

NHG Monitoring Programme for Human Biomedical Research Studies

Jaslin Tan

Senior Executive

Research Quality Management

Research & Development Office

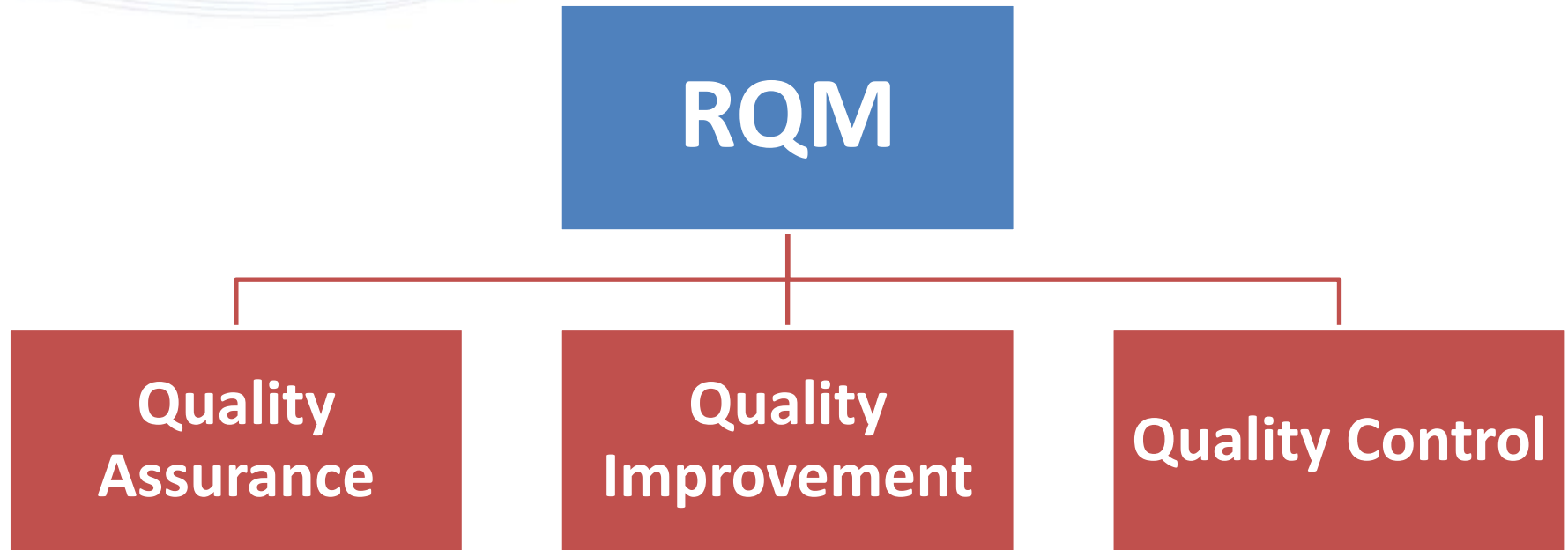


Adding years of healthy life

Outline

- **Introduction to NHG Research Quality Management**
- **Overview of the NHG Monitoring Programme for Human Biomedical Research (HBR) studies**
 - Objectives
 - Selection of Studies
 - Monitoring Plan
 - Collaborative Model
- **Implementation and its challenges**

