

Part I: Requirements for Declaration of Financial Conflict of Interest (for Principal Investigators and Study Team Members of Research Conducted Under the Oversight of NHG or its Partner Institutions)

Disclosure of Financial Interest to the DSRB

The primary purpose of conflict of interest declaration is to prevent bias in the design, conduct, or reporting of research projects.

With effect from **1 January 2015**, the **Principal Investigator** 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 study as follows:

- a. Financial interests (e.g. stocks, stock options or other ownership interests) in the assets or liabilities of any company that may benefit from the research activity.
- b. Payments (e.g. salary, consultation fees, speaking fees, or honoraria) from any company that may benefit from the research activity.
- c. Employment or executive relationships with any company that may benefit from the research activity.
- d. Intellectual property rights or proprietary interests (e.g. patents, copyrights and royalties from such rights) related to the research.
- e. Options or other compensation arrangements that could be affected by the outcome of the research.

1. REQUIREMENTS for Disclosure of Financial Interests to the DSRB

The Principal Investigator must reveal to the DSRB at **annually and at any point arising during the conduct of the study** if any of the investigators, study team members or their immediate family members have any financial interests related to the research study as follows:

Compensation by any commercial sponsor company where value of compensation affected by study outcome.

Proprietary interest in the tested product, e.g. patent, trademark, etc

Equity interest in any commercial sponsor company, e.g. any ownership interest, stock options, or financial interest whose value cannot be readily determined through reference to public prices held during study conduct and 1 year after study completion.

Equity interest in any commercial sponsor company, if sponsor is a publicly held company and interest is >SGD\$10,000 in value or >10% of the voting stock or controlling interest of the commercial company (whichever is lower), during study conduct and 1 year after study completion.

Significant payments of other sorts ((SPOOS) cumulative value of more than SGD\$10,000, during study conduct and 1 year after study completion.

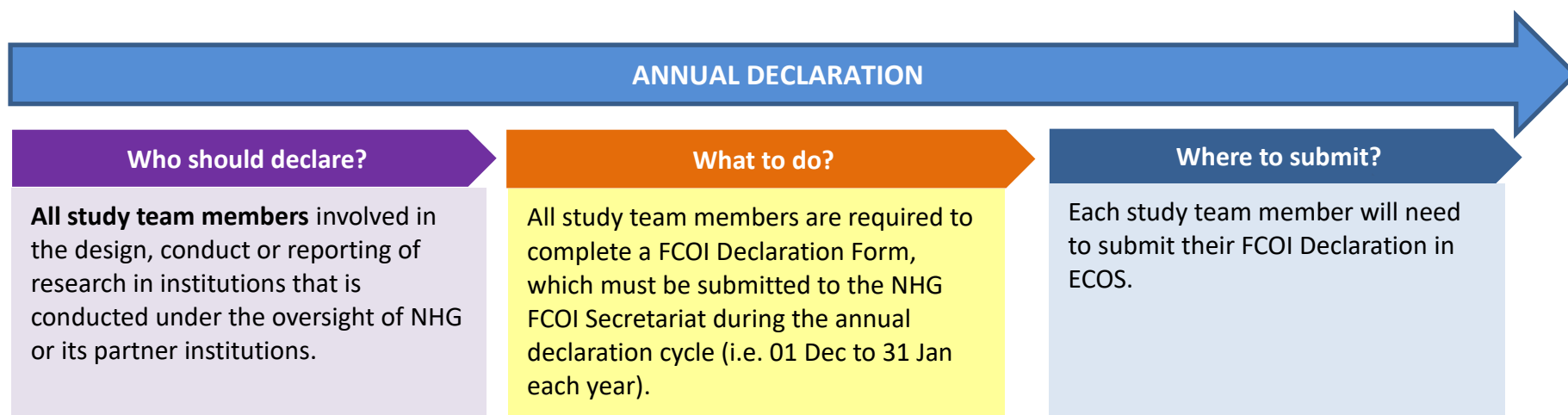
- SPOOS are payments that have a cumulative value of more than \$10,000 and are made by all commercial sponsors of the study to the investigator, study team member or their institution during the time the investigator or study team member is carrying out the study and for one year following completion of the study. This would include payments that support activities of the investigator or study team member (e.g. a grant to the investigator or to the institution to specifically fund the investigator's other ongoing research or compensation in the form of equipment that is not meant to be used for the study), or to provide other reimbursements such as retainers for ongoing consultation or honoraria.
- Payments for the cost of conducting the study or other studies which are already under a contractual arrangement with the commercial sponsor(s), as well as miscellaneous payments that would be controlled by the institution's finance/HR department (e.g. transportation and accommodation costs to attend investigators' meetings) are excluded.

