

Appendix 5: Timeline for Reporting and Managing Unanticipated Problems and Non-Compliance of IRB approved research

Type of Event	Required Action and Timeline
<p>Unanticipated Problem: Serious Adverse Event</p>	<p>A person reporting a serious adverse event submits Unanticipated Problem Form to IRB Chair within 24 hours of when serious adverse event occurred.</p>
	<p>IRB Chair completes review of Unanticipated Problem form with 48 hours to determine if it is a serious adverse event has occurred.</p>
	<p>If the occurrence qualifies as a serious adverse event, the IRB Chair will suspend the protocol for up to 2 weeks until the convened IRB meets to review and act on the protocol.</p>
	<p>Convened IRB will meet with PIs to discuss the event, and may suspend or terminate the protocol. If IRB decides to suspend, IRB will recommend corrective plan to minimize harm. If PI agrees to implement corrective plan, the suspension will be lifted. If IRB votes to terminate, PI can appeal to Provost for external review.</p>
	<p>IRB Chair will write report within 2 weeks after the convened IRB meeting and submit to PIs for review. PIs have 2 weeks to complete a written response to the IRB report. All parties will have a chance to respond to written comments before the report is finalized. The IRB Chair will then submit all documents to OHRP and notify all appropriate parties.</p>
<p>Unanticipated Problem: Non-Serious Adverse Event</p>	<p>A person reporting a non-serious event submits an Unanticipated Problem Form to IRB Chair as soon as possible and not later than 2 weeks after the event occurred. All IRB members will be notified that an Unanticipated Problem Form has been submitted.</p>
	<p>IRB Chair reviews Unanticipated Problem Form within 48 hours to determine if event qualifies as non-serious adverse event. The IRB Chair may consult with IRB members who have relevant expertise if needed.</p>
	<p>If it is determined to be a non-serious adverse event, the UP form is assigned for expedited review to be completed within 5 days.</p>
	<p>Expedited reviewer can suggest corrective action or request suspension for 2 weeks until convened IRB meets to discuss and act on protocol. The PIs will be invited to the convened IRB meeting to respond to the UP form. The PI can request an extension on the 2 week suspension, if needed, to prepare for the convened IRB meeting.</p>

	<p>Convened IRB will meet with PIs to discuss the event, and may suspend or terminate the protocol. If IRB decides to suspend, IRB will recommend corrective plan to minimize harm. If PI agrees to implement corrective plan, the suspension will be lifted. If the IRB votes to terminate the protocol, PI can request to the Provost an external appeal.</p>
	<p>IRB Chair will write report within 2 weeks after the final decision and submit to PIs for review. PIs have 2 weeks to complete a written response to the IRB report. All parties will have a chance to respond to written comments before the report is finalized. The IRB Chair will then submit all documents to OHRP and notify all parties involved.</p>
<p>Non-compliance</p>	<p>A person alleging non-compliance submits written notification to IRB Chair as soon as possible and not later than 2 weeks after the non-compliance event occurred.</p>
	<p>IRB Chair will review non-compliance report within 48 hours to determine a) whether noncompliance is alleged; and b) whether the allegation indicates that an immediate action such as suspension by the IRB is warranted.</p>
	<p>If it is determined that the noncompliance is neither serious nor continuing, the IRB Chair will devise a corrective plan within 2 weeks, which generally will involve immediate remediation.</p>
	<p>If it is determined that the noncompliance is serious or continuing, IRB will conduct an audit that takes no longer than 4 weeks. PI may decide voluntarily to suspend or terminate some or all of the research activities that may be under current review or investigation. The PI should inform IRB of this action, so that the IRB Chair can place the protocol on the agenda for the next available IRB meeting.</p>
	<p>Convened IRB will meet with PIs to discuss the event, and may suspend or terminate the protocol. If IRB decides to suspend, IRB will recommend corrective plan to minimize harm. If PI agrees to implement corrective plan, the suspension will be lifted.</p>
	<p>IRB Chair will write report within 2 weeks after the convened IRB meeting and submit to PIs for review. PIs have 2 weeks to complete a written response to the IRB report. All parties will have a chance to respond to written comments before the report is finalized. The IRB Chair will then submit all documents to OHRP and notify appropriate parties.</p>