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University of Miami Medical Group	Origination:	02/2021
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	Owner:	<i>Helen Miletic: Director, GxP Compliance</i>
	Area:	<i>Research Compliance and Quality Assurance</i>
	References:	
	Applicability:	<i>University of Miami System-Wide</i>

Responsibilities of Researchers Using Electronic Signatures

PURPOSE:

Researchers using electronic signatures in the conduct of human subject research must be aware of the associated responsibilities.

SCOPE:

This policy applies to all researchers at the University of Miami who are using electronic signatures in the conduct of human subject research. This applies to both FDA-regulated and non-FDA regulated studies.

POLICY:

It is the policy of the University of Miami that electronic signatures are equivalent to handwritten signatures. Researchers using electronic signatures in the conduct of human subject research are responsible for actions taken under their electronic signature. As such, the following is strictly forbidden:

1. sharing of passwords
2. access sharing whereby an individual logs into a system and allows another individual to work under their login identity

To safeguard the integrity of electronic signatures, researchers must take all reasonable steps to ensure that their credentials are not compromised, including but not limited to:

- A. not sharing passwords
- B. not allowing others to work under their credentials
- C. logging out immediately once the work is complete
- D. never walking away from a computer without logging out
- E. never writing down the password and storing it near the computer

Failure to adhere to this policy shall be subject to disciplinary actions.

DEFINITIONS:

Electronic signature: a computer data compilation of any symbol or series of symbols executed, adopted, or authorized by an individual to be the legally binding equivalent of the individual's handwritten signature

FDA: Food and Drug Administration

PROCEDURE:

Researchers at the University of Miami who are using electronic signatures as part of the conduct of human subject research, are responsible for actions taken under their electronic signature. Therefore, it is the responsibility of these researchers and their study teams to maintain passwords or access to their electronic signatures strictly confidential.

If a researcher discovers or suspects that their electronic signature has been compromised, they should immediately notify the Vice Provost for Research and Scholarship.

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

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