OFFICE OF HUMAN RESEARCH PROTECTION PROGRAMME

(OHRPP)

9b. DSRB EXPEDITED 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 - Expedited

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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DSRB Review Category – Expedited

How is Expedited Review Determined?

The DSRB determines whether the research qualifies for a review by the expedited process.

To qualify for Expedited Review, your research proposal **MUST** meet the following criteria:

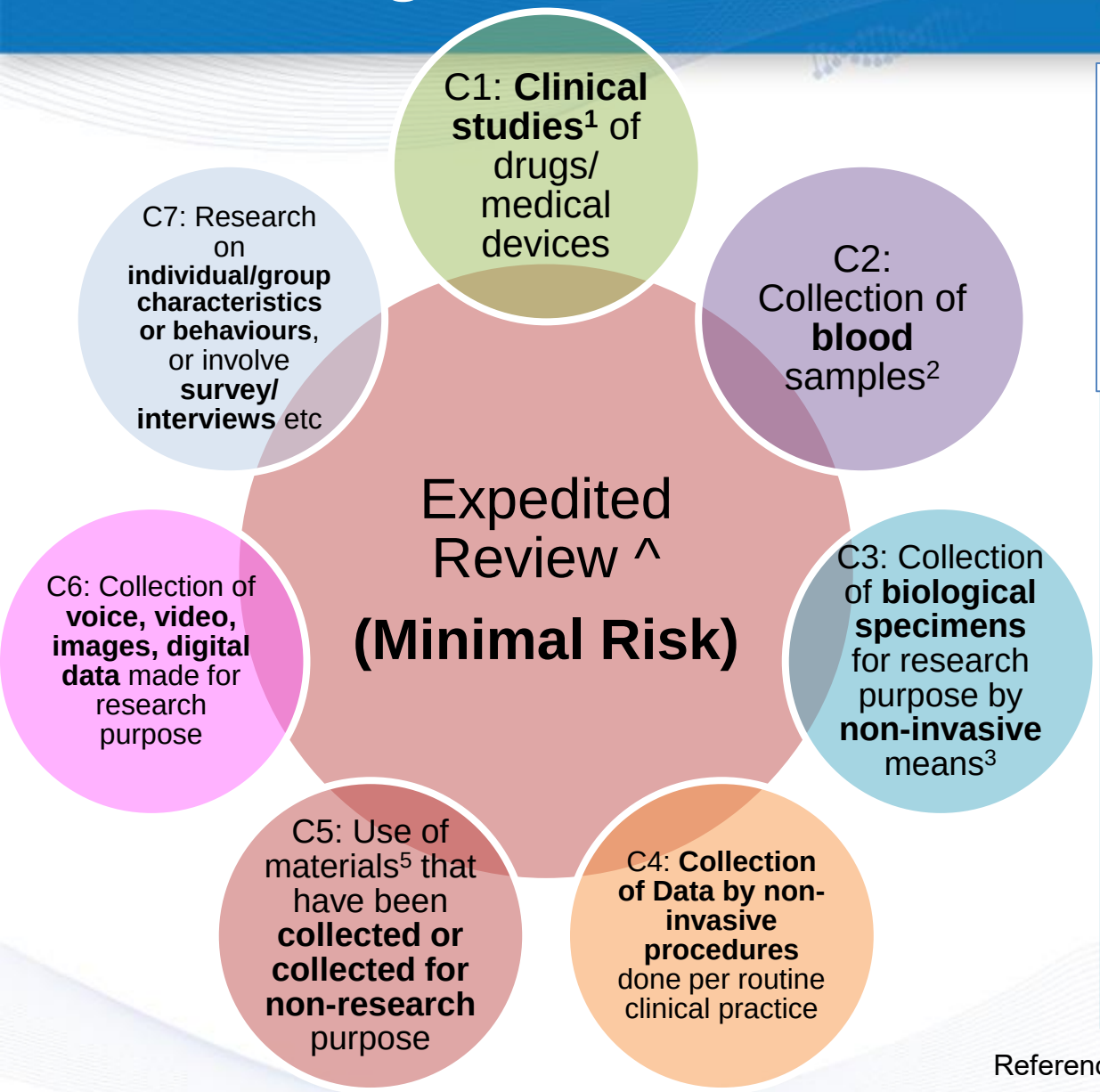
a. The research proposal presents no more than minimal risk to research subjects.

b. Identification of subjects and/or their responses does not reasonably place them at risk or criminal/ civil liability or be damaging to their financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy & breach of confidentiality are not greater than minimal.

c. Research is not classified

d. The research activity is listed in the Categories of Research (*refer to slide #4*).

Categories of Research - Expedited



^ Research should:

- Involve no more than minimal risk
- Not reasonably place subjects at risk or other liabilities/ potential damages if they and/or their responses can be identified
- Not be classified
- Fall into 1 of the 7 listed categories
- Be submitted to DSRB on ROAM using **Non-Exempt Application Form 1**

Notes:

[1] One of the following must be met: a) investigational new drug application is not require; or b) investigational device exemption application is not required or the device has been approved for marketing and used according to its product label

[2] By Finger stick, Heel stick, Ear stick or venepuncture and do not exceed recommended volume

[3] Nail clippings, hair, excreta and external secretions

[4] E.g. Ultrasound, ECG, MRI without contrast. Exclude general anaesthesia, sedation, x-rays and microwaves

[5] Data, records, biological specimens

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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