The declaration should give full disclosure of the facts giving rise to the financial interest and to detail the steps proposed to eliminate any conflict of interest that arises from the financial interest.

2. WHEN should Financial Conflict of Interests be disclosed to DSRB?

Annual FCOI Declaration

The Financial Conflict of Interest (FCOI) declaration cycle is an annual process, and will be held from 01 December to 31 January. The validity will be from the date the FCOI declaration form is submitted during the cycle, till 31 December. Principal investigator(s) and study team members **involved in the design, conduct or reporting of research** will need to submit their individual electronic FCOI Declaration Form for their declaration of their financial status. The completed form is to be submitted in the Ethics and Compliance Online System (ECOS) to the NHG FCOI Secretariat.



NOTE: If you missed the annual FCOI declaration cycle, you may still submit the declaration form throughout the year. However, the declaration will only be valid until the next declaration cycle. For example, if you submit the declaration form on 1 August 2022, this declaration would be valid only from 1 August 2022 till 31 December 2022.

FCOI Arising during the Conduct of the Study



FCOI ARISING DURING THE CONDUCT OF STUDY

Financial conflict of interests may also **arise during the conduct** of the study. If such interests arise, the investigator and/or affected study team member should submit an updated electronic FCOI Declaration Form as soon as possible but not later than **30 calendar days** following first knowledge of these conflicting interests.

The updated/revised financial conflict of interest declaration form should be submitted in ECOS.

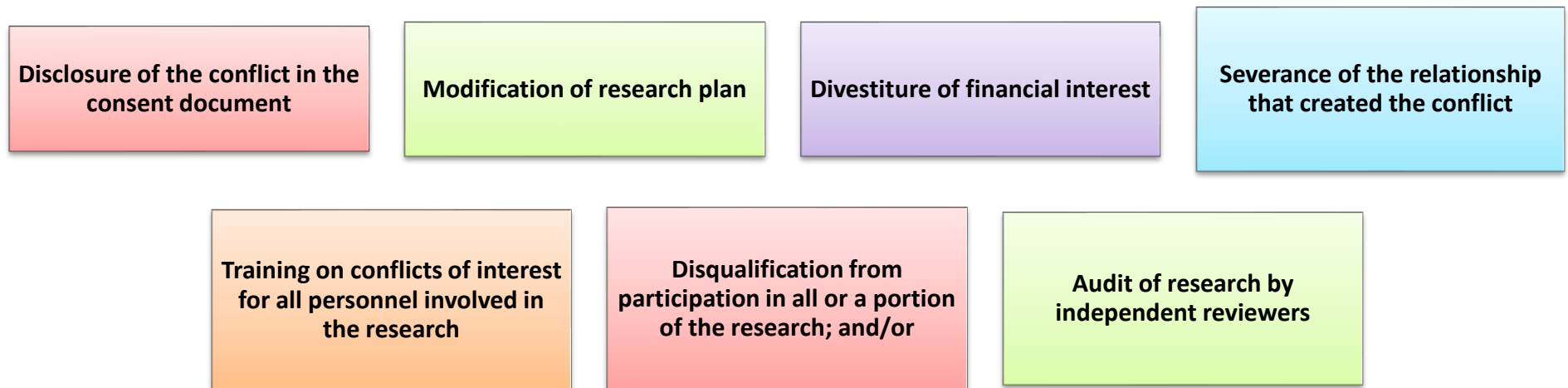
Researchers and research staff members who are reviewing and endorsing study applications in the role of a **Department Representative (DR)** or **Institution Representative (IR)** must also reveal to the DSRB if they or their immediate family members have any financial interests related to the research being endorsed.

The DRs and IRs will be prompted to make the declaration every time they review a study that is due for submission to the DSRB. If the **DR / IR has a conflict of interest**, he/she would need to inform the DSRB, and the study will be **routed to another DR / IR who does not have a conflict of interest for endorsement**.

3. HOW will the Review and Management of Financial Conflict of Interest be carried out?

The NHG FCOI Secretariat will process all the electronic FCOI Declarations submitted, with positive declarations to be further reviewed by the DSRB.

