This worksheet is used to determine whether an advertisement for non-exempt Human Research can be approved.

1. The following has been reviewed
   1.1 The information contained in the advertisement
   1.2 The mode of the advertisement’s communication
   1.3 If a print advertisement, the final print copy
   1.4 If an audio advertisement, the final audio
   1.5 If a video advertisement, the final video

2. Criteria for approval of an advertisement 45 CFR §46.116 and 21 CFR §312.25
   2.1 The advertisement does not state or imply a certainty of favorable outcome or other benefits beyond what is in the consent document and protocol
   2.2 The advertisement does not include exculpatory language
   2.3 The advertisement does not emphasize the payment or the amount to be paid by such means as larger or bold type
   2.4 The advertisement does not promise “free treatment” when the intent is only to say subjects will not be charged for taking part in the research
   2.5 The advertisement is limited to the information prospective subjects need to determine their eligibility and interest (see Footnote 1)

3. Additional criteria for approval of an advertisement for clinical trial
   3.1 The advertisement does not make claims, either explicitly or implicitly, about the drug, biologic, or device under investigation that are inconsistent with FDA labeling
   3.2 The advertisement does not use terms, such as “new treatment,” “new medication,” or “new drug,” without explaining that the test article is investigational
   3.3 The advertisement does not include compensation for participation to include a coupon good for a discount on the purchase price of the product once the drug has been approved for marketing

4. Notes

5. Footnotes
   Example information that might be needed to determine their eligibility and interest:
   - 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 the subjects
   - The location of the research and the person or office to contact for further information