OFFICE OF HUMAN RESEARCH PROTECTION PROGRAMME

(OHRPP)

9c. DSRB FULL BOARD REVIEW CATEGORIES

& REVIEW CRITERIA

BIOMEDICAL DOMAINS A-E

&

POPULATION HEALTH – DOMAIN F

Reference:

NHG Investigator Manual

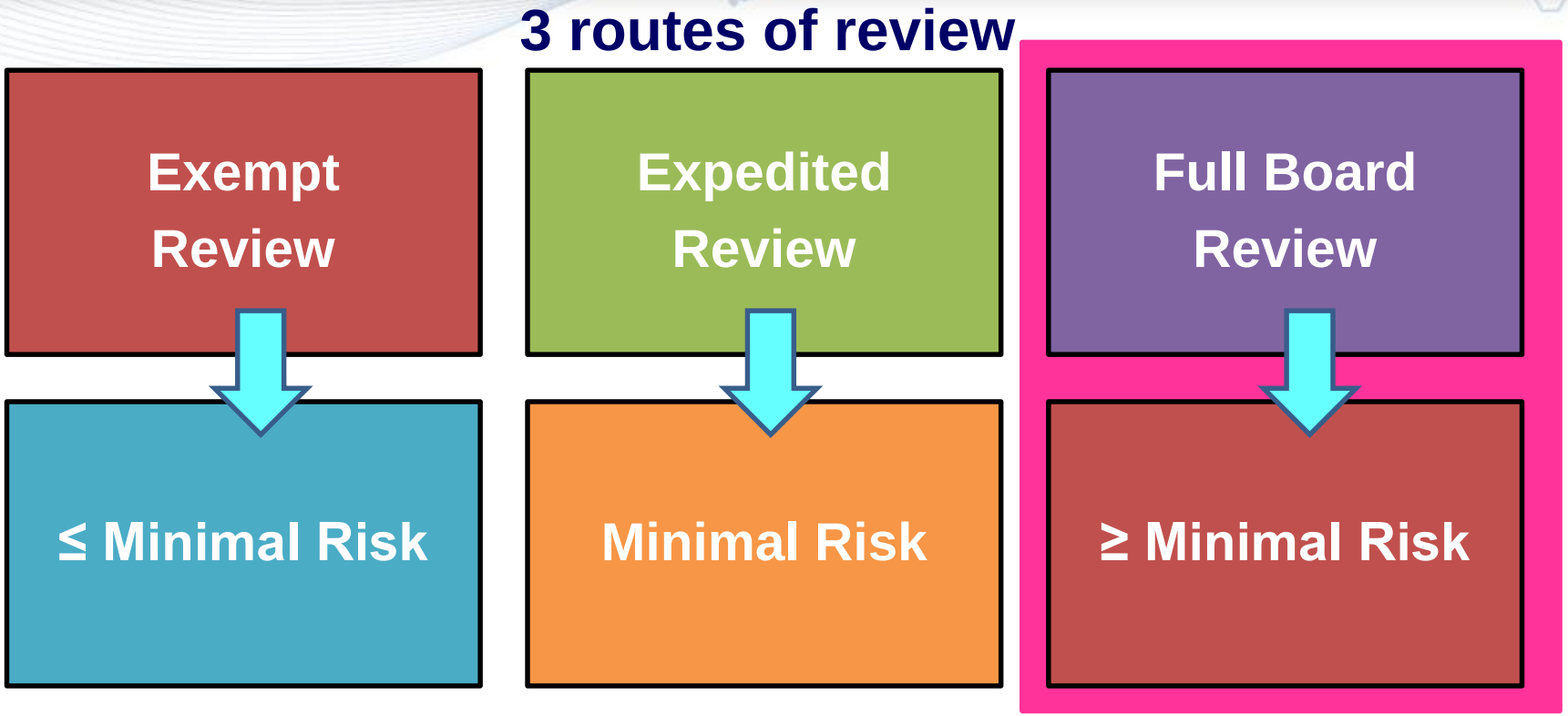
NHG Group Research

Version November 2022

National Healthcare Group

Adding years of healthy life

DSRB Review Categories – Full Board



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.

