HRP-321 | 3/29/2024

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

1. Review Determination(s) (Check if “Yes”)

**Additional information required to make a determination** (Describe information needed in Section 5.)

**Unanticipated Problem Involving Risks to Subjects or Others** **(UPIRTSO)** (Check if “Yes”. If a box cannot be checked, then the information item does not meet the criteria for an Unanticipated Problem Involving Risks to Subjects or Others.)

Is unexpected (in terms of nature, severity, or frequency) given (a) the procedures described in the research protocol documents (e.g., the IRB-approved research protocol and informed consent document) and (b) the characteristics of the human subject population being studied.

Is related or possibly related to participation in the research (in this Instruction, possibly related means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research).

Suggests that the research places human subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

**Suspension**: Temporarily or permanently withdraw IRB approval of some or all research procedures short of a Termination of IRB Approval. Suspended studies remain open and are subject to continuing review. (Check all that apply)

Suspend all research activities

Suspend research-related intervention/treatment

Suspend recruitment and enrollment of new subjects

Suspend collection and/or analysis of private identifiable information

**Termination**: Permanently withdraw IRB approval of all research procedures.

**Serious Non-Compliance**: Non-Compliance such that the failure to comply adversely affects the rights, safety, or welfare of a human subject; places a human subject at increased risk of harm; causes harm to a human subject; affects a human subject’s willingness to participate in research; or significantly damages or compromises the scientific integrity of research data.[[2]](#endnote-3)

**Continuing Non-Compliance**: A pattern of non-compliance that indicates a repeated unwillingness to comply or a persistent lack of knowledge of how to comply with applicable regulations, the Investigator Manual (HRP-103) and/or the determinations and requirements of the IRB that may affect participants’ rights and welfare, increase risk to participants, or may compromise the scientific integrity or validity of the research.

**Non-compliance that is neither serious nor continuing**. Non-compliance is the failure to follow applicable regulations, the Investigator Manual (HRP-103), and/or the determinations or requirements of the IRB. Noncompliance may range from minor to serious; be unintentional or willful; and may occur once, sporadically, or continuously. The degree of noncompliance is evaluated on a case-by-case basis.

**Allegation of non-compliance with no basis in fact**

**Lift prior suspension of IRB approval**

**None of the above**

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 re-consent.

Increase the frequency of continuing review.

Observe the research.

Observe the consent process.

Require additional training of the investigator and/or study team personnel.

Notify investigators at other sites.

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.

Require a corrective and/or preventive action plan and identify time point to validate effectiveness of implementation.

Request initiation of a formal investigation by the Research Integrity and Compliance Office.

Request a for-cause audit by the QA program.

Consider whether changes without prior IRB review and approval were necessary to eliminate apparent immediate hazards to participants.

Other: Click or tap here to enter text.

1. Comments: Use the space below to provide a brief summary of the Report Form or include other notes that will assist you in review.

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)
2. For additional federal agency criteria see HRP-001-SOP-Definitions. [↑](#endnote-ref-3)