OFFICE OF HUMAN RESEARCH PROTECTION PROGRAMME

(OHRPP)

10. DSRB REVIEW OUTCOMES & ADDITIONAL REMINDERS

BIOMEDICAL DOMAINS A-E

&

POPULATION HEALTH – DOMAIN F

Reference:

NHG Investigator Manual

NHG Group Research

Version November 2022

National Healthcare Group

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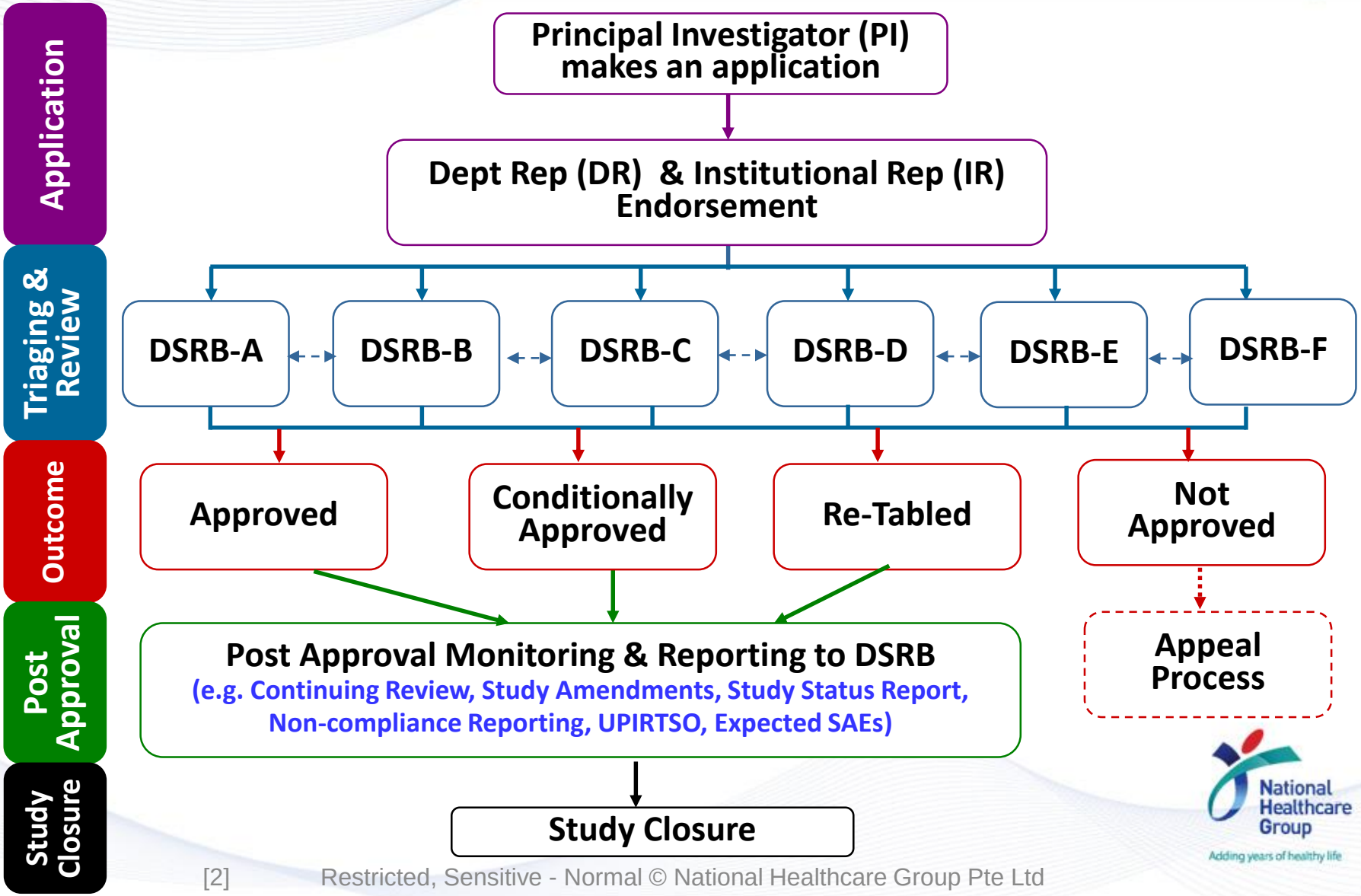
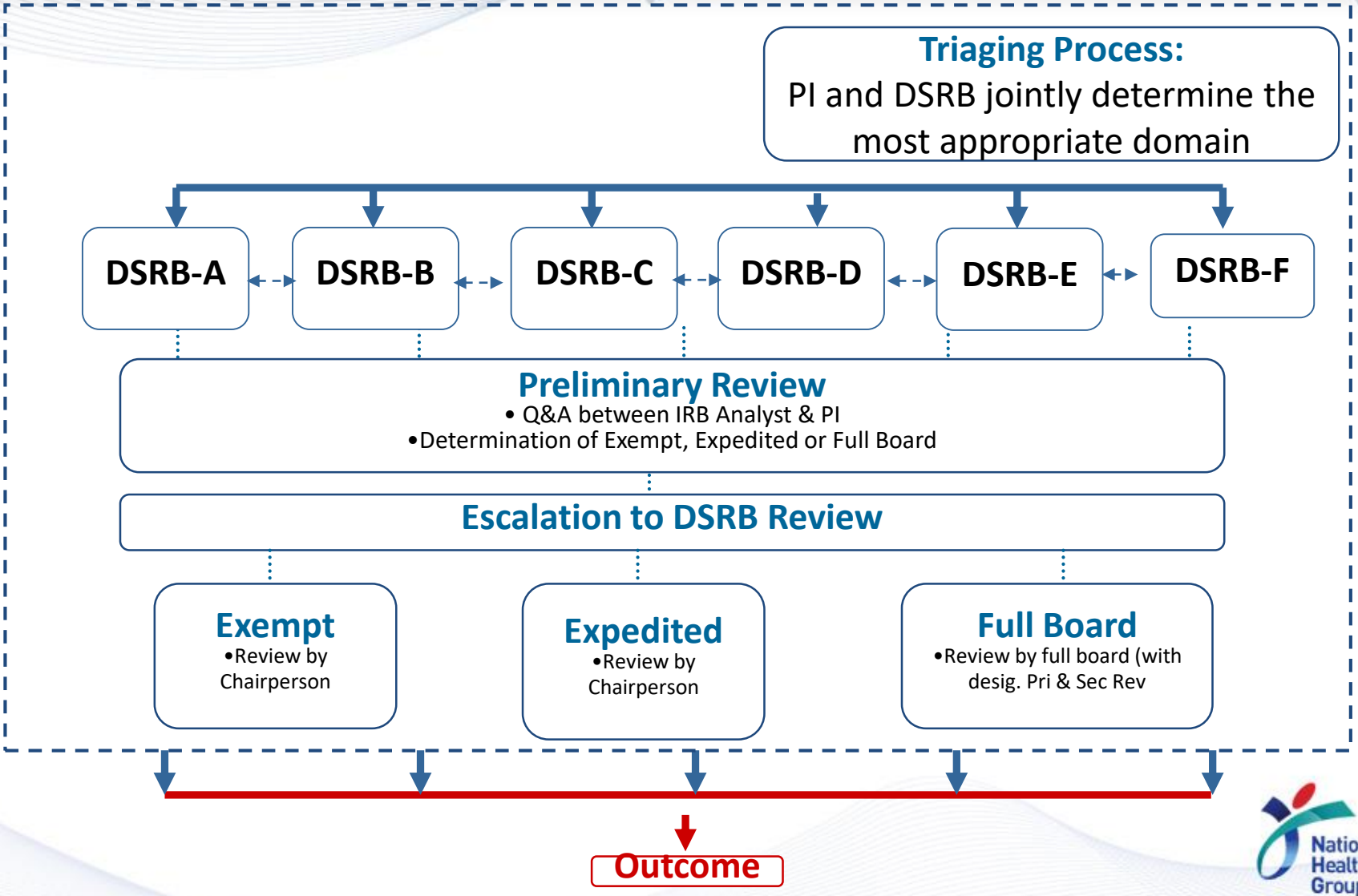
Overview of DSRB Review Outcomes



