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FOR THE NATIONAL CANCER INSTITUTE

NCI CIRB

REVIEWER WORKSHEET

Determination of Unanticipated Problem and/or Serious or Continuing Noncompliance

Attachment_B31_Determination_UP_SCN 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 10 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. Briefly describe the incident, experience, or outcome reported to the CIRB.

Note: Incidents, experiences or outcomes described on this worksheet can be an unanticipated problem, serious or continuing non compliance, both or neither.

_____

2. I have reviewed the following documents (check all that apply).

- ☐ Memorandum from the Study Chair describing the potential unanticipated problem and/or serious or continuing noncompliance
- ☐ Adverse event report
- ☐ Participant/Family letter(s)
- ☐ Doctor letter(s)
- ☐ Protocol
- ☐ Model Version of the Informed Consent Document

☐ Other (specify) _____

Section 1: Unanticipated Problem Determination

Background: OHRP and FDA regulations require reporting of unanticipated problems involving risks to subjects or others (45 CFR 46. 103(b)(5) and 21 CFR 56.108(b)(1)). OHRP Guidance defines an unanticipated problem as being
(A) unexpected,
(B) related or possibly related to participation in the research, and
(C) placing participants or others at a greater risk of harm.

3. Reviewer Analysis (A) "unexpected" – Is the incident, experience, or outcome unexpected (in terms of *nature*, *severity*, or *frequency*) given (a) the research procedures that are described in protocol-related documents, such as the IRB-approved research protocol and informed consent document; and (b) the characteristics of the subject population being studied?

NOTE: Findings from planned interim analysis are not considered "unexpected".

☐ Yes, it is unexpected. -- Provide an explanation. _____
☐ No, it is not unexpected. -- Provide an explanation. _____

4. Reviewer Analysis (B) "related or possibly related to participation in the research" – Is the incident, experience, or outcome related or possibly related to participation in the research (possibly related means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research)?

☐ Yes, it is related or possibly related. Provide an explanation. _____
☐ No, it is not related or possibly related. Provide an explanation. _____

5. Reviewer Analysis (C) "places subjects or others at greater risk of harm" – Does the incident, experience, or outcome suggest that the research places participants or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized?

☐ Yes, there is greater risk of harm. Provide an explanation. _____
☐ No, there is not a greater risk of harm. Provide an explanation. _____

6. Reviewer Determination Regarding Unanticipated Problem

If you have answered Yes to all parts of question one (A, B, or C), the incident, experience, or outcome is an unanticipated problem.

If you have answered No to any part of question one (A, B, or C), the incident, experience, or outcome is not considered an unanticipated problem.

Reviewer Recommendation regarding Unanticipated Problem Determination:

☐ Yes, it is an Unanticipated Problem because it meets all three criteria above.
☐ No, it is not an unanticipated Problem because it does not meet all three of the criteria above

7. Additional Considerations - Regardless of whether or not the event constitutes an unanticipated problem, please consider the following:

Are appropriate steps being taken to notify participants or others affected by the incident, experience, or outcome of any information that would impact participants' willingness to continue in the research?

☐ Yes, describe what steps are being taken. _____
☐ Not Applicable
☐ No

8. If No, should participants be notified of this incident, experience or outcome?

☐ Yes, describe what steps are being taken. _____
☐ No

Section 2: Serious or Continuing Noncompliance Determination

Background: OHRP and FDA regulations require reporting of serious or continuing noncompliance (45 CFR 46. 103(b)(5) and 21 CFR 56.108(b)(2)).

9. The CIRB SOPs define "noncompliance" as a failure to meet the requirements of Federal regulations pertaining to human subjects protection and/or the requirements and decisions of the CIRB. Is the incident, experience, or outcome evidence of noncompliance?

☐ Yes, Explain and complete questions 10 and 11. _____
☐ No, Explain and go to question 12. _____

10. The CIRB SOPs define "serious" noncompliance as noncompliance that adversely affects the rights and welfare of study participants or results in any untoward medical occurrence that meets the criteria of "serious" or significantly impacts the integrity of study data.

Serious is defined as side effects that may require hospitalization or may be irreversible, long-term, life-threatening, or fatal. The CIRB may also consider as serious those events which, based on appropriate medical judgment, may jeopardize the patient or subject and am require medical or surgical intervention to prevent one of the outcomes above..

Is the incident, experience, or outcome evidence of serious noncompliance?

☐ Yes, Explain and complete questions 10 and 11. _____
☐ No, Explain and go to question 12. _____

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11. The CIRB SOPs define "continuing" noncompliance as a systematic and habitual disregard of the requirements of Federal regulations pertaining to human subjects protection and/or of the requirements or decisions of the CIRB. Continuing noncompliance is an indication of a pattern that, if unaddressed, could jeopardize the rights and welfare of research participants or the integrity of the study data due to noncompliance with the protocol, Federal regulations, and/or the requirements of the CIRB. Is this incident, experience, or outcome continuing noncompliance?

☐ Yes, Explain and go to question 12. _____
☐ No, Explain and go to question 12. _____

12. Additional Considerations

Regardless of whether or not the event constitutes serious or continuing noncompliance, please consider:

Are appropriate steps being taken to notify participants or others affected by the incident, experience, or outcome of any information that would impact participants' willingness to continue in the research?

☐ Yes, describe what steps are being taken. _____
☐ Not Applicable
☐ No, explain. _____

13. If No, should participants be notified of this incident, experience, or outcome?

☐ Yes, describe what steps should be taken. _____
☐ No

14. FINAL NOTE: Per the regulations, the CIRB reports determination of unanticipated problems and/or serious or continuing noncompliance to OHRP and FDA.