Current Status: *Active*			**PolicyStat ID:** *7291862*
	Origination:		*12/2019*
	Effective:		*12/2019*
	Last Approved:		*12/2019*
	Last Revised:		*12/2019*
	Next Review:		*12/2021*
University of Miami Medical Group	**Owner:**	*Helen Miletic: Director, GxP Compliance*	
	Area:	*Research Compliance and Quality Assurance*	
	References:		
	Applicability:	*University of Miami System-Wide*	

Electronic Medical Record Access by External Parties

PURPOSE:

Federal regulations and international guidelines require Sponsors to ensure monitoring of their clinical research studies. In addition, federal agencies have the right to inspect all documentation relating to a research participant's involvement in a trial. This policy outlines the process and terms for granting access to the University's electronic medical record system to external monitors and auditors, to facilitate compliance with these regulatory requirements.

SCOPE:

This policy applies to all clinical research studies where external monitors/auditors require access to the electronic medical record of research participants, for the purpose of reviewing the conduct of a research study.

POLICY:

It is the policy of the University of Miami (UM) to facilitate "*View-Only*" access of external monitors and auditors to electronic medical records of research participants, for the purpose of reviewing the conduct of human subject research studies.

External monitors and auditors include clinical research monitors from study Sponsors or Contract Research Organizations, as well as FDA Investigators or inspectors from other federal agencies.

This policy limits the access granted to the electronic medical record to only those research participants enrolled in the particular study that is being reviewed and only for the duration of the monitoring visit or audit/ inspection.

DEFINITIONS:

Care Link: Internet-based portal that provides real-time secure access to view patient electronic medical records in UChart

Contract Research Organization: A person that assumes, as an independent contractor with the sponsor, one or more of the obligations of a sponsor, e.g., design of a protocol, selection or monitoring of investigations,

evaluation of reports, or preparation of materials to be submitted to the Food and Drug Administration.

Principal Investigator: An individual who actually conducts a clinical investigation and under whose immediate direction the investigational drug or device is administered, dispensed or used.

Sponsor: A person who initiates, but does not actually conduct, the investigation; that is, the investigational drug or device is administered, dispensed or used under the immediate direction of another individual.

UChart: University of Miami's electronic medical record system

UM: University of Miami

View-Only Access: The ability to view and print electronic records without edit capability

PROCEDURE:

It is the responsibility of researchers and their study teams to follow this procedure to grant "*View-Only*" access to UM's electronic medical record system to external monitors and auditors, upon request.

The process is outlined below:

- The research team must complete the "*Care Link Access Request Form for Research Monitors/Auditors*" available via the PolicyStat Forms platform
- The following key information must be provided on the form:
  - Study number
  - Study title
  - Monitor/Auditor information
  - Onsite visit start date
  - Onsite visit stop date
  - Research participant names and Medical Record Numbers (MRNs)
- The Principal Investigator (or designee) of the study must sign and date the request form
- The completed and signed form must be emailed to ucharthd@med.miami.edu as indicated on the form, a minimum of 2 weeks prior to the visit but no more than 30 days ahead of the visit start date
- UHealth IT will create a username and password for the external monitor/auditor
- Upon login, the external monitor/auditor:
  - will have access to tip sheets to assist him/her with navigating the system
  - must agree to the terms and conditions with respect to not sharing his/her Care Link access
- "*View-Only*" access to the electronic medical record of the research participants listed on the form will be limited to the date range specified on the request form

APPLICABILITY:

The following parties are responsible for knowing this policy:

- Provost, Vice Provosts, Deans, Center Directors, Department Chairs

- Chief Compliance Officer
- General Counsel
- Human Subjects Research Office
- Research Administrators
- Principal Investigators
- Research Professionals
- Office of Research Compliance and Quality Assurance
- Office of Clinical Research Operations and Regulatory Support
- Office of Research and Research Education
- Office of the Vice Provost for Research
- Health Information Management
- UHealth Information Technology

REFERENCES:

- 21 CFR 312.50 – Investigational New Drug Application: General Responsibilities of Sponsors
- 21 CFR 812.40 – Investigational Device Exemptions: General Responsibilities of Sponsors
- ICH-GCP (R2) 5.18 – International Council for Harmonisation-Guideline for Good Clinical Practice: Monitoring

Attachments

No Attachments

Approval Signatures

Approver	Date
John Bixby: Vice Provost	12/2019
Johanna Stamates: Executive Director, Research Compliance	12/2019
Helen Miletic: Director, GxP Compliance	12/2019

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