1. PURPOSE
The purpose of this policy is to describe COMIRB's process for reviewing and addressing COMIRB audit findings.

2. POLICY
Improvement of COMIRB process and compliance is a top priority. The Office of Regulatory Compliance oversees semiannual audits of COMIRB's processes including, but not limited to, panel review of research, documentation of meeting minutes, and office procedure. Additionally, audits by external oversight bodies such as OHRP, FDA, and AAHRPP occur on a for-cause and not-for-cause basis. Having a systematic process for reviewing and addressing audit findings will increase the effectiveness of our efforts to strengthen the HRPP through directed change.

3. SPECIFIC POLICIES
3.1. COMIRB's Process for Receiving and Reviewing Audit reports
3.1.1. The Office of Regulatory Compliance Audit team will present written findings of scheduled semiannual audits to the COMIRB Director, Assistant Director, and Assistant Vice Chancellor for Regulatory Compliance per their written SOPs. External audit reports will typically be received by the Vice Chancellor for Research, the Assistant Vice Chancellor for Regulatory Compliance, or the COMIRB Director.
3.1.2. Upon receipt of an audit report, a meeting will be scheduled between the COMIRB Director, Assistant Director, and the Office of Regulatory Compliance Audit team to discuss the findings and obtain necessary clarifications.
3.1.3. The audit findings will be distributed to the COMIRB panel Managers, and the findings will be discussed at a subsequent Managers' meeting. At this meeting, the Managers will determine which findings represent serious compliance issues or serious inadequacies in IRB process.
3.1.4. All findings that are determined to be serious by the COMIRB Management team will be formally addressed by the procedures described in section 3.2. If there are no findings determined to be serious, the Management team may identify one or more quality improvement initiatives derived from the audit findings to formally address.

3.2. COMIRB's Process for Systematically Addressing Audit Findings
3.2.1 The Management team will draft an audit response report, for each finding identified as serious, that contains the following elements:
   • A description of the finding and the problem(s) created by the finding
   • One or more goals to achieve in mitigating the finding
3.2.2 Once the report has been finalized, the Managers will execute the action plan(s), providing any necessary training to COMIRB Chairs and staff.

3.2.3 The COMIRB Director will provide a copy of the report(s) to the Assistant Vice Chancellor for Regulatory Compliance and the Office of Regulatory Compliance Audit team. A meeting will be scheduled between the Director and/or Assistant Director and the Office of Regulatory Compliance Audit team to review the new compliance measures needed, along with recommendations on how to change the audit tool to capture the necessary outcomes.

3.2.4 The Director and Assistant Director will meet with the Audit team, at the Audit team’s request, to review the revised audit tool to ensure the changes accurately capture the outcomes needed to evaluate the action plan.

3.3 Documentation of the Audit Review and Response Process:

3.3.1 The Director will file the audit report and the audit response report in a dedicated binder within the COMIRB Office.

4. RESPONSIBILITY

It is the responsibility of the COMIRB Director, Assistant Director, and Panel Managers to implement this SOP. The COMIRB Director, Assistant Director, and Panel Managers are responsible for day to day oversight of this SOP.

5. APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 46
21 CFR 50, 56, 312, and 812
Federal Wide Assurance
AAHRPP accreditation standards

6. PROCEDURES EMPLOYED TO IMPLEMENT THIS POLICY

<table>
<thead>
<tr>
<th>Who</th>
<th>Task</th>
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<tbody>
<tr>
<td>Director</td>
<td>Review audit findings; identify serious findings or quality improvement initiatives; develop goals, action plans, and compliance measures; and draft audit response reports</td>
</tr>
<tr>
<td>Assistant Director</td>
<td>Review audit findings; identify serious findings or quality improvement initiatives; develop goals, action plans, and compliance measures; and draft audit response reports</td>
</tr>
<tr>
<td>Panel Managers</td>
<td>Review audit findings; identify serious findings or quality improvement initiatives; and develop goals, action plans, and compliance measures</td>
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