OFFICE OF HUMAN RESEARCH PROTECTION PROGRAMME

(OHRPP)

14d. ADDRESSING COMMON ERRORS IN THE DSRB ROAM APPLICATION FORM

SECTION G – STUDY INFORMATION

POPULATION HEALTH (DOMAIN F)

Reference:

NHG ROAM – Online DSRB Application Form Guidebook for Population Health Study

NHG Group Research

National Healthcare Group

Adding years of healthy life

Version November 2022

Study Information

Explain sample size calculations clearly and ensure that these **tally** with recruitment targets (ROAM Section H1).

If no sample size power calculation is performed (i.e. pilot studies), the PI may indicate the following:

- Sample size is chosen based on a **realistic estimation** of the number of patients that that may be recruited over the study period.
- Sample size is derived from **previous similar studies**.

Data analysis – state the software (e.g. SPSS, imaging software, etc.) and/or methods that will be used to analyse relevant data.

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Study Information

Section G4: Sample Size & Power Calculations

Common issues:

- *"No sample size calculation is required."*
- Sample size calculations did not tally with minimum and/or maximum recruitment targets section.
- It was not stated how data would be analyzed and interpreted (required by question).

How does this delay my DSRB application?

- DSRB is unable to evaluate if the scientific merit of the protocol justifies the risk/ benefit ratio.

- Ensure sample size is same as Section G4 and Informed Consent Forms. Consider dropouts (i.e. Min – Max Recruitment Target)

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Study Information

Section G8: What is the estimated time needed to conduct the study?

- This question has been amended for the study team to indicate the estimated time needed to conduct the study

Reminder:

- Buffer time for DSRB's approval as the start date should not be before DSRB approval.
- **NO** study activities should be initiated prior to obtaining DSRB approval.

Study Information

Section G9: The PI is responsible for ensuring that all Research Participants give informed consent before enrolling into the study. Select appropriate applicable consent scenarios.

The common error: Selection of the wrong category of Consent Scenario

There are 3 types of consent:

1. Written Consent
2. Verbal Consent
3. Implied Consent

Study Information

ROAM Section G9: The PI is responsible for ensuring that all Research Participants give informed consent before enrolling into the study. Select appropriate applicable consent scenarios.

1. Written Informed Consent (Research Participants' *identifiers are collected*):

usually from surveys/ focus groups/ interviews/ observations

2. Verbal Consent (Research Participants' *identifiers are NOT collected*):

usually from anonymous surveys/ focus group discussions/ interviews/ observations

Note : Select "Informed Consent" will be obtained from individual participants.

Study Information

Section G9: The PI is responsible for ensuring that all Research Participants give informed consent before enrolling into the study. Select appropriate applicable consent scenarios.

3. Implied Consent (Research Participants voluntarily agree to complete a survey upon being approached for a survey): usually for studies where identifiers' will NOT be collected/ no documentation for consent is needed (i.e. online surveys – NO physical interaction with the Participants)

Note : Select "Informed Consent" will be obtained from individual participants.

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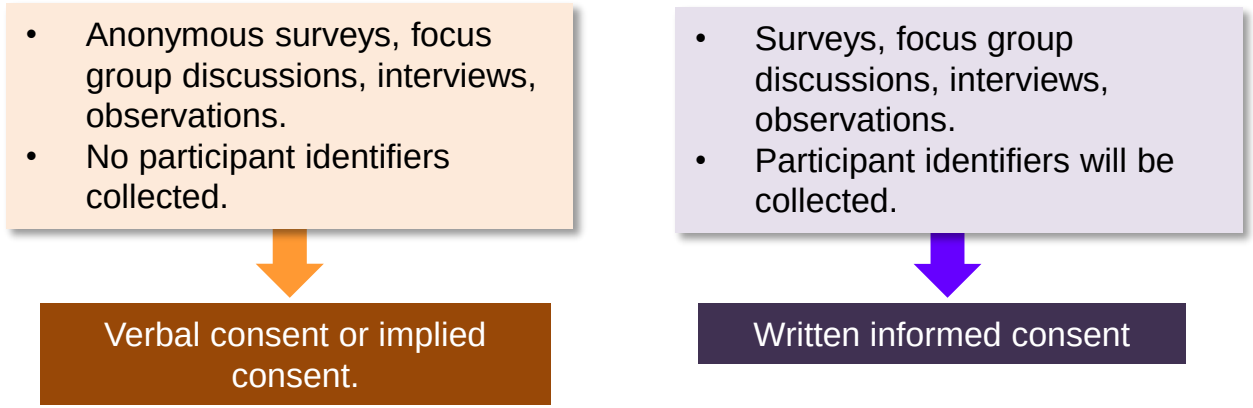
Study Information

Waiver of Informed Consent

When? Usually for the collection of retrospective medical records / data review.

When to use Verbal, Implied or Written Informed Consent?



Note: If the study is a HBR regulated study, Section L “Consent Process – waiver of consent” the waiver criteria relevant to the scenarios selected will be displayed. If the study is not a HBR regulated study, the waiver criteria will be displayed according to the DSRB policies.

Questions?

Refer to www.research.nhg.com.sg

Or contact the NHG Research Education Unit @ researchcoord@nhg.com.sg

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