NHG RESEARCH EDUCATION

Qualité

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Human Biomedical Research Case Study: Who Can Recruit Subjects?

Case Study

A Principal Investigator (PI) had assigned 2 non-study team members to obtain consent for a Human Biomedical Research (HBR) Study. This had occurred due to the PI's misconception that to avoid bias, an independent party should obtain consent from research subjects. 6 subjects were recruited. Subsequently, the PI had to re-consent the subjects.

What are the implications?

Involving untrained non-study team members in the consent taking process put research subjects at risk of receiving inaccurate and incomplete information. In addition, non-study team members may not be trained to adequately address questions from subjects. This further compromises subjects' understanding of their research involvement.

Outcome

As consent was not appropriately obtained, this non-compliance constitutes a contravention to the Human Biomedical Research Act and was reported to the Ministry of Health.

What the PI Should Have Done

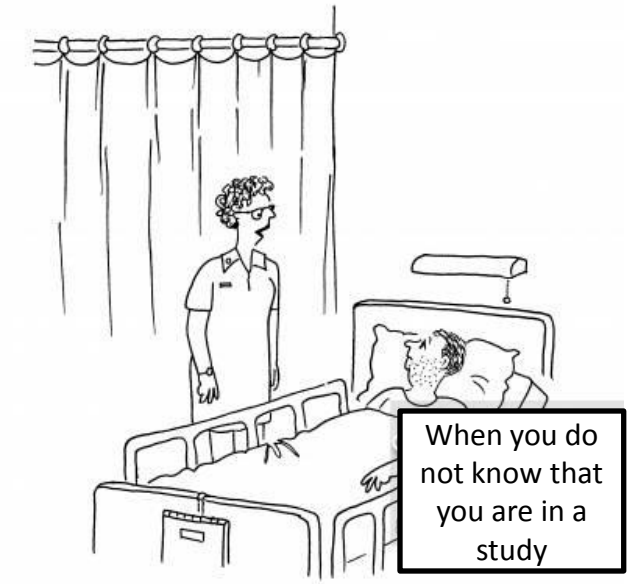
Informed consent discussion must always be conducted by the PI, or a qualified and designated member of the study team as listed in the DSRB Application Form.

If the subject is illiterate or non-English speaking, there should be a witness for the informed consent process. This witness should be impartial (i.e. independent of the study team), and his role is to attest that (1) the research information was accurately explained by the study team to the subject/legal representative (LAR) and (2) the subject/LAR had understood the informed consent.

In addition, for HBR involving research interventions, a "HBR" witness is required for the informed consent process. The role of this "HBR" witness is to ascertain the identity of the individual giving the appropriate consent and to ensure that consent was given voluntarily by the subject without any coercion or intimidation. The "HBR" witness can be a study team member.

References

1. Human Biomedical Research Act 2015
2. Human Biomedical Research Regulations 2017
3. NHG Proper Conduct of Research Standard Operating Procedures - *PCR SOP 501-C01: Informed Consent Form and Process*



"I don't need informed consent to take your temperature."

Ms. Li Huijuan Samantha
Executive
Research & Development Office
National Healthcare Group