

Human Research Audit Program



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Objectives

1. Understand the purpose of the audit program
2. Identify the stakeholders and their roles and responsibilities
3. Describe the audit process, preparation, and reporting

What's with all the Auditing Anyway?



ACRP2012
GLOBAL
CONFERENCE/EXHIBITION
with the Research Program
4801, 14-17 November, 1990

What is an audit?

“A systematic and independent examination of trial related activities, documents and data to determine whether the IRB-approved protocol was followed and if subjects (ethical treatment) and data were appropriately managed (recorded, analyzed, and reported) per protocol and applicable regulatory requirements.”

Purpose

- Joint collaboration between Human Research Compliance and JCTO to audit all active WCM IRB-approved protocols, regardless of funding source.
- Facilitate the ethical and regulatory-compliant conduct of human research and improve human subject protections by:
 - ensuring the rights, safety, and well-being of participants in human research are properly protected in adherence to all applicable regulations.
 - providing a mechanism to evaluate and categorize non-compliance
 - promoting researchers' accountability.
 - ensuring integrity of study data.
- Proactively evaluate and establish standards to identify resources and constraints for the research community by collecting metrics for:
 - monitoring emerging trends.
 - developing and modifying institutional policies and training.
 - provide Investigator-specific management and training.
 - assist investigators with self-assessment tools for research compliance.

Types of Audits

For-Cause Audit

- In-depth examination of all components of a research study
- Initiated due to substantive written or verbal allegation of noncompliance

Not-For-Cause

- Routine
- Low level /absence of reporting to the IRB
- Less likely if a QAU or an external audit has been conducted in the past 2 years

QAU Monitoring

- Same format as a routine audit
- Focuses on IITs and multi-site studies
- Informal basis
- Preparation for external auditors

Responsible Parties

- **Human Research Compliance and JCTO**
 - Oversee and manage all audit activities.
 - Report finding to PI, IRB, and Department Chair.
 - Cultivate open communication to better support the research community.
- **Principal Investigators**
 - Ensure research is conducted in compliance with the IRB approved protocol.
 - Responsible for complete oversight and conduct of research.
 - Ensure proper training and delegation of tasks to research staff.
 - Are available and make accessible all required documents during an audit.

Responsible Parties (cont'd)

- **The Department Chair**

- Confirm adequate resources are available to conduct the research safely and in compliance with all requirements.
- Ensure investigators are qualified.
- Request For-cause audit at any time

- **IRB**

- Provide final determination of noncompliance
- Request a For-Cause audit at any time

- **Others**

- Institutional Official
- Research Integrity Officer
- General Counsel
- Division Chiefs

Protocol Selection

- All active protocols are eligible for an audit, including exempt studies.
- Protocols are randomly selected to account for
 - Tier of risk (negligible risk, low risk and greater-than-low risk)
 - Control for repeated audits of the same protocol
- Length of audit may vary from several hours to days and is contingent upon the scope of the audit activities.

Sample Size Determination

	Protocols with <25 participants	Protocols with >25 participants
Not-For-Cause Audits	100%	Random sample that will consist of at least 10% of the enrolled participants, but no less than 25.
For-Cause Audits	100%	Determined by the audit plan received by the PI at the time of audit scheduling.
Investigator Requested Audits	At least 20% of participants, but no less than 3.	At least 20% of participants, but no less than 3.
	The participant's research record, informed consent, and other related documents will be reviewed. The Principal Investigator or study team may request additional records to be reviewed.	
External Audit and Inspection Preparation	At least 20% of participants, but no less than 3.	At least 20% of participants, but no less than 3.

Audit Notification

- For a routine Not-For-Cause audit, the audit team and the investigator will work on an agreed upon date.
- For-Cause audits may be unscheduled and/or occur without prior notice.
- PI will be notified by email of an audit and be provided with a pre-audit preparation tool and an audit plan by the audit team.
- The audit plan outlines:
 - Scope of Audit
 - Date and type of audit activity
 - Randomized list of subjects to be reviewed
 - Request for access to database(s), etc.



