

## **SOP: 902**

### **AUDITS BY REGULATORY AGENCIES**

#### **1. POLICY**

The University of Oklahoma acknowledges that certain regulatory agencies have the responsibility and authority to audit the operations of IRBs and supports such audits as part of its continuing effort to maintain high standards for human research protection.

Entities that may audit IRBs include, but are not limited to, FDA, OHRP, and appropriate certified auditors of foreign countries where data from clinical research has been submitted in an application for drug or device approval. Sponsors or funding entities of research may also be authorized to audit specific documents and procedures.

#### **Specific Policies**

##### **1.1 Audit Preparation & Participation**

Preparation includes notification of institutional officials; organization of all IRB documents; and allocation of staff, space, and equipment.

The auditor is oriented to the IRB Office and ancillary facilities. A daily and final exit interview is requested.

##### **1.2 Follow-up after the Audit**

The HRPP Director will provide reports of the audit, either verbal or written, to Institutional officials or designees as soon as possible following the audit.

#### **2. SCOPE**

These policies and procedures apply to both the HSC IRB and the Norman Campus IRB.

#### **3. RESPONSIBILITY**

The Institutional Official is responsible for answering to all regulatory agency matters regarding regulatory compliance, participating as needed in regulatory agency audits, and providing support in response to and correction of audit findings.

The HRPP Director or designee and the Compliance Officer will serve as the key institutional contacts during such audits. In conjunction with the IRB Chair and/or the Compliance Officer, the HRPP Director will draft policy and procedural changes as indicated by such audit.

The HRPP Director or designee, with assistance from the Compliance Officer and/or IRB Chair, is responsible for all formal regulatory agency correspondence and interactions and for establishing logistical support during regulatory agency audits.

The IRB Chair, IRB members, and IRB staff are responsible for participating in regulatory agency audits as determined by HRPP Director and for fully cooperating with government officials during their participation in such audits.

#### **4. APPLICABLE REGULATIONS AND GUIDELINES**

21 CFR 56.115

45 CFR 46.115

FDA Compliance Program Guidance Manual 7348.809, Institutional Review Boards

#### **5. REFERENCES TO OTHER APPLICABLE SOPS**

None.

#### **6. ATTACHMENTS**

None.

#### **7. PROCESS OVERVIEW**

##### **Audit Preparation & Participation**

7.1 For external audits involving OHRP or FDA, the HRPP Director notifies the following individuals immediately:

- Senior Vice President and Provost or designee
- Director of Compliance
- IRB Chair

7.2 The HRPP Director or designee will organize and make available to the auditor an organizational chart, IRB documents (i.e., membership rosters, policies, procedures, investigator manuals). IRB study files, agenda and minutes are organized and made available to the auditor.

7.3 The HRPP Director or designee will provide auditors with an adequate work area and necessary equipment (i.e., telephone, copy machine).

7.4 Senior institutional officials or designees and IRB staff are available for interviews and/or to assist the auditor. IRB staff and members make every reasonable effort to be available and to accommodate and expedite the requests of auditors.

7.5 Prior to being granted access to IRB documentation, inspectors and auditors must exhibit proof of their authority or authorization to conduct the audit and to access IRB documents. No entity or person other than those listed on the consent forms may access any document that includes participant identifiers, except as otherwise provided by law.

7.6 The HRPP Director provides a brief orientation to the auditor of the IRB office system.

7.7 The auditor will be asked to give a daily and final exit interview to provide an opportunity for the IRB to answer questions or address problems.

7.8 Only individuals authorized in writing by the HRPP Director or by law may copy documents and take them off-site.

An additional copy of all documents provided to the auditor is made and kept in the IRB Office files.

- 7.9 If the auditor requests interviews with IRB staff and/or IRB members, the HRPP Director or designee will receive the names of the interviewees.
- 7.10 Notes on the audit and copies of all documents that are reviewed will be placed in a folder or notebook so that responses can be made quickly and easily regarding any questions and/or concerns by the auditor.
- 7.11 Reports of the audit, either verbal or written, are addressed by the Senior Vice President and Provost or designee, with the assistance and support of the Director of Compliance, HRPP Director, and/or IRB Chair, as soon as possible after the audit.

**APPROVED BY:** \_\_\_\_\_ **DATE:** 09/01/2009

**NEXT ESTABLISHED REVIEW DATE:** MAY 2012