement?
6. **IRB Decision:** Can the advertisements be approved as part of the entire protocol?
7. Are all advertisement materials, reviewer comments, and approvals included in the IRB record?

**Case Studies**

Case 1. A researcher wants to conduct a research survey of employees at a company concerning opinions on appropriate use of vacation and sick days. The plan is to have supervisors read an IRB-approved script to their employees. Is this an appropriate recruiting strategy? What, if any, changes would you require for approval?

Case 2. A clinical researcher proposes to recruit subjects for a clinical trial by posting an ad on an online support group site. In the advertisement he states that all clinical care related to participation in the research will be free of charge. Is this acceptable language for the advertisement? What, if any, changes would you require for approval?

Case 3. A researcher submits an advertisement that will be posted on a website. The ad is acceptable with some minor changes. The reviewer views the final ad on the website and sees that payment amount, $50, appears in bold red with a flashing animation. Is the animation acceptable? What, if any, changes would you require for approval?

**Prospective Thinking:** Plan an IRB education session where you distribute copies of, and discuss, the privacy policies of Facebook, Twitter, Linked In, and any other social media sites used at your organization. Discuss how the policies will influence your IRB review and what information should be included in advertisements and consent forms.