Data Security Plan Example

Based on Template Version 1.4

External Industry-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: STU12345678
Study Name: Sponsored Research Example

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: **Dr. Jane Smythe - PI**

2) Identify, by name and role/title in the protocol, who will be the backup to the primary Data Custodian:
N/A – Dr. Smythe will be the only researcher working with the study data

Commented [A4]: A backup Data Custodian is 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*)*

__***X***___*Protected Health Information (HIPAA defined**)*

_____*LDS as a subset of Protected Health Information****

__***X***___*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>:

__***X***___*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 and Recruitment Methods <select one or more options>:

_____ *Electronic Medical Records System (directly)*

__X___ *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>:

__X___*Electronic Medical Records System (directly)*

__X___*Northwestern Medicine® Enterprise Data Warehouse (EDW)*

_____*NU (or research academia/commercial partner) Client-server Application*

_____*NU (or research academia/commercial partner) Browser-based Application*

__X___*NU (or research academia/commercial partner) Mobile Device Application* ***[Sponsor-provided eCRF]***

_____*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 form 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])

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

_____*FSM/NUCATS Services*

_____*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>*

__***X***___*Research Academia/Commercial Partner Services* ***[Sponsor's EDC]***

_____*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:

A list of patients that match inclusion criteria will be pulled from an EDW report. Patient records in PACS will then be looked up and the abstracted information will be entered directly into the EDC system on sponsor-provided, encrypted tablet devices. Once all data collection is complete, tablets will be returned to the sponsor.

Commented [A10]: Make sure the selections made in questions 5 and 7 are referenced / explained here.

Commented [A11]: Note how each specific system / device is also selected in question 5 or 7:

EDW: Input in Q5
PACS: Input in Q5
EDC: Processing/analysis in Q5 and storage in Q7
Tablet devices (eCRFs): Input in Q5

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)*

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

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

__***X***___*Research Academia/Commercial Partner Storage (e.g., sponsor-provided storage)* **[Sponsor's EDC]**

_____*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>*

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>:

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

__***X***___*Additional personnel access is required:*
Study Monitors / Sponsor

_____*<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)*

__***X***___*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>*

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: ***N/A – all data storage is managed and maintained by sponsor.***

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: **The sponsor will maintain and archive all data through their EDC system. The sponsor will also send the PI a CD or DVD for archival purposes at the conclusion of the study, which will be stored long-term with any other paper records at O'Jones Record Storage for 5 years.**

Commented [A12]: Required question. NU policy requires sponsored study data be retained for a minimum of 3 years following study conclusion / publication.

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)*

__***X***___*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>*

__***X***___*Offsite Location <please specify>* **[O'Jones Record Storage]**

_____*Lab equipment, medical devices*

_____*Other <please explain>*