**TITLE: Corrective Action for Non-Compliance found during Reviews Procedure**

**PURPOSE:** To define the procedures utilized in resolving non-compliance discovered during on-site reviews of IRB approved Protocols. Non-compliance is to be resolved by corrective action.

**RESPONSIBILITY:** The ORI QA/QI Office Staff will be responsible for the execution of the SOP.

**Approval:** The Associate Vice Chancellor of Research Integrity & Compliance (Joe Rosse) approved this SOP as of 1/14/2019.

**PROCEDURES:**

* 1. Corrective Action for reports containing serious non-compliance:
     + The report, a corrective action form filled with the noncompliant findings, and instructions on how to complete the form will be given to the PI via email within 24 hours of the on-site review.
     + Due to the sensitive nature of the serious noncompliance findings, the findings will be required to be addressed with corrective action within 24 hours of receiving the report.
       - The corrective action form will be filled out by the PI describing what immediate action they are taking to resolve the serious non-compliance finding, then they will send the corrective action form to the QA/QI Coordinator and immediately complete the action they described in the form.
     + The QA/QI Staff will follow up with the PI within 1 business day of receiving the populated corrective action form and check era if there was any need to submit new information or an amendment.
     + The QA/QI Staff will inform the next convened IRB panel about the serious noncompliance.
     + The QA/QI staff will inform the IRB Director once all non-compliance has been resolved with corrective action.
       - Once the noncompliance is resolved with correction action, the review is officially closed out.
     + If the PI does not pursue immediate corrective action processes, the IRB will take appropriate action.
  2. Corrective Action for reports containing non-serious non-compliance and “other findings”:
     + The report, including a table filled with the noncompliant findings, and instructions on how to complete the form will be given to the PI at a pre-determined date/time during the Close-Out meeting
     + The QA/QI staff will describe the following corrective action process in great detail for the research’s understanding
       - For each non-serious noncompliance finding, the PI will submit a protocol amendment (or a Reported Event if necessary) by the requested due date. The amendment will address the finding(s) and resolve them.
       - Corrective Action must be complete within 4 weeks of the issuance of the final report.
     + The QA/QI Staff will follow up with the PI within 4 weeks of the issuance of the final report to assure they have implemented corrective action (aka submitted an amendment).
     + The QA/QI Staff will inform the IRB Director once all non-serious non-compliance has been resolved with corrective action.
       - Once the noncompliance is resolved with correction action, the review is officially closed out.
     + If the PI does not pursue corrective action processes, the IRB will take appropriate action.