



HRP-315 | 12/1/2025

WORKSHEET: Advertisements

The purpose of this worksheet is to provide support for the convened IRB or Designated/Staff Reviewers when evaluating advertisements meant to be seen or heard by subjects.ⁱ

1. Context (Check if “Yes”. All must be checked)

- The application describes the mode of communication.
- For printed advertisements, the final copy is being reviewed.
- For audio/video tape, the tape is the final version.

2. The advertisement: (Check if “Yes”. All must be checked)

- Does NOT state or imply a certainty of favorable outcome or other benefits beyond what is outlined in the consent document and the protocol.
- Does NOT promise “free treatment,” when the intent is only to say subjects will not be charged for taking part in the research.
- Does NOT include exculpatory language.
- Does NOT emphasize the payment or the amount to be paid, by such means as larger or bold type.
- The advertisement is limited to the information prospective subjects need to determine their eligibility and interest, such as:
 - The name and address of the investigator or research facility.
 - The condition under study or the purpose of the research.
 - In summary form, the criteria that will be used to determine eligibility for the study.
 - A brief list of participation benefits, if any.
 - The time or other commitment required of the subjects.
 - The location of the research and the person or office to contact for further information.

3. For FDA-Regulated research, the Advertisement: (Check if “Yes”. All must be checked)

- Does NOT make claims, either explicitly or implicitly, that the drug, biologic or device is safe or effective for the purposes under investigation.
- Does NOT make claims, either explicitly or implicitly, that the test article is known to be equivalent or superior to any other drug, biologic or device.
- Does NOT use terms, such as “new treatment,” “new medication” or “new drug” without explaining that the test article is investigational.

- Does NOT include a coupon good for a discount on the purchase price of the product once it has been approved for marketing.

4. For Veterans Administration (VA)-Regulated research, the advertisement: (Check if “Yes”. All must be checked)

- Does NOT use the VA Facebook page as a method of advertising non-VA studies at VA facilities.
- If the research is non-VA research being conducted at a VA facility, the advertisement includes a clear and legible disclaimer that states:
- The research is not VA research.
 - The research will not be conducted by the VA.
 - The research has not been reviewed by VA’s Institutional Review Board.
- The research is not endorsed by VA.

ⁱ This document satisfies AAHRPP elements II.3.C-II.3.C.1, III.1.E.