UC San Diego
INSTITUTIONAL REVIEW BOARD ADMINISTRATION

OIA-321 WORKSHEET: Review of Reportable Events

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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

3 If the determination involves non-compliance, is the corrective and preventive action (CAPA) plan adequate?[1] Yes ☐ No ☐
Suggested actions:

4 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 ☐

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

☐	Modify the protocol.	☐	Notify investigators at other sites.
☐	Modify the information disclosed during the consent process. Should enrollment be halted until consent form is revised? Yes ☐ No ☐	☐	Consider whether changes without prior IRB review and approval were consistent with ensuring the subject's continued welfare.
☐	Provide additional information to current subjects, whenever the information may relate to the subject's willingness to continue.	☐	Allow continuation of some research activities under the supervision of an independent monitor.
☐	Provide additional information to past subjects.	☐	Make arrangements for clinical care outside the research.
☐	Have current subjects re-consent.	☐	Transfer subjects to another investigator.
☐	Increase the frequency of continuing review.	☐	Require follow-up of subjects for safety reasons.
☐	Observe the research.	☐	Require adverse events or outcomes to be reported to the IRB and the sponsor.
☐	Observe the consent process.	☐	Suspend IRB approval.
☐	Require additional training of the investigator.	☐	Terminate IRB approval
☐	Request audit by appropriate compliance group.	☐	Notify funding agency and/or Food and Drug Administration (FDA), as appropriate.
☐	Other:		

[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).