OFFICE OF HUMAN RESEARCH PROTECTION PROGRAMME

(OHRPP)

9a. DSRB EXEMPT REVIEW CATEGORIES & REVIEW CRITERIA

BIOMEDICAL DOMAINS A-E

&

POPULATION HEALTH – DOMAIN F

Reference:

NHG Investigator Manual

NHG Group Research

Version November 2022

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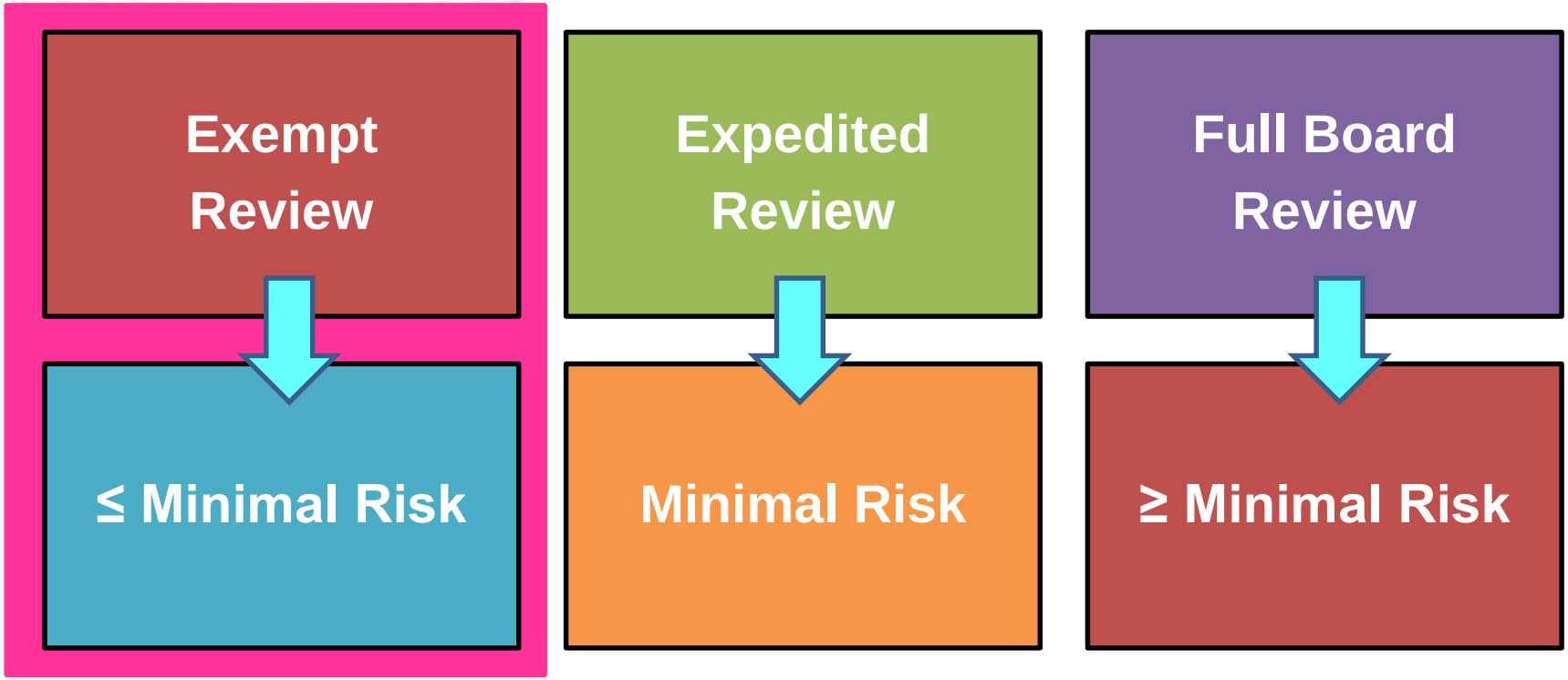
DSRB Review Categories - Exempt

3 routes of review



In general, the determination is based on the level of risk in which research participants are exposed to. Taking into other considerations, DSRB may escalate the category of review as needed.

Refer to Chapter 4.3 of the NHG Investigator Manual for all categories and more examples.

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NHG DSRB Review Category – Exempt

Does Exempt Review mean that my research is exempted from submission to DSRB?

NO

Application is exempted from the requirements of *regulations, NOT from the ethics review and oversight of the DSRB.

Researchers should continue to adhere to DSRB guidelines, Proper Conduct of Research SOPs and institutional guidelines in the conduct of exempt research.

If the research fulfils the review under ^Exempt status, the outcome will be notified.

^If the application does not fulfil any of the exemption categories, the PI will be informed to re-submit the research proposal using the Non-Exempt application form.

