

GENERAL CONSIDERATIONS on Ethics Submission

Reference:

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

NHG Group Research

Version November 2022

Restricted, Sensitive - Normal © National Healthcare Group Pte Ltd



General Considerations

1. Ensure each investigators' CV is updated with their current appointment and their relevant institution (accordingly to their ROAM profile).
2. For study(ies) that do not have a hypothesis, PIs are to list the research questions they are trying to address in Section F2 (Biomedical)/ **G2 (Population Health)**. This should not be confused with the study's aim.
3. In the event where study involves both documented consent and waiver of documentation of consent (e.g. implied consent), study team should provide the justification on how study meets the criteria for waiver of documentation of consent under Section P10 (Biomedical) or **Section K8 (Population Health)**.
4. **(Population Health only)** Community Consent in Section G9, it is only used in a setting where obtaining individual consent may be sensitive to local/ cultural and/or political context. Therefore, researchers are required to seek community consent from the appropriate person. This should not be confused with obtaining consent from participants.

General Considerations

5. **(Population Health only)** For Section M1-5, the response should only be application if the study will affect the study population in general; regardless if they participate in the study or otherwise. If the risk mentioned does not affect the whole population/ group, this section should not be filled up.
6. Ensure information on the application form is consistent.
7. Ensure relevant study documents (where applicable) are attached in the application form (e.g. Study Protocol, Informed Consent Forms, FCOI). Information in the study documents are consistent the application form.
8. Whenever changes are made to the study documents, ensure contents and version control of documents have been updated.

Questions?

Refer to www.research.nhg.com.sg

Or contact the NHG Research
Education Unit @
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