SO, ARE YOU READY FOR AN **AUDIT?**

YES!



NO!



Preparation Before an Audit

- ✓ **Confirm** audit date
- ✓ **Review** the audit plan
- ✓ **Secure** a private area for the auditor(s) to work
- ✓ **Make accessible** all requested documents for the audit
- ✓ **Grant access** to databases and shared drives to the auditor (s), if needed
- ✓ **Be available** for questions during the duration of the audit



What To Expect During An Audit Visit

- Pre and Post-Interview
- Review the site Standard Operating Procedures (SOPs), if applicable
- Review of Informed Consent Forms
 - Survey Study Participants.
 - Observation of informed consent by research team.
- Tour of Facility
 - Verify control, storage, and accountability of investigational product (if applicable) and/or to confirm availability of related research equipment.
- Review study database to determine that data is collected in accordance with eIRB application.
- Determine if the PI has a plan for record and data retention once study is completed.

What Are We Trying to Determine?



Study Conduct

- Interviews with Principal Investigator, research staff members, and participants
- Review of regulatory binder, including IRB approvals
- Review of personnel credentials and training
- Tour and review of research facility and document storage



Protocol Adherence

- Approved Protocol followed accordingly
- Participants inclusion and exclusion criteria
- Proper randomization
- Deviations
- Amendment(s) implemented accurately

What Are We Trying to Determine?



Informed Consent

- Informed Consent Documentation
- Surveying research subjects enrolled in the study about their experiences as research participants



Investigational Product/Device

- Thorough accountability
- Proper dispensing and dose modification
- Appropriate storage and destruction



Subjects Records (Verification, Retention and Storage)

- Review of participant records for adherence to protocol
- Copies of clinical assessments and results
- Adverse events are assessed and reported
- Review of information security process

Survey Participants and Observation Informed Of Consent



- Process
 - Review any written procedures (SOPs) regarding consenting process
 - Interview research participant(s)
 - Evaluate their overall comprehension of informed consent process
 - PI or co-investigator involved in the consenting process and listed on eIRB application
- Overall Compliance
 - Were all subjects consented
 - Were the appropriate versions of the ICF used at the correct time
 - Are all forms signed and dated
 - Copies in medical chart or EMR
 - Copies provided to participants

After the Audit



Audit Report and PI's Response

- Prior to the written report, the auditor and PI will discuss the audit findings at the exit interview.
- PI receives an audit report within 3 weeks of the exit interview.
- The audit report may or may not identify any areas of reportable non-compliance.
- Principal Investigator must respond in writing to the audit report and is required to implement a corrective action plan (CAPA) commensurate with the degree of the noncompliance.
- The auditor may recommend specific items to include in the corrective actions plan. However, the PI may choose whether or not to implement the recommendations or provide his/her own.
- Principal Investigator must submit a corrective action plan to the audit team within 21 days of the receipt of the audit letter.
- The audit report containing the PI's response is provided to the IRB and presented at a convene board meeting.
- IRB makes final IRB determination of compliance and the letter is distributed to the Principal Investigator, Assistant Dean of Human Research Compliance, Associate Dean of Clinical Research and Department Chair.

Examples of IRB Determinations

- Accept the PI's CAPA with no further requests.
- Issue additional corrective actions.
- Restrict research of the PI or limit the amount of activity on certain projects.
- Suspend or terminate one or more research projects conducted by the PI.
- Require educational sessions for the PI and research team.
- Suspend enrollment of new study participants on one or more research projects conducted by the PI.
- Require additional reporting to the IRB or conducting early Continuing Review.
- Require re-reviewing of research by the IRB, DSMB, or CSEC (Clinical Study Evaluation Committee).
- Report serious or continuing noncompliance to regulatory and funding agencies

Human Research Audit Program Team

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I Have A Question



Reference

- WCM Human Research Audit Policy
- 45CFR46
- 21CFR312
- ICH GCP E6(R2)