

Data Security Plan Example

Based on [Template Version 1.4](#)

Internally-Sponsored Study

All entered information is in **red text**.

Additional guidance can be found in the comments in the right column.

Data Security Plan

Study Number: **STU00001111**

Study Name: **Assessment of Data Security Plans for RSS Submission**

Commented [A1]: For Study Number please include the eIRB+ Study Number (STU#####)

Commented [A2]: Include the official full study name as listed on the IRB application

Data Custodian

Additional Reference: [Research Data: Ownership, Retention and Access](#)

Commented [A3]: The Data Custodian is responsible for ensuring that the study's data is handled appropriately. The PI is accountable for proper data handling practices, even if not designated as a Data Custodian.

1) Identify, by name and role/title in the protocol, who will be the Data Custodian. In most cases, this should be the Principal Investigator: **Feinberg Abbott, MD/Principal Investigator**

2) Identify, by name and role/title in the protocol, who will be the backup to the primary Data Custodian: **James Smith, Research Coordinator**

Commented [A4]: A backup Data Custodian recommended but not required.

Data Sensitivity

Additional Reference(s):

* [NUIT Data Access Policy](#)

** [HIPAA Privacy Protected Health Information](#)

*** [HIPAA Privacy Limited Data Sets \(LDS\)](#)

3) Identify the level(s) of data sensitivity that will be collected/maintained during the research. Example categories of sensitivity include HIPAA PHI and/or non-PHI personally identifiable information (PII) <select one or more options>:

Commented [A5]: If collected data falls into more than one category, select all that apply

Legally/Contractually Restricted (FERPA, Illinois Personal Information Protection Act) Information*

NU Internal Information (see NUIT Data Access Policy*)

Protected Health Information (HIPAA defined)**

LDS as a subset of Protected Health Information***

De-identified information**

Public Information*

Other <please explain>

Commented [A6]: If data doesn't fit into any of the above categories, describe the data that is being gathered. Include the specific data fields if possible.

4) Indicate the approximate number of research subjects anticipated <select one or more options>:

Less than 500 research subjects

500 or more research subjects

Other <please explain>

Commented [A7]: Choose the selection that estimates your maximum number of potential research subjects / records.

For multi-site studies, provide an estimate of the number of records that the NU site will be working with.

Data Flow & Transmission

5) Identify the services and platforms used for data collection and processing by selecting the options below:

Recruitment Data Sources <select one or more options>:

- Electronic Medical Records System (directly)
- Northwestern Medicine® Enterprise Data Warehouse (EDW)
- Physician referral
- NU IRB approved patient registry
- In-clinic solicitation
- Public solicitation (e.g., fliers, billboards)
- Direct email solicitation
- Other <please explain>

Input Sources and Input Platforms <select one or more options>:

- Electronic Medical Records System (directly)
- Northwestern Medicine® Enterprise Data Warehouse (EDW)
- NU (or research academia/commercial partner) Client-server Application
- NU (or research academia/commercial partner) Browser-based Application [REDCap]
- NU (or research academia/commercial partner) Mobile Device Application
- Public Cloud Application (e.g., Box.com, OneDrive, Google, Amazon, Qualtrics) <please specify>
- Portable storage (e.g., external hard drives, flash drives, digital recorders)
 - Encrypted?
- Paper Forms (e.g., Case Report Forms, Paper Surveys)
- Lab equipment, medical devices
- Other <please explain>

Commented [A8]: If data is abstracted directly from an NM EMR system, you should only select this box to refer to it (even though the EMR is also a client-server application).

An exception to the EDW policy is also required for cases where data is obtained directly from the EMR.

Commented [A9]: If you are using multiple applications that fit under one check box, please specify each by writing in the names of each application in brackets. (e.g. [REDCap, SharePoint])

Commented [A10]: If you are collecting data in paper form of any kind, select this option.

Processing and Analysis Platforms/Services <select one or more options>:

- FSM/NUCATS Services [Biostatistics Collaboration Center]**
- NUIT Services (e.g., NUcloud, Quest)
- Government-contract Services (e.g., NIH, NSF, DoD)
- Public Cloud Services (e.g., Box.com, OneDrive, Google, Amazon, Qualtrics) <please specify>
- Research Academia/Commercial Partner Services (includes sponsor-provided platforms)
- FSM Department Desktops
- FSM Department Laptops
- FSM Department Smartphone Devices (includes tablets or smartwatches)
 - Encrypted?
- Portable storage (e.g., external hard drives, flash drives, digital recorders)
 - Encrypted?
- Personally-owned devices <please specify>
 - Encrypted?
- Lab equipment, medical devices
- Other <please explain>

6) Describe the flow of research data from input, to processing and storage, including how data will be transferred between each processing location and technology platform: <insert description>

Potential research subjects will be screened by the study coordinator for eligibility during their regular doctor's visit. Eligible subjects will be scheduled for a study visit. During the study visit, the study coordinator will manually enter data onto paper forms. After the study visit, the study coordinator will copy the data into REDCap. Subject name, date of birth, and copy of consent will be entered into StudyTracker. Data exported from REDCap in a spreadsheet will be stored on the department shared drive (FSMFiles), where only study personnel have access. The spreadsheet will be shared between the study team via their shared drive access, REDCap access or if necessary secured @northwestern email accounts. Data will be analyzed by the FSM Biostatistics Collaboration Center. Paper documents will be stored in a locked cabinet in a locked room in the office of the PI.

