

CHICKEN SOUP FOR THE BUSY COORDINATOR

July 2023

DSRB Application Submission: Selection of Domain & Category of Review for Research Studies

[Scenario] Principal Investigator (PI), Dr Busy, intends to submit a research study to the NHG DSRB for review. Unsure of which Domain and category of review the research study falls under; Dr Busy consulted Ms Joy, his Clinical Research Coordinator (CRC) on this.

Ms Joy shared that prior to the commencement of the research study, approval from the NHG DSRB is required, and provided related information on the DSRB application process and requirements from the NHG Research Website's Resources segment and NHG Investigator Manual to the PI, Dr Busy.

Triaging of Research Studies to the Relevant DSRB Domain

Ms Joy also shared that the PI (Dr Busy) should select the most appropriate NHG DSRB domain to review his research application. His research application will first be assigned to the domain selected by him but may be assigned to another domain based on the NHG DSRB secretariat's determination. The NHG DSRB secretariat will evaluate Dr Busy's choice of domain based on the following considerations:

- a. Dr Busy's discipline – His research study will be triaged to the domain that reviews the discipline under which the research study may be categorised.
- b. Disease studied in the research study – Depending on the primary disease group that is being studied in the research study, it study will be triaged to the domain that includes experts in this disease group.

Categories of Review

All research studies submitted to the NHG DSRB will be classified under one of the following review categories:

- i. Exempt Review – less than minimal risk
- ii. Expedited Review – minimal risk
- iii. Full Board Review – more than minimal risk

The determination of the review category is made by the NHG DSRB. In general, the determination is based on the level of risk in which research participants are exposed to. Research studies that involve minimal or less than minimal risk are reviewed under the Exempt or Expedited review categories, and studies that involve more than minimal risk are reviewed under the Full Board review category.

Note on Application Process

Dr Busy should submit the research application well before the stipulated submission deadline, to allow time for the NHG DSRB secretariat to check for any missing documents and / or information. The materials submitted must be complete and provide sufficient information about the research study, for the NHG DSRB secretariat to adequately assess if the application meets the criteria for approval. After the NHG DSRB Secretariat has thoroughly reviewed the submitted research proposal, it will then be scheduled for NHG DSRB review.

References:

1. NHG Research Website
2. NHG Investigator Manual, Chapter 4 - Submissions to DSRB

REMINDER: Readers are advised to comply with their approving IRBs guidelines and/or SOPs relating to the submission process for their research studies.

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**Disclaimer: All characters appearing in this article are fictitious. Any resemblance to real persons is purely coincidental. Best practices may differ between institutions. Readers are encouraged to follow their institution's policies/guidelines relating to the above scenarios/case study.*

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