1. PURPOSE

To define situations wherein issues identified during compliance activity reviews must be immediately reported by the principal investigator to the IRB.

2. SCOPE

This procedure applies to all Compliance Activity Reviews performed by the ECO-HSR.

3. RESPONSIBILITIES

The Education and Compliance Office Coordinators are responsible for instructing the principal investigator to report to the IRB any event that may represent serious non-compliance, continuing non-compliance or an unanticipated problem involving risks to human subjects or others.

4. PROCEDURES

4.1. The Education and Compliance Coordinators will instruct the principal investigator to promptly report to the IRB any events identified during a compliance activity review that may represent serious non-compliance, continuing non-compliance or an unanticipated problem that may involve risks to human subjects or others. Examples of which include the following:

- Evidence of a serious adverse event or unexpected adverse event of moderate or greater severity appearing to be associated with the research intervention and not reported to the IRB.
- Evidence of the performance of research procedures of greater than minimal risk not previously approved by the IRB on multiple subjects.
- No documentation or evidence of informed consent for multiple subjects enrolled in research activities of greater than minimal risk.
- Evidence that the majority of the research subjects audited did not meet the eligibility criteria as written in the IRB approved protocol.
- Deviation from IRB approved experimental procedures observed in the majority of the research subjects audited.
- IRB-approved follow-up procedures not performed on the majority of the research subjects audited.
4.2. Any of the above findings should also be reported by the ECO coordinator via email to the Director of the Education and Compliance Office, the IRB Chair and the Adverse Events Coordinator for the IRB within 72 hours of their identification with subsequent discussion and follow-up as mandated.

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