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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 (Check if “Yes”. All must be checked) | |
|  | The application describes the mode of communication |
|  | For printed advertisements, the final copy is being reviewed |
|  | For online advertisements, the final screen shots (including all images) are being reviewed |
|  | For audio/video tape, the tape is the final version |
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| 1. The advertisement: (Check if “Yes”. All must be checked) | |
|  | States that the participant is being asked to take part in research |
|  | Includes the Seattle Children’s logo\* |
|  | 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 Department/Division of the investigator and the investigator’s institutional affiliation (e.g., Seattle Children’s or University of Washington) * 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 description of the project (e.g., whether it involves a blood draw, use of an investigational drug, or an interview) * A brief list of participation benefits, if any * The time or other commitment required of the subjects * Compensation, payment or inducement participants will receive * 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: (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 | **The letter or email:** (Check if “**Yes**”. All must be checked) |
|  | Is signed by a person who has access to the potential subject’s name, address and confidential information about their diagnosis or care (e.g., the potential subject’s doctor or the director of the clinic where the subject received care) |
|  | Is written on the approaching institution’s letterhead |
|  | Includes instructions on what will happen if the subject does not respond |
|  | Includes instructions on how the subject can contact investigators and request no further contact |

\*Questions about using the Children's logo should be referred to Children's Communications Department.

\*\* Note that certain kinds of advertisements may be approved which do not include one or more of these elements, depending on the specific situation. For example, some advertising (e.g. bus ads or internet sites) may have space restrictions precluding inclusion of all of the above elements.