Attachment 6J:

NCI CIRB

STATISTICAL REVIEWER FORM

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 2 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.

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1. From the statistical perspective, briefly explain how the risks to subjects are minimized per 45. CFR 46.111(a)(1), "by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes."

As you respond, you may want to consider these points:

- The primary clinical objective(s) and the corresponding primary statistical hypothesis
- Whether the statistical hypothesis properly addresses its clinical counterpart
- Whether the plans for data analysis, including the decision rule, type I and II error rates, are clearly defined
- Whether an appropriate group sequential design, with both efficacy and futility bounds is employed
- If this is a non-inferiority (or equivalence) trial, what the margin of non-inferiority (or equivalence) in terms of an odds-ratio (for binary outcomes) or hazard-ratio (for time-to-event outcomes) is

Note: If you wish, you may contact the Group statistician for additional information prior to the CIRB meeting.

Reviewer Comments: