Qualité

Non-Compliance Report: Informed Consent Process for Non-English Speaking Subjects

At a recent review of an investigator-initiated study, it was noted that the informed consent process with non-English speaking subjects had not been carried out according to the NHG Proper Conduct of Research (PCR) procedures.

The study team had used an approved English version of the informed consent form (ICF) to consent non-English speaking subjects, and this consent process had been done using a study team member as the witness.

What the study team should have done:

(A) To recruit non-English speaking subjects, the study team should have utilized utilsed properly translated informed consent forms which had been submitted and acknowledged by DSRB.

(B) When recruiting non-English speaking subjects, if the study team member was using an English consent form with a translated short consent form, an impartial witness would be required. This witness should not be a member of the study team.

Tips to Help in Your Study Conduct

1. Make sure you are prepared for recruitment of subjects:

Evaluate the recruitment strategies of the study and ensure that there are sufficient resources to carry out subject recruitment. It is important to note that ultimately, it is the Principal Investigator's (PI's) responsibility to ensure that adequate and appropriate resources are available to obtain proper informed consent from all subjects.

2. Ensure proper informed consent documents for non-English speaking subjects are available:

For non-English speaking subjects, the preferred method of informed consent is to provide the subjects with consent forms written in a language understandable to them. As such, it is preferable that a fully translated copy of the approved English ICF should be provided to the subjects. This translation should be performed by either a qualified translator or translation company.

- The fully translated ICF(s) must be submitted to the Domain Specific Review Board (DSRB) for acknowledgement before they can be used at site.

For investigator-initiated studies, where the cost of translation is a concern, informed consent documents can be fully translated by an individual who is fluent in the given language.

- These fully translated ICF(s) must also be submitted to DSRB for acknowledgement before they can be used at site.

In the event that the ICF cannot be translated, investigator-initiated studies can combine (1) the approved English language ICF together with (2) the short consent form (SCF) in the language understandable to the subject, and use it for the informed consent process.

An appropriate naming convention of this combined document (1) + (2) would be:

- "Short Consent Form (Chinese) Version X dated XXX for approved English ICF Version X dated XXX".

The SCF template in simplified Chinese, Malay and Tamil are available on NHG Research website.

- The combined consent documents must be submitted to DSRB for acknowledgement before they can be used at site.

3. Informed consent process when utilising the translated SCF:

When the combined SCF document is used, do ensure that:

- The oral presentation and the SCF should be in a language understandable to the subject;
- An impartial witness is available and the impartial witness should be fluent in both English and the language understandable to the subject;
- The study team member who is obtaining consent is not the witness to the consent process;
- The subject / subject's legally acceptable representative, the study team member who is obtaining consent and the impartial witness must sign on both the approved English language ICF and the SCF;
- The subject / subject's legally accepted representative must be provided with a copy of the signed English language ICF and the SCF.
- An original signed copy of the ICF and SCF should also be retained at site.

As described in the Singapore Guideline for Good Clinical Practice (SGGCP) section 1.26, an impartial witness is a person who is independent of the clinical trial. As such, study team members listed in the study responsibility / delegation log should not act as an impartial witness.

The informed consent process should also be clearly documented in the subject's source documents (e.g. medical case notes / study-specific source document templates). The following information should be included:

- Protocol reference (e.g. study name / study number)
- Date of informed consent
- Details of the informed consent process (e.g. use of a translator / impartial witness)
- Documentation that a copy of the informed consent document was provided to subject

WRITE IN TO US!

Confused about what essential documents you need to maintain for your research study? Puzzled about how certain study procedures should be carried out? Clueless about the local regulations and guidelines governing research? Wondering where you can find information and resources to aid your research? Unsure about what proper conduct of research entails?

If you have a research-related question you are unsure about, you are invited to write in to us at researchcoord@nhg.com.sg. Your questions, together with our recommendations, may be selected for feature in subsequent issues of Qualite. In your email, please include your name, job designation, institution and contact information, together with your query.

Remember, other readers facing similar issues may benefit from the questions you ask. We look forward to hearing from you!

