



SEPTEMBER 2026

Informed Consent Involving Non-English Speaking Subjects

SCENARIO

1

Dr X, Site Principal Investigator (PI) from a NHG Health Institution, wanted to recruit eligible non-English speaking subjects into his Investigator-Initiated study.



2

The Study team proceeded to recruit the non-English speaking subjects with existing English Informed Consent Form (ICF) to avoid delays to recruitment timeline.



3

Clinical Research Coordinator (CRC) Mandy verbally translated the English ICF to the first 2 Mandarin-speaking subjects. **(without any Chinese-translated ICF and with no impartial witness present)**



4

While preparing for the next recruitment, Mandy discovered that NHG Health DSRB translated Short Consent Form templates were available. She used these for 3 subsequent Mandarin-speaking subjects. **However Mandy, a study team member, signed off as the impartial witness herself.**



5

During a monitoring visit, the study Monitor flagged issues with the informed consent documentation and the use of an impartial witness.

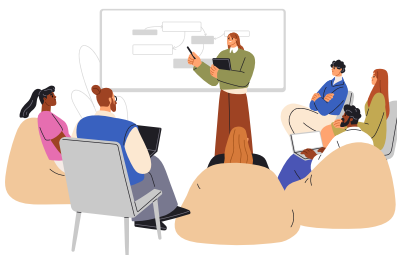


What Should Have Been Done?

Immediate Corrective & Preventive Actions

- ✓ Assess whether affected subjects genuinely understood the study and are willing to continue participation.
- ✓ Submit a Deviation/Non-Compliance (DNC) report to the approving IRB not later than 14 calendar days after first knowledge by the PI. (Per approving IRB's requirements)
- ✓ Re-train the study team on the correct informed consent process for non-English speaking subjects.

- Review policy & SOPs
- Conduct training
- Reinforce best practices



Recruiting Non-English Speaking Subjects



- The preferred approach is to provide subjects with an ICF written in the language understandable to them.



- Where an ICF is not available in the language understandable to the subject, the acceptable alternative for Investigator-initiated studies is:
 - to provide an oral presentation of the informed consent information and
 - document using both the IRB approved English ICF together with the Short Consent Form (in the language understandable to the subject),
 - in the presence of an impartial witness.



- The English ICF serves as the written summary of information to be orally translated to the subject.



- The Short Consent Form states that the elements of informed consent were presented orally.



- The impartial witness should be independent and must not be a member of the study team. The translator may serve as the impartial witness only if they are not part of the study team.



- Refer to PCR SOP 501-C01 Informed Consent Form and Process for more in-depth info.

Important Reminder: Institution-Specific Requirements Apply to ALL Studies at NHG Health Sites



- The requirement to use English ICF and DSRB Short Consent Form for non-English speaking subjects in the presence of impartial witness **applies to all studies recruiting at NHG Health sites.**
- The NHG Health Site PI is responsible for ensuring compliance with IRB's requirements and NHG Health's institutional requirements.

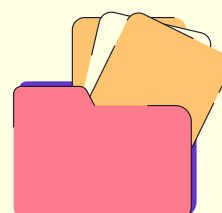
Other Reminders



All parties involved in the consent process (i.e. subject, consenting study team member and impartial witness) must personally sign and date both IRB approved English consent form and Short Consent Form.



The subject must be provided with a completed copy of both signed forms.



For other studies with fully translated documents, ensure the certification of translation is maintained and filed.



Maintain the ICF tracking log. NHG PCR SOPs and templates are available for download from the [NHG Health Research Website](#).

Reference: The Short Consent Form Templates (in local languages) are available at NHG Health research website. PCR SOP 501-C01 Informed Consent Form and Process, Section 8 and Appendix 1 PCR SOP 501-B04 Interactions with DSRB, Section 7

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*Disclaimer: All characters appearing in this article are fictitious. Any resemblance to real persons is purely coincidental.
Best practices may differ between institutions. Readers are encouraged to follow their institution's policies/ guidelines relating to the above scenarios/case study.