

3.5 Subject Recruitment Through Advertisements

1.0 Purpose

The purpose of this policy is to describe the Organization's requirements for recruitment of subjects through advertisements. For the purpose of this policy, "advertisements" refer to printed advertisements (including bulletins, newsletters, posters, fliers, and magazine or newspaper ads); radio and television advertisements; and electronic advertisements (including social media or other on-line venue).

Note: Invitations to participate directed to specific persons are covered by HRPP policy 3.6 (Subject Recruitment Through Direct Invitation).

Note: References in this policy to information provided to, or decisions made by, potential subjects also means information provided to, or decisions made by, parents, guardians or legally authorized representatives (LARs) as appropriate.

2.0 Policy

It is the policy of the Organization that

- 2.1. All advertisements must be reviewed and approved by the IRB or Office of Regulatory Affairs (ORA) before the material can be used to recruit potential subjects.
 - 2.2. Advertising must be clear, promote equitable enrollment and not represent undue influence or coercion.
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3.0 General Requirements and Prohibitions

- 3.1. Advertisements should be limited to information a potential subject may need to determine if they are interested, and eligible to participate, in a study.
- 3.2. Advertisements may not include any of the following:
 - 3.2.1. Statements implying a certainty of a favorable outcome or other benefits beyond those described in the consent document and the protocol.
 - 3.2.2. Claims, either explicit or implicit, that the research procedures and/or the test article (drug, biologic or device) are safe or effective for the purposes under

investigation.

- 3.2.3. Claims, either explicit or implicit, that the research procedures are known to be equivalent or superior to other interventions off-study.
 - 3.2.4. Terms such as “new treatment”, “new medication”, or “new drug”.
 - 3.2.5. Promises of “free medical treatment” regardless of whether the treatment will be provided without charge.
 - 3.2.6. The amount of compensation for participation (monetary or related to free or reduced price for services).
 - 3.2.6.1. The advertisement may include that compensation is available, but this information may not be in any font, font size, color, or other manner that is intended to draw attention to the value or availability of compensation.
 - 3.2.7. Any exculpatory language.
 - 3.2.8. Claims, either explicit or implicit, about the drug, biologic, or device under investigation that are inconsistent with FDA labeling.
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4.0 Printed Advertisement

- 4.1. All printed advertisements developed by the investigator or staff, or developed by an outside sponsor must be uploaded to RSS, and reviewed and approved by the ORA.
 - 4.2. Printed advertisement must include the following items:
 - 4.2.1. Name of the PI and associated institution.
 - 4.2.2. A clear statement that the activity is research.
 - 4.2.3. Purpose of the research
 - 4.2.4. IRB number (in the format XXXX-XX-XX).
 - 4.3. Printed advertisement may include the following information, as appropriate:
 - 4.3.1. Brief major relevant eligibility criteria (specifically, why a person might believe they are a potential subject)
 - 4.3.2. Time or other commitments required from the subject, including the duration of the person’s participation in the study.
 - 4.3.3. A brief description of potential benefits to the subject, and of reasonably foreseeable risks and discomforts, if any. If potential benefits are stated in recruitment material then the risks must also be stated.
 - 4.3.4. Location of the research, contact person, and phone number for further information.
 - 4.4. Whenever possible, the layout of the advertisements must conform to the Organization’s requirements regarding the use of logos and brands.
 - 4.5. It is the responsibility of the investigator to ensure that the final published copy (including font and size) matches that approved by the IRB.
 - 4.6. When accrual to the research is completed, the investigator is responsible for terminating newspaper or magazine ads.
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5.0 Radio and Television Advertisements

- 5.1. Radio and Television advertisement must include the following items:
 - 5.1.1. Name of the PI and associated institution.
 - 5.1.2. A clear statement that activity is research.

- 5.1.3. Purpose of the research.
 - 5.2. Radio and Television advertisement may include the following information, as appropriate:
 - 5.2.1. Brief major relevant eligibility criteria (specifically, why a person might believe they are a potential subject).
 - 5.2.2. Time or other commitments required from the subject, including the duration of the person's participation in the study.
 - 5.2.3. A brief description of potential benefits to the subject, and reasonably foreseeable risks and discomforts, if any. If potential benefits are stated in recruitment material then the possible risks must also be stated.
 - 5.2.4. Location of the research, contact person, and phone number for further information.
 - 5.3. It is the responsibility of the investigator to ensure that the final broadcast matches that approved by the IRB.
 - 5.4. When accrual to the research is completed, the investigator is responsible for assuring that radio or television ads cease.
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6.0 Electronic Advertisements (including social media or other on-line venue)

