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| University of Virginia IRB for Health Sciences Research  Full Board Recruitment Material Reviewer Checklist  **IRB-HSR Study#/ UVA Study Tracking #:**       **Reviewer:**  **Principal Investigator:**       **Date of Meeting:**  *By completing this form as the IRB member reviewer, I confirm I had no conflicts with the protocol.*  *When complete, please upload this form into IRB Pro by 10 AM of the IRB-HSR meeting day.*  *The current application, protocol and consent(s) are available in IRB Pro.*  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | | |
| Reviewer's Oral Presentation  *The reviewer should state the following during their oral presentation to the IRB. Planned responses need to also be written below.*  *See Appendix A for Definitions and Resources*  **What is the purpose of the study:**  **What type of recruitment material is being submitted for review:** | | | | |
| ***If any of the boxes below are marked NO, the reviewer may make a motion to approve with suggestions, with conditions or disapprove the recruitment material.*** | | | | |
| 1. **Privacy** | | | | |
| **YES** | **NO** | **N/A** | **QUESTION: Does the submitted recruitment material meet the following requirements?** | |
|  |  |  | The material protects the privacy of the potential subject and does not disclose potential subject’s health information as it pertains to inclusion/exclusion criteria. | |
|  |  |  | The material discloses where/how contact information was obtained and is in accordance with the recruitment methods as documented in the IRB application and/or protocol. | |
| 1. **Content and Language** | | | | |
| **YES** | **NO** | **N/A** | **QUESTION: Does the submitted recruitment material meet the following requirements?** | |
|  |  |  | The language used is approximately **8th grade reading level**. | |
|  |  |  | The content of the recruitment material clearly represents that subjects are being **recruited for research and not treatment**. The message of the recruitment material does not have the potential to contribute to confusion between research participation and standard clinical care? *Language does not explicitly or implicitly imply "new treatment," "new medication" or "new drug" without explaining that the test article is investigational.* | |
|  |  |  | Information presented **does NOT imply a certainty of favorable outcome** or other benefits beyond what is outlined in the consent form(s) and the protocol. | |
|  |  |  | There are **NO claims, either explicitly or implicitly, that research procedures are safe/effective/equivalent/superior** to any other drug/biologic/device/intervention. | |
|  |  |  | The recruitment material **does NOT offer FREE care, treatment, goods, or services**. *Study may provide items related to study participation “free of charge” or “at no cost”.* | |
|  |  |  | The recruitment material **does NOT emphasize payment** or the amount to be paid: *e.g. use of formatting does not accentuate payment in the forms of larger or bold font, underline, use of punctuation, font color, etc.* | |
| 1. **Additional Protections** | | | | |
|  |  |  | When minors are enrolled, the recruitment material is written in a way that the parent/guardian is the intended audience. | |
|  |  |  | The recruitment material includes a statement that participation is voluntary and refusal to participate will not negatively impact healthcare or relationships with employer/healthcare providers/coaches/teachers, etc. | |
| 1. **Items to Consider** | | | | |
| * Name of condition/disease under study is included in the recruitment material. | | | |
| * Brief purpose of the study is included in the recruitment material. . | | | |
| * Brief list of study procedures required is included in the recruitment material. *The material discloses important features of the study design that may influence enrollment: e.g. surgical procedures, the use of placebos, imaging, etc.* | | | |
| * Time commitment for participation is included in the recruitment material. *e.g. number of visits, length of each visit and total length of study participation.* | | | |
| * A brief statement of potential benefit and risks is included in the recruitment material. | | | |

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| **Motion:**  **Approve modification (recruitment material)**  **Approve modification with suggestions (recruitment material)**  **Approvable with Conditions**  *PI will need to submit revised recruitment material.*  **Deferred**  *PI will need to re-submit the revised recruitment material for review at future IRB-HSR Meeting.*  **Disapproved**  *The investigator may attend a future IRB-HSR meeting to defend the modification if he/she wishes to pursue the modification.*  **Comments:** |

**The reviewer requests the following conditions:**

**The reviewer has the following suggestions that do not affect the approval criteria for continuation:**

**By placing my name below, I confirm I had no conflicts with this protocol.**

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Name Date

Scientific Reviewer

Non-Scientific Reviewer

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| **Appendix A: Definitions and Resources** |
| **Definitions (**[**OHRP Guidance Informed Consent FAQs**](https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/informed-consent/index.html)**)**  **Coercion**occurs when an overt or implicit threat of harm is intentionally presented by one person to another in order to obtain compliance. For example, an investigator might tell a prospective subject that he or she will lose access to needed health services if he or she does not participate in the research.  **Undue influence**, by contrast, often occurs through an offer of an excessive or inappropriate reward or other overture in order to obtain compliance. For example, an investigator might promise psychology students extra credit if they participate in the research. If that is the only way a student can earn extra credit, then the investigator is unduly influencing potential subjects. If, however, she offers comparable non-research alternatives for earning extra credit, the possibility of undue influence is minimized.  **Resources** |

**Excerpt from** [**FDA Information Sheet: Recruiting Study Subjects**](https://www.fda.gov/regulatory-information/search-fda-guidance-documents/recruiting-study-subjects) FDA expects IRBs to review the advertising to assure that it is not unduly coercive and does not promise a certainty of cure beyond what is outlined in the consent and the protocol. This is especially critical when a study may involve subjects who are likely to be vulnerable to undue influence. [21 CFR 50.20, 50.25, 56.111(a)(3), 56.111(b) and 812.20(b)(11).]

When direct advertising is to be used, the IRB should review the information contained in the advertisement and the mode of its communication, to determine that the procedure for recruiting subjects is not coercive and does not state or imply a certainty of favorable outcome or other benefits beyond what is outlined in the consent document and the protocol.

**Excerpt from** [**Attachment C: Approved by SACHRP July 20, 2011- SACHRP Recommendation regarding application of 45 CFR 46 and 21 CFR 56 to early processes in research, such as identifying potential subjects, contacting subjects and recruiting subjects**](https://www.hhs.gov/ohrp/sachrp-committee/recommendations/2011-october-13-letter-attachment-c/index.html)SACHRP recommends that OHRP and FDA should take the necessary steps to issue a single joint guidance on recruitment of subjects so that IRBs have a single source of information regarding the agencies’ viewpoint on this issue. This will reduce administrative burden on IRBs and ease compliance requirements. SACHRP recommends that OHRP should adopt the FDA approach to this issue as exemplified in FDA’s guidance and take steps necessary to interpret the Common Rule so that this is possible.