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:

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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)

_____

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?

_____

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?

_____

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.

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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)?

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9. Will informed consent be obtained from the research subjects or thei 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 tany 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)

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10. 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?

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11.

12. Additional Remarks: _____