



**Nova Southeastern University
Standard Operating Procedure for GCP**

Title: <u>Direct Advertising for Study Subjects</u>		Version # 1
SOP Number: OCR-RR-003	Effective Date: August 2013	Page 1 of 3

PURPOSE: Direct advertising for research subjects (i.e. advertising that is intended to be seen or heard by prospective subjects) may be an effective means of communicating the availability of the study to a large population. Direct recruiting advertisements are seen as part of the informed consent and subject selection processes. The Center/College shall take the necessary steps to ensure that the information presented in print, radio, television, internet or other media advertisements are not misleading to subjects and conform to both the FDA and the NIH Office of Human Research Protections standards as interpreted by the IRB.

POLICIES:

1. Advertisements geared towards recruiting subjects for protocols shall be objective and non-coercive. The below criteria shall be met:
 - 1.1. Any advertisement to recruit subjects should be limited to the information the prospective subjects need to determine their eligibility and interest.
 - 1.1.1. The ad should contain the name of the research Center/College.
 - 1.1.2. The ad should state the condition under study and/or the purpose of the research.
 - 1.1.3. The ad should contain the person or office to contact for further information.
 - 1.1.4. The ad may contain, in summary form, the criteria that will be used to determine eligibility for the study.
 - 1.1.5. The ad may contain a brief list of participation benefits, if any (e.g., a no-cost health examination).
 - 1.1.6. The ad may contain the time or other commitment required of the subjects.

- 1.1.7. The ad shall not state or imply a certainty of favorable outcome or other benefits beyond what is outlined in the consent document and the protocol.
- 1.1.8. Language used in print ads should conform to referencing investigational products in public policy
- 1.1.9. 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. If the ad intends to promote that study related medical care will be provided at no cost, then this should be clearly described.
- 1.1.10. Advertisements may state that subjects will be paid, but should not emphasize the payment or the amount to be paid.
- 1.2. The relative size of type used and other visual/audio effects shall not be coercive in nature.

Procedures For Pre-Approval Of Media

1. Prior to the submittal of any printed ads to a publication agency (e.g. newspaper, journal, Web Center/College host) that fit the requirement for IRB approval, the Center/College shall have written verification that the IRB has approved such ad
 - 1.1. This verification shall be in writing and on the letterhead of the IRB.
 - 1.2. The verification shall have an attached copy of the ad.
2. Prior to the submittal of any taped ads (e.g. radio, TV) to a media agency, the Center/College shall have written verification that the IRB has approved such ad.
 - 2.1. It is required that the IRB review and approve the wording of the advertisement prior to taping to preclude re-taping because of inappropriate content.
 - 2.2. The IRB must review images for television ads
 - 2.3. The IRB should review the final audio/video tape.
 - 2.4. This verification shall be in writing and on the letterhead of the IRB.
3. The Center/College shall, early on in the process, invoke its usual media approval and/or purchasing process in proceeding with the project and for final approval of the advertisement. You should contact NSU Marketing Communications for information.
4. You may access the required form for IRB submission at the following NSU website: <http://www.nova.edu/irb/manual/forms/amendmentform.pdf>

Procedure for Internet Study website or NSU website Listings

1. Websites dedicated to recruitment for a particular study require IRB approval. All language, questionnaires, images etc must be submitted for IRB approval
2. Internet listing's must adhere to the FDA Guidance on this topic: that of "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 Center/College location(s); and how to contact the Center/College for further information."
3. If fitting the format, although the FDA does not require IRB review, the NSU IRB requires review of the listing.
4. Obtain documentation of IRB approval to list as evidenced by either standing permission from the IRB (i.e. in the Formal Agreement) or a study specific listing.
5. Periodically review the ad to make sure it molds to the format acceptable and for removal when study closes.