C›I›R›B
FOR THE NATIONAL CANCER INSTITUTE

NCI CIRB

REVIEWER WORKSHEET

Statistical Reviewer Form

Attachment_B32_Stat_Rev

OMB# 0925-0753, Expiration Date: 07/31/2021

The purpose of the information collection is to conduct reviews of clinical trial studies. NCI guidelines mandate the participation of institutions in the CIRB for Network group studies. You are being requested to complete this instrument so that we can conduct activities involved with the operations of the NCI CIRB Initiative. Although your participation in Network group research and completion of the forms is voluntary, if you wish to participate in the CIRB, you must complete all questions on the form. The information you provide will be combined for all participants and reported as summaries. It will be kept private to the extent provided by law.

NOTIFICATION TO RESPONDENT OF ESTIMATED BURDEN

Public reporting burden for this collection of information is estimated to average 15 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 (0925-0753). Do not return the completed form to this address.

STUDY ID:

STUDY TITLE:

NAME OF CIRB REVIEWER:

DATE COMPLETED:

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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: _____