

CHICKEN SOUP FOR THE BUSY COORDINATOR

March 2016

Declaration, Submission & Filing of the Financial Conflict of Interest Declaration Form

Scenario

Miss C, a clinical research coordinator, has been working with Dr A on several clinical trials. She recently realised that with Dr A's track record of conducting industry-sponsored clinical trials; Dr A has taken up the role as a Consultant with Company X, in which he owns some stocks. Company X also sponsors Dr A to speak at conferences about the clinical trials that he conducts for the company.

What did Miss C do?

At a weekly study meeting, Miss C updated Dr A about the progress of the upcoming and ongoing clinical trials and went through the documents that are required to be filed in the Investigator File.

Miss C additionally discussed with Dr A about the NHG Policy for Declaration of Financial Conflict of Interest (FCOI), where the PI must reveal to DSRB if any of the investigators, study team members or their immediate family members have any financial interest related to the research so as to prevent bias in the design, conduct, or reporting of research projects.

- **Declaration process** (for all studies that the members are involved in):

WHEN	WHO SHOULD DECLARE	WHAT TO DO	WHERE TO SUBMIT
*Before 31 Dec 2016	All study team members involved in the design, conduct or reporting of research in institutions under the oversight of NHG DSRB.	Each study team member must complete and sign on Annex B - Financial Conflict of Interest Declaration form. This declaration is valid until 31 Dec 2016.	Scan and send the completed declaration form in softcopy to the DSRB FCOI Secretariat (DSRB_FCOI@nhg.com.sg).
Annually, from Jan 2017		Each study team member must complete and sign on Annex B - Financial Conflict of Interest Declaration form during the annual declaration cycle.	
Arising during the study	The investigator and/or affected study team member	Each study team member must complete and sign on Annex B - Financial Conflict of Interest Declaration form as soon as possible but not later than <u>30 calendar days</u> following first knowledge.	The hardcopy form should be filed in the Investigator File.

- **Other documents to be submitted to DSRB** (for each study):

WHEN	WHAT TO DO	WHERE TO SUBMIT
Initial DSRB application	PI must submit Study Team Member List for FCOI Declaration (205-034) if there are team members who are <u>not</u> listed in Section B1(ii) of the ROAM Application Form, and are involved in the design, conduct or reporting of research in institutions under the oversight of NHG DSRB.	Attach Study Team Member List to Section C of the ROAM Application Form.
Continuing Review		Attach Study Team Member List to Study Status Report.

NHG FCOI Training Requirements for All Investigators and Study Members

- All study team members must also complete the NHG FCOI CITI course. The completion certificate should be uploaded on each member's ROAM profile (if applicable).
- A copy of all completed forms listed above should be filed in the Investigator File.

References:

- NHG Investigator's Manual, 2nd Edition, May 2013 (Chapter 7.5 – Conflict of Interest).
- Addendum to the Investigator's Manual, 2nd Edition, January 2016
- *Refer to the [NHG Policy/ Requirements for Declaration of Financial Conflict of Interest \(for Principal Investigators and Study Team Members Version 2, Updated 1 July 2015\)](#) for more details.
- **Requirements for declaration:** Refer to NHG FCOI declaration policy website: <https://www.research.nhg.com.sg/wps/wcm/connect/romp/nhgromp/h spp/financial+conflict-of+interest/fcoi+policy+>

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**Disclaimer: All characters appearing in this article are fictitious. Any resemblance to real persons is purely coincidental.*

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