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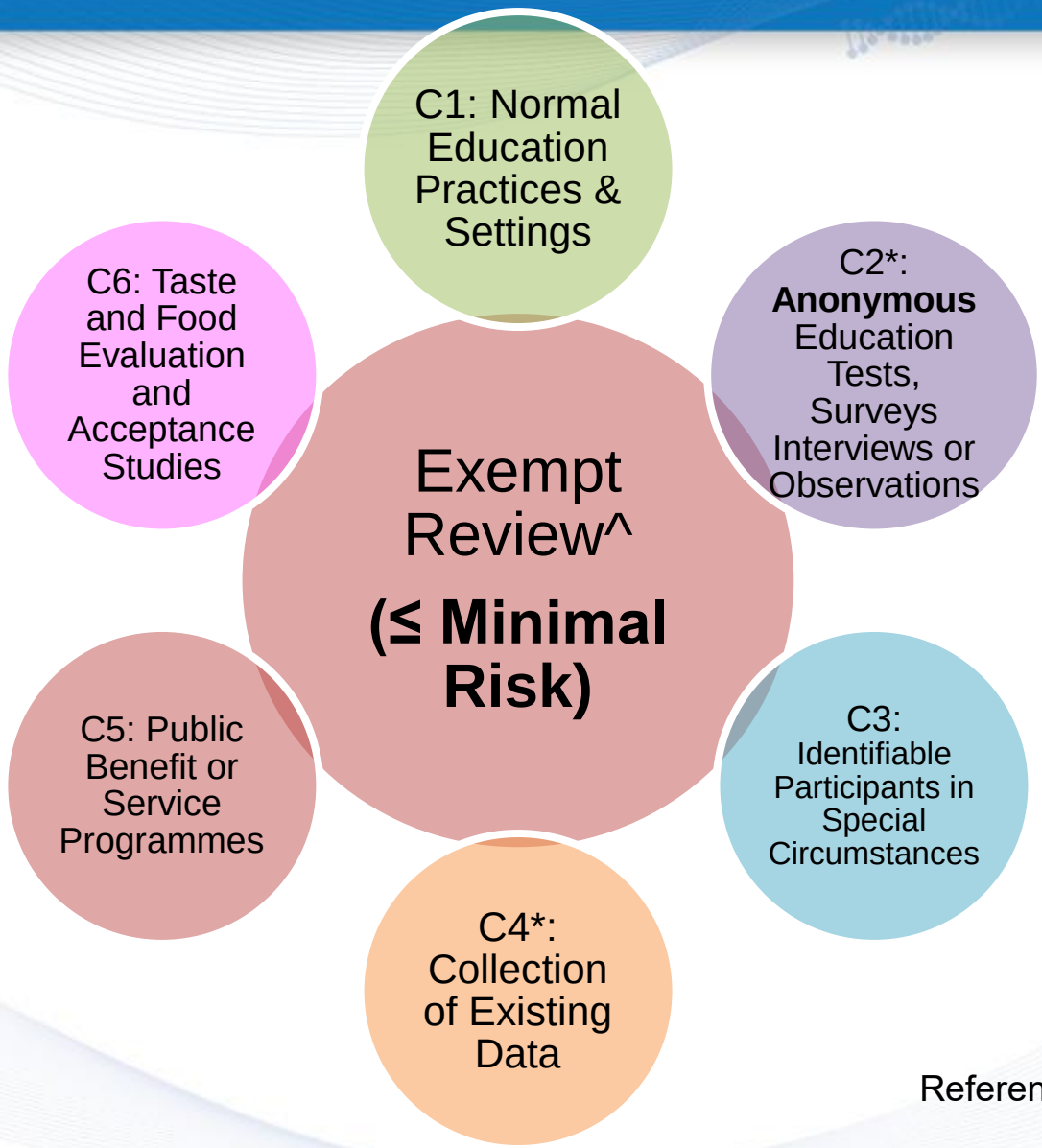
Categories of Research – Exempt



^NOTE:

- Not applicable for research:
  - Involving Prisoners
  - Involving Children (unless research involves observations of public behaviour and the investigator(s) do not participate in the activities being observed)
  - Regulated by US FDA
- To be submitted to DSRB using **Exempt Application Form 2**

*Recording of **identifiable** information is NOT permitted for C2 and C4.

Reference: NHG Investigators' Manual Section 4.3.1

Review Criteria

Submitted ROAM application will be reviewed, adhering to the following review criteria:

1. Risks to participants are minimised.

2. Risks to participants are reasonable in relation anticipated benefits (if any) to subjects.

3. Selection of participants is equitable.

4. *Informed consent will be sought from each prospective participant or the participant's legally acceptable representative.

**Patient information sheet must be submitted.*

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Review Criteria

5. Informed consent will be appropriately documented.

6. Adequate provision for monitoring the data collected to ensure the safety of participants.

7. Adequate provisions to protect the privacy of participants and maintain the confidentiality of data.

8. Additional safeguards incorporated for vulnerable populations.

9. The Human Biomedical Research Act prohibits the commercial trading of human tissue (whether for research, therapy or any other purpose). Therefore, the DSRB will not approve any research that involves the use of human tissues that are purchased commercially.

Reference:

45 CFR 46.111 (a) and 21 CFR 56.111 & NHG Investigator Manual Chapter 4.3.2 Review Considerations and Criteria

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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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