

# 14h. ADDRESSING COMMON ERRORS IN THE DSRB ROAM APPLICATION FORM

## SECTION O – BIOLOGICAL SAMPLE POPULATION HEALTH & SECTION P – RESULTS AND OUTCOME RESEARCH

### *POPULATION HEALTH (DOMAIN F)*

#### *Reference:*

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

*NHG Group Research*

*Version November 2022*

# Biological Sample

## Section O – 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?

# Biological Sample

## Section O1(e) – 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.

# Biological Sample

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

- ☐ No Identifiers
- ☒ 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.

# Biological Sample

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

☐ No Identifiers

☒ 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.

# Biological Samples

**Section O1(d): Will test results be communicated to the research participants? If not, please explain.\***

**Section O1(g): 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.



# Results & Outcome of Research

## Section P1: Will research be disseminated to the community?

**The common error:** “No” commonly selected. However, results published contributes to generalisable knowledge.

If yes, indicate the reason(s) for sharing the information to the community and describe how the results will be disseminated (i.e. through reports, brochures or mass media.)

**Questions?**

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**Or contact the NHG Research  
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