OFFICE OF HUMAN RESEARCH PROTECTION PROGRAMME

(OHRPP)

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

SECTION K – CONSENT

POPULATION HEALTH (DOMAIN F)

Reference:

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

NHG Group Research

Version November 2022

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Consent

Section K1: Describe <u>when</u> the consent process will take place with the potential research participant, including the time provided for him/her to consider his/her participation in the study.

Reminder:

- Consent process should occur prior to the initiation of any activities.
- The PI is responsible for ensuring that all research participants give informed consent before enrolling into the study.
- Give adequate time to consider participation;
- Patient should be in right frame of mind to give consent

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Section K2: Where will consent be taken (e.g. room, ward, outpatient clinic etc.)? How will privacy, freedom from intrusion and comfort be ensured?

Reminder:

- Research participants should be approached in a quiet and conducive environment to allow the participant to be in the right frame of mind to consider participation.
- The PI should also protect the privacy of the research participant when approaching the patients to participate in research (e.g. researchers who are conducting the consent process in the "Waiting Area" of the general clinic may violate the participant's privacy.
- Ensure suitable venue for consent taking, e.g. quiet, respect patient his/her privacy.
- Environment should be similar/ appropriate even for remote consent.

Consent

Section K3: Who will take consent from potential research participants (e.g. PI, Co-Investigators etc.)?

Common error: Vague reply. Common reply includes, "*the research team will be obtaining consent from the participants*".

How does this delay my DSRB application?

DSRB considers the type of relationship exists between patient and the person approaching the patient for consent and if the person obtaining consent/ assent is appropriate to perform this.

E.g. Are they qualified/ adequately trained?

Consent Process

List the roles of the study team members who will be taking consent, e.g. PI, co-investigator, research coordinator, external surveyors, etc.

The PI should ensure that the study team members who will be taking consent in the study:

- Should be qualified and trained;
- Should/ Will be delegated on the study delegation log.

Consent

Section K4: Besides the consent document, will any other materials or documents be used to explain the study to potential research participants? (e.g. scripts, handouts, brochures, videos, logs, etc.).

Common error:

- No attachment or incorrect attachments (e.g. recruitment brochures/ posters)

Example: Use of graphical consent aids, for studies involving implied consent or verbal consent, the verbal consent script / survey preamble should be included as an attachment. This section is different from recruitment materials.

Example of verbal consent script:
"Hello Mr/Ms XXX, may I know if you would like to participate in my survey on "How important is mental health to you?"
If recipient agrees verbally, to continue with the rest of the survey questions.

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Section K5: Monetary Payments to Subjects

Common error:

- Mode of reimbursement not stated.
- Description of payment schedule to subjects was vague.
- Reimbursements were given out as a lump sum to subjects only at the end of the study.

Clearly specify:

- Mode(s) of payment, e.g. cash etc.
- At which study visit(s) subjects will be paid, and the amount paid each time.

REMINDER: Subject payments should not be disbursed as a lump sum at the end of the study to avoid coercion.

Note: Check with your institution's policy on the mode of reimbursement to subject.

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Section K6: Will consent be documented in the form of a written and signed Informed Consent Form?

If "**No**", Consent will not be documented (verbal consent), waiver of documentation will only granted if certain conditions are fulfilled in either **Category A** or **Category B**.

Category A (All the following are true):

- The only record linking the subject and the research would be the consent document,
- The principal risk would be potential harm resulting from a breach of confidentiality;
- Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern;
- The research is not subject to FDA regulations.

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Section K6: Will consent be documented in the form of a written and signed Informed Consent Form?

Category B (All the following are true):

- The research presents no more than minimal risk of harm to subjects, and

- The research involves no procedures for which written consent is normally required outside of the research context.

Consent

Section K7: Will the study enroll non-English research participants?

Common errors:

- While other parts of the ROAM application form indicated that the study intended to enroll non-English speaking subjects, the response given for this section indicated that only English-speaking subjects would be recruited.

REMINDER: Translated Informed Consent Forms (including Short Consent Forms) & Translated Study Documents (e.g. Subject Diary) Are No Longer Required To Be Submitted to the NHG DSRB

Please ensure there are adequate documentation on tracking on the use of these documents (Refer to PCR Logs 509-017 and 509-018).

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Reminders:

- To ensure equitable selection of research participants, **ALL** potential subjects who meet the inclusion/exclusion criteria should be recruited.
- Non-English speaking subjects can be recruited using translated consent documents / short form consent forms.
- Proper justification should be given to restrict recruitment to only English-speaking subjects.

Questions?

Refer to www.research.nhg.com.sg

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

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