INTRODUCTION
The primary objective of The Ohio State University College of Medicine Office of Research (COMOR) Clinical Research Compliance Assessment program is to ensure the appropriate management and oversight of clinical research within the College of Medicine. Multiple regulations apply to the conduct of clinical research. Failure to meet these regulations and requirements may result in research subject harm, invalidation of study results, financial penalties, and reputational harm for OSU. The compliance assessment is an opportunity for research study teams to proactively recognize and address potential issues before developing into violations.

The Principal Investigator (PI) is ultimately responsible for the overall conduct of the research, appropriate delegation of tasks, and compliance with applicable laws and policies. Regardless, it is the responsibility of all members of the clinical research team involved in supervising, managing, or conducting study-related activities to follow the protocol and standard operating procedures (SOPs) and execute tasks as delegated in compliance with regulatory requirements and institutional policies.

ASSESSMENT OBJECTIVES
COMOR may conduct routine and directed (for cause) assessments of any clinical research activity conducted within the College of Medicine. The College will select clinical research activities for routine assessments on the basis of a risk analysis based on research subject risk and regulatory complexity. Directed assessments can be requested by the IRB, Office of Responsible Research Practices, institutional officials or as a result of any official complaint.

The clinical research compliance assessment is a systematic and independent examination of study-related activities for the following:

- Oversight and appropriate delegation of tasks
- Screening and consenting process
- Safety of clinical research participants
- Validity and integrity of the data
- Compliance with the approved research protocol
- Investigational product management and accountability
- Compliance with regulatory requirements
- Compliance with institutional standards and policies

The exact items reviewed during the compliance assessment will depend on the activity and applicable regulations. Appendix A lists the general elements as well as corresponding documents that will be requested in an inspection.
COMPLIANCE ASSESSMENT NOTIFICATION PROCEDURES

Scheduling
- The PI will be notified of the compliance assessment by email. The PI and research support staff will have **10 business days** to schedule a mutually agreed upon date for the assessment.
- A copy of the most currently IRB approved protocol, consent forms, and HIPAA authorization forms will be sent by the research team to COMOR staff at least **5 business days** prior to the selected date for review.

Active Review
- The compliance assessment will begin with an opening meeting. Attendees will include the COM Regulatory Manager(s), lead study coordinator, and additional key personnel. The Principal Investigator is not required to attend if he or she has had a trial reviewed by COMOR in the last two years with an Acceptable outcome.
- During the active protocol review period, all source documents for the study must be made available for review. Members of the research team should be made available to answer questions that may arise during the compliance assessment process.
- A random sample of subjects will be selected for the assessment; however, all subjects may be reviewed.

Reporting and Resolution
- A written report of the initial observations will be sent to the PI and study team. The PI and study team can request an in-person meeting with COMOR staff to review the initial observations.
- The PI will have **15 business days** from receipt of initial observation report to respond in writing. The response should include details of corrective actions to be implemented, if applicable.
- A Final Compliance Evaluation Report will be sent to the PI after considering the additional information provided in the written response. A summary of the compliance assessment will be sent to the Vice Dean of Research.
- If the PI and research team fail to respond within the required time period, the Final Compliance Evaluation Report will be deemed Unacceptable and the Department Chair and COM Administration leadership will be notified immediately.
COMPLIANCE ASSESSMENT OUTCOMES
One of four assessment outcomes below will be noted in the Final Compliance Evaluation Report.

**Acceptable: No Deficiencies/Minor Deficiencies Resolved**
No deficiencies identified; compliance with all regulatory and investigational product assessments; minor deficiencies identified but were addressed promptly when identified during the compliance assessment.

**Acceptable: Minor Deficiencies, Follow-up Required**
Multiple minor deficiencies identified. PI indicates that matters will be addressed and implements a corrective action plan.

**Opportunities Exist: Major Deficiency(ies), Follow-up Required**
Major deficiency(ies) and/or non-compliant categories identified; excessive number of minor deficiencies identified that indicates systemic problems.

**Unacceptable: Immediate Attention Required**
Deficiency(ies) discovered that may negatively impact Research Subject(s) immediate safety, OSU’s reputation, or may be a severe regulatory violation. The Department Chair and COM Administration leadership will be notified immediately. Corrective action plan(s) will be developed with input from Department Chair and COM Administration leadership.

