OFFICE OF HUMAN RESEARCH PROTECTION PROGRAMME

(OHRPP)

13g. ADDRESSING COMMON ERRORS IN THE DSRB ROAM APPLICATION FORM

SECTION R – RESEARCH DATA CONFIDENTIALITY

&

SECTION S – BIOLOGICAL MATERIALS

Reference:

NHG ROAM – Online DSRB Application Form Guidebook for Biomedical Study

Group Research

Version November 2022

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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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Research Data Confidentiality

Section R1(ii): 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 RI requirements/ policies and/or Data Sharing Agreements prior to releasing/ sharing of any data.
3. Researchers are strongly advised to consult with the Research Office if in doubt.

Biological Materials Usage & Storage

Section S: Biological materials usage and storage

Decide upfront and state clearly whether your study will deal with:

- Anonymized or coded data
- Anonymized or coded biological samples

For coded data/ biological samples, who will maintain the source code?

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Biological Materials Usage & Storage

Section S1(v) – How are biological materials identified?

Common issue: Confusion between “coding” and “anonymisation” of research data and/or biological samples, resulting in inconsistencies on ROAM application form.

Example:

The Pi and co-PI.

Data collection forms are hard copy and will be stored under physical lock and key in the PI Office. The data collected in anonymous, and study subjects are identified by code numbers.

“**De-identified”** or **‘coded**“ means that the personal identifiers have been extracted from the data, such that any individual handling the data will not be able to match the codes back to the subjects (except for the person who holds the source codes).

"**Anonymised**" means that all of the links between a person and the person's record have been **irreversibly broken** so that it would be virtually impossible to re-establish any of the people in the original record.

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Biological Materials Usage & Storage

vi. How are the biological materials identified? (Please tick all the applicable boxes.)

- [ ] No Identifiers
- [x] Biological materials are coded and the code is maintained at source
- [ ] Identifiers present
- [ ] Other methods - Please elaborate more in the textboxes provided

Coding

d. How will these stored biological materials be identified?*

- ( ) The stored biological materials are stripped of any identifiers and cannot be linked or traced back to its donor.
- (•) The stored biological materials are coded.

Who will maintain the codes linking the stored biological materials and its donor?*

The PI will maintain the codes.

- ( ) By other methods.

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Biological Materials Usage & Storage

vi. How are the biological materials identified? (Please tick all the applicable boxes.)

- [ ] No Identifiers
- [x] Biological materials are coded and the code is maintained at source
- [ ] Identifiers present
- [ ] Other methods - Please elaborate more in the textboxes provided

Anonymisation

d. How will these stored biological materials be identified?*

- ( ) The stored biological materials are stripped of any identifiers and cannot be linked or traced back to its donor
- (•) The stored biological materials are coded.

Who will maintain the codes linking the stored biological materials and its donor?*

The PI will maintain the codes.

- ( ) By other methods.

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Biological Materials

Section S1(iv): Will test results be communicated to the research participants? If not, please explain.*

Section S1(vii)): Will biological materials be destroyed on study completion or stored for future use?

Common issues:
Responses to this section were often discrepant with the information provided in the ICF

Ensure that information entered into the ROAM application form and that in the ICF tally.

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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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