07 Dec 2012

DSRB-052012: New Minimum Training Requirements for Principal Investigators Who Are Conducting Clinical Trials

With effect from **1st August 2014**, Principal Investigators (PI) and Site Principal Investigators who are conducting Clinical Trials will have to complete Singapore Guideline for Good Clinical Practice (SGGCP) course in addition to the CITI Program.

The purpose of this new training requirement is to ensure that the PI will receive the minimum training for good clinical practices prior to the initiation of a clinical trial as he/she will be responsible for ensuring proper conduct of clinical trial and safety of the subjects by adhering to the relevant local regulations and guidelines.

There is a grace period from now till 1st August 2014 for PIs to submit produce proof of attendance or completion of SGGCP training to the DSRB.

Conditions for Waiver of Completion of SGGCP Training

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

(a) The Investigator submits the supporting documents for the clinical trials (completed and ongoing) that he/she had conducted as Principal Investigator within NHG or partner institutions under the oversight of DSRB over the last 6 years, and

(b) The Investigator 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).

The submitted request form and supporting documents will be reviewed by the NHG Research Ethics Committee and Investigators will be notified of the outcome.

The request form is available for download here.

For more information on the minimum training requirements, please click here.