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| The purpose of this worksheet is to provide support for the Full (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 does not need to be completed or retained. |
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| 1. Considerations:
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|[ ]  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:      |