Triage & Review Processes



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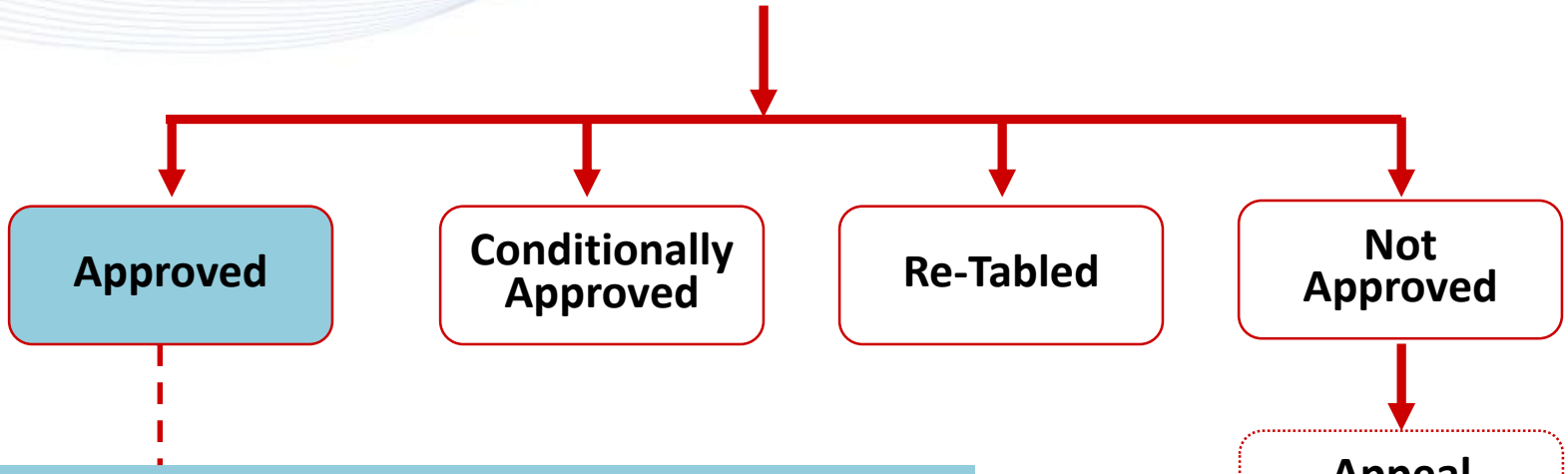
DSRB Review Outcomes – Expedited/ Exempt Reviews



- Approved as submitted.
- Expiry Date: 1 year from date when approval was granted (i.e. 1 year from Full Board meeting date).

Approval process: Outcome by one domain is recognised by all domains.

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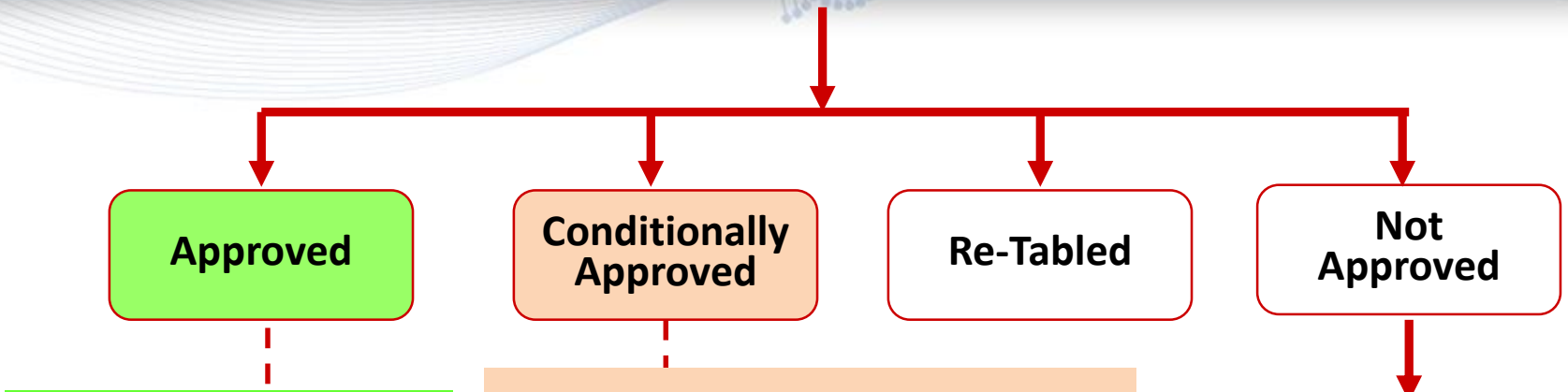
DSRB Review Outcomes – For Full Board Reviews