Commented [A11]: Make sure the selections made in questions 5 and 7 are referenced / explained here.

Commented [A12]: Q5 Input Source and Q7 storage location

Commented [A13]: Q5 Input Source and Q7 Storage location

Commented [A14]: Q5 Source and Q7 Storage location

Commented [A15]: Q5 Processing/Analysis Services

Data Storage

Additional Reference(s):

[NUIT File Sharing Policy](#)

[FSM IT Storage Options](#)

7) Identify each storage location that will be utilized in the course of this research project <select one or more options>:

FSM/NUCATS/NM Managed Storage (e.g., FSMFILES/departmental shared drive, REDCap) [FSMFiles and StudyTracker]

NUIT Managed Storage (e.g., NUcloud, NU Sharepoint)

Public Cloud Storage (e.g., Box.com, OneDrive, Google, Amazon, Qualtrics)

Research Academia/Commercial Partner Storage (e.g., sponsor-provided storage) [REDCap]

FSM Department Desktops

FSM Department Laptops

FSM Department Smartphone Devices (includes tablets or smartwatches)

Encrypted?

Portable storage (e.g., external hard drives, flash drives, digital recorders)

Encrypted?

Personally-owned devices <please specify>

Encrypted?

Lab equipment, medical devices

Other <please explain> [Paper Fomrs]

8) <Question Removed>

Data Access

Additional Reference(s):

[NUIT Data Access Policy](#)

[FSM Information Security & Access Policy](#)

[Identifying the Study Team](#)

9) Identify each individual and their research job role having access to data and confirm that access is consistent with those on the Study Team/Authorized Personnel List of the IRB approved protocol (if applicable) <select one or more options>:

Access is maintained consistent with those on the approved study's Study Team / Authorized Personnel list.

Additional personnel access is required:
<List additional personnel access and their role in the study>

<Please explain other circumstances if necessary>

Data Backup & Recovery – Research data must be recoverable in the event of equipment malfunction, physical facilities impairment, theft or natural disaster.

Additional Reference(s):

[FSM General Information Security Policy \(see Section III Item 9\)](#)

10) Describe the backup and recovery plan for data that is not reproducible from other sources and related research computer programming that may have been customized for this research data collection. Where are backups being stored <select one or more options>:

FSM/NUCATS/NM Managed Storage (e.g., FSMFILES, REDCap, CrashPlan)

NUIT Managed Storage (e.g., NUcloud, NU Sharepoint)

Public Cloud Storage (e.g., Box.com, OneDrive, Google, Amazon, Qualtrics)

Research Academia/Commercial Partner Storage (includes sponsor-provided storage)

FSM Department Desktops

FSM Department Laptops

Portable storage (e.g., external hard drives, flash drives, digital recorders)

Encrypted?

Personally-owned Devices <please specify>

Offsite Location <please specify>

Lab equipment, medical devices

Other <please explain> **paper forms**

11) If FSM/NUCATS/NM Managed Storage is selected above, then backup and recovery services are already included; otherwise describe the frequency at which backups are taken and the schedule of sending backups to an offsite storage location <please describe the data backup plan>: **NA, all electronic data will be stored on FSMFiles.**

Data Retention (Archiving) – Once a research project is completed research data must be stored and secured for the length of time required by the grant, the contract or Northwestern University Policy.

Additional Reference(s):

[University policies for data retention are Retention of University Records \(see Appendix A\)](#)

[Research Data: Ownership, Retention and Access](#)

12) Describe the data retention (archiving) plan including when the data will be removed from the active study storage location to the long term data retention location: <specify the retention period> **Data will be kept on FSMFiles and REDCap for three years following the end of the study. Paper documents will be kept indefinitely at O'Jones storage.**

Commented [A16]: Required question. Explain your selections from question 13 and specify retention periods.

13) Archive data will be stored <select one or more options>:

FSM/NUCATS/NM Managed Storage (e.g., FSMFILES)

NUIT Managed Storage (e.g., NUcloud, NU Sharepoint)

Public Cloud Storage (e.g., Box.com, OneDrive, Google, Amazon, Qualtrics)

Research Academia/Commercial Partner Storage (includes sponsor-provided storage)

FSM Department Desktops

FSM Department Laptops

Portable storage (e.g., external hard drives, flash drives, digital recorders)

Encrypted?

Personally-owned Devices <please specify>

Offsite Location <please specify> **Paper documents stored at O'Jones storage facility**

Lab equipment, medical devices

Other <please explain>