OFFICE OF HUMAN RESEARCH PROTECTION PROGRAMME

(OHRPP)

1c. ADDRESSING COMMON ERRORS IN THE DSRB ROAM APPLICATION FORM

SECTION F – RESEARCH METHODOLOGY

Reference:

NHG ROAM – Online DSRB Application Form Guidebook for Biomedical Study

NHG Group Research

Version November 2022

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Research Methodology

Section F7: Discuss in detail the experimental design and procedures to be used to accomplish the specific aims of the study. (If the study involves the extraction of data from existing medical records/ database, please indicate the period of data that will be extracted and the database to be accessed.)

Common issues:

For studies involving retrospective medical record reviews, the period of data collection was

- Not specified; or
- Encompassed prospective dates.

Research Methodology

- Remember to indicate the period of medical records data that will be extracted for review. Period of interest should be reflected in full elements (ddmmyyyy). *E.g. Data will be extracted from patients admitted to the MICU from 01 Jan 2020 to 31 Dec 2020.*
- Reviewed material must be in existence at the time the research is proposed.
- Collection of prospective data requires informed consent to be taken from subjects.
- Check with your Research Institution on Research Policies involving use of data for research.

Note:

1. 1You are advised to check with your Research Institution's policy on the engagement of a "Trusted Third Party" (TTP) / "Centralised TTP" (CTTP) for the extraction and de-identification / anonymization of datasets before analysis.

2. Information on how data will be extracted and de-identified should be added into Section I1.

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Research Methodology

Section F7: Discuss in detail the experimental design and procedures to be used to accomplish the specific aims of the study. (If the study involves the extraction of data from existing medical records/ database, please indicate the period of data that will be extracted and the database to be accessed.)

Common issues:

For studies regulated under the HBRA, it is not indicated if the study may/will result in any anticipated/ unanticipated incidental findings (IF).

If your study involves IF: Develop an adequate IF management plan (RI policy) to manage IF and submit to DSRB for review.

If your study does not involve IF: Provide justification under Section F7 of the DSRB application form.

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Research Methodology

Section F8:

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.

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Explain sample size calculations clearly and ensure that these **tally** with recruitment targets (Section I1).

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.

Research Methodology

Section F9: List all activities carried out for the purpose of research in this study and attach data collection form.

Section F10: List all activities that are performed for routine diagnostic or standard medical treatment as part of research participant standard of care.

Section F11: Describe subject visits, attach study schedule.

Section H6: Length of time of subject's involvement in study.

Common errors:

- Insufficient elaboration provided for study methodology.
- Research-related procedures and standard of care procedures not clearly distinguished.
- No data collection form / questionnaire attached.
- No document footer on data collection form and/or other documents.

Research Methodology

How does this delay my DSRB application?

- Inconsistencies across sections of the application form and between study documents.
- Generates queries on missing study details / attachments.
- Difficulties in differentiating which procedures are standard of care and which procedures are research-related.
- Missing document footers – difficult to track updated versions of the documents and potential gap in downstream implementation

Research Methodology

Section F9 and 10:
Procedures performed for purpose of research and those done routinely should not be overlapped in both sections.

- ✓ Ensure information is complete and accurate
- ✓ Provide all required documents in the attachments
- ✓ Ensure document footer states the version and date [Note that ROAM does not automatically detect the document version and date]

Questions?

Refer to www.research.nhg.com.sg

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

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