

Qualité

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/dsrp+forms+and+templates>

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Responsible Conduct of Research

The Responsible Conduct of Research (RCR) Unit under the Office of Human Research 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?

- Data Management Practices
- Collaborative Research
- Mentor & Trainee Relationship
- 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.)

- Pretend that nothing has happened and request to stop being Mr Z's mentor.
- Thank Mr Z for helping him attain his tenure and have a celebration.
- Talk to Mr Z to find out why he had doctored the data records, and then speak with the Dean regarding the manipulated data.
- 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/hssp/responsibleconductofresearch/responsibleconductofresearch>

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