|  |  |  |  |
| --- | --- | --- | --- |
| 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]](#footnote-1) | | | |
|  | | | |
| 1. Considerations | | | |
|  | Modify the protocol.  Require additional follow-up with subjects  Modify eligibility criteria  Discontinue a treatment arm  Other |  | Terminate IRB approval.  *Consider whether such suspension could result in harm to currently enrolled subjects* |
|  | Modify the information disclosed during the consent process. |  | Suspend IRB approval.  Enrollment only  All research activities  *Consider whether such suspension could result in harm to currently enrolled subjects* |
|  | Provide additional information to current subjects (whenever the information may relate to the subject’s willingness to continue).  1. Determine the subjects who should be informed:  Information is required as one or more of the elements of consent (21 CFR 50.25 or 45 CFR 46.116) No new subjects can be enrolled until a revised IRB-approved consent document is available.  Information could affect currently enrolled subjects willingness to continue in the study  2. Determine how subjects will be informed:  Inform currently enrolled subjects by asking them to sign a revised consent document  Verbally tell currently enrolled  Inform currently enrolled via IRB-approved letter  3. Determine whether PI should be informed not to enroll subjects until s/he has obtained an IRB-approved consent document that includes all of the elements required by regulations. Yes  No |  | Transfer subjects to another investigator. |
|  | Provide additional information to past subjects.  Verbally tell past subjects  Inform past subjects via IRB-approved letter |  | Make arrangements for clinical care outside the research. |
| ☐ | Increase the frequency of continuing review. |  | Allow continuation of some research activities under the supervision of an independent monitor.  Request a Quality Review |
|  | Observe the research. |  | Require adverse events or outcomes to be reported to the IRB and the sponsor. |
|  | Observe the consent process. |  | Table review and 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 for multi-site studies. |  | Consider whether changes without prior IRB review and approval were consistent with ensuring the subject’s continued welfare. |

1. This document satisfies AAHRPP elements I.5.A, I.5.D, I-9, II.2.G [↑](#footnote-ref-1)