OFFICE OF HUMAN RESEARCH PROTECTION PROGRAMME

(OHRPP)

5. WHEN IS DSRB REVIEW REQUIRED

Reference:

NHG Investigator Manual

NHG Group Research

Version November 2023

National Healthcare Group

Adding years of healthy life

When is DSRB Review Required ?

DSRB reviews all human subject research that will be:

Conducted within NHG premises including partner institutions under NHG DSRB purview and/or

Utilizes NHG facilities and/or

Conducted by or under the direction of an NHG employee, or

Involves NHG patients.

What Types of Studies Do Not Require DSRB Review?

- **Quality improvement / assessment projects***

  *Exceptions (may require DSRB review depending on the nature of the project) :

  - *When the project is designed to contribute to generalizable knowledge*
  - *Where participants are subjected to additional risks or burdens beyond usual clinical practice.*

- **Case Reports/ Outbreak Investigations/ Disease Management/ Infection Control**
- **Retrospective review of 1-2 case reports**
- **[New – Effective 1 Nov 2023] Studies Involving Anonymised Data and/or Human Biological Materials** *These studies do not meet the definition of human subject research, as there is no use of identifiable private information or identifiable biospecimens. These studies do not require review and approval by the DSRB.*
- **Animal research**

Refer to NHG IM 4th Edition Chapter 1.5 Does My Study Require DSRB Approval & pg.11 NHG IM: Checklist to determine if a QA/QI study will require DSRB review

What Types of Studies Do Not Require DSRB Review?

For QI/QA projects, use the checklist on the NHG research website to determine if your QA/QI study(ies) requires DSRB review.

When Is Ethics Approval Required

1. When is Ethics-DSRB Approval Required?

Any study which involves systematic investigation, including research development, testing, and evaluation, and are designed to develop or contribute to generalisable knowledge is considered research and will require NHG DSRB review and approval if it involves patients, staff, premises or facilities of NHG institutions and all other institutions under the oversight of NHG DSRB.

Click here to learn more about using the ROAM System for submissions to the DSRB.

Click here to find out what documents are required for the submission of an application via ROAM.

2. Why is Ethics-DSRB Approval Required?

All research proposals that intend to enrol human subjects must meet certain criteria before study procedures can be initiated. The criteria are based on the principles of respect for persons, beneficence and justice as discussed in the Belmont Report.

The Principal Investigator is strongly encouraged to submit their application well before the deadline for submission to allow some time for the DSRB to check for any missing documents for information. The DSRB relies solely on the documentation submitted by the Principal Investigator for review.

3. How do I determine if my research requires Ethics-DSRB Approval?

Types of studies that may require DSRB Approval:

- Case series (3 or more subjects)
- Database studies
- Tissue Repositories

Types of studies that may not require DSRB Approval:

- Case reports
- Outbreak investigations
- Disease Management
- Infection Control
- Quality Assessment & Improvement (QA/QI)*.

** This Checklist may be used to determine if a QA / QI study requires DSRB review. Where the response to all questions in the QA / QI checklist is "No", and where there is no intention to share the information with others (i.e. contributing to generalisable knowledge) at the onset of the study, the QA / QI study will not be subject to DSRB review.*

Checklist to determine if a QA / QI study requires DSRB review (Version 30 June 2020)

Where the response to all these questions is "No", the QA/QI study is unlikely to require an IRB review. If you require a formal IRB letter of waiver from review, fill in and submit the DSRB exempt application form for review.

Where the response to any of these questions is "Yes", the QA / QI study may need an IRB review. Fill in the appropriate application form on ROAM and submit for DSRB review.

S/N	Questions	Yes	No
1.	Does the proposed quality assurance activity require additional consent from subjects, beyond what is already obtained for clinical practice?		
2.	Does the proposed quality assurance activity pose any risks for subjects beyond those of their routine care?		
3.	Does the proposed quality assurance activity impose a burden on subjects beyond that experienced in their routine care?		
4.	Is the proposed quality assurance activity to be conducted by a person who does not normally have access to the subjects' records for clinical care?		
5.	Does the proposed quality assurance activity risk breaching the confidentiality of any individuals' personal information, beyond that experienced in the provision of routine care?		

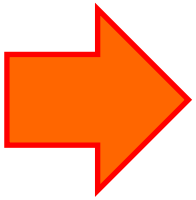
https://www.research/nhg/com.sg > Conducting Research > Who Can Be A Principal Investigator > When is Ethics Approval Required

[4]

What Type of Studies Do Not Require DSRB Review?

When in doubt whether an activity requires DSRB review and approval:

- The Principal Investigator may write to the DSRB Secretariat with a summary of the proposal for preliminary assessment, and for the Domain to advise.



The DSRB will advise accordingly.

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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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