Introduction to NHG Research Quality Management

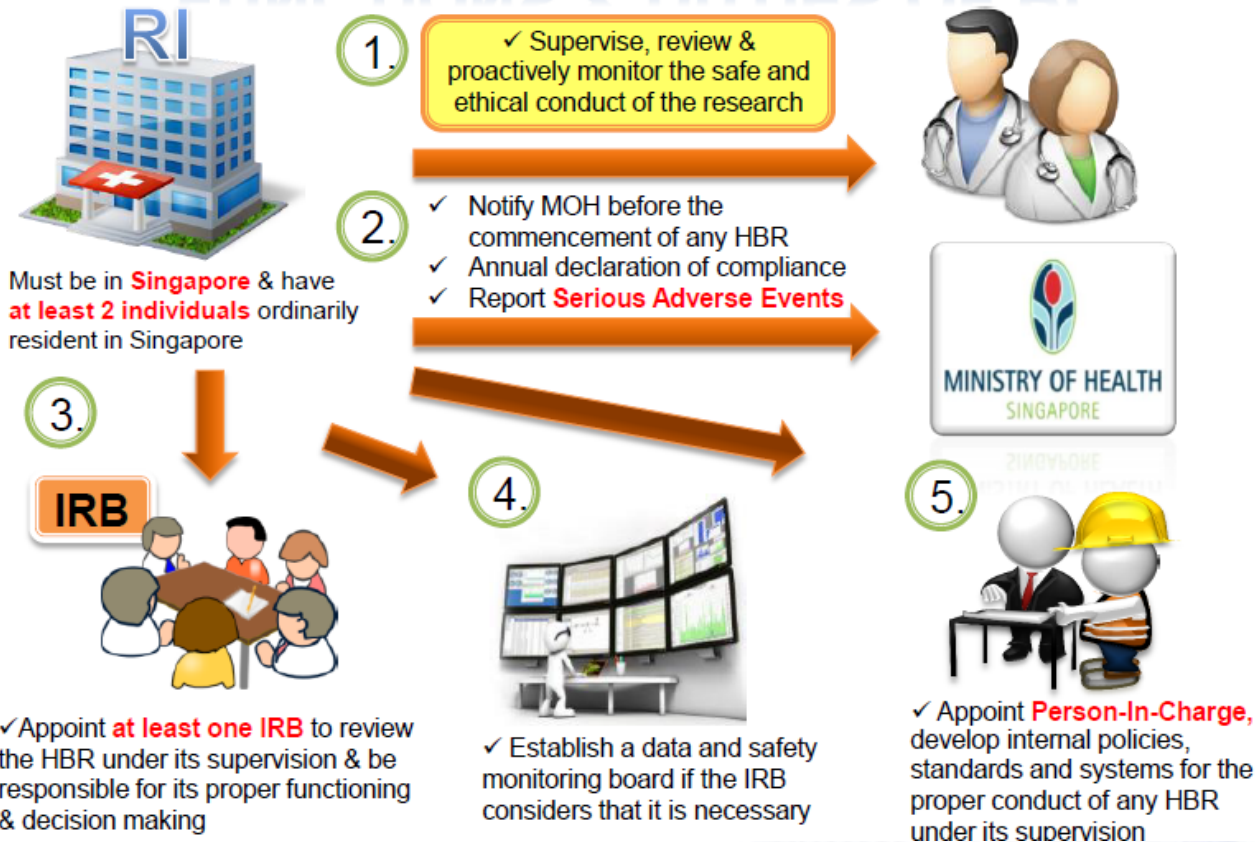


HBRA Requirement

Scope of Research Institution (RI) Responsibilities

Sections 23, 24

FUNCTIONS & DUTIES OF RI



Adapted from MOH Stakeholders Consultation Version 4 Feb 2016

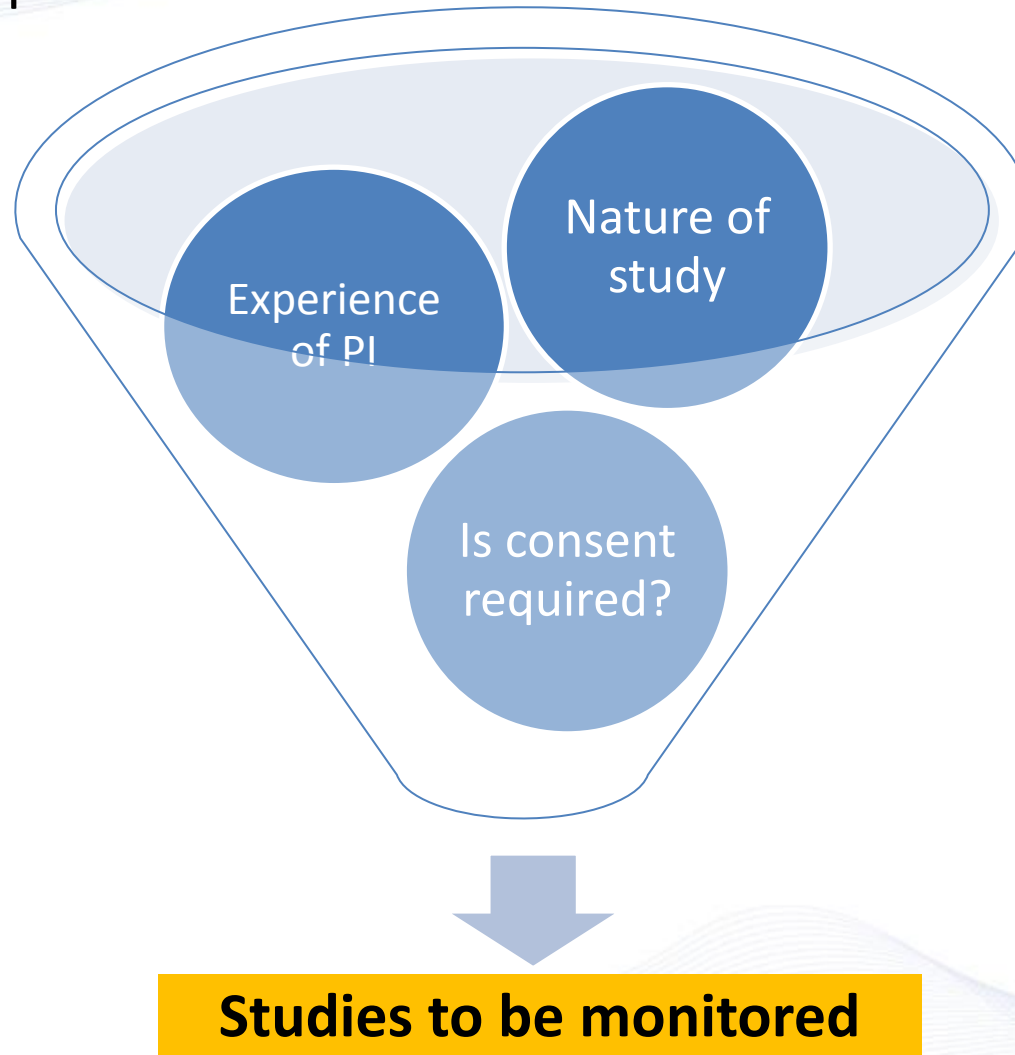
Objectives

The objectives of the NHG Monitoring Programme for HBR studies are to:

- i. Safeguard the **safety and well-being** of the research participants;
- ii. Ensure good **quality and integrity** of the research data;
- iii. Ensure the **conduct** of the study is in accordance to applicable regulations, policies and guidelines; and to
- iv. Fulfill the **responsibility** of the RI according to HBRA

Selection of Studies

- Risk-based approach



Extent of monitoring

For studies conducted in **NHG Institutions**:

| Risk Category | Criteria | Mode of Monitoring | Frequency |
|---------------|--|--|---|
| 2B | Expedited studies <ul style="list-style-type: none">• No waiver of Consent• New PI | PI Self-Monitoring (Mandatory) | Once |
| 3A | Full Board studies <ul style="list-style-type: none">• Restricted HBR• Vulnerable Population• Devices*• Surgical Procedures• PI 1st Full Board study | On-site + Remote Monitoring | <ul style="list-style-type: none">• Site Initiation Visit• Yearly monitoring visits• 3 or 6 monthly remote monitoring |
| 3B | All other Full Board studies | PI Self-monitoring + On-site Monitoring (Selected at random) | <ul style="list-style-type: none">• 6 or 12 monthly Self-Monitoring• One-time on-site monitoring visit for selected studies |

*Unregistered or registered with HSA under Class B, C or D.

- Studies with Industry-Monitoring available will not be selected under this Programme.
- Studies may be upgraded/ downgraded in their risk category subject to certain conditions.

Mode of Monitoring

