

## WORKSHEET: Advertisements

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

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All criteria in 2 must be met. All criteria in 3 must be met for clinical trials.

### 1. The following has been reviewed

1.1	<input checked="" type="checkbox"/>	The information contained in the advertisement
1.2	<input checked="" type="checkbox"/>	The mode of the advertisement's communication
1.3	<input checked="" type="checkbox"/>	If a print advertisement, the final print copy
1.4	<input checked="" type="checkbox"/>	If an audio advertisement, the final audio
1.5	<input checked="" type="checkbox"/>	If a video advertisement, the final video

### 2. Criteria for approval of an advertisement *45 CFR §46.116 and 21 CFR §50.25*

2.1	<input type="checkbox"/>	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	<input type="checkbox"/>	The advertisement does not include exculpatory language
2.3	<input type="checkbox"/>	The advertisement does not emphasize the payment or the amount to be paid, by such means as larger or bold type
2.4	<input type="checkbox"/>	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	<input type="checkbox"/>	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	<input type="checkbox"/>	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	<input type="checkbox"/>	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	<input type="checkbox"/>	The advertisement does not include compensation for participation to include a coupon good for a discount on the purchase price of the product once it has been approved for marketing

### 4. Notes

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### 5. Footnotes

5.1	<p>Example information that might be needed to determine their eligibility and interest:</p> <ul style="list-style-type: none"> <li>• The name and address of the Researcher or research facility</li> <li>• The purpose of the research or the condition under study</li> <li>• In summary form, the criteria that will be used to determine eligibility for the study</li> <li>• A brief list of benefits to subjects, if any</li> <li>• The time or other commitment required of the subjects</li> <li>• The location of the research and the person or office to contact for further information</li> </ul>
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