Attachment 6C:

NCI Adult CIRB

REVIEWER FINDINGS

COOPERATIVE GROUP RESPONSE TO CIRB REVIEW

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

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 1 hour 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

COOPERATIVE GROUP RESPONSE TO CIRB REVIEW

DOCUMENT NAME:

DOCUMENT DESCRIPTION:

Name of Reviewer:

Date Completed:

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1. This Cooperative Group response is in reference to (check one):

- ☉ **CIRB Stipulations from Initial Review**
- ☉ **CIRB Stipulations from Amendment/Revision/Update Review**
- ☉ **CIRB Stipulations from Continuing Review**

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2. I have reviewed the following documents (check all that apply):

- ☐ **Cooperative Group Response Letter/Memo**
- ☐ **Revised Study Protocol**
- ☐ **Revised Cooperative Group Model Informed Consent Document(s)**
- ☐ **CIRB Approved Informed Consent Document(s) with changes incorporated**
- ☐ **Revised NCI Adult CIRB Application for Treatment Studies or NCI Adult/Pediatric CIRB Application for Ancillary Studies**
- ☐ **Revised Summary of CIRB Application Revisions**
- ☐ **Other (specify):**

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3. Has the Cooperative Group and/or Study Chair adequately addressed the CIRB stipulations and/or recommendations from the prior CIRB review?

☐ **Yes**

☐ **No**

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4. Did the Cooperative Group response include additional changes aside from the CIRB stipulations and/or recommendations?

☐ **Yes (If yes, check all that apply below)**

☐ **No (If no, skip to Question 6)**

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5. If "yes" to Question 4, above, check all below that apply.

☐ **Change in treatment period/design**

☐ **Change in statistical design**

☐ **Additional changes in the informed consent document(s)**

☐ **Editorial and/or administrative changes**

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6. Briefly described the changes indicated above.

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7. Do the additional changes alter the risk/benefit ratio to the participants?

☐ **Yes**

☐ **No**

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8. Please provide your comments and/or concerns (if any) regarding the Cooperative Group response and revised documentation.

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9. Please provide your recommendation for CIRB action on the Cooperative Group response and revised documentation.