CHICKEN SOUP FOR THE BUSY COORDINATOR

JULY 2022

Research Data Management (Data Collection, Storage and Transfer)

Scenario

A new Clinical Research Coordinator (CRC), A, has been tasked by the PI of a study to assist in the research data collection, storage and transfer (while ensuring confidentiality of the data being handled). What should CRC A do?

CRC A should first be trained on and familiarised with the Personal Data Protection Act (PDPA) and applicable Research Institution's policy and SOPs on research data management.

Note: As the Principal Investigator (PI) is responsible for protecting confidentiality of research subjects, the PI 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 CRFs, data entry, and analysis (where applicable).

How can CRC A ensure confidentiality in research data collection and storage of data?

1. Data Collection Forms (DCFs) should not contain information directly identifiable to a subject (e.g.: name) unless it is to be used as a source document. Instead, subjects should be assigned an unique identification code. In addition to the subject identification code, subject initials may also be entered. The link between the subject identification code and identifiers should be stored in a separate document.

2. All personal data files (containing patients' name, IC no. etc.) must be protected with strong passwords (e.g. minimally 12 characters, include a mix of numbers, symbols and upper/lower case letters, and does not contain any personal information (e.g. Name) (For super user having administrators with privilege access, password must contain at least 15 characters)

3. Researchers are 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 IHiS security recommendation.

4. Research data and research documents should be stored in corporate approved secure data storage facilities (Storage Area Network (SAN) or equivalent) managed by IHiS.

5. Researchers should seek to use anonymised data for their research or for datasets to be processed for statistical outputs to safeguard patient or participant confidentiality from exposure or loss as far as possible. The use of anonymized data is outside the scope of the Personal Data Protection Act. Researchers can obtain anonymised data from the institution's Information Management (IM) team or equivalent.
   "**Anonymised Data**" means data from which the subject(s) cannot be identified by the recipient of the information. All information, held individually or collectively, which could identify the subject(s) must be removed.

How can CRC A transfer data safely?

1. Only authorised corporate devices (corporate-issued encrypted external hard disks and thumb drives) should be used and only for specific circumstances. For example, to transfer data between computers and when sharing data with collaborators or individuals beyond the institution network. It is strongly advised to track the issuance and use of corporate issued devices. Personal hard disks or thumb drives are unauthorised and should not be used for transferring subject related-data.

2. Personal email accounts cannot be used to send patients' or research subjects' personal data. Emails containing personal data must not be forwarded to personal email accounts.

3. If transferring data out of institution/ overseas, the organisation transferring out data must have taken appropriate steps to ensure its own compliance with the data protection requirements in the PDPA while the personal data to be transferred remains in its possession or under its control (The Personal Data Protection Regulations 2014). There should be a research agreement for the transfer of data in accordance to the PDPA requirements.

References:

1. NHG Research Website: Personal Data Protection Act (PDPA) NHG :: RDO :: Personal Data Protection Act (PDPA)
2. NHG Research Data Policy, version 1, dated 11 May 21
3. NHG PCR SOP 501- B08 Data Collection and Handling

Article Contributed By: **Emily Tay, Research Assistant, National Skin Centre**
Edited By: NHG Group Research, OHRPP

Proudly brought to you by: Clinical Research Coordinator Society (CRCS)
(researchcoord@nhg.com.sg)