CAPE FEAR VALLEY HEALTH	**IRB Guidance:** Use of Advertisements

Advertisements used to recruit subjects issued to the public regarding human subject research activities at CFVHS will be reviewed an approved by the IRB as part of the initial/new protocol review or via an amendment.

Please check with the CFVHS Marketing and Outreach department prior to submitting all advertisement materials to the IRB for approval. Investigators must follow procedures found in the CFVHS Policy: Media Contact (48374_4) found on CFVHS's InfoWeb under PolicyTech.

Principal Investigator Responsibilities and Procedures

1. The CFVHS IRB considers advertising for or soliciting subjects to be the start of the informed consent process and subject selection process. Advertisements must be reviewed and approved by the IRB as part of the IRB submission for new projects or by submitting an amendment after the project has been approved.
2. A Principal Investigator (PI) must obtain IRB approval for all television, radio, videotape or print advertisements, electronic (including email) solicitations, Internet websites, and other recruitment methods and materials intended for the recruitment of prospective subjects. All methods of advertisement require approval from the IRB prior to their use.
    - The following examples do not qualify as an advertisement:
        - Communications intended only to be seen or heard by health professionals, such as "dear doctor" letters and doctor-to-doctor letters; unless these health professionals are the subjects of the project;
        - Communications intended only to be seen or heard by academic professionals, such as teacher to teacher letters or colleague to colleague; unless these academic professionals are the subjects of the project;
        - News stories, as long as they are not intended for recruitment purposes (e.g. including phone number at the end to contact for more information to participate in a particular project, full details of inclusion/exclusion criteria of a particular project, etc.); and
        - Publicity intended for other audiences.
3. When advertising is to be used, the IRB must review the information contained in the advertisement and the mode of its communication to determine that the document for recruiting subjects is not coercive and does not state or imply a certainty of favorable outcome or other benefits beyond what is outlined in the consent document and the protocol. The IRB must review the printed advertisements in final format to evaluate the relative size of type used and other visual effects. When advertisements are to be taped for broadcast, the IRB must review the final audio or video tape prior to use.
4. After an advertisement or press release has been approved by the IRB, it may require submission to other applicable CFVHS departments for review and approval. Such as but not limited to CFVHS Media and Outreach.

Content of Advertisements

1. When preparing an advertisement, website posting or approach letter/email to be used to recruit potential subjects to their project, PIs should ensure the content of the advertisement is appropriate and consistent with this procedure.

2. Advertisements used to recruit subjects should be limited to the information the potential subjects need to determine their eligibility and interest. When appropriately worded, the following items must be included in advertisements:
    - The name and address of the PI or the facility where the project will be conducted;
    - The purpose of the project unless otherwise justified;
    - The criteria that will be used to determine eligibility for the project;
    - A brief summary of participation benefits, if appropriate;
    - Time or other commitment required of the subject;
    - Location of the project and the person to contact for additional information;
    - A statement that the project has been reviewed and approved by the CFVHS IRB.
3. Advertisements used to recruit subjects should NOT include the following:
    - Claims of safety, effectiveness, equivalence or superiority in reference to the drug, device or procedure under investigation;
    - Use of the terms "new" or "exciting" 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, or asking subjects to give up legal rights;
    - Claims that the subject will receive therapeutic benefit from participation in the project;
    - The use of any inappropriate pictures or images that would be inconsistent with 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 venues which are not in line with the project's purpose or intent.

Contact Scripts

The first contact prospective subjects make is often with an individual who follows a script to determine basic eligibility for the specific project. The IRB must review the procedures and script/list of talking points to assure that they adequately protect the rights and welfare of the prospective subjects. The IRB must have assurance that any information collected about prospective subjects will be appropriately handled.

Internet Recruitment

1. All uses of internet recruitment should be described in the IRB submission. PIs should utilize the information under *Content for Advertisements* in this guidance with regard to acceptable wording or content.
2. The content of websites, web postings and/or various internet recruitment practices must be reviewed and approved prior to posting.