HRP-321 | 1/13/2023

WORKSHEET: Review of Information Items

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[[1]](#endnote-2).

1. Considerations

[ ]  Modify the protocol.

[ ]  Modify the information disclosed during the consent process.

[ ]  Provide additional information to current subjects (whenever the information may relate to the subject’s willingness to continue).

[ ]  Provide additional information to past subjects.

[ ]  Have current subjects to re-consent.

[ ]  Increase the frequency of continuing review.

[ ]  Observe the research.

[ ]  Observe the consent process.

[ ]  Require additional training of the investigator.

[ ]  Notify investigators at other sites.

[ ]  Terminate IRB approval.

[ ]  Suspend IRB approval.

[ ]  Transfer subjects to another investigator.

[ ]  Make arrangements for clinical care outside the research.

[ ]  Allow continuation of some research activities under the supervision of an independent monitor.

[ ]  Require follow-up of subjects for safety reasons.

[ ]  Require adverse events or outcomes to be reported to the IRB and the sponsor.

[ ]  Obtain additional information.

[ ]  Consider whether changes without prior IRB review and approval were consistent with ensuring the subject’s continued welfare.

[ ]  Other: Click or tap here to enter text.

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