**PURPOSE and SCOPE**

The purpose of this worksheet is to assist the IRB in determining whether an advertisement for non-exempt human subjects research can be approved. This worksheet is to be used. It does not need to be completed or retained.

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| **1 The following has been reviewed** | |
|  | The information contained in the advertisement. |
|  | The mode of the advertisement’s communication. |
|  | If a print advertisement, the final print copy. |
|  | If an audio advertisement, the final audio. |
|  | If a video advertisement, the final video. |
| **2 Criteria for approval of an advertisement** *45 CFR §46.116 and 21 CFR §50.25* | |
|  | The advertisement does not state or imply a certainty of favorable outcome or other benefits beyond what is in the consent document and protocol. |
|  | The advertisement does not include exculpatory language. |
|  | The advertisement does not emphasize the payment or the amount to be paid, by such means as larger or bold type. |
|  | The advertisement does not promise “free treatment” when the intent is only to say subjects will not be charged to take part in the research. |
|  | The advertisement is limited to information prospective subjects need to determine their eligibility and interest.  Examples:   * The name and address of the researcher or research facility. * The purpose of the research or the condition under study. * In summary form, the criteria that will be used to determine eligibility for the study. * A brief list of benefits to subjects, if any. * The time or other commitment required of subjects. * The location of the research and the person or office to contact for further information. |
| **3 Additional criteria for approval of an advertisement for a clinical trial** | |
|  | The advertisement does not make claims, either explicitly or implicitly, about the drug, biologic, or device under investigation that are inconsistent with FDA labeling. |
|  | The advertisement does not use terms such as “new treatment”, “new medication”, or “new drug” without explaining that the test article is investigational. |
|  | The advertisement does not include compensation for participation to include a coupon good for a discount on the purchase price of the produce once it has been approved for marketing. |