

OFFICE OF HUMAN RESEARCH PROTECTION PROGRAMME  
(OHRPP)

14d. ADDRESSING COMMON ERRORS IN  
THE DSRB ROAM APPLICATION FORM  
SECTION I – RESEARCH PROCEDURES  
*POPULATION HEALTH (DOMAIN F)*

**Reference:**

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

***NHG Group Research***

***Version november 2022***



# Research Procedures

**Section I1: List all activities carried out for the purpose of research in this study and attach data collection form.**

**Section I1: 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 J2: Length of time of subject's involvement in study.**

**Section I1: In your list, indicate the procedures that are being done for non-research purposes.**

## **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 Procedures

## 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 Procedures

Procedures performed for purpose of research and those done routinely should be clearly distinguished in this section.

- ✓ 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]

# Research Procedures

**Section I1: 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. You 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.

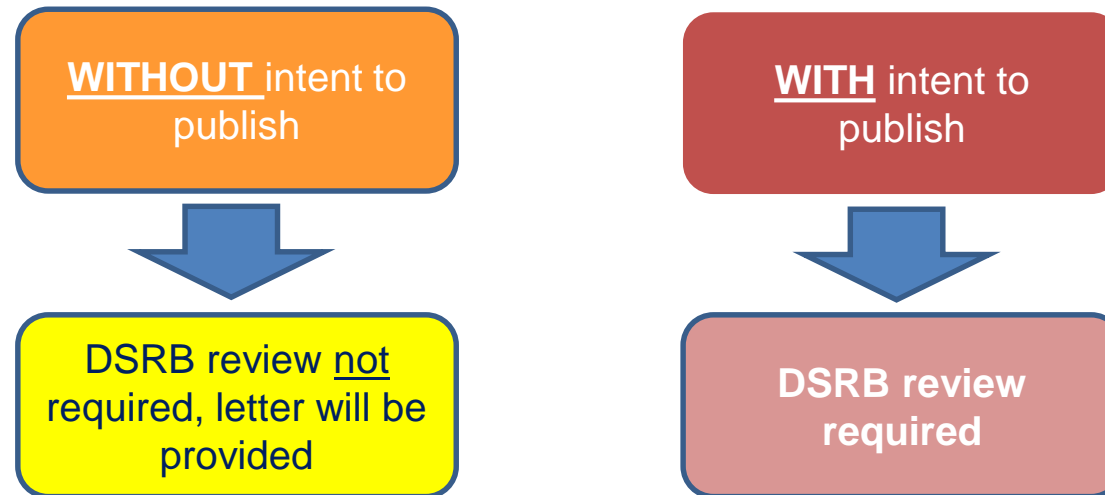
# Research Procedures

**Section I1: Please list all procedures, measures and means by which data will be collected, analyzed and interpreted in this study. If you are extracting data from existing records, please indicate the period of data that will be extracted (E.g. 1 Jan 2000 to 31 Dec 2010) and the database to be accessed.**

**(Note: NEHR cannot be accessed for research)**

**In your list, indicate the procedures that are being done for non-research purposes (i.e. Procedures that are performed as part of curriculum / is performed for diagnostic/standard clinical purposes).**

**If the study is conducted as part of your institution's QI/QA's project**



**Quality Improvement Vs Quality Assurance (QI/QA) project**

# Research Procedures

**Section I2: Please attach the Data Collection Form (if applicable), Questionnaire Form (if applicable), Interview/Focus Group Discussion Guide (if applicable) and/or List of Variables that will be extracted from medical record/database (if applicable).**

**The common error:** No data collection form / questionnaire attached. In addition, no document footer can be found on the document.

Informed Consent Form Version XX, Dated XXXX

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Informed Consent Form Version XX with Short Consent Form (English), dated DD-MMM-YYYY

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## **Reminder:**

Ensure that all documents used in your DSRB study application have a document footer containing the document name, version number and date.

**IMPORTANT NOTE:** The DCF/ CRF should not contain any subject identifiers (e.g. Name, NRIC, DOB) or allow sticker labels containing subject identifiers to be pasted on it unless they are to be used as source documents. This is to ensure data confidentiality.



# Research Procedures

**Section I1: 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 I1 of the DSRB application form.

**Questions?**

**Refer to [www.research.nhg.com.sg](http://www.research.nhg.com.sg)**

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