Children's Hospital LOS ANGELES

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 Considerations

☐	Modify the protocol.	☐	Terminate IRB approval
☐	Modify the information disclosed during the consent process.	☐	Suspend IRB approval.
☐	Provide additional information to current subjects (Whenever the information may relate to the subject's willingness to continue.)	☐	Transfer subjects to another investigator
☐	Provide additional information to past subjects.	☐	Make arrangements for clinical care outside the research
☐	Have current subjects to re-consent.	☐	Allow continuation of some research activities under the supervision of an independent monitor
☐	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.	☐	Obtain additional information.
☐	Require additional training of the investigator.	☐	Consider whether changes without prior IRB review and approval were consistent with ensuring the subject's continued welfare.
☐	Notify investigators at other sites.		
☐	Other:		