The DSRB will review the disclosed financial interests to determine their impact on the integrity of the research and whether the management plan to eliminate any conflict of interest is appropriate. The DSRB may also impose a management plan to eliminate, mitigate or manage the financial interests. Possible measures that may be taken to resolve the financial conflicts of interest may include (but are not limited to):



The Principal Investigator and/or affected study team member will be informed by the NHG FCOI Secretariat/DSRB if any modifications are required to the management plan to eliminate or mitigate the identified conflicts of interest.

NOTE: *Information on Conflict Interest is also available in the NHG Investigator's Manual.*

4. Can INVENTORS of the Investigational Product/Device participate in the research? How can the Conflict of Interest be mitigated?

Investigators who are also the inventors of the investigational product/device are not immediately prohibited from participating in the research as they would be most familiar with the investigational product/device. It should first be considered if additional mitigation measures could be put in place to mitigate the financial conflict. These measures may include, but is not limited to:

- a. Increased monitoring or audit frequency by the Research Institution(s)/independent reviewer(s)/review committee(s);
- b. Preventing the investigator(s) from receiving any Intellectual Property-related payouts during the interim period before there is sufficient evidence-based recommended usage of the investigational product/device;
- c. Restricting the investigator(s)'s involvement in the research (e.g. he/she should not participate in the safety and efficacy assessments, data analysis, and/or report writing); and/or
- d. Allowing the investigator(s)'s to conduct only the initial proof-of-concept study on a limited number of subjects (e.g. no more than 20 subjects in the study)

The FCOI mitigation measures/management plan should be described to the DSRB for review. The Principal Investigator and/or affected study team member will be informed by the NHG FCOI Secretariat/DSRB if any modifications are required to the management plan to eliminate or mitigate the identified conflicts of interest.

NOTE: Investigators with financial interests in a company whose product(s)/device(s) is/are being considered should recuse themselves from the negotiations with the company, and tender and procurement processes.

Part II: Minimum Training Requirements for Financial Conflict of Interest

Education on Financial Conflict of Interest Declaration Requirements

All Investigators and study team members are required to read through the requirements and updates (if any) on the Declaration of Financial Conflict of Interest Requirements during submission of a new ethics application (for new researchers), annually, whenever there is a revision (updates) to the requirements, or when required by the DSRB for researchers or study team members found to be non-compliant to financial conflict of interest requirements.

Principal Investigators and study team members are required to declare that the Declaration of Financial Conflict of Interest requirements have been read at the annual submission of their FCOI Declaration Form.

Minimum Training Requirements on Financial Conflicts of Interest

All investigators and study team members involved in the design, conduct or reporting of research in institutions will be required to fulfil the minimum training requirements on financial conflicts of interest.

WHAT are the training requirements for FCOI?

The FCOI course is a sub-component of the CITI (Collaborative Institutional Training Initiative) Program. It comprises the following core modules:

1. NHG – Singapore. Overview of Domain Specific Review Board (DSRB) Review Process (ID: 810)
2. Conflicts of Interest in Human Subjects Research (ID: 17464 or 488)

The 2 FCOI modules are also encompassed within the 10 core modules in the CITI course. Therefore, investigators who have completed these 2 modules in their minimum CITI ethics training need not complete the FCOI course/modules separately.

Alternative Method

Investigators who have completed the following would also fulfil the FCOI minimum training requirements:

1. Completed the CITI Conflicts of Interest Course* and
2. Declared that they have read the latest FCOI Declaration Requirements in the electronic FCOI Declaration Form

*The CITI Conflicts of Interest Course contains the following modules:

- a. Financial Conflicts of Interest: Overview, Investigator Responsibilities, and COI Rules (COI-Basic) (ID: 15070)
- b. Institutional Responsibilities as They Affect Investigators (COI-Basic) (ID: 15072)

OR

1. Completed the CITI Biomedical Basic Course which contains the Conflicts of Interest in Human Subjects Research (ID: 17464) module and
2. Declared that they have read the latest FCOI Declaration Requirements in the FCOI Declaration Form

Please refer to the [Guide to Completing Financial Conflict of Interest Course \(FCOI\) Course](https://www.research.nhg.com.sg/wps/wcm/connect/romp/nhgromp/06+conducting+research/fcoi+intro+), for more information, available at: <https://www.research.nhg.com.sg/wps/wcm/connect/romp/nhgromp/06+conducting+research/fcoi+intro+>