NHG RESEARCH QUALITY MANAGEMENT PROGRAM

QUALITÉ

THE PROGRAM WITH A MISSION TO ENSURE AND ENFORCE THE RESPONSIBLE CONDUCT OF RESEARCH MEETING HIGH ETHICAL STANDARDS.

Informed Consent Documentation

The Use of Short Form Consent Forms

What is the Short Form Consent?

Informed consent must be obtained from all human subjects, prior to their participation in any research studies approved by the NHG Domain Specific Review Board (DSRB), unless the process has been waived by DSRB.

In addition, DSRB recognizes the requirements of Good Clinical Practice and United States Food & Drug Administration Code of Federal Regulations, that the informed consent document should be in a language understandable to the subject. However, in view of the budget constraints of investigator-initiated research studies, DSRB recognizes the fact that sometimes it is not possible for investigators to develop translated versions of the consent document.

Considering the above, DSRB created a Short Form Consent Template for these researchers to obtain consent from non-English speaking subjects, where a translated version of the complete set of consent documents is not available. The Short Form Consent Template is intended to be used as a tool, in addition to the original English consent document, and the consent process and procedure has to be performed or obtained in the presence of an investigator, translator, impartial witness and subject. The subject would then sign on the Short Form Consent Template which was in the language understandable to him/her.

Health Sciences Authority's Recommendation on the use of Short Form Consent

In HSA's recommendations of the informed consent process, for subjects who were unable to read the informed consent form, there is no legal provision for the subjects to sign on the Short Form Consent alone (without signing on the original English consent document).

Hence, in order to harmonize with HSA's requirements, DSRB will be recommending some changes to the practices of informed consent for non-English speaking subjects.

New Recommendations on the Use of Short Form Consent

Consent from non-English speaking subject
The preferred method of obtaining informed consent from non-English speaking subjects, is to provide the subjects with consent forms written in the language understandable to the subject (i.e. translated version of the complete Patient Information Sheet & Consent Form).

For Investigator Initiated Studies
For all types of research studies (for the recruitment of non-English speaking subjects, where a fully translated ICF is not available), investigators are allowed to conduct the informed consent process for the non-English speaking subjects using the DSRB-approved Short Form Consent Template. However, the short consent form must be used together as a complete set with the DSRB-approved English version Patient Information Sheet & Consent Form.

- The Subject, Investigator and Impartial witness need to sign on BOTH the Short Form Consent Form and the English version Patient Information Sheet & Consent Form.
- These 2 documents are considered a set of documents, and a copy of the full set of documents is to be provided to the subject.
- A document footer and a page number will be required as essential elements on these documents. This is an added measure to ensure the study team and the subject understand that they are indeed a set of documents.

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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