

UHealth Research Data HSRO Security Assessment

Version: 1.0

Study Number:

Study Title:

Date:

Last Update/Review Date:

Review Cycle: Annual

Primary Data Custodian:

(Provide name and role/title as identified in the study protocol)

Backup to Primary Data Custodian:

(Provide name and role/title as identified in the study protocol, (a backup data custodian is recommended but not required))

I. Data Sensitivity:

A. Identify the level(s) of sensitivity or regulatory compliance for the data collected and/or transmitted during the research: *(Check all that apply)*

- Protected Health Information (PHI) e.g., HIPAA
- Limited Data Set (LDS) as a subset of PHI
- HIV
- Mental Health
- Substance Abuse
- Personally Identifiable Information (PII)
- FDA 21 CFR Part 11 *(required if study involves IND or IDE)*
- De-identified information
- Vulnerable populations *(elderly, minors, prisoners, pregnant women, cognitively impaired, etc.)*
- Government Provided
- Public information *(See UMIT Data Classification Policy)*
- Other *(please explain)*

(Please explain)

II. Data Collection and Storage Media Types

A. Indicate the media type(s) that will be used to store research data:

- Paper *(e.g., case report forms, paper surveys)*
- Electronic

Both

If data collection and storage method is paper only, questionnaire is complete. If electronic or both, please complete Section B.

B. Electronic Data Flow and Transmission

Identify methods and computerized systems used for data collection and processing:

1. Data Sources and Methods (Check all that apply):

- IRB approved patient registry
- Direct email solicitation
- Social Media
- University Hosted Website(s)
- 3rd Party Website(s)

Please explain:

2. Software Environment, Tools And Platforms Used For Research Data Collection And Storage (Check all that apply):

a. University Manage Information Systems:

- UChart (Epic EHR)
- Beacon Research (Epic EHR)
- Velos CTMS (Clinical Trial Management System)
- REDCap (<https://redcap.med.miami.edu>)
- Qualtrics (<https://umiami.qualtrics.com>)
- Secure Workbench (UHealth Research IT)
- Center for Computational Sciences (CCS)
- UM Procured Workstation, Laptop or Server

b. System provided and maintained by study sponsor:

- Yes
- No

If yes, identify information system:

c. System provided and maintained by collaborating institution:

- Yes
- No

If yes, identify information system:

d. University Managed Cloud Services:

- Box
- OneDrive
- Google Drive
- Azure UM Private Cloud

e. Business Unit Managed Platform:

- Lab equipment
- Application/Software
- Medical Device(s)
- Mobile Device(s) (e.g., external hard drives, flash drives, smart devices, smart phones, digital recorders, wearable device)
- MS Excel
- MS Access
- Personally or sponsor owned device (e.g., laptop, tablet, workstation, etc.)

Please provide description of Business Unit or personally managed device types:

f. Other:

Provide description:

3. Secondary Location for Processing and Analysis Platforms/Services

a. Data stored in a processing and analysis platform will be:

- Personally identifiable
- De-identified
- Anonymized
- Limited Data Set
- Government Provided
- Not applicable (a secondary platform will not be used for data analysis).

If a secondary platform will be used, (click all that apply):

b. UM provided and maintained information system:

- REDCap (University of Miami)
- Center for Computational Sciences (CCS)
- Secure Workbench (UHealth Research IT)
- UM Azure Private Cloud
- UM Procured Workstation, Laptop or Server
- UM Procured Mobile Device(s) (e.g., external hard drives, flash drives, smart devices)

c. System provided and maintained by study sponsor:

- Yes
- No

Identify information system:

d. System provided and maintained by collaborating institution:

- Yes
- No

Identify information system:

e. Business Unit Managed Platforms:

- Yes
- No

If yes, identify data analysis platform and location:

f. Other:

- Yes
- No

If yes, identify platform and location:

4. **Data Backup and Recovery**

a. A data backup and recovery method will be utilized:

Yes

No

If yes, identify where study data backups that are not recoverable from sources identified above will be stored: