OFFICE OF HUMAN RESEARCH PROTECTION PROGRAMME (OHRPP)

14f. ADDRESSING COMMON ERRORS IN THE DSRB ROAM APPLICATION FORM SECTION L – WAIVER OF CONSENT POPULATION HEALTH (DOMAIN F)

Reference:

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

NHG Group Research



Waiver of Consent

Section L: Justification of Waiver of Consent

The PI is responsible for ensuring that all research participants give informed consent before enrolling into the study.* Click here for help

Please select all the applicable consent scenarios.*

Informed Consent will be taken for study subjects.

Waiver of Informed Consent is requested for study subjects.

to use their individually-identifiable data and/or biological material that was/were obtained or compiled on/after 1 November 2017.

to use their individually-identifiable data that was obtained or compiled before 1 November 2017.

In addition, there will be use of anonymised data and/or biological materials from an independent third party for a specific study population. * Click here for help

Use of individually-identifiable data that was obtained or compiled before 1 November 2017

Q3Bi The research cannot be reasonably carried out without the use of the health information in an individually-identifiable form

Please elaborate and justify why your study meets this criterion. * Click here for help

Common errors:

- Did not select the correct option
- Unable to provide sufficient justification for Waiver.
- Researchers do not additionally select the last checkbox on the use of anonymized data if they use a 3rd party/ the last checkbox is selected when researchers de-identify the data themselves but not through a 3rd party.

Reminder:

Comply with your Research Institution's requirements.



Waiver of Consent

Ensure accurate selection of criteria (Section G9).

Provide adequate and reasonable rationale to justify for Waiver.

Note: Click on the help link available next to the question and provide justification(s) on how the study meets the Waiver of Consent criteria.



Waiver of Consent

Section L5: The study would reasonably be considered to contribute to the greater public good.

Use of individually-identifiable data and/or biological that was/were obtained or compiled on/after 1 November 2017

Q5 The study would reasonably be considered to contribute to the greater public good*Click here for help

The information gained would be very useful in predicting which group of patients will respond to use. This will help clinicians select the group of patients to use

Q6 Do you have any additional comments supporting the waiver of informed consent?*

No

Yes

Use of individually-identifiable data and/or biological that was/were obtained or compiled on/after 1 November 2017 Q5 The study would reasonably be considered to contribute to the greater public good*Click here for help

Common error: Unable to provide sufficient justification for Greater Public Good.

→ Need to justify how the research would be beneficial to the greater public



Definition of "Greater Public Good"

Reference: (17 May 2019) Guidance of the Requirement of Appropriate Consent for the Conduct of HBR and Handling of Human Tissue

What is the definition of "greater public good"?

Generally, research can be considered to contribute to the greater public good if it falls under one of the following categories:

- Epidemiology research or population wide studies at national or regional level with potential direct benefit to the public at large; or
- Research with apparent or tangible benefits with measurable outcomes to the public at large and may include those less privileged community or a subcommunity; or
- c. Research that contributes or could contribute to impact at a national, regional or international level with potential to lead to improvement in policy and prevailing standards on innovation, management and practice in healthcare and other human biomedical related fields.



Questions?

Refer to www.research.nhg.com.sg

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

