

AUDITS BY REGULATORY AGENCIES

SOP #:	902	VERSION #:	1	EFFECTIVE DATE:	5/1/09	SUPERSEDES DOCUMENT:	/ /
THIS POLICY PERTAINS TO:			ALL RESEARCH SUBMITTED TO THE IRB				
RESPONSIBILITY FOR EXECUTING POLICY:		ASSOCIATE VICE PRESIDENT FOR RESEARCH AND ECONOMIC DEVELOPMENT, IRB CHAIRPERSON, IRB COORDINATOR					
LAST REVIEWED ON:		/ /		RESULTS:	REVISED		
APPROVAL AUTHORITY:		Associate Vice President for Research and Economic Development					
APPROVED BY:						DATE:	/ /

1. POLICY

The University of North Dakota acknowledges that certain regulatory agencies have the authority to audit the operations of the IRB, and supports such audits as part of its continuing effort to maintain high standards for human research protections.

Entities that may audit the IRB include the FDA and OHRP. Sponsors or funding entities of research may also be authorized to audit specific documents and procedures.

2.1 Preparing for an Audit

2.1.1 For external audits involving OHRP or FDA, the following must be notified

- Vice President for Research and Economic Development
- IRB Chairperson
- IRB Coordinator

2.2 Participating in an Audit

Investigators and IRB Staff are expected to know and follow the procedures outlined for the conduct of an internal or external audit of specific studies. Prior to being granted access to IRB documentation, inspectors or auditors must exhibit proof of their authority or authorization to conduct the audit and to access IRB documents.

Auditors will be provided with adequate working area to conduct an audit and IRB Staff and IRB members must make every reasonable effort to be available and to accommodate and expedite the requests of such auditors.

2.3 Follow-up After an Audit

Reports of the audit, either verbal or written, should be addressed by the Associate Vice President for Research and Economic Development, (with the assistance and support of IRB Staff), as soon as possible after the audit.

3. RESPONSIBILITY

The Associate Vice President for Research and Economic Development is responsible for serving as the responsible institutional official in all regulatory agency matters regarding regulatory compliance, participating as needed in regulatory agency audits, and providing support in responding to and correcting audit findings.

The Associate Vice President for Research and Economic Development is responsible for all formal regulatory agency correspondence and interactions, establishing logistical support during regulatory agency audits, serving as key institution contact during such audits, and drafting responses to regulatory agency correspondence received following such audits.

The IRB Chairperson, IRB Members and IRB Staff are responsible for participating in regulatory agency audits as determined by the Associate Vice President for Research and Economic Development, and in fully cooperating with government officials during their participation in such audits.

The Associate Vice President for Research and Economic Development, the IRB Chairperson, and the IRB Coordinator are responsible for formal responses to regulatory agency audits and in implementing policy and procedure changes indicated by 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. ATTACHMENTS

QA 902-A FDA Site Inspection Preparation Checklist

6. PROCEDURES EMPLOYED TO IMPLEMENT THIS POLICY

Who	Task
<i>Associate Vice President for Research and Economic Development</i>	Upon being notified of an impending audit, notify all IRB staff, and staff of any other institutional entity designated. Using the FDA Site Inspection Preparation Checklist, assign responsibilities as indicated on the checklist.