CHICKEN SOUP FOR THE BUSY COORDINATOR

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Study Data Collection and Database Maintenance

Scenario: A Principal Investigator (PI), Dr. A was conducting a Human Biomedical Research (HBR) study involving the collection of blood samples for research purposes. The Research Electronic Data Capture (REDCap) System was used to store the study database, which would then be used for data analysis. Data would be transcribed from the subjects' medical records into the REDCap database. Dr. A also captured the **subjects' NRIC numbers** in the REDCap database (storing the research data), for easier reference to check if a potential subject had previously been recruited into the study.

Can personal identifiers be captured in the study database?

Study databases containing data for analysis should not contain subject identifiers. Studies may use Data Collection Forms (DCFs) or Case Report Forms (CRFs) to capture the information required in the study database for data analysis. DCFs or CRFs (whether it is a hardcopy or an electronic copy) should not contain information directly identifiable to a subject (such as name, identity card number) unless it is to be used as a Source Document.

Each subject should be assigned a unique subject identification code to be used on DCFs, CRFs and any other research related documents. In addition, subject initials may also be entered. The link between the subject identification code and the subject identifiers should be stored in a separate document (e.g. in the Subject Identification (ID) Log).

What is the difference between Source Documents and DCFs/CRFs?

Source Documents contain original records and certified copies of original records of clinical findings, observations, or other activities in a research study that is necessary for reconstruction and evaluation of the research. It is where information is first captured (e.g. medical records, lab reports, study questionnaires etc.).

DCFs/CRFs are hardcopy or electronic forms designed to record study required information for data analysis. DCFs/CRFs may be used to directly record study observations and findings (i.e. used as a source document) or it can be used to consolidate information from existing source documents (e.g. medical records) for study analysis.

What should Dr. A have done?

Dr. A should have replaced the NRIC numbers with subject identification codes in the REDCap database to protect subjects' privacy and confidentiality of data. Dr. A could refer to the Subject Identification (ID) Log if identifiers were needed for verification purposes.

Dr. A should ensure that all personal data files e.g. Subject ID Log (containing patients' name, IC no. etc.) are protected with strong passwords *(e.g. minimally 8 alphabets, includes upper and lower case and special character and cannot include the name of the Principal Investigator).*

What requirements should the study team follow when collecting data and maintaining a study database?

1. Research staff should be fully compliant to the study ethics approval, Proper Conduct of Research (PCR) SOPs, Institutional SOPs/guidelines and applicable local regulations e.g. Personal Data Protection Act (PDPA), Human Biomedical Research Act (HBRA), HealthTech Instruction Manual – Data Management Chapter (HIM-DM).
2. Reasonable steps and safeguards including rendering information non-identifiable should be taken to avoid accidental or unlawful loss, modification or destruction, or unauthorised access, disclosure, copying, use or modification. For example, data in study databases should be coded, stored in a validated system (e.g. have audit trail, access control) and only accessible to designated study team members.

References:

1. *NHG PCR SOP 501-B05 (Documentation) & NHG PCR SOP 501-B08 (Data Collection and Handling), section 4.1 and 6.1*
2. *ICH GCP E6 (R2) Glossary 1.11 and 1.52*
3. *Human Biomedical Research Act (HBRA) 2015, Part 5, Section 27(1)*
4. *1601-B01 NHG Research Data Policy (only NHG readers are able to access the policy via NHG SharePoint)*
5. HIM-DM *(only NHG readers are able to access the manual via NHG SharePoint)*

Article Contributed By: **Ms. Zhang Cailian, Senior Executive, RQM, NHG Group Research**
Edited By: NHG Group Research, OHRPP

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(researchcoord@nhg.com.sg)