OFFICE OF HUMAN RESEARCH PROTECTION PROGRAMME (OHRPP)

2. ROLE OF INSTITUTIONS

(DEPARTMENT & INSTITUTION REPRESENTATIVES, INVERSTIGATORS AND STUDY TEAM)

Reference:

- ***NHG Investigator Manual 2nd Edition***
- ***Addendum to the NHG Investigator Manual***

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2. Role of Institutions

- The DSRB as well as the Institutions must approve a research protocol before it can be conducted in institutions under the oversight of the NHG DSRB.
- The protection of human subjects in research is a collaborative effort by DSRB and all institutions under the oversight of NHG DSRB.
- Each institution ensures that the proposal is in keeping with its overall research direction, objectives, standards and image, while DSRB (an independent review committee) is responsible for ensuring that the research proposal protects the well-being, safety and rights of the research subjects.

Refer to NHG IM 2nd Edition Chapter 1.3 The Role of Institutions (Investigators, Department Representatives and Institution Representative)

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2. Role of Department Representative

The Department Representative (DR) plays a key role in ensuring that a research study is in keeping with the research objectives, image and standards of the relevant departments and institutions. The DR will be the “Head of Department:, Chief, Department Research Head or equivalent of the PI’s and Site PI’s department.

The role of the DR is:

i. Provide an overview assessment of the significance, concept and innovation of a research study.

ii. Determine whether the PI is adequately trained, qualified, possesses sufficient time and resources to carry out the research study.

iii. Endorse all applications made to the DSRB.

Refer to NHG IM 2nd Edition Chapter 1.3 The Role of Institutions (Investigators, Department Representatives and Institution Representative)

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2. Role of Institution Representative

The Institution Representative (IR) has been determined by each institution as the authority to approve any research study to be conducted in the institution.

The role of the IR is:

i. To assess if the research is in keeping with the institution's research objectives, image and standards.

Generally, the IR's role is not to evaluate the scientific or ethical merits of the research study, although they may offer their comments, as these will be considered by the DR, DSRB or a grant approving body (if applicable).

Refer to NHG IM 2nd Edition Chapter 1.3 The Role of Institutions (Investigators, Department Representatives and Institution Representative)

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2. Role of Principal Investigators

Principal Investigator (PI)

- The **PI** is the person primarily responsible for the proper conduct of research.
- The **PI** bears the overall responsibility for completing and submitting the DSRB Application Form on ROAM, even if these tasks have been delegated to other research staff. The rights, safety and well-being of the research subjects are of utmost importance, and the research proposal should demonstrate that there are adequate provisions to protect the rights, safety and well-being of research subjects.
- If a team of individuals is involved in the conduct of the research study, the PI is responsible for the oversight of the research team.

Refer to NHG IM 2nd Edition Chapter 1.3 The Role of Institutions (Investigators, Department Representatives and Institution Representative), Chapter 8.3 & Addendum Responsibilities of the Principal Investigator

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2. Responsibilities of Principal Investigators

- Delegate and train study team members to discharge their responsibilities.
- Maintain the investigator file and all essential documents.
- Provide adequate medical care to subject throughout the study, e.g. at screening, enrolment, study visits, managing adverse events, etc.
- Obtain informed consent from subjects.
- Communicate with DSRB, e.g. study approvals, continuing reviews, UPIRTSOs, non-compliances, etc.
- Manage the investigational products (if any).

Reference: SGGCP Section 4 – Investigator & NHG PCR SOP 501-A02 Responsibilities of the Research Team

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2. Role of Co-Investigators

Co-Investigators are members of the research/clinical trial team designated by the PI to perform study related procedures and/or make important research related decisions.

Refer to NHG IM 2nd Edition Chapter 1.3 The Role of Institutions (Investigators,
Department Representatives and Institution Representative), Chapter 8.3 &
Addendum Responsibilities of the Principal Investigator

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2. Role of Other Study Team Members

Collaborators are members of the research/clinical team designated by the PI to assist with research related activities that do not involve subject contact (i.e. scientists, research fellows, data analyst etc.)

Research Coordinator/ Clinical Research Coordinator/ Study Nurse are members of the study team who handle most of the administrative responsibilities of a research study, act as a liaison between investigative site and sponsor, and review all data and records before the monitor's visit. (Synonyms: trial coordinator, clinical research coordinator, research coordinator, clinical coordinator, clinical trial coordinator.)

Refer to NHG IM 2nd Edition Chapter 8.3 & Addendum Responsibilities of the Principal Investigator

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2. Who Can be A Principal Investigator

Minimal Risk Studies

- Research proposals that qualify for exempt / expedited review will be considered to be minimal risk studies. To be a PI for a minimal risk study, the individual should at least be:

  a) Clinician – Fully Registered medical practitioner, or a Level 2 Conditionally Registered medical practitioner

  b) Nursing - registered nurse

  c) Allied Health staff – registered allied health practitioner

  d) Research scientists, research fellows and health services research staff, or as determined to be eligible by the DSRB

***Note**: For more information, refer to:*

- *NHG IM Chapter 8.1 – Who Can Be A Principal Investigator*
- *NHG Proper Conduct of Research_501-A02 Responsibilities of the Research Team*

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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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