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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. | |
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| 1. Context (All must be “Yes”) | |
| Yes  No | The application describes the mode of communication |
| Yes  No | For printed advertisements, the final copy is being reviewed |
| Yes  No | For audio/video tape, the tape is the final version |
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| 1. The advertisement: (All must be “Yes”) | |
| Yes  No | Does NOT state or imply a certainty of favorable outcome or other benefits beyond what is outlined in the consent document and the protocol |
| Yes  No | Does NOT promise “free treatment,” when the intent is only to say subjects will not be charged for taking part in the research |
| Yes  No | Does NOT include exculpatory language |
| Yes  No | Does NOT emphasize the payment or the amount to be paid, by such means as larger or bold type |
| Yes  No | 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 |
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| 1. For FDA-Regulated research, the advertisement: (All must be “Yes”) | |
| Yes  No | Does NOT make claims, either explicitly or implicitly, that the drug, biologic or device is safe or effective for the purposes under investigation |
| Yes  No | 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 |
| Yes  No | Does NOT use terms, such as “new treatment,” “new medication” or “new drug” without explaining that the test article is investigational. |
| Yes  No | Does NOT include a coupon good for a discount on the purchase price of the product once it has been approved for marketing. |