**GUIDANCE 1**

**GUIDANCE FOR ADVERTISING**

Advertising for subjects may include but is not limited to radio, television, Internet, billboards, bus signs, Facebook, Craigslist, etc. The IRB must approve the content of all recruiting advertisements for all research studies. An exact copy of the statements and graphics noted in advertisements must be provided to the IRB. Advertisements should not contain any promises about outcome or promise of direct benefit or other potentially misleading information. Advertisement on Facebook or any other social media cannot be direct. The principle investigator shall provide a secondary means such as a website to provide additional information, consent, etc. so the proprietary information is not posted in the social media. This is done to protect the intellectual property of the proposed project.

A template for the proper use of a flyer is available on the following link:

<https://research.rowan.edu/officeofresearch/compliance/irb/index.html>.

1. **IRB requirements for advertisement**

The IRB reviews the material to assure that the material is accurate and is not coercive or unduly optimistic, creating undue influence to the subject to participate which includes but is not limited to:

A. Statements implying a certainty of favorable outcome or other benefits beyond what was outlined in the consent document and the protocol;

B. Claims, either explicitly or implicitly, that the drug, biologic or device was safe or effective for the purposes under investigation;

C. Claims, either explicitly or implicitly, that the test article was known to be equivalent or superior to any other drug, biologic or device;

D. Using terms like “new treatment,” “new medication,” or “new drug” without explaining that the test article was investigational;

E. Promising “free medical treatment” or behavioral or other forms of treatments when the intent was only to say participants will not be charged for taking part in the investigation;

F. Emphasis on payment or the amount to be paid, such as bold type or larger font on printed media and

G. The inclusion of exculpatory language.

1. **Advertisement content requirements**

Any advertisement to recruit subjects should be limited to the information the prospective subjects need to determine their eligibility and interest. When appropriately worded, the following items may be included:

A. The name and address of the investigator and/or research facility;

B. The condition being studied and/or the purpose of the research;

C. In summary form, the criteria that will be used to determine eligibility for the study;

D. The time or other commitment required of the subjects;

E. The location of the research and the person or office to contact for further information;

F. A clear statement that this is research and not treatment;

G. A brief list of potential benefits (e.g. no cost of health exam) and

H. Advertisements will not include compensation for participation in a trial offered by a sponsor to involve a coupon good for a discount on the purchase price of the product once it has been approved for marketing

Advertisements cannot be altered without the IRB approval. Once approved by the IRB, if modification to an approved advertisement is necessary, you must submit a modification to change the content of the advertisement.

For additional information on advertising at RowanSOM, please go to: <https://sites.rowan.edu/officeofresearch/compliance/irb/policiesguidance/guidancelisting/advertisingrecruit.html#p7EPMc1_16>.

1. **Advertisement for Clinical trials**

FDA considers direct advertising for study subjects to be the start of the informed consent and subject selection process. Advertisements should be reviewed and approved by the IRB as part of the package for initial review. However, when the clinical investigator decides at a later date to advertise for subjects, the advertising may be considered a modification to the ongoing study.

When direct 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 procedure 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.

Generally, FDA believes that any advertisement to recruit subjects should be limited to the information the prospective subjects need to determine their eligibility and interest. When appropriately worded, the following items must be included in advertisements.

1. The name and address of the clinical investigator and/or research facility;

2. The condition under study and/or the purpose of the research;

3 In summary form, the criteria that will be used to determine eligibility for the study;

4. A brief list of participation benefits, if any (e.g., a no-cost health examination);

5. The time or other commitment required of the subjects; and

6. The location of the research and the person or office to contact for further information.