|  |  |  |  |
| --- | --- | --- | --- |
| *Recruitment-Advertising Review and Approval Checklist*  *IRB-HSR#/UVA Study Tracking#:* **\_\_** | | | |
| **If any of the boxes below are checked NO, request a modification to either the ad or to the protocol/protocol application and consent. If issues cannot be resolved, then Full Board Review will be required.**   * **See page 2 for Center/Departmental Research program research that is not study specific** * **See page 2 Sponsor/sponsor designee recruitment materials** | | | |
| 1. **Use of Correct Templates:** | | | |
| **YES** | **NO** | **N/A** | **QUESTION** |
|  |  |  | Appropriate template used for all recruitment where subject is being contacted by someone from UVa (email, letter or telephone call) This response must be YES or NA in order for approval to occur |
|  |  |  | Is it clear by looking at the ad, what type of ad is being submitted? . Ads must clearly display the TYPE of ad (poster, flyer, newspaper etc) |
| 1. **Advertisement Content and Language** | | | |
| **YES** | **NO** | **N/A** | **QUESTION** |
|  |  |  | Does the advertisement make it clear that subjects are being recruited for research and not treatment? There are NO statements present that imply a certainty of favorable outcome or other benefits beyond what was outlined in the consent document and the research plan. The message of the advertisement does not have the potential to contribute to confusion between research participation and standard clinical care? |
|  |  |  | There are NO claims, either explicitly or implicitly, that the test article (drug, biologic or device) is safe or effective for the purposes under investigation or that the test article is/was known to be equivalent or superior to any other drug, biologic or device. |
|  |  |  | Ad does not use terms, such as “new treatment,” “new medication,” or “new drug,” without explaining that the test article is investigational |  |  | Ad does not use terms, such as “new treatment,” “new medication,” or “new drug,” without explaining that the test article is investigational. |
|  |  |  | Does NOT offer for a coupon good for a discount on the purchase price of an investigational product once it has been approved for marketing. |
|  |  |  | The language present in the advertising is approximately 6th grade reading level. |
|  |  |  | The language in the ad would generally not be considered offensive ( Yucky words like pus etc. have been edited) |
|  |  |  | Does the ad contain a Universal Product Code (UPC) icon, a QR code or link?   * If so, the study team must submit (OR the IRB must view and print) all information that will be linked to the icon, QR code or link present with the advertisement. This information must be reviewed and consistent with the recruitment. The approval of the UP, QR code or link must also be noted in the comment section of the Assurance Form when approved |
|  |  |  | The ad does NOT offer FREE care/treatment? |
|  |  |  | Nothing in the ad (e.g. wording, background photos, sounds,) alters the interpretation of the ad? (*No false hope due to pictures etc.). No exculpatory language* |
|  |  |  | Name of facility as UVA Heath System (can be waived for UVA website ads, link and Cville ads) should NOT be present for sponsor produced advertisements where the sponsor or designee will be the initial contact |
| 1. **Advertisement consistent with Protocol/Protocol Application/Consent/IRB Online?** | | | |
| **YES** | **NO** | **N/A** | **QUESTION** |
|  |  |  | The ad includes the IRB-HSR#? IRB number is not required for ads about a particular center nor should they be present on sponsor ads where the sponsor or designee will be fielding initial responses. |
|  |  |  | Name of Condition/Disease under study in lay language. |
|  |  |  | Brief purpose of research in lay language is present. |
|  |  |  | BRIEF list of procedures required is present Does the advertisement disclose important features of the study design that may influence enrollment: e.g. the use of placebos or the requirement for prior medication withdrawal? |
|  |  |  | Time commitment for participation is listed: *For example, number of visits, length of each visit and total length of study participation.* |
|  |  |  | Major inclusion/exclusion criteria such as age/gender requirements: *This list should not be copied from the protocol because this is too much technical information and too soon in the process. Age, gender and major requirements in lay terminology are sufficient* |
|  |  |  | Very brief statement of possible/potential benefit stated in such as way as not be promising of treatment or cure.. |
|  |  |  | Compensation listed on advertising is consistent with compensation in protocol/protocol application/consent/IRB OnLine |
|  |  |  | Is the type of recruitment material submitted consistent with the recruitment plan in the protocol with regards to how potential subjects are identified or contacted?   * *If NO, AND direct recruitment will be added, then request a modification to the ad OR to the Protocol/Protocol application/Consent to include this new type of recruitment as appropriate* |
|  |  |  | Is the information in the recruitment material consistent with the protocol with regard to study population (adults vs children, ages , compensation, |
|  |  |  | Does the advertisement contain UVA contact information? (No personal contact information should be present) |
|  |  |  | Are all personnel listed on the ad in the IRB-HSR database for this protocol?   * *If no, request a Personnel Change Form from PI or study coordinator to add them and verify they have completed training.)* |
|  |  |  | Name of Principal Investigator (PI) is present: *This is only necessary if it is not the primary contact. SHOULD NOT BE PRESENT IN MOST SPONSOR ADVERTISEMENTS where the sponsor or designee is the initial contact.* |
| 1. **Other Approvals Required?** | | | |
|  |  |  | If the protocol has an outside sponsor, has the ad been approved by the sponsor? |
|  |  |  | If the ad requires approval from the UVa Health System Marketing Communications department (MCO Department), has that approval been obtained?  *The following types of ads require Marketing approval: add that charge a fee to be posted (print ads such as newspaper or journal ads) and any ads that “have a public face” (such as l: radio, television,social media ads) Note Marketing approval is not needed for classified announcements or for CVille ads* |
|  |  |  | If an advertisement, does a website ad exist in the IRB database? If no, work with the study team to develop and post one in conjunction with this ad. |

