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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: | | | |
|  | 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: | | |