PI Self-Monitoring

- Using NHG RQM PI Self-Assessment Form

On-Site Monitoring

- Conducted at the research site
- Involves review of ICFs, source documents, safety reporting, Investigational Products, study database and essential documents

Remote Monitoring

- Typically conducted off-site
- Monitor will discuss study conduct with the study team to check on compliance

A Collaborative Effort

NHG RQM

- Programme development
- Training support to Monitors
- Reporting to Research institution



NHG Institutions

- Site management activities

Implementation & Challenges

Programme was implemented from March 2017 (Tier 2B) and April 2018 (Tier 3A & 3B).



Teamwork



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Trans
High

- Introduction to Ethics ▶
- Apply for Ethics Approval ▶
- DSRB Announcements
- DSRB FAQ
- Standing Databases & Tissue Banks ▶
- Research Quality** ▶
- Quality Improvement

- Overview of Quality
- Study Review (Audits)
- PI Self Assessment
- Monitoring** ←

I want to...

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Announcements

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31 Dec 2018

See latest Grant Calls Announcements here!

18 Nov 2018 **NEW**

Results for Skin Innovation Grant Call 2018

08 Oct 2018

The HELIOS-EDC Grant Call 2 is now open!
Closing Date: Closing date for Letter of Intent (LOIs): Friday, 9 November 2018, 12noon

27 Jul 2018

Latest News

VIEW ALL >

30 Nov 2017

The Third Edition of the NHG Investigator's Manual (for DSRB Biomedical Domains) has been launched!

01 Sep 2016

Launch of the NHG Research Database Platform (REDCap)

11 Aug 2016

Revisions to RQM PI Self-Assessment Programme

Upcoming Events

VIEW ALL >

Join us for our upcoming NHG Research Training Courses and Events! Click

www.research.nhg.com.sg

QUESTIONS?

ResearchQuality@nhg.com.sg

THANK YOU!