|  |  |  |  |
| --- | --- | --- | --- |
| 1. **FDA Regulated Studies  NA** | | | |
| **YES** | **NO** | **N/A** | **QUESTION** |
|  |  |  | Ad does not make claims, either explicitly or implicitly, about the drug, biologic, or device under investigation that are inconsistent with FDA labeling. |
|  |  |  | Protocol does not allow compensation for participation in a trial offered by a Sponsor to include a coupon good for a discount on the purchase price of the product once it has been approved for marketing. |

|  |  |  |  |
| --- | --- | --- | --- |
| 1. **DoD Regulated Studies  NA** | | | |
| **YES** | **NO** | **N/A** | **QUESTION** |
| Verify DoD section included in Recruitment and Compensation sections of protocol application and that the items below are reviewed.  When research involves U.S. military personnel policies and procedures include additional protections for military research participants to minimize undue influence: | | | |
|  |  |  | Officers are not permitted to influence the decision of their subordinates. |
|  |  |  | Officers and senior non-commissioned officers may not be present at the time of recruitment. |
|  |  |  | Officers and senior non-commissioned officers have a separate opportunity to participate. |
|  |  |  | When recruitment involves a percentage of a unit, an independent ombudsman is present. |
| When research involves U.S. military personnel, policies and procedures require limitations on dual compensation: | | | |
|  |  |  | Prohibit an individual from receiving pay of compensation for research during duty hours. |
|  |  |  | An individual may be compensated for research if the participant is involved in the research when not on duty. |
|  |  |  | Federal employees while on duty and non- federal persons may be compensated for blood draws for research up to $50 for each blood draw. |
|  |  |  | Non-federal persons may be compensated for research participating other than blood draws in a reasonable amount as approved by the IRB according to local prevailing rates and the nature of the research. |

|  |  |  |  |
| --- | --- | --- | --- |
| 1. **CENTER /DEPARTMEMENTAL ADS – Complete this section and section 2** | | | |
| **YES** | **NO** | **N/A** | **QUESTION** |
|  |  |  | Does this ad pertain to research being performed by a department and it not study specific?   * May or may not list IRB numbers. If IRB numbers are present, the information in the ad must be consistent with the current protocol, consent, IRB OnLine |
|  |  |  | Basic language about the disease processes being studies is present |
|  |  |  | Basic overview of purpose of research studies is present? |
|  |  |  | Contact information is present |

|  |  |  |  |
| --- | --- | --- | --- |
| 1. **Sponsor/Sponsor designee/central advertising campaign materials – Complete this section and section 2** | | | |
| **YES** | **NO** | **N/A** | QUESTION |
|  |  |  | NO IRB numbers |
|  |  |  | Basic language about the disease processes being studies is present |
|  |  |  | Basic overview of purpose of research studies is present? |
|  |  |  | NON UVA Contact information is present |
|  |  |  | The words UVA , UVA HEALTH SYSTEM ETC. are absent |
|  |  |  | IF local contact is desired, a “Stickie” template is provided for any materials that will be distributed locally |

**Receipt Event:**

* Date= Date of receipt
* Meeting date does not matter – this will not be posted to the agenda
* Review type = Expedited
* Agenda = None
* Event Type = Receipt of Advertising
* Comment: List types of recruitment material received and detail any issues
* File reviewed recruitment pending resolution on U drive>prereview>Subject Recruitment

**Approval Event:**

* Date= Date of approval
* Meeting date: Next upcoming IRB Meeting Date for which the agenda is not closed.
* Review type = Expedited
* Agenda = Agenda
* Event Type = Advertising Approval
* Comment: Modification expedited: Minimal risk/Minor change: The following recruitment materials were approved: List types of recruitment material received

\_\_**\_**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_**\_\_**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Reviewers Name Date of review