Advertisements (HRPP 3.5)

Description:

This policy describes UNMC's requirements for recruitment of subjects through advertisements.

Advertisements MAY NOT INCLUDE:

- Claims suggesting guaranteed positive outcomes beyond what's stated in the consent form
- Claims, explicitly or implicitly, that:
  - The study drug/device/procedure is safe or effective for the purpose under investigation
  - The study intervention is better than other available interventions
- Terms like *"new treatment"*, "*new medication"*, or "*new drug*"
- A stated amount of compensation, or manipulating font (size, bold, etc.) to draw attention to compensation
- Exculpatory language (*e.g, language waiving rights or releasing liability*)
- Unsubstantiated or promotional claims about the investigational product that are inconsistent with FDA labeling

Printed Advertisements

All printed ads (investigator-created or sponsor-supplied) must be uploaded to RSS adn approved by the Office of Regulatory Affairs (ORA) before use.

REQUIRED CONTENT:

- PI's name and institution
- A clear statement that the activity is research
- The purpose of the research
- The IRB number (format: XXXX-XX-XX)

Optional Content:

- Brief eligibility criteria
- Time commitment or study duration
- Potential benefits and risks/discomforts
  - **NOTE**: if benefits are listed, risks MUST also be included
- Location of the research

- Contact person and their phone number

Investigator Responsibilities:

- Follow branding/logo guidelines when possible
- Final version (including font/size/layout) must match IRB-approved version
- Terminate ads in print (newspaper, magazine, etc.) once enrollment is complete

Radio and TV Advertisements

REQUIRED CONTENT:

- PI's name and institution
- Statement that the activity is research
- Purpose of the research

Optional Content:

- Brief eligibility criteria
- Time commitment or study duration
- Potential benefits and risks/discomforts
    - **NOTE**: if benefits are listed, risks MUST also be included
- Location of the research
- Contact person and their phone number

Investigator Responsibilities:

- Final broadcast version must match IRB-approved script
- Stop airing the ad once the study enrollment is completed

Electronic Advertisements (Including Social Media)

REQUIRED CONTENT:

- PI's name and institution
- A clear statement that the activity is research
- The purpose of the research
- The IRB number (format: XXXX-XX-XX)

Optional Content:

- Brief eligibility criteria
- Time commitment or study duration
- Potential benefits and risks/discomforts
    - **NOTE**: if benefits are listed, risks MUST also be included
- Location of the research

- Contact person and their phone number
- A link to an Organization-maintained website
- A link to a credible external site *(domain must be .org, .edu, or .gov)* related to the condition or research subject protection

Investigator Responsibilities:

- Final online content (including font/size) must match IRB-approved version
- Regularly check that any included links/URLs remain functional and accurate
- Disable online ads once enrollment is complete

Submission and Review of Advertisements

Submission Requirements:

- Final versions of all advertisements must be submitted to the ORA for review and approval (via RSS)
- Types of media requiring submission:
    - Printed advertisements
    - Audio scripts for radio
    - Video scripts for TV
    - Screenshots of online advertisements
    - All linked webpages associated with online advertisements