Section 3 – Minimum Training Requirements of Principal Investigators Who Are Conducting Clinical Trials

3) Minimum Training Requirements of Principal Investigators Who Are Conducting Clinical Trials

With effect from **1st August 2014**, Principal Investigators and Site Principal Investigators who will be conducting new Clinical Trial studies will have to complete Singapore Guideline for Good Clinical Practice (SGGCP) course regardless of whether they have completed the CITI Program. Clinical Trials are defined as studies that require a Clinical Trial Certificate (CTC) from the Health Sciences Authority (HSA) prior to initiation. This will apply to Clinical Trial studies that are received by DSRB from 1 August 2014 onwards (i.e. the application has been endorsed by the Institution Representative on/after 1 August 2014).

The purpose of this new training requirement is to ensure that the Principal Investigators and Site Principal Investigators will receive the minimum training for good clinical practices prior to the initiation of a clinical trial as they are responsible for ensuring proper conduct of clinical trial and safety of the subjects by adhering to the relevant local regulations and guidelines.

Principal Investigators and Site Principal Investigators will need to produce proof of attendance or completion by submitting a copy of the certificate.

3.1) What is the SGGCP Course?

The Singapore Guideline for Good Clinical Practice (SGGCP) course offered by the NHG Research & Development Office is a two-day course designed to provide training and understanding for personnel involved in the design, conduct, documentation and reporting of clinical trials. Participants will gain insight on the importance of having good clinical practices through case studies and completion of a pre- and post-course assessment. Participants will have to attend at least 75% of the course in order to attain the certificate of attendance.

DSRB also accepts the SGGCP Certificate as completion of the minimum training requirements. However, it **does not** exempt investigators and study team members from completing the FCOI course. Also, investigators who are conducting population health research **may not** substitute completion of CITI Program with SGGCP course. This is because the contents covered in the SGGCP course focuses on clinical trials

involving medicinal products or devices, which are not relevant to the population health research.

3.2) What are the accepted SGGCP/GCP Courses?

The SGGCP courses that are currently recognised and accepted are:

- Singapore Guideline for Good Clinical Practice *conducted by* NHG Research Training and Development Unit (RTDU), NHG RDO
- Singapore Guideline for Good Clinical Practice Course (ONLINE) *conducted by* NHG Research Training and Development Unit (RTDU), NHG RDO
- Singapore Guidelines to Good Clinical Practice (SG-GCP) *conducted by* SingHealth Academy
- Singapore Good Clinical Practice Programme (Basic Course on Clinical Trial Management) *conducted by* National University of Singapore
- iGood Clinical Practice (iGCP) Programme *conducted by* Department of Pharmacy, National University of Singapore
- Clinical Investigation Course for Investigators *conducted by* AO Foundation

If you have attended a SGGCP course conducted by an organisation not listed above, you can email a copy of the completion certificate and the course agenda with the speakers' designations to min_ethics_training@nhg.com.sg for consideration. These will be reviewed on a case-by-case basis.

3.3) I've conducted multiple clinical trials, can I apply for a waiver of SGGCP Course?

Experienced Investigators who have assumed the roles and responsibilities of a Principal Investigator for multiple clinical trials may apply for a waiver of the additional requirement provided the following conditions are met:

(a) The applicant must have conducted a minimum of five clinical trial studies, either as a Principal Investigator or Site Principal Investigator, within NHG or its partner institutions under the oversight of DSRB over the last six years.

(b) The applicant must have enrolled at least one subject for these clinical trials.

(c) The applicant certifies that there were no major research ethics violation or non-compliance, unjustified DSRB SOP deviation, RCR citation and complaints for these clinical trials (completed and ongoing).

You can complete the Request Form for the Waiver of SGGCP Training and email a copy of the waiver form to min_ethics_training@nhg.com.sg. If these clinical trial studies were not submitted through ROAM, you should submit your CV and the approved protocol(s) together with the request form. The submitted request form and supporting

documents will be reviewed by the NHG Research Ethics Committee and applicants will be notified of the outcome.

Please note that approval for the waiver of SGGCP certification **does not** exempt investigators and study team members from taking 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.