NCI CIRB

REVIEWER WORKSHEET

Statistical Reviewer Form

OMB#: 0925 – 0625
Expiry Date: 01/31/2014

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: _____