<u>Section 1 – Minimum Training Requirements of Principal Investigators and Co-Investigators for DSRB Applications</u>

- Minimum Training Requirements of Principal Investigators and Co-Investigators for DSRB Applications
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1) Minimum Training Requirements of Principal Investigators and Co-Investigators for DSRB Applications

All <u>Principal Investigators</u>, <u>Site Principal Investigators</u> and <u>Co-Investigators</u> of research conducted within NHG and partner institutions have to submit proof of research ethics training to the DSRB. The minimum training requirement is to complete the **CITI Program's "Biomedical Research Investigators and Key Personnel" course** or the **Singapore Guideline for Good Clinical Practice (SGGCP) course**.

The DSRB will continue to accept and review applications from Investigators who have yet to complete the CITI Program or SGGCP course. However, the DSRB will NOT grant ethics approval for the applications until receipt of the Investigator's CITI or SGGCP Certificate.

The intention of the Minimum Training Policy is to enable the Principal Investigators, Site Principal Investigators and Co-Investigators to appreciate and apply the ethical principles underlying research to the day to day practice of research.

1.1) What is the CITI Program?

The Collaborative Institutional Training Initiative (CITI Program) is a leading provider of research education content that is web-based to facilitate the training of investigators and staff who are conducting research.

Staff from NHG and partner institutions can access the CITI Program's "Biomedical Research Investigators and Key Personnel" course, amongst other courses such as Responsible Conduct of Research and Financial Conflicts of Interest. The "Biomedical Research Investigators and Key Personnel" course provides a comprehensive selection of 26 educational modules.

It is important to affiliate with "National Healthcare Group – Singapore" so that you can access the correct curriculum.

You should choose to complete the appropriate modules depending on the type of research that you intend to conduct – Biomedical Research or Population Health Research.

1.2) I'm conducting Biomedical Research (Submission to DSRB Domains A-E), which CITI modules should I complete?

Curriculum: Human Research

(A) Core Modules

You will need to complete 7 fundamental research ethics modules and the following 3 modules specific for NHG Investigators:

- 1. National Healthcare Group Singapore
- 2. NHG Singapore. Overview of the Regulatory Framework and Guidelines in Singapore
- 3. NHG Singapore. Overview of Domain Specific Review Board (DSRB) Review Process

(B) Elective Modules

You will need to select 5 elective modules from the remaining 21 modules based on the relevance to the nature of your studies and your areas of specialty.

1.3) I'm conducting Population Health Research (Submission to DSRB Domain F), which CITI modules should I complete?

Curriculum: Human Research

(A) Core Modules

You will need to complete 7 fundamental research ethics modules and the following 3 modules specific for NHG Investigators:

- 1. National Healthcare Group Singapore
- 2. NHG Singapore. Overview of the Regulatory Framework and Guidelines in Singapore
- NHG Singapore. Overview of Domain Specific Review Board (DSRB) Review Process

(B) Elective Modules

You will need to complete 5 elective modules out of the 11 Social, Behavioural and Educational (SBE) related modules based on the relevance to the nature of your studies and your areas of specialty. These modules can be identified by 'SBE' in the suffix.

1.4) How do I register for the CITI Program?

You can register for the program through the online system at www.citiprogram.org.

It is important to affiliate with "National Healthcare Group – Singapore" so that you can access the correct curriculum.

Upon completing the registration form, you can immediately begin your learning with the CITI program.

Please refer to the Guides/Forms available for download in Section 4 – List of Available Guides, Forms and Useful Links.

1.5) I've completed other research ethics training programmes, can I use it to waive the completion of the CITI Program?

DSRB also accepts the SGGCP Certificate as completion of the minimum training requirements. However, if you have completed other research ethics training programmes that is organised and conducted by a reputable body such as NHG institutions, Health Sciences Authority, National University of Singapore etc., you may apply for a waiver of the CITI Program for DSRB's evaluation. Any programme that qualifies as a research ethics training equivalent to the CITI Program, should be at least an 8-hour programme and should address most of the following topics:

- 1. History & Ethics Principles of Research Ethics
- 2. Regulatory Framework and Guidelines in Singapore
- 3. Informed Consent
- 4. Privacy and Confidentiality Issues

1.6) How do I apply for the waiver of CITI Program?

You can complete the CITI Minimum Training Requirement Waiver Form and email a copy of the waiver form to min_ethics_training@nhg.com.sg. The DSRB will review the submitted form and determine whether waiver can be granted.

Please note that approval for the waiver of CITI certification <u>does not</u> exempt investigators and study team members from completing the FCOI course (see section 2).

Please refer to the Guides/Forms available for download in Section 4 – List of Available Guides, Forms and Useful Links.