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 (
    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

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:

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: