HRP-315 | 12/9/2022

WORKSHEET: Advertisements

The purpose of this worksheet is to provide support for the convened IRB or Designated Reviewers when evaluating advertisement meant to be seen or heard by subjects.[[1]](#endnote-2)

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

1. 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.
1. 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.

1. 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 no-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.
1. This document satisfies AAHRPP elements II.3.C-II.3.C.1, III.1.E [↑](#endnote-ref-2)