- Approved as submitted.
- Expiry Date: 1 year from date when approval was granted (i.e. 1 year from Full Board meeting date)

- No major issues with the study.
- Minor amendments to be made by the PI, and PI's responses will be reviewed via the expedited route.
- Study will be formally approved by the DSRB once amendments are completed.
- Study approval expires 1 year from the date conditional approval was granted.

Approval process: Outcome by one domain is recognized by all domains.

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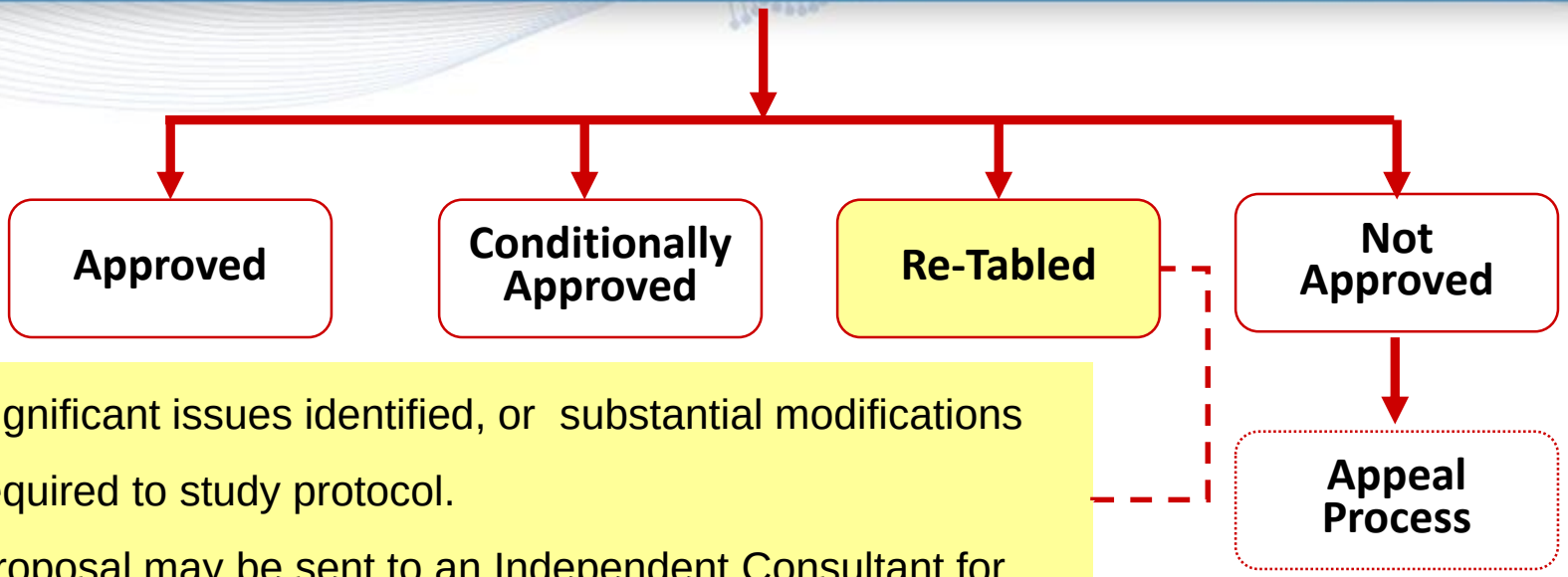
DSRB Review Outcomes



