Advertising in Clinical Research

I. Purpose
This policy establishes an approval process for Advertising in Human Subject Research at Ochsner Health System (OHS).

II. Scope
This policy applies to individuals at OHS whom are engaged in Human Subject Research including but not limited to any person paid by, under the control of or affiliated with the institution such as scientists, investigators, research coordinators, medical education, medical staff, guest researchers and collaborators.

III. Definitions
A. Advertising– Any research-related information that will be seen or heard by a potential subject before her or she has read and signed a consent form for the study. Advertising may include: printed items in newspapers, magazines, flyers, poster, etc. / radio / TV / video / internet postings / web pages / informational brochures / letters to potential subjects / imprinted items (notebooks, bags, etc).

B. Human Subject Research- A systematic investigation conducted to obtain data through intervention or interaction with a living individual or using identifiable private information. Human Subject Research and Clinical Research are synonymous.

C. Institutional Review Board (IRB)- An independent body constituted of medical, scientific, and nonscientific members, whose responsibility it is to ensure the protection of the rights, safety, and well-being of human subjects involved in a trial by, among other things, reviewing, approving, and providing continuing review of trials, of protocols and amendments, and of the methods and material to be used in obtaining and documenting informed consent of the trial subjects.

D. Principal Investigator (PI)- An individual who actually conducts a clinical investigation, i.e., under whose immediate direction the test article is dispensed, or, in the case of an investigation conducted by a team of individuals, is the responsible leader of that team. An individual who actually conducts a clinical investigation, i.e., under whose immediate direction the test article is dispensed, or, in the case of an investigation conducted by a team of individuals, is the responsible leader of that team. This term is synonymous with investigator.

IV. Policy Statements
A. Advertisements can originate from the PI, the funding source, or the sponsor.

B. Ochsner’s Marketing Department shall be consulted in development and placement of advertising.
C. Clinical trial advertisements shall be approved by the IRB and the sponsor or funding source.

V. Procedures/Standards and Roles & Responsibilities
   A. The PI is responsible for ensuring the appropriate approvals have been obtained prior to public viewing.
   B. Advertisements for externally sponsored trials which are generated by the PI are reviewed and approved by the sponsor.
   C. The Office of Sponsored Projects (OSP) is responsible for the allocation of funding for Advertising and ensures the study budget has the funding for the advertisement(s).
   D. The OHS Marketing Department shall:
      1. Review sponsor-generated advertisements for formatting.
      2. Assist in the creation, formatting, editing and producing of PI generated advertising.
      3. Approve the placement of print, radio, TV ads, and/or bulk mailing (as appropriate), regardless of the origin of the advertisement.
   E. The Human Research Protection Program (HRPP) office approves advertising that will be seen by the public.
      1. This does not apply to clinical trials posted on the OHS website or clinicaltrials.gov.
      2. TV/video scripts receive final approval only after the IRB reviews the actual video.
   F. Print Advertising placed within OHS departments requires approval by the department manager.
   G. Documentation of approvals will be maintained in the study regulatory binder.
   H. Any Advertising that is not addressed in this policy should be discussed with the HRPP Manager.

VI. Enforcement and Exceptions
   Failure to comply with this policy may result in progressive discipline up to and including termination of employment for employees or termination of contract or service for third-party personnel, students or volunteers.
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VII. Internal References

IRB Written Procedures at https://ersa.ochsner.org

VIII. External References

FDA Regulations
21 CFR 50
21 CFR 56
21 CFR 312
21 CFR 812
21 CFR 314
21 CFR 814
21 CFR 56.102 h
ICH E6 1.31

IX. Policy History
8012-1-23 Advertisements

X. Approved

Warner Thomas, President and Chief Executive Officer
William Pinsky MD, Executive Vice President & Chief Academic Officer

Reviewers

System Policy Review Committee, 2/3/2016

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