Attachment 6E:

NCI Adult CIRB

REVIEWER FINDINGS

AMENDMENT TO COOPERATIVE GROUP PROTOCOL

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 1.5 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

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AMENDMENT TO COOPERATIVE GROUP PROTOCOL

DOCUMENT NAME:

DOCUMENT DESCRIPTION:

Name of Reviewer:

Date Completed:

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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**
- ☐ **Summary of CIRB Application Revisions**
- ☐ **Summary of Changes related to the Amendment**
- ☐ **Study Protocol**
- ☐ **Cooperative Group Model Informed Consent Document(s)**
- ☐ **CIRB Approved Informed Consent Document(s) with changes incorporated**
- ☐ **Other (specify)**

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2. The amendment includes the following changes (check all that apply)

- ☐ **Increase or decrease in accrual (impacts statistical design)**
- ☐ **Addition or deletion of a treatment group/arm**
- ☐ **Addition or deletion of a study drug**
- ☐ **Change in treatment period/treatment design**
- ☐ **Changes in the informed consent document(s)**
- ☐ **Editorial and/or administrative changes**
- ☐ **Other (specify)**

3. Please provide a brief summary of the current approved protocol. (Note to reviewer: Not applicable for amendments containing solely editorial and/or administrative changes)

4. Please provide the rationale for the amendment. (Note to reviewer: Not applicable for amendments containing solely editorial and/or administrative changes)

5. Do the changes in the amendment alter the risk/benefit ratio to the participants?

☐ **If yes, explain**

☐ **No**

6. In your judgment, do the benefits of this study continue to outweigh the risks?

☐ **Yes**

☐ **If no, please explain**

☐ **If uncertain, please explain**

7. Please provide your comments and/or concerns regarding the amendment.

8. Please provide your recommendation for CIRB action on the amendment.