

UNC Greensboro IRB Guidelines: Converting Paper-Based Research Records to Electronic Format

Purpose

This guidance provides UNC Greensboro researchers with procedures for converting signed paper consent forms and other research-related documents into electronic format. It aims to ensure compliance with applicable federal, state, and institutional regulations while maintaining data integrity, participant confidentiality, and long-term accessibility of research records.

1. General Principles

- All converted electronic records must be complete, accurate, legible, and faithfully represent the original paper documents.
- Electronic records must meet the same ethical and regulatory requirements as paper documents.
- IRB approval must be obtained via a protocol modification before transitioning to electronic storage, unless electronic storage was pre-approved in the original IRB application.

2. IRB Submission Requirements

For ongoing (active) studies:

- Submit a modification in Cayuse IRB detailing:
 - The rationale for digitization.
 - The scanning and verification process.
 - The electronic storage system
 - Data retention,

For closed studies:

- IRB notification is not required, but researchers must follow the same procedures to ensure accuracy and compliance.

3. Verification of Electronic Copies

Before destroying original paper documents, research teams must verify that the electronic versions meet all quality and completeness criteria:

- A designated team member must review each scanned document to confirm:
 - All pages are present, legible, and properly oriented.
 - File names and labels accurately reflect participant and date information.
 - The content is an exact match to the original paper version.
- Verification must be documented in the study records (e.g., a review log, study notes, or email correspondence retained in the regulatory binder).
- The Principal Investigator (PI) is ultimately responsible for ensuring compliance but may delegate this task to appropriately trained team members.

4. Technical Requirements for Electronic Storage

- Security and Access Controls:
 - Store electronic records only on secure, UNCG ITS-approved platforms.
 - Do not use personal devices, unencrypted storage, or unauthorized cloud services.
- File Format and Naming Conventions:
 - Save documents as PDF or standard image format.
 - Use standardized, descriptive file names (e.g., IRB#_ParticipantInitials_DateSigned.pdf).
 - Use bookmarks for multi-participant files organized by participant name and date.

5. FDA and HIPAA Considerations

- For FDA-regulated research, electronic systems must comply with 21 CFR Part 11, including validation, audit trails, and restricted access.
- For studies involving Protected Health Information (PHI), all systems must be HIPAA-compliant, incorporating encryption and access safeguards.

6. Retention and Destruction of Paper Copies

- Retain paper documents until the corresponding electronic versions are verified as complete and accurate.
- Follow applicable record retention timelines based on:
 - UNCG records management policies.
 - IRB-approved protocols.

- Sponsor or regulatory agency requirements (typically at least 3 years after study closure or longer for FDA/HIPAA-covered studies).

- Once verified and approved, securely destroy paper records using cross-cut shredding or other irreversible destruction methods.

7. Responsibilities

- Principal Investigator (PI):

- Ensure accurate and compliant electronic conversion.

- Oversee or delegate verification and documentation processes.

- Maintain required study documentation.

- Submit IRB modifications as needed.

- Research Staff:

- Receive appropriate training on digital record handling.

- Consistently follow study-specific SOPs and institutional guidance.