**OIA-321 WORKSHEET: Review of Reportable Events**

The purpose of this worksheet is to provide support for the convened IRB reviewing serious non-compliance, continuing non-compliance, unanticipated problem involving risks to subjects or others/unanticipated problem report (UPR), suspension of IRB approval, and termination of IRB approval. This worksheet, or equivalent, is to be used. This worksheet does not need to be completed or retained.

### 1 Considerations for Review of Reportable Events

**What is/are the event(s)?**

Does the event involve risk(s) to subjects? **Yes ☐ No ☐**

If yes, what risk is posed:

- Does the event involve risk(s) to data integrity/analysis? **Yes ☐ No ☐**
  - If yes, how:
    - If yes, is there an appropriate plan to mitigate the effect? **Yes ☐ No ☐**
    - If yes, what is the plan:

- Is the root cause accurately/completely identified? **Yes ☐ No ☐**
  - If yes, what is the root cause:

- Is a determination in Section 2 able to be made based upon the information provided? **Yes ☐ No ☐**
  - If no, obtain more information from the investigator and/or research team.
  - If yes, proceed to Section 2.

### 2 Determinations (At least one must be checked)

- Non-compliance that is neither serious nor continuing
- Serious non-compliance
- Continuing non-compliance
- Unanticipated problem involving risks to subjects or others/unanticipated problem report (UPR)
- None of the above

If the determination involves non-compliance, is the corrective and preventive action (CAPA) plan adequate? **Yes ☐ No ☐**

Suggested actions:

### 3 If the determination involves unanticipated problem involving risks to subjects or others/unanticipated problem report (UPR)

If the determination is unanticipated problem involving risks to subjects or others/unanticipated problem report (UPR), are additional actions required to mitigate risk(s) to subjects or others? **Yes ☐ No ☐**

### 4 Post-Review Actions Needed (More than one may be checked)

- Modify the protocol.
- Modify the information disclosed during the consent process. Should enrolment be halted until consent form is revised? **Yes ☐ No ☐**
- Provide additional information to current subjects, whenever the information may relate to the subject’s willingness to continue.
- Provide additional information to past subjects.
- Have current subjects re-consent.
- Increase the frequency of continuing review.
- Observe the research.
- Observe the consent process.
- Require additional training of the investigator.
- Request audit by appropriate compliance group.
- Other:

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1 The corrective and preventive action plan is adequate if it addresses the identified root cause of the event and does not rely solely on re-training of personnel or the memory of study personnel. That is, there should be a physical/electronic check to ensure compliance (such as a checklist or calendar reminder, as appropriate).