APPLICABLE REGULATIONS AND POLICIES

<table>
<thead>
<tr>
<th>Regulation/ Guidance</th>
<th>Title</th>
</tr>
</thead>
<tbody>
<tr>
<td>ICH E6</td>
<td>Good Clinical Practice: Consolidated Guidance</td>
</tr>
<tr>
<td>21 CFR 11</td>
<td>Electronic Records; Electronic Signatures</td>
</tr>
<tr>
<td>21 CFR 50</td>
<td>Protection of Human Subjects</td>
</tr>
<tr>
<td>21 CFR 54</td>
<td>Financial Disclosure by Clinical Investigators</td>
</tr>
<tr>
<td>21 CFR 56</td>
<td>Institutional Review Boards</td>
</tr>
<tr>
<td>21 CFR 312</td>
<td>Investigational New Drug Application</td>
</tr>
<tr>
<td>21 CFR 812</td>
<td>Investigational Device Exemptions</td>
</tr>
<tr>
<td>45 CFR 46</td>
<td>Protection of Human Subjects</td>
</tr>
<tr>
<td>45 CFR 160 + 164</td>
<td>HIPAA Privacy Rule</td>
</tr>
<tr>
<td>42 CFR 50 + 94</td>
<td>Responsibility of Promoting Objectivity in Research</td>
</tr>
<tr>
<td>2 CFR 220</td>
<td>Cost Principles for Educational Institutions</td>
</tr>
<tr>
<td>Code</td>
<td>Title</td>
</tr>
<tr>
<td>----------</td>
<td>------------------------------------------------------------</td>
</tr>
<tr>
<td>49 CFR 107 + 171</td>
<td>Transportation of Hazardous Materials</td>
</tr>
<tr>
<td>OSU HRPP</td>
<td>Human Subjects Research Protection Program Policies</td>
</tr>
<tr>
<td>OSU ORC</td>
<td>Financial Conflict of Interest Disclosure</td>
</tr>
<tr>
<td>OSUWMC</td>
<td>Use of Patient Information by Hospitals and Medical Staff</td>
</tr>
<tr>
<td>OSUWMC</td>
<td>Investigational Drug Services</td>
</tr>
<tr>
<td>OSU EHS</td>
<td>Environmental Health &amp; Safety Policies</td>
</tr>
<tr>
<td>OSU ORC</td>
<td>Institutional BioSafety Policies</td>
</tr>
<tr>
<td>OSU ORC</td>
<td>Research Misconduct</td>
</tr>
</tbody>
</table>

**History**

Issued: 1/21/2011  
Edited: 4/29/2011
Appendix A

ITEMS TO BE ASSESSED

The following items may be reviewed during the compliance assessment, as they apply to the specific research study being evaluated. Electronic versions of documents are acceptable, as long as they are made available to the person(s) reviewing the research.

Documentation
- Copies of signed Form FDA 1572 (drug or biologic studies) or Investigator Agreement (device studies)
- Copies of CVs, medical licenses, and study-specific financial disclosures
- Current versions of protocol, informed consent, HIPAA Authorization form, investigator’s brochure/device manual, data collection forms, any patient materials, any other IRB approved materials
- IRB submissions and approvals
- Submissions to the FDA, including but not limited to initial IND/IDE application, annual reports, amendments, safety reports, and any relevant communication
- Submissions and approvals to any other necessary committees or regulatory bodies (e.g. Institutional Biosafety Committee, scientific review boards, radiation safety boards, etc.)
- Delegation of Authority log
- SOP Training log
- Training documentation
- Laboratory credentials for all labs
- Investigational product (IP) accountability
- Screening and Enrollment logs
- Adverse Event documentation
- Protocol Deviation Log, Note to File(s)
- Submission of Data Safety Monitoring Board/Committee report

Activities
- Participant screening and enrollment
  - Verification study personnel did not access medical records or record protected health information (PHI) without proper approval (written authorization or HIPAA waiver as applicable)
  - Verification of appropriate access of screened subjects by study personnel
  - Sufficient source documentation to verify that participant meets eligibility criteria
  - Documentation of eligibility verification by the PI or other qualified study team member
  - Verification that no protocol specific procedures/interventions occurred prior to participant consent
  - Verification study subjects were enrolled during IRB approval period and within enrollment limit

- Protocol Adherence
  - Verification that research activities were executed according to the protocol
• Documentation that the participant was updated/re-consented regarding any significant changes to the research that may affect his/her desire to participate
  
• Proper documentation of any protocol deviations
  
• Verification any unblinding was carried out according to protocol

• **Adverse events**
  
• Verification that PI and any relevant study staff are reviewing external safety reports
  
• Verification of reportable events to sponsor, IRB, DSMB within appropriate time frame
  
• Type, grade, and attribution assessed by PI or qualified study personnel

• **Data management**
  
• Proper submission to and review by the Data Safety Monitoring Board/Committee per the protocol
  
• Verification data is obtained, recorded, stored, and disposed of according to the protocol
  
• Subject associated to protocol in EMR, and associated research documentation in EMR is appropriate and routed to PI or qualified study personnel (if applicable)

• **PI Oversight**
  
• Training of all study personnel on protocol, study-specific procedures before delegation
  
• Appropriate delegating of study-related duties based on education, training, and experience
  
• Adequate supervision of the conduct of trial, including timely review of subject eligibility, informed consent, case report forms, laboratory tests, and event reports.