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Translation of consent documents
For investigator-initiated research studies, investigators should include the costs of consent documents translations into grants and contracts. It is the responsibility of the Principal Investigator to ensure that there is provision of adequate resources to obtain proper informed consent from the subjects.

DSRB has developed the following recommendations for translated consent documents, applicable for all types of research studies:

- A certified translation is preferred. This should be accompanied by a letter of certification from the translator or translation service provider.

- For Investigator-Initiated studies, whereby cost of translation is a factor of concern, DSRB accepts documents translated by an individual fluent in the given language in place of a certified translation. A letter from the translator describing their qualifications should be provided with the translated documents.
  More information on the guidance will be released to the research community in the coming months as DSRB seek to help Investigators ensure compliance to the recommended revisions in the informed consent processes.

Other References:
Health Sciences Authority Website (Frequently Asked Questions) - [H] INFORMED CONSENT FORM (ICF)
http://www.hsa.gov.sg/publish/hsaportal/en/health_products_regulation/clinical_trials/faqs.html#(H)

Protocol Non-Compliance:
Compromising the Privacy and Confidentiality of Subject's Information

Background
A multicenter study involving several sites in Singapore recently have been sending hardcopies of the Case Report Forms (CRFs) from the various participating sites to the overall Principal Investigator for consolidation and filing. However, attached to the CRFs were also copies of the source documents and records from the various participating sites. This included subjects' admission records, medical history, etc.

Findings & Implications
The study team had attached a copy of source document/records with the CRFs to facilitate in the verification and clarification of potential discrepancies.

However whilst doing so, the study team had inadvertently compromised on the research subjects' privacy and confidentiality as records containing their identifiers and medical information had been sent out to the various institutions.

Tips and Recommendations

a. Data entry should be completed at site and data should be verified with source data/documents before it is entered into case report forms.

b. Case report forms should not contain any subject identifiers (eg. Name and NRIC number). Instead, unique codes could be assigned to subjects when data is being collected. These codes would be linked to subject identities in a separate and secured document to minimize the risk of exposing subjects' identities.

c. Research data sent outside the institution should not contain any subject identifiers, unless specific approval has been obtained from DSRB. Principal Investigators should also check their institution policies with regards to data management or transfer of data outside of the institution and obtain necessary approval before releasing patients' records to members located outside the institution.

d. If there is a need to send copies of source records outside your institutions; subjects' identifiers should be obliterated or obscured.. This can be done by using a black marker and photocopying the document to ensure that the subject identifiable information cannot be seen.

References from NHG – Proper Conduct of Research SOPs (PCR-SOPs):

[PCR 501-B08 Item 4.] The CRFs should not contain patient identifiers such as name, date of birth, address, etc. Each subject should be assigned a unique subject identification code which should be used in the CRFs, serious adverse event reports, UPIRTSOs and any other research related data. In addition to the subject identification code, subject initials may also be entered. The link between the subject identification code and the subject identifiers should be stored in a separate document.

[PCR 501-B05 Item 9.] To protect the confidentiality of subjects, the CRF should not have a provision to enter the subjects' name. The CRF should be linked to the subject only by subject identification code and if needed the subject initials. Sticky labels with the subject name and other personal information that is generally used in institutions for medical records and other forms should never be stuck on CRF pages. When laboratory test results are filed as part of the CRF, the subjects' name should be obscured.

PCR 501-B05 (Definition) b. Source Data – All information in original records and certified copies of original records of clinical findings, observations, or other activities in a clinical trial that is necessary for reconstruction and evaluation of the research. Source data are contained in source documents.

The NHG Proper Conduct of Research Standard Operating Procedures are found at the following portal:

http://www.research.nhg.com.sg/wps/wcm/connect/romp/nhgromp/resources/research+sops

Protocol Non-Compliance:

Compromising the Privacy and Confidentiality of Subject's Information

Q1: What is the Purpose of having Source Documents?

The fundamental purpose of source documents is to confirm the existence of the subject; confirm the validity of the trial conducted and the integrity of data collected. Therefore, in a clinical trial, records on which clinical observation are initially recorded are considered source documents. These records are also legitimate raw data that supports a trial's findings. At an investigational site, usually a hospital, the medical record is often the source documentation. It can also be a computer print out of laboratory value results or patients' diaries.

Q2: What are source documentations and how is it used in clinical trials?

Source documentation serves to substantiate the integrity of the trial data collected, which include original documents related to the trial, to medical treatment, and history of the subject. To substantiate the integrity of the trial data collected, the information on a subject's medical record should correspond to the data on the case report form, and in turn should support the data listings and statistical results which are provided to regulatory agencies.

According to Singapore Guideline for Good Clinical Practice (SGGCP) 4.9.3, data reported on the CRF, that are derived from source documents, should be consistent with the source documents or the discrepancies should be explained.

Definition/Glossary:

Source data are information in original records and certified copies of original records inclusive of original records of clinical findings, observations, or other activities in a clinical trial that is necessary for reconstruction and evaluation of the research. Source data are contained in source documents.

Source documents refers to all documents that have source data, including original documents, data, and records (i.e. hospital medical records, clinical and office charts, laboratory notes, memoranda, subjects' diaries or evaluation checklists, pharmacy dispensing records, recorded data from automated instruments, copies or transcriptions certified after verification as being accurate copies, microfiches, photographic negatives, microfilm or magnetic media, x-rays, subjects files, and records kept at a pharmacy) at the laboratories, and at medico-technical departments involved in the research.

Case report forms are printed, optical or electronic document designed to record all of the protocol required information for each study subject.

References:

- Singapore Guideline for Good Clinical Practice (SGGCP
- NHG PCR SOP 501-B05: Documentation
- Good Clinical Practice: A Question & Answer Reference Guide, May 2011 (Published by Barnett Education Services)

Reference Guide: Protecting Privacy and Maintaining Confidentiality

The Office of the Human Research Protection Programme of UCLA published a quick reference guide or tool intended to aid researchers and IRB members to ensure that adequate provisions exist for the protection of research participant privacy, the maintenance of confidentiality of identifiable research data and data security.

Some of the issues to consider in protection of subject's privacy are explained in this guide.

Protecting Privacy:

Privacy is about people and their control over the factors of extent, timing, and circumstances of sharing oneself whether physically, behaviorally, or intellectually with others.

For privacy in research, the following factors are considered:

a) Subject Population (cultural norms and age may affect privacy preferences)
b) Recruitment Methods (acceptable methods of identifying and contacting subjects)
c) Sensitivity of the Information being collected (the greater the sensitivity, the greater the need for privacy)
d) Method of Data Collection (e.g focus group, individual interview, covert observations)

Maintaining Confidentiality:

Confidentiality pertains to data and is explained as treatment of information that an individual has disclosed in a relationship of trust and with the expectation that it will not be divulged to others without permission in ways that are inconsistent with the understanding of the original disclosure.

For the maintenance of confidentiality, the following factors are to be considered:

a) Research Design (minimizing the need to collect and maintain identifiable subject information)
b) Collecting and maintaining Identifiable Data (protocol includes safeguard to maintain confidentiality of data and data security appropriate to the degree of risk from disclosure)
c) Provisions to maintain confidentiality of data (should be included in the protocol)
d) Limit access to Data (the informed consent states who should have access to the data, usually authorized personal e.g auditors, regulatory inspectors)

For more detailed information, reference to the guidance document is recommended (link below).

Reference:

UCLA Office Of Human Subject Protection Program (OHRPP)'s Quick Reference: Protecting Privacy and Maintaining Confidentiality in Research, AAHRPP Elements – II.2.B., II.3.D-F, II.5.A.