ORLANDO HEALTH®
1414 Kuhl Ave.
Orlando, Florida 32806
321.843.7000

| Type of Policy: | ***PROTECTION OF HUMAN RESEARCH PARTICIPANTS*** | Category: | **Orlando Health Institutional Review Board (IRB)** |
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|---|---|---|---|
| Title: | ***Advertising, Recruiting and Media Contact for Research Subjects*** | Policy #: | **0330-1021** |
| | | Replaced #: | ORMC 6000-300; MDACCO 1000-0001 |
| Page 1 of 2 | | Issued By: | Orlando Health Institutional Review Board |
| Issue Date: | **7/19/95** | Approved By: | Philip Giordano, MD Institutional Official **SIGNATURE ON FILE** |
| Revision Dates: | 1/1/01, 5/17/05, 11/9/07, 8/11/14, 4/4/17, 4/21/20, 10/17/23 | | |

## I. PURPOSE:

To maintain ethical and legal standards when advertising for the recruitment of research subjects.

## II. DEFINITIONS:

A. Direct Advertisement: an advertisement that is intended to be seen or heard by prospective subjects to solicit their participation in a research study. Direct Advertisements includes, but are not limited to, newspaper, radio, TV, bulletin boards, posters and flyers.

B. Direct Advertisements do not include the following:

a. "Dear Doctor" letters (written communication from the Principal Investigator to other clinicians requesting for the referral of potentially eligible patients),
b. Subject retention materials,
c. News stories or advertising that is publicly intended for other audiences such as financial pages directed toward investors.

C. For studies using an external IRB, all advertisements shall be submitted determine if additional approvals are required.

## III. POLICY:

All Direct Advertisements for research subjects shall be reviewed and approved by the IRB prior to publication.

## IV. PROCEDURE:

A. Prior to publication, Principal Investigators shall submit the advertisement with the appropriate Advertisement IRB form to the IRB for review, acknowledgement, and determination via IRBNet. No claims should be made on the advertisement, either explicitly or implicitly, that a drug or device is safe or effective for the purpose under investigation, or that is in any way equivalent or superior to any other drug or device. In addition, the advertisement may not promise "free medical treatment".

B. Advertisements should be limited to:

a. name and address of clinical investigator and/or research facility
b. purpose of research and eligibility criteria
c. description of benefits [payment (for travel, time, etc.), study drug, medical care, etc.]
d. location of research and person to contact for further information

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## V. REFERENCES:

A. Code of Federal Regulations - 21 CFR 56.107(a)
B. FDA Guidance– Recruiting Study Subjects Information Sheet
C. IRBNet's Forms and Templates

## VI. ATTACHMENTS:

None.