THE UNIVERSITY OF ARIZONA Research & Partnerships

Audit Preparation Guidance

Background

The University of Arizona (UA) is committed to promoting excellence in its research activities and conducts routine reviews of active research. Reviews are conducted to ensure compliance with regulations and local requirements and present educational opportunities to the research community. The goal of routine monitoring is to ensure compliance with organizational policies and procedures and applicable laws, regulations, and guidance.

Definitions

- **Corrective Action and Preventative Action (CAPA) Plan**: Corrective actions are those taken to resolve a problem and preventive actions are those actions that keep the problem from recurring.
- **For-Cause Audit**: Audits requested by the Institutional Review Board (IRB) Committee, IRB Chair, the HSPP Director, or anyone who reports concerns about the conduct of research activities generally related to reported or suspected noncompliance.
- **Investigator-Initiated Audit**: Audits requested by the study team to ensure continuing compliance.
- **Routine Audit**: Audits conducted as part of a planned auditing schedule.

Preparing for an Audit

After an audit notification has been received, it is important to adequately prepare for the meeting by reviewing the research files. Please respond within 2 weeks of receipt of the audit notification. The following questions should be considered when preparing for an audit:

- Does the researcher have available the most recently approved protocol, consent form(s), and study documents for review?
- How many participants are currently enrolled? How many have been approved by the IRB?
- Are all key personnel listed on the Local Study Team Members list in eIRB? Are personnel conducting procedures according to their role in the study?
- Have any participants withdrawn/dropped from study? If so, is the reason documented?
- Have any adverse events occurred? Were all unanticipated or serious adverse events reported to the IRB?
- Are participants consented with the most recent IRB-approved version of the consent form? Have all the consent forms been signed and dated by the participant and the person obtaining consent (if applicable)?
- Have all study measures and procedures been approved by the IRB before implementing?
- Are all advertisements and methods of recruitment IRB approved?
- Are study documents and data maintained as outlined in the protocol?
- Have all enrolled participants met eligibility criteria? Is there documentation of eligibility?
- Have there been any protocol deviations? Have they been reported to the IRB?
- Have there been any unanticipated problems with protocol implementation?
- Has participant compensation been documented?
- Have there been any participant complaints?
- Are raw data files organized, complete, and legible?

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During the Audit

The auditor will briefly meet with the Principal Investigator (PI) or PI designee to discuss the study, and the PI will provide the study files for review. The PI must make available the use of a quiet space to review the study files. The PI or designee who is familiar with the study should be available during the audit in case the reviewer has questions. As needed, during the audit, the reviewer will provide recommendations and educational support on record retention and documentation, and other compliance related issues.

Review of Regulatory Compliance may include review of the following:

- Roles and responsibilities of investigators and key personnel
- Protocol file/regulatory documentation
- IRB Documentation
- Consent/Assent Forms
- Individual participant records to determine if:
    - The participants met the inclusion/exclusion criteria for the study
    - Study related procedures are performed according to the protocol
    - Study related procedures are scheduled and performed per the study timeline
    - Data is recorded and stored securely as described in the consent form and protocol
    - Adverse events and/or protocol deviations have been reported according to institutional policy
    - Payments were made to participants as described in the consent form and protocol
    - Participant ID numbers are assigned according to the protocol

After the Review

There will be time for auditors to discuss recommendations for improvement with the research team. The PI will receive an audit summary report within two (2) weeks of completion of the audit. A Reportable New Information submission along with a CAPA plan may be requested. Please review the *Reporting New Information* guidance for more information.

Records and Confidentiality

Documents pertaining to research will be held confidential, except as necessary to report to regulatory bodies (at the UA, partner IRBs, and to federal agencies) and to institutional leadership as appropriate.