

# CHICKEN SOUP FOR THE BUSY COORDINATOR

July 2021

## Minimum Training Requirements for PI and Study Team Conducting Human Biomedical Research (HBR)

### Scenario:

Dr X is a new Principal Investigator (PI) who is currently conducting a HBR study at site ABC. As Dr X is a first time PI, an institution monitor (IM) is assigned to monitor and provide feedback for Dr X's study. During the first monitoring visit, the IM reviewed the Study team's training documentation and discovered the following findings:

- 1) The PI and Co-I completed the NHG CITI course but not the FCOI CITI training course.
- 2) Some of the study team members did not complete the NHG HBR Essential Research Conduct (ERC) course but have started study activities.

### Corrective Action:

The IM reminded the study team that all study team members of the study team are required to undergo all the necessary trainings prescribed by the NHG DSRB/IRB & Research Institution before any study procedures should commence. As the Study Team has already performed study procedures, a Non-Compliance report should also be submitted to the NHG DSRB.

### Minimum Training Requirements:

#### 1) Financial Conflicts of Interest (FCOI) Course (sub-component of the CITI Program)

Financial Conflict of Interest (FCOI) training requirements aim to educate researchers on how conflicting interests may adversely affect the protection of subjects or the credibility of the human research protection programme. All investigators and study team members involved in the design, conduct or reporting of research in institutions that is conducted under the oversight of NHG or its partners institutions will be required to fulfill the minimum training requirements on FCOI. Staff from an external institution who is involved in the design, conduct or reporting of research that is conducted under the oversight of NHG or its partners institutions will also need to complete the FCOI training. This may be accomplished through completing 2 core CITI modules:

- a. Conflicts of Interest in Research Involving Human Subjects (ID: 488/ 17464)
- b. NHG - Singapore. Overview of Domain Specific Review Board (DSRB) Review Process (ID: 810)

In addition to the training, all investigators and study team members who are involved in the design, conduct or reporting of research that is conducted under the oversight of NHG or its partners institutions are also required to declare any financial interests related to their studies at the annual submission of their FCOI Declaration Form.

When the FCOI CITI trainings are completed, the users are required to upload a copy of the completion certificate onto your Research Online Administration & Management (ROAM) profile under 'Personal Info' -> 'Upload Minimum Training Status Proof'. Upon receipt and verification, the Administrator will update the Minimum Training status in the ROAM profile to "Completed".

#### 2) NHG HBRA Minimum Training Requirements

From **1 November 2019**, for all new HBR studies / sites\* approved by a NHG appointed IRB (i.e. NHG DSRB, SingHealth CIRB, NUS IRB, NTU IRB), all **NHG Institution staff** (Principal Investigators, Site-PIs, Co-Investigators and other study team members) involved in the design, conduct or reporting of the Human Biomedical Research Act (HBRA) regulated studies will be required to complete the NHG HBR Essential Research Conduct (ERC) Course prior to the commencement of their study involvement. The HBR ERC course aims to equip all NHG PIs and study team members conducting HBR studies with knowledge on the regulations and institutional policies to ensure the proper conduct of research.

[Click here](#) for more information on the type of HBR ERC Course (Online and Workshop) required to be completed by PI, Co-I and supporting Study Team members (CRC/RAs).

### References:

- 1) NHG Investigator's Manual 3<sup>rd</sup> Edition Sept 2017 Chapter 3.2 Minimum Training Requirements for Investigators and Study Team Members
- 2) 501-A03 Training and Education

**Article Contributed By: Khoo Jin Rong, Senior Clinical Research Coordinator, NHGP**  
**Edited By: NHG Group Research, OHRPP**

*\*Disclaimer: All characters appearing in this article are fictitious. Any resemblance to real persons is purely coincidental. Best practices may differ between institutions. Readers are encouraged to follow their institution's policies/guidelines relating to the above scenarios/case study.*