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. 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