



WORKSHEET: Review of Information Items

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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, Suspension of IRB Approval, and Termination of IRB Approval. This worksheet is to be used. This worksheet does not need to be completed or retained. ¹

1 Considerations

<input type="checkbox"/>	Modify the protocol.	<input type="checkbox"/>	Terminate IRB approval
<input type="checkbox"/>	Modify the information disclosed during the consent process.	<input type="checkbox"/>	Suspend IRB approval.
<input type="checkbox"/>	Provide additional information to current subjects (Whenever the information may relate to the subject's willingness to continue.)	<input type="checkbox"/>	Transfer subjects to another investigator
<input type="checkbox"/>	Provide additional information to past subjects.	<input type="checkbox"/>	Make arrangements for clinical care outside the research
<input type="checkbox"/>	Have current subjects to re-consent.	<input type="checkbox"/>	Allow continuation of some research activities under the supervision of an independent monitor
<input type="checkbox"/>	Increase the frequency of continuing review.	<input type="checkbox"/>	Require follow-up of subjects for safety reasons.
<input type="checkbox"/>	Observe the research.	<input type="checkbox"/>	Require adverse events or outcomes to be reported to the IRB and the sponsor
<input type="checkbox"/>	Revise the corrective action plan		
<input type="checkbox"/>	Observe the consent process.	<input type="checkbox"/>	Obtain additional information.
<input type="checkbox"/>	Require additional training of the investigator.	<input type="checkbox"/>	Consider whether changes without prior IRB review and approval were consistent with ensuring the subject's continued welfare.
<input type="checkbox"/>	Notify investigators at other sites.		

Other:

¹ This document satisfies AAHRPP elements I.5.A, I.5.D, I-9, II.2.G
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