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

REVIEWER WORKSHEET/CIRB OUTCOME LETTER FOR TRANSLATED DOCUMENTS

Attachment_B34_Rev_Translated_Docs 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: _____
PROTOCOL VERSION DATE: _____
STUDY CHAIR: _____

CIRB Operations Office Verification of Complete Submission

Staff Member completing verification: _____ *(Note: upon posting remove member name and add the word "Verified".*
Check off below to indicate required documents are attached:

- ☐ A completed Request to Review Translated Documents (specific to this request)
- ☐ The CIRB-approved English language document corresponding to the translated document
- ☐ A translated copy of the CIRB-approved English language document
- ☐ Translator's Certificate(s) of Accuracy or equivalent document(s)
- ☐ A copy of the CIRB approval letter for the English language document and protocol with corresponding Protocol Version Date (from CIRB Operations Office files)

Review
Reviewer: _____ *(Note: upon posting remove reviewer line)*
The reviewer must confirm the following by checking off each of the boxes below:

- ☐ The submitted English language document is CIRB-approved
- ☐ The Protocol Version Date, if applicable, corresponds with the CIRB-approved protocol

CENTRAL IRB FOR THE NATIONAL CANCER INSTITUTE
NCI CIRB Operations Office › 401 N. Washington St. › Suite 700 › Rockville, MD 20850

☐ A Translator's Certificate of Accuracy or equivalent document is provided

If all of the above are confirmed, then the translated document may be approved.

Determination

Check one:

☐ Approve

Date of Approval: _____

☐ Forward for review by the convened CIRB

Additional Comments: _____

_____ _____

Reviewer Name Role