



NCI ADULT CIRB

REVIEWER WORKSHEET

Initial Review of Cooperative Group Protocol

OMB#: 0925 – 0625

Expiry Date: 01/31/2014

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STUDY ID:

STUDY TITLE:

NAME OF CIRB REVIEWER:

DATE COMPLETED:

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

- NCI Adult CIRB Application for Treatment Studies or NCI Adult/Pediatric CIRB Application for Ancillary Studies
- Study Protocol
- Cooperative Group Model Informed Consent Document(s)
- Information Sheets
- Investigator's Brochure
- Study instruments to be completed by participants
- Recruitment materials
- Other (specify _____)

2. Does the study have scientific value?

- Is the study worthwhile?

3. Does the study have scientific validity?

Points to consider:

- Are the background assumptions that lead to the hypothesis valid?
 - Is literature/background described to justify the trial?
 - Is the hypothesis or research question clearly stated?
 - Is the study design appropriate to prove the hypothesis?
(Consider sensitive and specific measures of difference, statistical testing, sample size)
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4. Does the study have a valid scientific design and yet pose an inappropriate risk for subjects?

- Is there substantial evidence that one of the arms is inferior to another or to standard/conventional care or will deprive a subject of his/her right to receive a life-prolonging treatment?
 - Is it possible that one arm will expose a subject to a serious risk of harm?
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5. Are risks to subjects minimized?

- Does the research design minimize risks to subjects?
 - Do the procedures expose subjects to unnecessary risks?
 - Are procedures already being performed on the subjects for diagnostic or treatment purposes being used whenever appropriate?
 - Can alternative procedures be used that would expose the subjects to fewer risks?
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6. Are the risks to subjects reasonable in relation to anticipated benefits, if any, to subjects and the importance of the knowledge that may reasonably be expected to result?*

Points to consider:

- What is the anticipated level of risk/discomfort/inconvenience to the subject?
- Is there the prospect of direct benefit to the subjects?

*Consider only those risks and benefits that may result from research as opposed to those that may result from therapies not involved in the research.

7. Is the selection of subjects equitable?

Points to consider:

- Who is to be enrolled?
 - How will the subjects be identified and recruited?
 - Are these subjects appropriate for the protocol?
 - What is the rationale for the inclusion/exclusion of specific populations?
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8. Are additional safeguards in place for subjects likely to be vulnerable to coercion or undue influence?

Point to consider:

- Are appropriate protections in place for vulnerable subjects (e.g., pregnant women, fetuses, socially – or economically – disadvantaged, decisionally impaired, extremely ill/desperate)?

9. **Will informed consent be obtained from the research subjects or their legally authorized representatives?**

- **Does the informed consent document include the eight required elements?**
- **Is the consent document understandable to subjects/legal guardian?**
Is the CIRB requested to waive or alter any informed consent requirement?

10. **Is there adequate provision for monitoring the data collected to ensure the safety of participants?**

Point to consider:

- What research oversight process will be used to enhance subject safety? (e.g., data safety monitoring board)

11. **Are there adequate provisions to protect the privacy of participants and to maintain the confidentiality of data?**

Points to consider:

- Will personally-identifiable research data be protected to the extent possible from unauthorized access or use?
- Are any special privacy and confidentiality issues properly addressed, e.g., use of genetic information?

12. **Additional Remarks:** _____