MCW Office of Research
Standard Operating Procedure

RESEARCH CONSENT STORAGE: ELECTRONIC COPIES OF PAPER INFORMED CONSENT FORMS

Unit: Human Research Protections Program (HRPP), Office of Research

Applies to: Faculty and Staff involved in human research

PURPOSE:

Under various regulations and institutional policies (Common Rule, 21 CFR 50, MCW Corporate Policy, and others), Investigators are required to archive their research records upon completion of the project, including the original copies of all Informed Consent Forms (ICFs), for a minimum of ten years and often much longer for FDA-regulated clinical trials. The requirement to store these documents for long periods of time is a burden associated with increased challenges and costs.

Background

This policy outlines an acceptable process for the creation of electronic copies of signed paper ICFs that will reduce the burden storage issues.
The Food and Drug Administration (FDA) allows electronic storage of research records if the ***electronic copies are certified***. As defined by the FDA, a ***certified copy*** is a copy of original information that has been **verified**, as indicated by **a dated signature**, as an exact copy, having all of the same attributes and information as the original.

ELECTRONIC STORAGE BEST PRACTICES:

1. Catalogue the electronic copies for ease of retrieval
2. Certify the electronic copies of ICFs
    a. Trained research staff must review each page in the electronic copy to confirm that: (i) all pages are present and legible, and (ii) each ICF was completed compliantly (correctly), unless the case example of non-compliance was previously reported to the MCW IRB via eBridge,
    b. Complete a certification statement (*MCW Electronic Copy Certification for Informed Consent Forms)* that is maintained in the study file, and
    c. Use appropriate security measures to protect electronic files from unauthorized access

DEFINITIONS:

POLICY/PROCEDURE

IRB Approval:

1. For new research projects, written documentation of the planned process for creating an electronic copy of signed paper ICFs must be described within the eBridge PRO SmartForm along with any supporting documents.
2. For currently approved projects, an amendment must be submitted with the changes made in the applicable sections of the eBridge PRO SmartForm along with any supporting documents to add this process to their approved project.
3. IRB approval for each process is required prior to implementation. After IRB approval, paper ICF documents can be scanned and stored electronically when:
    - The individual subject has completed the entire project protocol, or

- For projects with long-term follow-up ONLY for purposes of documenting morbidity, mortality, or quality of life, after the individual subject has moved into the "follow-up" phase, or
- If the project is a bank

4. Closed projects, which have never submitted a planned process for creating an electronic copy of the ICF to the IRB, may not convert signed paper ICFs to electronic storage unless:
    1. The investigator notifies the HRPP Director of their intent in advance to convert their paper ICFs, and
    2. The investigator agrees to follow the "universal protocol" defined by this policy.

Universal Protocol for creating and maintaining Electronic Storage of paper Research Consent Forms

1. ICF Certification Process:

1. To certify an electronic copy of a paper ICF, the Principal Investigator (PI) must complete the *Electronic Copy Certification for Informed Consent Form*. The tasks of certifying may be delegated by the Principal Investigator to project team members, but the Principal Investigator is always responsible for the quality of work and must always sign the certification form.
    a. **Important Note**: The Principal Investigator who completes the *Electronic Copy Certification for Informed Consent Forms* certifies that they have completed all the following:
        - Documented Sponsor's agreement that original paper ICFs may be electronically stored (if applicable).
        - Reviewed all pages of the scanned document and confirmed that they are EXACT copies of the original.
        - Confirmed that each scanned page is legible, has correct resolution, and is facing in the appropriate direction.
        - Confirmed that the scanned consent is bookmarked, named, and indexed appropriately.
        - Confirmed that each paper ICF was completed compliantly (correctly), unless the case example of non-compliance was previously reported to the MCW IRB via eBridge. Non-compliant ICFs must be set aside and discussed one-by-one with the MCW IRB.
        - Confirm the scanned documents are stored in a secured manner in accordance with *MCW Corporate Policy: Collection and Security of Research Data (RS.GN.050)*

