OFFICE OF HUMAN RESEARCH PROTECTION PROGRAMME (OHRPP)

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

SECTION H – RESEARCH POPULATION

POPULATION HEALTH (DOMAIN F)

Reference:

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

NHG Group Research

Version November 2022

National Healthcare Group

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Research Population

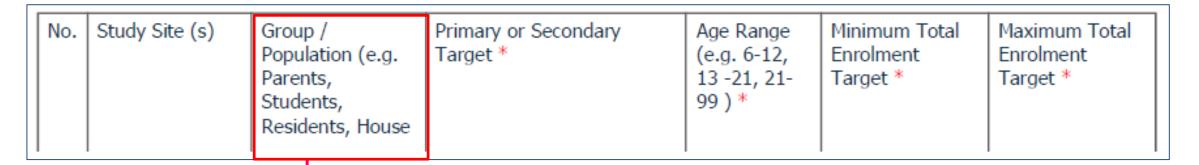**How does this delay my DSRB application?**

To identify if there is any bias in enrolment and that all subjects are included when appropriate.

- Ensure the numbers across Males, Females (or Children) tally with Max. recruitment #

- Ensure sample size is same as Section G4 and Informed Consent Forms. Consider dropouts (i.e. Min – Max Recruitment Target)

- If study has special considerations in recruiting a particular gender, explain in Section H5 (Population Health)

- Section H1: List all applicable population in the (Population / Group) column and specify the age range of each population under the (Age Range) column. The total enrolment target should be the <u>sum </u>of all populations listed.

Submit an amendment to DSRB if you anticipate your recruitment number to increase from the initially approved target.

Research Population

No.	Study Site (s)	Group / Population (e.g. Parents, Students, Residents, House	Primary or Secondary Target *	Age Range (e.g. 6-12, 13 -21, 21-99) *	Minimum Total Enrolment Target *	Maximum Total Enrolment Target *

Common issue:
- Different populations and age range were not listed.

Note: Group/ Population column to tally with section H9 (e.g. if Outpatients was selected in H9, then to state "Outpatients" in this column.

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Section H3: Inclusion Criteria

Common errors: Inconsistency in information between application form and study protocol and/or eligibility checklist.

- Provide a separate list of inclusion criteria for each study population if the study involves different participant groups.

- Define 'healthy controls' if they will be involved in the study.

- Avoid using symbols in the application form as they do not align with the protocol e.g. ">=" in the separate study protocol turns into ">" in the application form.

Note: The inclusion criteria should be in accordance to the protocol and approved by the DSRB

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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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