HRP-321 | 1/1/2024

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[i].

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.

☐ Lift prior suspension of 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.

[i] This document satisfies AAHRPP elements I.5.A, I.5.D, I-9, II.2.G, III.2.D