



WORKSHEET: Advertisements

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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. This worksheet is to be used. It does not have to be completed or retained.

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

- | | |
|--------------------------|--|
| <input type="checkbox"/> | The application describes the mode of communication |
| <input type="checkbox"/> | For printed advertisements, the final copy is being reviewed |
| <input type="checkbox"/> | For audio/video tape, the tape is the final version |

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

- | | |
|--------------------------|--|
| <input type="checkbox"/> | Does NOT state or imply a certainty of favorable outcome or other benefits beyond what is outlined in the consent document and the protocol |
| <input type="checkbox"/> | Does NOT promise “free treatment,” when the intent is only to say subjects will not be charged for taking part in the research |
| <input type="checkbox"/> | Does NOT include exculpatory language |
| <input type="checkbox"/> | Does NOT emphasize the payment or the amount to be paid, by such means as larger or bold type |
| <input type="checkbox"/> | The advertisement is limited to the information prospective subjects need to determine their eligibility and interest, such as: <ul style="list-style-type: none"> • 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)

- | | |
|--------------------------|--|
| <input type="checkbox"/> | Does NOT make claims, either explicitly or implicitly, that the drug, biologic or device is safe or effective for the purposes under investigation |
| <input type="checkbox"/> | 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 |
| <input type="checkbox"/> | Does NOT use terms, such as “new treatment,” “new medication” or “new drug” without explaining that the test article is investigational. |
| <input type="checkbox"/> | Does NOT include a coupon good for a discount on the purchase price of the product once it has been approved for marketing. |