NCI CIRB

REVIEWER WORKSHEET

CIRB Review of Recruitment Materials

OMB#: 0925 – 0625
Expiry Date: 01/31/2014

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STUDY ID:

STUDY TITLE:

NAME OF CIRB REVIEWER:

DATE COMPLETED:

Reminder to reviewers: Recruitment materials should be reviewed for the following three components:

- accuracy of the information presented,
- to ensure that the material is not coercive, and
- to ensure that the material does not promise a certainty of cure or benefit beyond what is outlined in the informed consent document and the protocol.

Remember that potential study participants will be given a consent document providing greater detail on the study and its foreseeable risks and benefits.

1. Indicate the documents reviewed (check all that apply):

- ☐ Updated NCI Adult/Pediatric CIRB Application for Treatment Studies
- ☐ Summary of CIRB Application revisions
- ☐ Recruitment Material. Indicate the material reviewed:
  - ☐ Pamphlets
  - ☐ Webpage

☐ Video
☐ Other:

2. Is a distribution plan provided (see section 5 of the CIRB Application)?

☐ Yes. If yes, briefly describe the plan:
☐ No. If no, a distribution plan is required before the recruitment material can be approved.

3. Does the recruitment material include any exculpatory language?

Exculpatory language is "language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence." (45 CFR 46.116). Examples of exculpatory language can be found in the 1996 OPRR Letter "Exculpatory Language in Informed Consent Documents: Examples of Acceptable and Unacceptable Language" available at: http://www.hhs.gov/ohrp/policy/exculp.html.

☐ Yes. If yes, identify the language and provide suggested revisions:
☐ No.

4. Does the recruitment material state or imply a certainty of a favorable outcome or other benefits beyond what is outlined in the informed consent document and protocol?

☐ Yes. If yes, identify the language and provide suggested revisions:
☐ No.

5. Does the recruitment material include language that in any way appears to place undue influence on the potential study participant to enroll in the study? (i.e. access to free drugs or treatment, compensation, etc).

☐ Yes. If yes, identify the language and provide suggested revisions:
☐ No.

6. Does the recruitment material suggest that the <u>investigational</u> article is safe, effective, equivalent, or superior to other options?

☐ Yes. If yes, identify the language and provide suggested revisions:
☐ No.

7. Does the recruitment material refer to an investigational drug, biologic or device as a "new drug" or "new treatment" without explaining that the test article is investigational?

☐ Yes. If yes, identify the language and provide suggested revisions:
☐ No.

8. Does the recruitment material emphasize any payment to be made to subjects or compensation for participation in the study?

Note that NCI-Sponsored research generally does not provide compensation for participation in a study. Nonetheless, if compensation is offered, it may be noted in recruitment materials but should not be emphasized over other elements of the material.

☐ Yes. If yes, identify the language and provide suggested revisions:
☐ No.

9. Does the recruitment material promise "free treatment" when the intent is only to say participants will not be charged for taking part in the study?

☐ Yes. If yes, identify the language and provide suggested revisions:
☐ No.

10. Recommendation to the CIRB

If a distribution plan is provided (per question 2) and there are no changes required to language in the recruitment materials (per questions 3 through 8) the recruitment material may be approved.

☐ **Approve**
A distribution plan is provided and there are no required or suggested revisions.

☐ **Approve Pending Modifications**
There are required changes to the recruitment materials (per questions 3 through 9).

☐ **Approve with Recommendations**
The reviewer has identified potential improvements to the material but has determined that they are not required.

☐ **Table**
There is insufficient information available to make a determination regarding the recruitment material, or substantive changes are required and warrants re-review by the convened CIRB.

☐ **Disapprove**
The submitted material is inaccurate and does not meet the regulatory and CIRB SOP requirements for approval.

11. **Comments**