Research Professionals Network

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Research Professional Network
Documenting Data Flow

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Why should I care about data flow?
Reasons

• Aid communication between offices (e.g., IRB, ISO, ORS, OCRC)
• Help you write your ICF and RDSP documents
• Think through contracts you may need
• Consider risks
• Speed up the process of getting your research project approved and started!
Data Flow Diagrams

A Data Flow Diagram (DFD) is an illustration that details the movement of information in a process.

A DFD can be easily drawn using simple symbols.
Key Points

• Think through the data flow - where data is generated, where it ends up, and who has access to it

• Be transparent

• Who owns the risk?

• What contracts need to be put in place?

• Present all of the information, don’t parcel out the info depending on who’s reviewing it
What types of things to include

1. Any external devices sending and receiving data
2. Data storage: locations and manner
3. Movement of data: where to and from and how it is moving (encrypted?)
4. Type of data
Data Types

• **Sensitive** – Duke is either required by law to protect, or which Duke protects to mitigate institutional risk.

• **Restricted** – not for public consumption, but also does not fit into the Sensitive category; disclosure would not significantly harm the institution.

• **Public** - can be accessible to the general public.
Example

Simple study with a REDCap survey, phone reminders from the team to fill in a daily paper log, and an Access database for tracking.
This may be more detailed than you will need to create, but it is a good practice to think through all of the steps.

Team enters participant info in REDCap

Survey email sent from REDCap to the participant
In this example above all of the data collection and storage live within DUHS – that means it falls under the covered entity.
On the same study you decided you do not want to use paper logs anymore and instead you want to collect some daily data using text messaging (SMS), and you are going to use a commercially available platform to send out text messages and get the data back.
What type of data and how is the data transmitted to and from this service?

Reminder: surveys via REDCap. This is PHI/SEI, and in encrypted in transit.
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Now let’s try one

Duke researcher will collect online survey data using a commercial cloud platform. The also plan to recorded telephone intervention calls from patients and those will be transcribed by an outside provider via a shared Box folder. Finally they will send them text reminders to take medications.

A deidentified copy of the study data will be shared with the study sponsor via Box.
Participant

Commercial cloud survey platform

Survey - PHI/SEI, website with HTTPS encryption

Recorded calls - PHI/SEI, using a Duke managed phone on our side and encryption

Text reminders – PHI/SEI, sent from Duke managed device, not encrypted in transit

Survey - PHI/SEI, web dashboard - HTTPS

Recordings – PHI/SEI, shared via Box

Deidentified unpublished data, restricted – shared via Box

Commercial transcription service

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As this is a third party company, use ICF language to explain to participant. Avoid terms like “secure” or “HIPAA compliant” unless vetted by ISO!
Another practice

You are planning on conducting a study of a new electronic education tool for people with diabetes. Participants would come in for a visit and complete Qualtrics surveys on a tablet, then staff give them a loaner smartphone with a native app on it to use for the study. The app collects self-reported blood glucose levels and provides education about managing diabetes and tracking glucose levels. The app was build by a contractor, and the data is stored on a commercial cloud service before being downloaded to a Duke server.
Blood glucose - PHI/SEI, phone is Duke loaned, conforms to IT requirements

Work with procurement and department IT to get phones and set them up

Built by contractor – consider their access to the data and contractual requirements

Surveys via Qualtrics - PHI/SEI, encrypted - HTTPS

Survey - PHI/SEI, web dashboard - HTTPS

Participant → App on smartphone → Commercial cloud data storage

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Other notes for mobile research

• Who owns and manages the device?
• IT requirements for devices
  – No rooting or jailbreaking, must have current OS, restrict to minimal necessary/least privilege, be encrypted (or request an exemption), and be inventoried
• Permissions
Questions?
More questions or need help?

• Email the outreach team:
  
  DOCR-StudyPlanning@Duke.edu

• Call
  
  681-6665
Thank you!

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