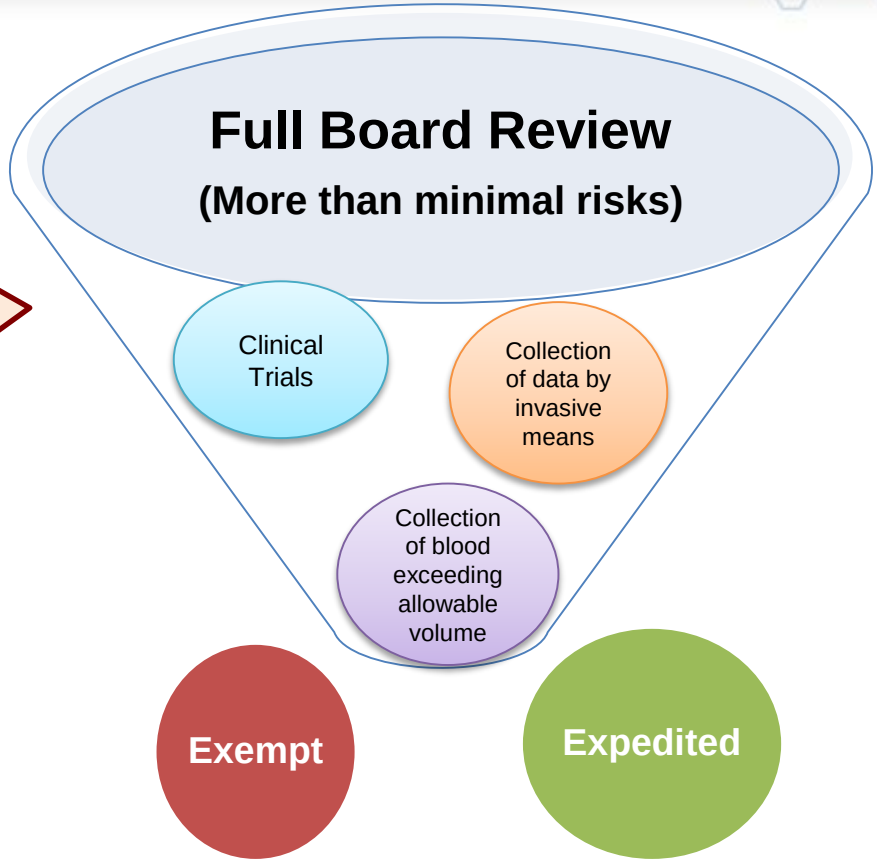
Refer to Chapter 4.3 of the NHG Investigator Manual for all categories and more examples.

National Healthcare Group
Adding years of healthy life

DSRB Review Category – Full Board

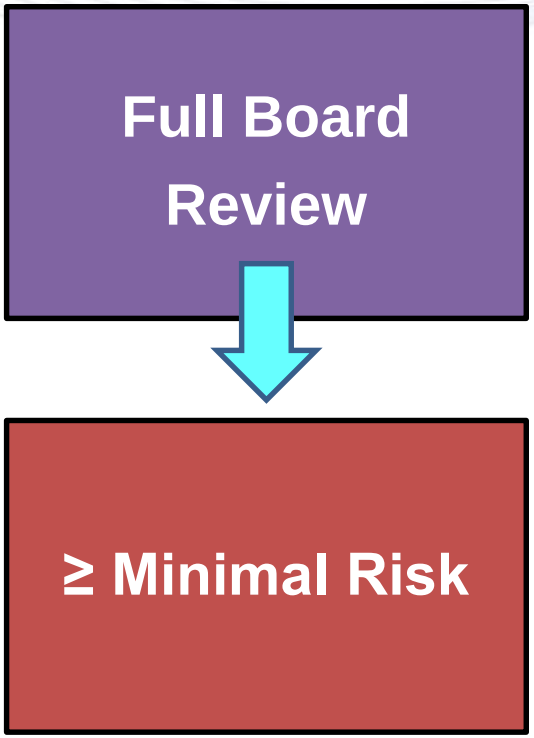
Research proposals that do not qualify for exempt or expedited review will be reviewed by the Full Board process.

In general, research studies that involve more than minimal risk will undergo Full Board review. Such studies may include research studies that are studying the safety and efficacy of a medicinal product or medical device, or research studies that involve invasive procedures.



National Healthcare Group
Adding years of healthy life

DSRB Review Category – Full Board

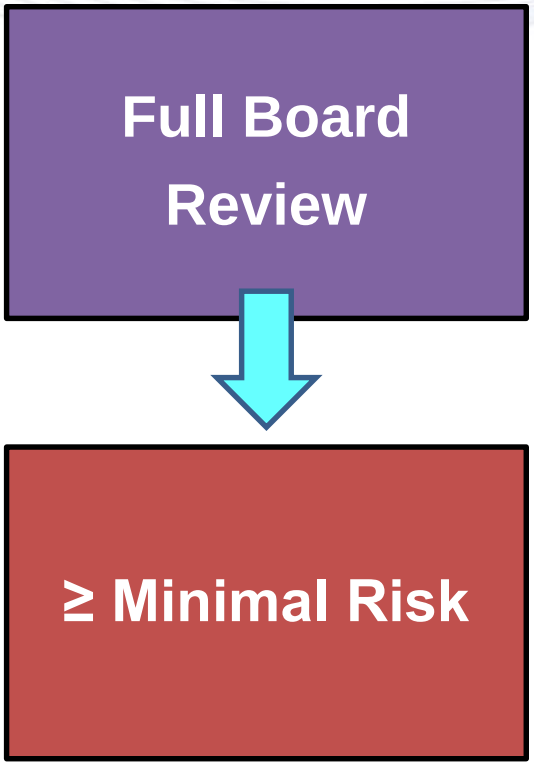


Examples of research that may qualify for FB review:

- Research studies (i.e. Clinical Trials) that involve the study of the safety and efficacy of a medicinal product, medical device or research study that involve invasive procedures.

National Healthcare Group
Adding years of healthy life

DSRB Review Category For Population Health (Domain F) – Full Board



Example of research that may qualify for Population Health (Domain F) Full Board review:

- High risk research studies involving evaluation of new exercise programme in elderly that will improve overall health of the participants.

Note: Population Health (Domain F) does not review clinical trial.

National Healthcare Group
Adding years of healthy life

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.*

National Healthcare Group
Adding years of healthy life

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

National Healthcare Group
Adding years of healthy life

Questions?

Refer to www.research.nhg.com.sg

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

National Healthcare Group
Adding years of healthy life