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).

2.0 Policy

It is the policy of the Organization that

- **2.1.** All advertisements related to research for which the UNMC IRB is the IRB of record, must be reviewed and approved by the IRB before the material can be used to recruit potential subjects.
- **2.2.** All advertisements related to research for which the Organization is relying on another IRB as the IRB of record, must 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.
- **2.3.** Advertising must be clear, promote equitable enrollment and not represent undue influence or coercion.
- **2.4.** For the purpose of this policy, references 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.

3.0 General Requirements and Prohibitions

- **3.1.** Advertisements should be limited to information a potential subject may need to determine if he/she is 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 (e.g. 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.** A stated amount of compensation for participation (monetary or related to free or reduced price for services), or indication that compensation is available, in any font, font size, or manner that is intended to draw attention to the value or availability of compensation.
  - **3.2.7.** Any exculpatory language.
  - **3.2.8.** Make claims, either explicitly or implicitly, about the drug, biologic, or device under investigation that are inconsistent with FDA labeling.

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 (except when the Organization is relying on another IRB as the IRB of record), and reviewed and approved by the IRB.
- **4.2.** Printed advertisement must include the following items:
  - **4.2.1.** Name and address 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
- **4.3.** Printed advertisement may include the following information, as appropriate:
  - **4.3.1.** Brief relevant eligibility criteria (e.g., why a person might believe he/she is a potential subject)
  - **4.3.2.** Time or other commitments required from the subject, including number of study

visits and duration of the study.
    - **4.3.3.** A brief list of potential benefits to the subject, and of 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.** 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.

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 relevant eligibility criteria (e.g., why a person might believe he/she is a potential subject).
    - **5.2.2.** Time or other commitments required from the subject
    - **5.2.3.** A brief list of potential benefits to the subject, and possible risks and discomforts, if any. Per FDA Guidance, 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.

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 and address 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
- **6.2.** Electronic advertisement may include the following information, as appropriate:
    - **6.2.1.** Brief relevant eligibility criteria (e.g., why a person might believe he/she is a potential subject).
    - **6.2.2.** Time or other commitments required from the subject.
    - **6.2.3.** A brief list of potential benefits to the subject, and possible risks and discomforts, if any. Per FDA Guidance, 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 must disable study-specific electronic advertising

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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) related to research for which the UNMC IRB is the IRB of record, must be submitted to the ORA in accordance with HRPP policy 2.1 (Submission of Items for Review) 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 (that is, the name of the publication {e.g., the Omaha World-Herald}, the specific media outlet {e.g., KETV} and/or the website or venue {e.g., specific Facebook page or community}), and the expected duration of the advertising.
    - **7.1.2.** The final version of any advertisement may be reviewed by either the full IRB or by the expedited method if it qualifies in accordance with 45 CFR 46.110(b) and HRPP policies 2.2 (Full IRB Review) and HRPP policies 2.3 (Expedited Review).
    - **7.1.3.** The IRB approval letter will cite the approved version of the advertisement.

- **7.2.** Advertisements related to research for which the Organization is relying on another IRB as the IRB of record need not be submitted to the ORA for review, unless such review is requested by the investigator or by the reviewing IRB.

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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)}

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