- Significant issues identified, or substantial modifications required to study protocol.
- Proposal may be sent to an Independent Consultant for further review.
- PI's responses / amendments will be reviewed at the next full board meeting.
- PI may be invited to attend the full board meeting to clarify issues.
- Approval date of study will be advised by DSRB secretariat.

Approval process: Outcome by one domain is recognized by all domains.

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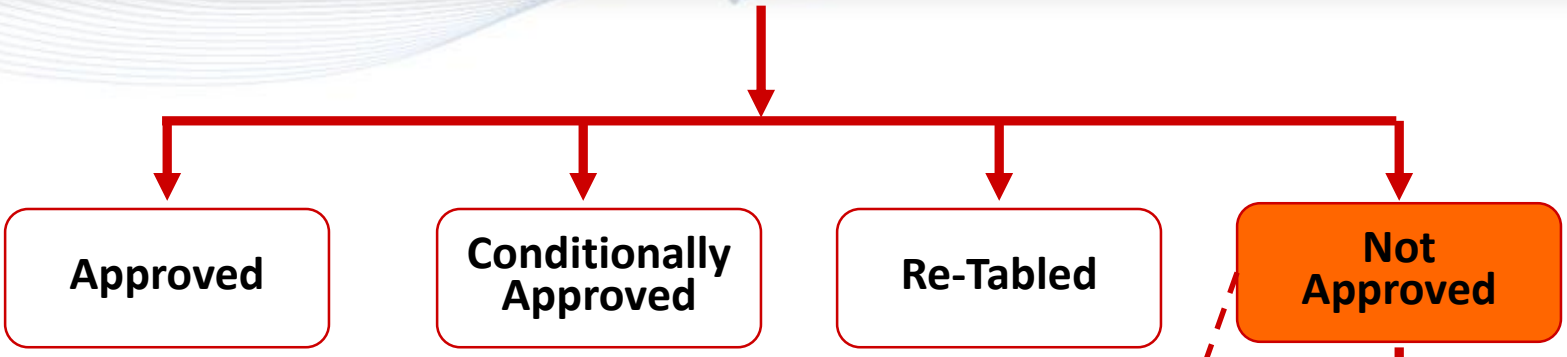
DSRB Review Outcomes



- The proposal fails to meet one or more criteria used by the DSRB for approval of research.
- Disapproval cannot be given through the expedited review mechanism and may only be given by majority vote at a convened meeting of the DSRB.
- PI may invoke appeal process (email respective Secretariat for assistance).

Approval process: Outcome by one domain is recognized by all domains.

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Additional Reminders

1. A **Clinical Trial Certificate (CTC) / Clinical Trial Authorization (CTA)** is required for studies:
   - Investigating the use of locally unregistered therapeutic products.
   - Investigating locally registered therapeutic products not used in accordance with approved product labelling.
   - Involving healthy volunteers.

2. A **Clinical Trial Notification (CTN)** is required for studies investigating the use of locally registered therapeutic products used in accordance with product label. DSRB approval is required prior to HSA application.
   - Application to the **Health Sciences Authority (HSA)** via PRISM.
   - Post-approval reporting obligations apply, e.g. serious breaches, adverse event reports, etc.

For more details on CTC/CTA/CTC, please refer to https://www.hsa.gov.sg > Clinical Trials > Regulatory overview of clinical trials

3. MOH approval should be obtained if the study is restricted HBR. Application of MOH approval needs to be submitted via **TIARAS**

For more details on restricted HBR and TIARAS, please refer to https://www.moh.gov.sg > Legislation > Human Biomedical Research Act.

Questions?

Refer to www.research.nhg.com.sg

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

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