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University of Miami Medical Group	**Owner:**	*Helen Miletic: Director, GxP Compliance*
	Area:	*Research Compliance and Quality Assurance*
	References:	
	Applicability:	*University of Miami System-Wide*

Certified Copies in Human Subject Research

PURPOSE:

This policy defines the process for creating certified copies of original documents for use in human subject research. Certified copies are needed when copies are used as a substitute for the original records in FDA-regulated research.

SCOPE:

This policy applies to researchers at the University of Miami who are conducting human subject research and who need to create certified copies of paper or electronic source records.

Researchers conducting FDA-regulated research, who include copies of source documentation, such as printouts from the electronic medical record, instruments, or copies of handwritten documents to complete a research record, must certify all copies as required by the FDA. All copies of source documentation must be made as certified copies, if they are used or referenced as a substitute for the original.

Certified copies may be requested for review by sponsors, study monitors, auditors, and federal agencies such as FDA, DOD, EMA or other agencies.

Researchers conducting non-FDA regulated research may choose but are not required to implement the use of certified copies as an added measure to ensure the quality and integrity of any referenced copies.

POLICY:

It is the policy of the University of Miami that all copies of paper or electronic source documentation or data for use in FDA-regulated human subject research, must be “certified copies” as defined below.

A certified copy is a copy of original information that has been verified with a dated signature, as an exact copy, having all of the same attributes and information as the original.

Source data includes all information in original records and certified copies of original records of clinical findings, observations, or other activities in a clinical investigation used for reconstructing and evaluating the investigation.

Access to source data is critical to the review and inspections of clinical investigations. As the review of source data by both the FDA and sponsor is important to ensure adequate protection of the rights, welfare, and safety of human subjects and the quality and integrity of the clinical investigation data; researchers may need to file

certified copies of source documentation from the electronic medical record or other source of information into research files, to create a complete research record.

For FDA-regulated studies, all copies of source documentation, whether from an instrument, electronic medical record or from handwritten original records, must be certified copies, as they are intended to substitute for the original.

DEFINITIONS:

Certified copy	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
Copy	A printout from the electronic medical record or instrument is considered a copy, similar to a photocopy of a paper document
DOD	Department of Defense
Electronic source data	Data that is initially recorded in electronic format such as in the electronic medical record
EMA	European Medicines Agency
FDA	Food and Drug Administration
Source data	All information in original records and certified copies of original records of clinical findings, observations, or other activities in a clinical investigation used for the reconstruction and evaluation of the trial
Source documents	Original documents and records including, but not limited to, hospital records, clinical and office charts, laboratory notes, memoranda, subjects' diaries or evaluation checklists, pharmacy dispensing records, recorded data from automated instruments, copies or transcriptions certified after verification as being accurate and complete, microfiches, photographic negatives, microfilm or magnetic media, x-rays, subject files, and records kept at the pharmacy, at the laboratories, and at medico-technical departments involved in a clinical trial

PROCEDURE:

Researchers at the University of Miami that need to create certified copies of paper or electronic source documentation for use in FDA-regulated human subject research, must implement a verification process that includes the following:

The person making printed copies of original paper or electronic source documents:

- must verify each page as having all of the same attributes and information as the original
- must indicate on each page that it is a copy (e.g. a “copy” stamp may be used)
- must sign or initial and date, in wet ink, each copied page (a signature stamp cannot be used)

The location of the original records must be documented within the research files.

APPLICABILITY:

The following parties are responsible for knowing this policy:

- Provost, Vice Provosts, Deans, Center Directors, Department Chairs
- Chief Compliance Officers
- Office of Privacy and Data Security
- General Counsel
- Human Subjects Research Office
- Research Administrators
- Principal Investigators
- Research Professionals
- Office of the Vice Provost for Research and Scholarship
- Office of Research Compliance and Quality Assurance
- Office of the Executive Dean for Research
- Office of Clinical Research Operations and Regulatory Support
- Office of Research Administration

Attachments

No Attachments

Approval Signatures

Approver	Date
Erin Kobetz-Kerman: Professor	02/2021
Johanna Stamates: Executive Director, Research Compliance	02/2021
Helen Miletic: Director, GxP Compliance	02/2021

Applicability

University of Miami, University of Miami Ambulatory Care Surgery, University of Miami Hospital and Clinics, University of Miami Laboratories, University of Miami Medical Group