HRP-2000 | 1/1/2024

WORKSHEET: Continuing and/or Serious Noncompliance[i]

The purpose of this worksheet is to provide support for the convened IRB when evaluating continuing and/or serious noncompliance. This worksheet does not have to be completed or retained.

Definitions:

Non-Compliance: Failure to adhere to federal state or local regulations governing human subjects research, organizational policies related to human subjects research, or the requirements or determinations of the IRB.

Continuing Non-Compliance: A pattern of Non-Compliance that suggests the likelihood that, without intervention, instances of Non-Compliance will recur, a repeated unwillingness to comply, or a persistent lack of knowledge of how to comply.

Serious Non-Compliance: Non-Compliance such that the failure to comply could adversely affect the rights, safety, or welfare of a human subject; place a human subject at increased risk of harm; cause harm to a human subject; affect a human subject's willingness to participate in research; or damage or compromise the scientific integrity of research data.

Questions for IRB to address upon review of Serious and/or Continuing Noncompliance

☐ Should new study enrollment be suspended?

- ☐ If so, for what period?

☐ Should any study procedures for currently enrolled subjects be halted?

- ☐ If so, for what period?

☐ Are any immediate changes to the protocol and/or study procedures required at this time in order to eliminate potential hazards/risks?

☐ Should currently enrolled subjects be notified of the event and/or provided with any new information?

- ☐ If so, what are the specifics and how should notification take place?

☐ Is additional information from the PI/study team needed?

- ☐ If so, what information and when is the deadline for PI submission?

☐ Is additional training of the PI and/or study team needed?

- ☐ If so, what type?

☐ Is an audit required?

- ☐ If so, what are the details of the audit?

[i] This document satisfies AAHRPP element II.2.E