- 6.1. Electronic advertisement must include the following items:
 - 6.1.1. Name of the PI and associated institution.
 - 6.1.2. A clear statement that the activity is research.
 - 6.1.3. Purpose of the research
 - 6.1.4. IRB number (in the format XXXX-XX-XX).
 - 6.2. Electronic advertisement may include the following information, as appropriate:
 - 6.2.1. Brief major relevant eligibility criteria (specifically, why a person might believe they are a potential subject).
 - 6.2.2. Time or other commitments required from the subject, including the duration of the person's participation in the study.
 - 6.2.3. A brief description of potential benefits to the subject, and reasonably foreseeable risks and discomforts, if any. If potential benefits are stated in recruitment material then the possible risks must also be stated.
 - 6.2.4. Location of the research, contact person, and phone number for further information.
 - 6.2.5. A link (and/or a URL) pointing to a site maintained by the Organization.
 - 6.2.6. A link (and/or a URL) pointing to a site maintained by an external organization with the domain "org", "edu" or "gov", that is relevant to the disease or condition which is being studied, or to the practice of human subject research or protection of human research subjects in general.
 - 6.3. It is the responsibility of the investigator to ensure that the final published copy (including font and size) matches that approved by the IRB.
 - 6.4. If the advertisement includes a link or a URL, it is the responsibility of the investigator to regularly check that link to be assured that it remains intact.
 - 6.5. When accrual to the research is completed, the investigator is responsible for assuring the study?specific electronic advertising is disabled.
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7.0 Submission and Review of Advertisements

- 7.1. Final versions of all advertisements including print media, audio scripts for radio, video scripts for television, and screenshots of online advertising (including all webpages linked to the advertisement) must be submitted to the ORA for review and approval. Copies will be maintained by the ORA.
 - 7.1.1. Submission of planned advertising to the ORA must include a description of the location the advertisement will be placed; specifically, the name of the publication (for example, “Omaha World-Herald”, the specific media outlet (for example, “KETV”) and/or the website or venue (for example, specific Facebook page or community).
 - 7.1.2. The final version of any advertisement may be reviewed by either the full IRB or by an expedited reviewer in accordance with 45 CFR 46.110(b) and HRPP policies 2.2 (Full IRB Review) and HRPP policies 2.3 (Expedited Review).
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DOCUMENT HISTORY: ? Written: 4/14/2016 (Approved: 4/14/2016) - original author not recorded

? Revised: 6/28/2018 - revision not documented

? Revised 9/9/2022 – Clarified that advertisements related to research for which the Organization is relying on another IRB as the IRB of record, must be adhere to this policy; however, the ORA will not routinely review such advertising unless requested to do so by the investigator or the reviewing IRB. {Approved Chris Kratochvil (Institutional Official), Bruce Gordon (Assistant Vice Chancellor for Regulatory Affairs, Executive Chair)}

? Revised 9/15/2022 – removed requirement that printed advertisements be prepared within RSS (functionality not yet implemented). {Approved Chris Kratochvil (Institutional Official), Bruce Gordon (Assistant Vice Chancellor for Regulatory Affairs, Executive Chair)}

? Revised 10/12/2022 - emphasized what information “must” be included vs “may” be included, in advertisements {Approved Chris Kratochvil (Institutional Official), Bruce Gordon (Assistant Vice Chancellor for Regulatory Affairs, Executive Chair)}

? Board Notified: 11/29/2022

? Revised: 12/1/2022 - typo corrected in 7.0 (Robert Lewis - IRB Assoc)

? Revised: 3/29/2023 - typos corrected in Section 2.0 and section numbering corrected 2.1-2.4 (Robert Lewis - IRB Assoc)

? Revised (10/10/2024) – modified so that ORA will review all advertisements, including those used when the Organization relies on another IRB; specified format of IRB number to be included in written advertisements; clarified advertisements must include a description of “reasonably foreseeable” risks; revised to require layout of the advertisements conform to the Organization’s requirements regarding the use of logos and brands “whenever possible” (section 4.4); clarified requirements regarding availability and value of compensation in advertisements (section 3.2.6); deleted requirement that IRB approval letter cite the approved version of the advertisement

(section 7.1.3); stylistic changes. {Approved Russell McCulloh (Institutional Official), Bruce Gordon (Assistant Vice Chancellor for Regulatory Affairs, Executive Chair)}

? Revised 12/11/2024 – deleted “address” from sections 4.2.1 and 6.1.1. {Approved Russell McCulloh (Institutional Official), Bruce Gordon (Assistant Vice Chancellor for Regulatory Affairs, Executive Chair)}

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