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|  | |  |  |  |  | | --- | --- | --- | --- | | **CHECKLIST: Recruitment Materials** | | |  | | POLICY | DATE | VERSION | PAGE | | 800.01 | 1/25/2019 | 2 | 1 of 1 | |

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| --- | --- |
| **Recruitment Materials** include: media advertisements, subject/patient letters, website advertisements, social media advertisements, online recruitment, phone-screen scripts, newsletters, pre-screening scripts, and generic pre-screening informed consents (ICs). The purpose of this checklist is to provide support for IRB members when research involves use of advertisement or recruitment material. This checklist must be used for all reviews (initial, continuing, modification, review by the convened IRB, and review using the expedited procedure.  This checklist is to be used as guidance. It does not need to be completed or retained. | |
| The purpose of this worksheet is to aid IRB staff and IRB members in reviewing recruitment materials. This checklist is to be used. It does not need to be completed or retained. | |
| 1 **Context** (Check if **“Yes”**. All must be checked) | |
| ☐ | The application describes the mode of communication |
| ☐ | All of the information in the advertisement is accurate and consistent with the protocol and consent form. |
| ☐ | Recruitment materials must be at a reading level accessible to a lay person. |
| 2 **Content:** (Check if **“Yes”**). Any advertisement to recruit research subjects should be limited to the information the prospective subjects need to determine their eligibility and interest. | |
| ☐ | The name and address of the clinical investigator and/or research facility. |
| ☐ | The condition being studied and/or the purpose of the research. |
| ☐ | The time or other commitment(s) required of the subjects. |
| ☐ | The location of the research and the person or office to contact for further information. |
| ☐ | A clear statement that this is research and not treatment. |
| ☐ | A clear statement that participation is voluntary. |
| 3 **The advertisement:** (Check if **“Yes”**. All must be checked) | |
| ☐ | 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 highlighted, larger or bold type |
| 4 **For FDA-Regulated research, the advertisement:** (Check if **“Yes”**. All must be checked)☐ **N/A** | |
| ☐ | 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. |

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