Attachment 6I:

NCI CIRB

PHARMACY REVIEWER FORM

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

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NCI Pediatric CIRB

PHARMACY FINDINGS

FROM REVIEW OF COOPERATIVE GROUP PROTOCOL

GROUP STUDY NUMBER: pCIRB NUMBER:

STUDY TITLE:

PROTOCOL VERSION DATE:

Name of Reviewer:

Date Completed:

1. Does this protocol have scientific value regarding use of the proposed investigational drugs?

- ? Are the background assumptions that lead to use of the study drug(s) valid?

2. Does the research design minimize study drug risks to subjects?

3. How does the inclusion/exclusion of specific populations support/justify the use of the investigational drug(s)?

- ? If a solid dosage form is being used, do the inclusion/exclusion criteria address ability to swallow dosage form intact where no liquid is available?
- ? Is the age group being studied supported in the background?

4. Is the generic name (if available) of the drug used throughout protocol and consent?

- ? Consent should list generic (abbreviation, brand name)
- ? Generic name should be used for all commercially available agents
- ? Abbreviations should only be used for schemas and charts where space does not allow use of generic name

5. Is a package insert or investigator's brochure provided for each agent used on the protocol?

6. Evaluate drug monograph for inclusion of the following areas. Use investigator's brochure or package insert to verify accuracy of information.

- ? Agent Stability
- ? Agent Preparation
- ? Agent Storage
- ? Agent Administration
- ? Adverse events
- ? Contraindications
- ? Warnings
- ? Drug/Herb/Food Interactions
- ? Neonatal dosing/adjustments for gestational age

7. Evaluate treatment plan.

- ? Dose delineated per dose and not per day/per course
- ? Adequate administration information
- ? Maximum number of courses for Phase I/II trials
- ? Premedication(s) described, if needed
- ? Patient monitoring described, if needed
- ? Dosing stratified if patients less than 1 year are included
- ? Laboratory monitoring is adequate for possible side effects

8. Is adequate information provided to order the investigational agent(s)?

- ? Are the appropriate forms provided or links to same?
- ? Is the vial/bottle size provided?
- ? Is the contact information provided for the vendor-providing agent? Are hours of operation provided? Is the expected shipment turnaround time included?

9. Does protocol address disposition of the investigational agent(s)?

- ? Should bottles/vials of agent be returned to site when patient off study?
- ? Should empty bottles/vials of agent be saved for return to sponsor?
- ? Should partial bottles/vials be saved for return to sponsor?
- ? What is the process for returning agent to sponsor? Are the appropriate forms included in the protocol?

10. Does the dose modification section address all agents used in the protocol?

- ? Is dosing for organ dysfunction included?
- ? Is dosing for obese patients included?

11. Assess the adequacy of the supportive care section

- ? Is PCP prevention therapy included if neutropenia is expected?
- ? Are the specific supportive care agents needed for drugs used in the study included?
- ? Extravasation management

12. Does the consent form include all relevant adverse events?

- ? All serious/life threatening events regardless of incidence
- ? All black box warnings
- ? All adverse events with an incidence > 5 %
- ? Are adverse events presented in appropriate lay language?
- ? Do these correspond to those listed in the protocol drug monograph?

13. Does consent advise on relevant drug/food/herb interactions?

14. Does consent properly list if agent(s) provided at no cost in financial concerns?

15. Additional Remarks

Pediatric Risk Assessment

- ? Research/clinical investigations not involving greater than minimal risk. Permission of at least one parent is required. (§ 46.404, § 50.51)

- ? Research/clinical investigations involving greater than minimal risk but presenting the prospect of direct benefit to the individual subjects. Permission of at least one parent is required. (§ 46.405, § 50. 52)

- ? Research/clinical investigations involving greater than minimal risk and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition. Permission of both parents is required. (§ 46.406, § 50.53)

- ? Research/clinical investigations not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children. Specific approval is required from the FDA Commissioner or DHHS Secretary. (§ 46.407, § 50.54)