

Attachment 6G:

NCI Adult CIRB

REVIEWER FINDINGS

CONTINUING REVIEW OF 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 30 minutes 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

CONTINUING 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/Pediatric CIRB Application for Continuing Review**
- Study Protocol**
- Cooperative Group Model Informed Consent Document(s)**
- CIRB Approved Informed Consent Document(s)**
- DSMB/Safety Monitoring Committee Report**
- Toxicity Summary**
- Presentations or publications for the study**
- Relevant information relating to participants' risks and benefits**
- Management plan to address new or revised conflicts of interest**
- Other (specify)**

2. Are there any important changes in the risks, benefits, or protocol schedule that you believe have an impact on the CIRB's approval of this protocol?

Yes

No

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

- Yes
- No
- Uncertain

4. Do you recommend that the CIRB approve continuation of this study?

- Yes
- No
- Uncertain

5. Additional Remarks