2. Creating an Electronic File:

1. All consents that are scanned should be in an acceptable format that is legible, has correct resolution, and is facing in the appropriate direction.
2. Consents can be scanned individually.
3. The .pdf file name should be labeled so that the project team can easily identify which project and which subject it belongs to (For example, PRO0001234 AB).
4. Consents can be scanned as a group.
    a. If scanning consents as a group, it is recommended that you keep the number of consents per .pdf in mind while considering size and number of consents per subject. (For example, you may only wish to scan 10 consents per .pdf if the consents are more than 20 pages each; however, you may wish to scan 50 consents per .pdf if the consents are only 2 pages each).
5. All scanned consents must be password protected and bookmarked. Please see the document titled "*How to Bookmark & Password Protect Scanned Informed Consent Forms*" for step-by-step instructions.
    a. Consents should be bookmarked by subject name and date signed (For example, Smith, Jane signed 7-2-2015).
6. If subjects have multiple consents, each of the consents should be labeled to clearly document this (For example, Smith, Jane PG ICF signed 7-2-2015).
7. A completed *Electronic Copy Certification for Informed Consent Forms* must accompany the electronic ICFs. The form can be included as a separate scanned .pdf file stored in the same folder as the electronic ICFs.
8. Once all of the original ICFs are scanned and certified, the original copies can be destroyed.

3. Modifying Scanned Records:

It is important to ensure that the original content of an Electronic Copy of an ICF is not altered or modified once it has been finalized. Scanned records should be "read only" to ensure that there is no improper alteration or modification. However, many times it is useful to add a note on a PDF using a text box. This should not be considered a modification of the Certified Electronic Copy and is an acceptable and necessary measure to ensure study communication.

4. Electronic ICF Storage:

1. Electronic files of scanned and certified ICFs should be password protected and stored on a central MCW, FH, or Versiti server.
2. It is highly recommended that consents not be stored on desktops, laptops, portable drives, or local PCs as they are not backed up by MCW, FH, or Versiti IT support systems.
    - Standard system back-ups are generally done once a day; however, back-up schedules may vary from one department to the next. You should contact your IT helpdesk to inquire about your department's specific scheduled back-ups and allowable data storage.
3. **Other storage options:**
    - Encrypted External Hard Drives: If external hard drives are used, the hard drives must be encrypted to MCW Corporate Policy standards and backed-up onto another encrypted hard drive.
    - It is highly recommended that external hard drives be backed up at least once a month.
    - Procedures for storing and backing up external hard drives should be outlined and uploaded to your eBridge PRO SmartForm application.

- Electronic files of ICFs should be kept at a minimum of 10 years following submission of the Final Report in eBridge and in accordance with *IRB SOP: Project Closure*. Additional considerations and timeframes for storage are dependent on each individual project protocol.
- FDA regulated and sponsored studies may have additional requirements which would need to be met in addition to institutional policy.

5. Documenting Sponsor's Permission of Electronic Storage of ICFs (if applicable):

Sponsors who agree to the electronic storage of ICFs should do so in writing. This can be in the form of an email or letter. The email or letter should specify the data, research protocol, person granting permission and their job title. This should be captured on the *Certification of Electronic Informed Consent Forms document*. Documentation of sponsor acceptance should be kept on file.

Possible Compliance Risks by not having Original Hard Copies:

The guidance presented herein this policy and the electronic storage best practices are intended to adhere to all necessary MCW IRB, FDA, and Health Insurance Portability and Accountability Act (HIPAA) policies and regulations.

All project teams should be aware that compliance risks may be possible if project teams do not follow this policy for storing electronic copies of ICFs. Such compliance risks may include but are not limited to non-legible electronic copies of ICFs, incomplete electronic copies of ICFs, and increased access to unauthorized personnel due to electronic files.

Staff Training:

1. Research teams and PIs who intend to implement the policy stated herein must state their intention to create electronic copies of signed paper ICFs and must identify all persons involved in scanning/storing/certifying ICFs within their eBridge SmartForm.
2. All personnel involved are considered research project team members and must fulfill the HSRP training requirements for project team members per *IRB SOP: Human Subject Research Protection Training Requirements*. In addition, the Principal Investigator has a responsibility to educate, train, and supervise project personnel who develop, maintain, or use the electronic copies of paper ICFs.

REFERENCES:
ICH E-6 Good Clinical Practice: Consolidated Guidance
Use of Electronic Informed Consent in Clinical Investigations: Questions and Answers-Guidance for Industry, March 2015

SUPPORTING DOCUMENTS:
MCW Corporate Policy: Collection and Security of Research Data (RS.GN.050)
IRB SOP: Human Subject Research Protection Training Requirements
IRB SOP: Project Closure
Certification of Electronic Informed Consent Forms

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