OFFICE FOR EDUCATION & QUALITY IN CLINICAL RESEARCH	CATEGORY	Clinical Research: Project Activities
	SUBJECT	Audit Preparation and Participation
	SOP #	4.3
	EFFECTIVE DATE	August 6, 2008
	REVISION DATE	August 27, 2018

OBJECTIVE

Describe the procedures in preparing for, and participating in, any kind of research audit. These procedures apply to all clinical research activities approved by the Office for Human Subjects Research conducted within the Hennepin County Medical Center campus.

APPLICABLE REGULATIONS AND GUIDELINES

21 CFR 312 Investigational New Drug Application
21 CFR 812 Investigational Device Exemptions
Information Sheet Guidance for IRBs, Clinical Investigators, and Sponsors: FDA Inspections of Clinical Investigators
FDA Oversight of Clinical Investigations —A Risk-Based Approach to Monitoring

REFERENCES TO RELATED SOPs

All SOPs are applicable to this SOP

ATTACHMENTS

Sample Audit Preparation Checklist
Auditor Allowable and Non-Allowable

1) Preparing for an audit
   a) Notify all involved personnel
      i) HHRI VP of Operations
      ii) Appropriate Grant Administrator
      iii) Office for Education and Quality in Clinical Research
      iv) Notify the sponsor if the audit is by a local, state, or federal agency.
   b) Ensure that all study documentation, including, but not limited to, consent forms, source documents, x-rays and ECGs, study drug or investigational device dispensing records, case report forms, and the regulatory binder are accurate, complete, and available. *If this is an FDA audit, the inspector can audit all clinical trial documents.*
   c) Conduct a review of study procedures, protocol, and case report forms.
   d) Ensure that records of staff qualifications and training are available.
   e) Assign an escort to the auditor or inspector to facilitate document copying, retrieving requested materials, and navigating the campus. *This is especially important in an FDA audit.*

2) Participating in an audit
   a) Meet with the auditor, request appropriate identification. *Request the FDA Form 482 if this is an FDA audit.*
   b) Wear your institutional ID badge at all times.
   c) Know the contents of your job description.
   d) Ensure that the auditor has a suitable area to work in, preferably a private area.
   e) Provide all requested documentation.
   f) Be aware of what items an auditor may or may not ask to examine.
   g) Questions posed by the auditor should only be answered by the appropriate study personnel.
   h) Seek clarification if a question is not understood.

i) Answer only the questions asked. Do not offer extraneous answers or comments.
j) Be yourself, remain calm and focused.
k) Do not fill in any silences.
l) Be aware of negative body language. Attempt to avoid mannerisms that may depict nervousness or anger such as repeatedly clicking a pen, hair twirling, standing with crossed arms, or avoiding eye contact.
m) Do not stay in the audit room to chat with the auditor after answering audit related questions.
n) Make photocopies of any study documents only if requested. Redact any personal information as defined by HIPAA regulations using a china marker to completely obliterate the protected health information. *If this is an FDA audit, FDA employees may receive records that identify subjects upon notice that the FDA has reason to suspect that adequate informed consent was not obtained or that reports required to be submitted by the investigator have not been submitted or are incomplete, inaccurate, false, or misleading.* Make additional copies for the research site, this often assists study personnel when responding to questions from the auditor.
o) Participate in the exit interview. *Request the FDA Form 483 if this is an FDA audit.*

3) After the audit
   a) Respond to the audit report as soon as possible.
   b) Reply to each item in the report; provide clarification or steps that will be taken to institute corrective action.
   c) Responses should be simple, direct, and dispassionate

SAMPLE AUDIT PREPARATION CHECKLIST

AUDIT PREPARATION			
1. ORGANIZATIONAL NOTIFICATION	**YES**	**N/A**	**COMMENTS**
Sponsor			
HHRI VP of Operations			
OHSR			
Office for Education and Quality in Clinical Research (OEQCR)			
Grants Administration			
Principal Investigator			
Sub-investigator(s)			
Study personnel			
Pharmacy			
Laboratory			
Medical Records			
2. SUBJECT LIST			
Name			
Address			
Phone Number			
Enrollment and completion date			
Medical record number			
3. HSRC DOCUMENTS			
Investigator's Brochure (all versions)			
Protocol and amendments (all versions)			
FDA Form 1572 or Investigators Agreement (if applicable, all versions)			
CVs for PI and Sub-Investigators listed on all versions of FDA Form 1572			
Initial HSRC study approval with original informed consent			
HSRC amendment approval with approved informed consent (if applicable)			

HSRC advertisement approval (if applicable)			
HSRC reports for renewal(s), adverse events, study termination, final summary			
AUDIT PREPARATION			
4. CORRESPONDENCE			
Sponsor			
CRO/Monitor			
Subject			
Monitoring Log			
5. LABORATORY			
Laboratory certifications Laboratory normal ranges			
6. DRUG/DEVICE ACCOUNTABILITY			
Inventory log			
Dispensing log			
7. SUBJECT DOCUMENTS			
Informed consents			
Case report forms (paper and/or EDC access)			
Query resolutions (paper and/or EDC access)			
Source documents (paper and/or EMR access)			

AUDITOR ALLOWABLES AND NON-ALLOWABLES

ITEMS THAT CAN BE SHARED WITH AN AUDITOR

Internal
All documents, procedures, notes, etc.

Sponsor
All records pertaining to their study
SOPs governing the functional aspect of the trial
CVs, monitor visit reports, drug/device accountability records
No documents pertaining to another study

Regulatory (FDA)
All records *except* financial documents, administrative meeting minutes, and internal audits

ITEMS THAT CAN BE TAKEN BY AN AUDITOR

Sponsor
SOP index *(not SOPs)*
Organizational charts
Copies of any study specific documents/records (redact all PHI identifiers)

Regulatory (FDA)
Federal inspectors may take copies of any record, photographs, CDs, samples, etc.