OFFICE OF HUMAN RESEARCH PROTECTION PROGRAMME (OHRPP)

13di. ADDRESSING COMMON ERRORS IN THE DSRB ROAM APPLICATION FORM SECTION I – RECRUITMENT TARGET

Reference:

NHG ROAM - Online DSRB Application Form Guidebook for Biomedical Study

NHG Group Research

Version November 2022



Recruitment Target

Section I1: Recruitment Target

Section I - Study Sites & Recruitment Targets

I1 Please state the target number of research participants to be recruited for each study site in Singapore. If the exact numbers are not available, please give an approximate number range in the Recruitment Target Minimum and Maximum columns.*

Please note that recruiting subjects beyond the Max. No. without DSRB's approval would constitute a Non-Compliance. If you intend to recruit beyond the Max. No., please submit a study amendment to increase the recruitment target.

For the distribution of Males, Females and Children to be recruited into the study, please use the Recruitment Target Max. No. to provide an approximate distribution ratio.

(Go back to Section B1 to add additional study site)

No.	Study Site	Recruitment Target Min *	Recruitment Target Max *	Males *	Females *	Children *
1		100	100	80	10	0

Click 'Add' to add study site that is missing or click X' to remove repeated study site. For addition of new study site or removing of pre-existing study site from this study, go back to Section B1.

Common issue:

- Numbers do not tally
 - e.g. Male + Female + Child ≠ Max. Target
 - Different from Section F8 (Sample size)



Recruitment Target

Section I1: Recruitment Target

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 *	
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Common issue:

Different populations and age range were not listed.



Recruitment Target

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 F8 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 K4

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

Questions?

Refer to <u>www.research.nhg.com.sg</u>

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

