Attachment 6A:

NCI Adult CIRB

REVIEWER FINDINGS

INITIAL REVIEW OF COOPERATIVE GROUP PROTOCOL

OMB#: 0925 – xxxx **Expiry Date: xx/xx/xx**

STATEMENT OF CONFIDENTIALITY

Collection of this information is authorized under 42 USC 285a. While your participation is completely voluntary, to participate in the NCI CIRB, completion of this form is required. Data collected as part of the NCI CIRB review is private and protected by law. Under the provisions of Section 301d of the Public Health Service Act, no information that could permit identification of a participating individual may be released. All such information will be kept private under the Privacy Act and will be presented only in statistical or summary form.

NOTIFICATION TO RESPONDENT OF ESTIMATED BURDEN

Public reporting burden for this collection of information is estimated to average 4 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. **An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.** Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-xxxx*). Do not return the completed form to this address.

NCI Adult CIRB

REVIEWER FINDINGS

INITIAL REVIEW OF COOPERATIVE GROUP PROTOCOL

DOCUMENT NAME:

DOCUMENT DESCRIPTION:

Name of Reviewer:

Date Completed:

1. I have reviewed the following documents (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)**

☐ **CIRB Approved Informed Consent Document(s)**

☐ **Investigator's Brochure**

☐ **Study instruments to be completed by participants**

☐ **Recruitment materials**

☐ **Other (specify)**

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2. Does this protocol have scientific value?

- **Is the study worthwhile?**

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3. Does the protocol have scientific validity?

- **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? *

- **What is the perceived 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 would result from alternative therapies not involved in the research.)**

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7. Is the selection of subjects equitable?

- **Who is to be enrolled?**
- **How will subjects be identified and recruited?**
- **Are these subjects appropriate for the protocol?**
- **What is the rationale for the inclusion/exclusion of specific populations?**

8. Are additional safeguards in place for subjects likely to be vulnerable to coercion or undue influence?

- **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 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 gardian?**
- **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 subjects?

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

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

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

12. Additional Remarks