CHICKEN SOUP FOR THE BUSY COORDINATOR

Oct 2023

Collecting, Handling & Storing Data for Research

(Scenario) Principal Investigator (PI), Dr M is looking forward to start his new study. He is unsure on how to collect, store and maintain the research data for the study. Dr M approached his Clinical Research Coordinator (CRC) for assistance. His CRC advices on the following:

1) Data Management - Dr M should ensure that the Study Responsibility Log clearly states who in the research team is responsible for data management activities such as transcription of data to Data Collection Form (DCF)/ Case Report Form (CRF), data entry, and analysis (where applicable). For example, the access to the Investigator File and shared drive folders containing personal data files must be restricted to authorised personnel only (e.g. delegated study team members).

2) Data Collection

- Use only IRB approved DCF/CRF prior to data collection.
- DCF/CRF should not contain information directly identifiable to a research participant (such as name, identity card number) unless it is to be used as a source document.
- Each research participant should be assigned a unique participant identification code to be used on the DCFs/CRFs and any other research-related data.
- Additionally, the research participants' initials may also be entered. The link between the research participant identification code and the research participant identifiers should be stored in a separate document.
- In the instances where a combination of data elements collected on DCF/CRF may potentially identify a research participant; care should be taken to ensure that the information collected is appropriately coded such that it cannot be traced back to the individual without the linking code unless it is to be used as a source document.

3) Research Data Capture Tools And Application

Dr M is strongly encouraged to use the Research Electronic Data Capture system (e.g. REDCap) for data capture. Alternatives could be explored, but they must comply with institutions' IT security recommendation.

- Private and public Cloud & Google Drive should not be used to capture Patients' Personal Data. Only corporate approved Cloud services (i.e. HCloud) is allowed.
- Data capturing tools used in pharmaceutical trials are allowed provided they comply with institutions' IT security recommendations.

4) Data Protection - Seek to use anonymised data for Dr M's research or for datasets to be processed for statistical outputs to safeguard research participant confidentiality from exposure or loss as far as possible.

- All personal data files (containing patients' name, NRIC etc.) must be protected with strong passwords that align with HealthTech Instruction Manual (HIM).

"Anonymised data" refers to data that is heavily processed to the extent that it is very unlikely a unique individual can be re-identified evidently (spontaneous re-identification), or through attempts to match with other identifiable datasets or publicly available information.

5) Storage Of Research Data - Corporate approved secure data storage facilities (e.g. Storage Area Network (SAN), Sharepoint or equivalent) should be used for the storage of research data. Ensure only authorised corporate devices (e.g. external hard disks, thumb drives) are used to store or transfer Dr M's research data. Corporate issued storage devices should only be accessed and used by authorized persons. Dr M should not use personal hard disks or thumb drives as they are unauthorized and should not be utilized.

References:

- NHG PCR SOP 501-B08 Data Collection and Handling
- NHG Research Compliance Unit Policy 1601-B01
- NHG Research Data Policy

Additional Readings:

- https://www.pdpc.gov.sg > Help-and-Resources > Guide to Basic Anonymisation
- HealthTech Instructional Manual https://www.moh.gov.sg > For Healthcare Professionals > Policies and Guidelines > HealthTech Instructional Manual

REMINDER: Readers are advised to comply with their Research Institutions and/or approving IRBs guidelines and/or SOPs relating to Research Data Management.

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