Guidance Table on the Informed Consent Process Requirements

Subject or Subject's LAR	Principal Investigator or delegated study team member	Language of written informed consent form	Requirement for Oral Translator / Presenter	Requirement for Impartial Witness
Literate in English	Literate in English	English	**No**	**No**
Literate in local language	Literate in local language	Local language	**No**	**No**
Literate in local language	Literate in English and unable to communicate with the subject / subject's LAR in the required local language	Local language	**Yes**	**No**
Literate in local language	Literate in local language	†English ICF with added SCF in local language	**No**	**Yes**
Literate in local language	Literate in English and unable to communicate with the subject / subject's LAR in the required local language	†English ICF with added SCF in local language	**Yes**	**Yes***
Illiterate or unable to read due to visual impairment	Literate in English and unable to communicate with the Subject/ Subject's LAR in the required local language	English	**Yes**	**Yes***
Illiterate or unable to read due to visual impairment	Literate in English and able to communicate with the Subject/ Subject's LAR in the required local language	English / Local language (the choice of language here should be the language which the impartial witness is literate in)	**No**	**Yes**

† Used only in the event where a fully translated consent document is not available.
** The impartial witness may act as the oral translator if he / she is able to speak the subject's local language.*

References

1. Singapore Guideline for Good Clinical Practice
2. NHG Proper Conduct of Research Standard Operating Procedures (PCR SOP) 501-C01 - Informed Consent Form and Process
3. Short Consent Form templates, available at: https://www.research.nhg.com.sg/wps/wcm/connect/romp/nhgromp/resources/dsrb+forms+and+templates

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Responsible Conduct of Research

The Responsible Conduct of Research (RCR) Unit under the Office of Human Protection Programme (OHRPP) oversees the propagation of an RCR culture within the NHG research community. It also aims to equip researchers with knowledge of research best practices to guide them in making the right decisions, especially in instances that challenge individual values and integrity.

Here is a brief of the eight components of RCR:

- Research misconduct
- Protection of human subjects
- Conflicts of interests & commitment
- Data management practices
- Collaborative research
- Authorship and publications
- Peer review
- Mentor and trainee relationship.

RCR Case Study

The example below illustrates some RCR concepts.

X was a professor at the University of A Big Country (ABC). He was working on a very important research project with his postdoctoral mentee Mr Z. The Dean of University of ABC informed Professor X that he would be recommended for a tenure position if his potential lifesaving research showed promising data within the next few months. Professor X and Mr Z were feeling the pressure to produce results. Mr Z wanted to help Professor X achieve tenure as the professor had been a very good mentor. To this end, Mr Z decided to fabricate some data in order to yield some reportable "positive" findings to the Dean, even though the research had not produced any significant data to date.

Which component or RCR would Mr Z's actions be categorized under?

a. Data Management Practices
b. Collaborative Research
c. Mentor & Trainee Relationship
d. Research Misconduct

Subsequently, the Dean congratulated Professor X and Mr Z on their significant findings from the research and announced that Professor X had very high chances of getting his tenure. Puzzled, Professor X checked through the data records and realised that the data had been manipulated by Mr Z.

What should Professor X do? (Please select the best answer.)

a. Pretend that nothing has happened and request to stop being Mr Z's mentor.
b. Thank Mr Z for helping him attain his tenure and have a celebration.
c. Talk to Mr Z to find out why he had doctored the data records, and then speak with the Dean regarding the manipulated data.
d. Resign because there would be no point in continuing to serve at University of ABC as he might be viewed by others as a fraud.

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Resources

To find out more about the RCR unit, please visit: https://www.research.nhg.com.sg/wps/wcm/connect/romp/nhgromp/hspp/responsibleconductofresearch/responsibleconductofresearch

To find out more about the RCR components, please visit: https://www.research.nhg.com.sg/wps/wcm/connect/romp/nhgromp/hspp/responsibleconductofresearch/corecomponentsofrcr

Correct Answers for Case Studies
1. d 2. c

References
Shamoo, A.E. and Resnik, D.B (2009). Responsible Conduct of Research 2nd Edition. Oxford University Press.