OFFICE OF HUMAN RESEARCH PROTECTION PROGRAMME

(OHRPP)

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

SECTION N – PRIVACY & CONFIDENTIALITY

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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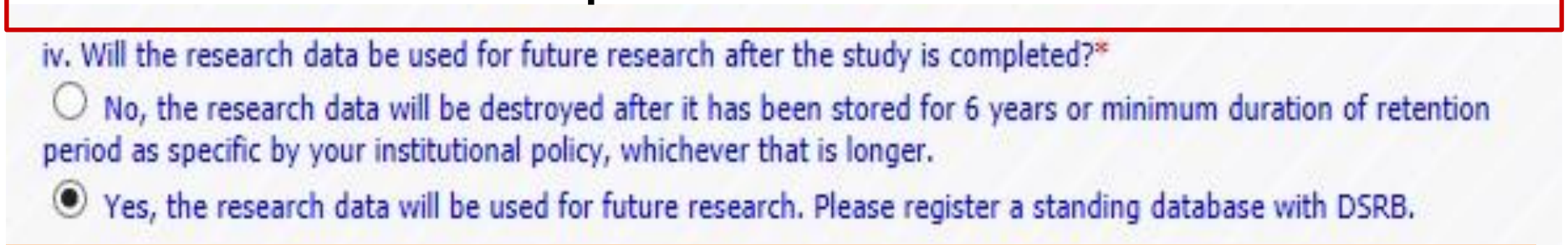
Privacy & Confidentiality

Section N1: What will happen to research data when study has been completed?


iv. Will the research data be used for future research after the study is completed?*

○ No, the research data will be destroyed after it has been stored for 6 years or minimum duration of retention period as specific by your institutional policy, whichever that is longer.

◉ Yes, the research data will be used for future research. Please register a standing database with DSRB.

Common issues:

- PIs unaware of their institution's / NHG's requirements on the minimum period for storage of research documents.
- If data from this research study will be used for future studies, it should also be stated.

How does this delay my DSRB application?

- Local regulations and institutional requirements impose minimum storage periods for research-related documents.
- Discrepant information between ROAM application form and ICF.

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Research Data Confidentiality

The NHG Proper Conduct of Research SOPs recommends a minimum storage period of 6 years for all research documents.

For clinical trials, the ICH GCP E6 (R2) section 4.9.5 stipulates a minimum retention period for clinical trial essential documents.

If data from the current study will be used for future research, this should be clearly explained in the ROAM application form. The ICF should also include a statement to seek the subject's consent on future use of his/her data.

Research Data Confidentiality

Standing databases created primarily for the purposes of possible future research should be registered. Databases that are created as part of a previous DSRB approved research study that has since been completed, may be stored for possible future research. Such databases should be registered upon completion of the research study.

This should be clearly explained in the ROAM application form. The ICF should also include a statement to seek the subject's consent on use of his/her data for future research.

Note: For Non-NHG SDB applications, there are no changes to the existing acknowledgement process.

Note:

- Non-NHG researchers should refer to their Research Institution's/ Institutions' policy on research data.

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Privacy & Confidentiality

Section N2: Who will have access to the research data, and how will access to the research be controlled and monitored? (Please state the personnel who will have access to the study data e.g. PI, co-investigator, study coordinator.)*.

There should be limited access to the study data in order to maintain confidentiality of the research data and subjects identifiers. State how access will be controlled and monitored (i.e. research data will be kept in password-protected file/under lock and key etc.).

Note:
1. Researchers may consider using REDCap to collect their data
2. Researchers are required to adhere/ comply with NUHS & RI requirements/ policies and/or Data Sharing Agreements prior to releasing/ sharing of any data.
3. Researchers are strongly advised to consult with their institutions' Research Office/ CRU if in doubt.

Privacy & Confidentiality

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This should be clearly explained in the ROAM application form. The ICF should also include a statement to seek the subject's consent on future use of his/her data.

Note: For Non-NHG SDB applications, there are no changes to the existing acknowledgement process.

Note:

- NHG researchers – refer to the NHG Research Data Policy for more information.
- Non-NHG researchers should refer to their Research Institution's/ Institutions' policy on research data.

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Questions?

Refer to www.research.nhg.com.sg

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

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