**TITLE: Routine On-site IRB Protocol Review Procedure**

**PURPOSE:** To define the procedures utilized in conducting a routine onsite review of a research protocol and its components including but not limited to all records and documents, observations, and processes. A routine on-site review is defined as a random selection of protocols for post approval monitoring.

**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. Protocol Selection:
   1. Approximately 5-10% of all non-exempt approved protocols will be selected annually, on a continuous basis, by the QA/QI office for an on-site compliance review. The selection is random and only includes non-exempt IRB approved human research, however ½ of the protocols selected will be selected so using the following criteria (due to their riskier nature):
      1. More than minimal risk, high enrollment, involving IND/IDE, FDA regulated, vulnerable populations, requiring more than annual review, federally funded research, and studies where identifiable data was obtained.
   2. Although this routine review is performed independently from the IRB office, The IRB Program Director will be informed of protocols selected for review.
2. PI Contact and Activities Prior to Review:
   1. Via email, the Investigator will be contacted to notify them that their protocol has been selected for an onsite review. The following will be included and requested:
      1. The purpose of the review and items that will be discussed/reviewed during the visit (maybe put attachment on email that is a summarized version of my review worksheet).
      2. How the protocol was selected.
      3. Confidentiality of the review
         1. No information gathered from the review will be shared with anyone outside the project’s personnel unless non-compliance is discovered. In the discovery of non-compliance, the IRB will be consulted for recommended corrective action.
      4. Request availability of the PI and study staff within the next 2 weeks for an onsite visit, including a date to observe 1-2 experimental procedures from the protocol.
      5. Request an Allocation of resources (files and access to electronic records) so that on the day of the review, the files can be reviewed succinctly.
   2. The review notification will be sent to the PI no less than 2 weeks before the estimated date of the onsite review.
3. During the On Site Review
   1. Conduct an opening meeting, discussing the intent of the review, the scope of review and a tentative schedule. Allow for questions to be asked.
   2. Perform a review of the protocol, utilizing the protocol review worksheet to interview the PI, check records related to the protocol, and observe any procedure or consent process that has been deemed a part of the review’s scope (See IRB protocol review worksheet template).
4. Post On Site Review:
   1. Within 2 weeks of the onsite review date, a final report will be issued to the PI responsible for the reviewed protocol at an in-person Close Out meeting, detailing any noncompliance that needs to be addressed and resolved with corrective actions as well as any observations that occurred during the on-site review.
   2. If the report contains serious non-compliance findings (see below for definitions), a final report will be emailed to the PI within 1 business day of the on-site review and immediate corrective action will be required.
   3. The following categories of findings found on reports:
      * 1. Serious non-compliance. Occurs when the welfare or rights of a human subject are adversely affected, as defined in IRB policy HRP-001. Immediate Corrective Action is required and findings are brought to the convened IRB panel for review. If necessary, findings of serious noncompliance can be reported to regulatory agencies and appropriate institutional officials.
        2. Non-serious Non-compliance. Occurs when there is a failure to follow the regulations, or the requirements or determinations of the IRB, as defined in IRB Policy HRP-001. An example is: when something is not being done in accordance with the protocol or recordkeeping and documentation is not complete, however there is no immediate threat to the health and rights of the human subjects. Corrective action is requested to be documented and completed within 2 weeks of the issuance of the final report for general non-compliance. This finding is managed administratively and not brought to the convened IRB panel for review (unless a collaborative outcome cannot be achieved).
        3. Other Findings. Non-Regulatory noncompliance issues and discrepancies that are easily fixed and do not affect data integrity or human subject rights/welfare in a negative way.
        4. Observations. Occurs when it is observed that improvements could be made to the management of the protocol. These are suggestions to improve quality and Best Practices when conducting research. These findings do not require corrective action.
      1. If Serious Non-compliance or non-serious noncompliance is not addressed within 30 days of the issuance of the final report, the IRB will take appropriate action (See corrective action procedure).
5. Documentation:
   1. All documents, reports, and evidence regarding all initiated routine on-site reviews will be stored in a secure folder on CU’s U: drive as well in an easily accessible, locked drawer in the QA/QI’s office.