

## **Part 1 – General FAQs**

### **1. What is the NHG Financial Conflict of Interest (FCOI) Declaration Requirements?**

With effect from 1 January 2015, all investigators and study team members who are involved in the design, conduct or reporting of research conducted under the oversight of NHG or its partner institutions have to declare if they and/or their immediate family members have any financial interests related to their research studies.

For staff who are from an external institution, e.g. SingHealth, but is involved in the design, conduct or reporting of a research that is conducted under the oversight of an NHG or its partner institution, then the declaration is required.

The declaration would need to be done annually and within 30 days if there are any changes to the financial interest status.

Note: For cross-cluster studies involving SingHealth study sites or its partner institutions which are submitted to NHG DSRB for review, previously the investigators and study team members would declare within the DSRB Application Form in the Research Online and Administration Management (ROAM) portal when the study is submitted for DSRB review. However, with the launch of the Ethics and Compliance Online System (ECOS) in May 2024, these investigators and study team members would now submit their FCOI declarations via the FCOI Module in ECOS.

### **2. Why is it important to declare FCOI?**

The NHG FCOI Declaration Requirements seeks to promote and protect the integrity of research, the welfare of participants, and the credibility of the NHG human research protection programme.

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

## **Part 2 – Annual Declaration Process FAQs**

### **1. When can the annual FCOI Declaration Form be submitted?**

The annual FCOI declaration cycle for 2024 will kick off on 01 Jun 2024. All investigators and study team members of research conducted under the oversight of NHG or its partner institutions are encouraged to submit their annual FCOI declarations to DSRB by 31 Jul 2024. FCOI Declaration Forms that were submitted in ECOS in May will also be accepted. This declaration will be valid through the calendar year 2024, with a one-time extension until 31 Dec 2025.

Subsequent annual FCOI declaration cycles will be from 01 Dec of the preceding year to 31 Jan of each year and will be valid until 31 Dec.

## **2. I missed the annual declaration cycle, can I still submit the FCOI Declaration Form?**

If you missed the annual declaration cycle, you may still submit the FCOI Declaration Form. However, the declaration will only be valid until the next declaration cycle. E.g. If you submit the FCOI Declaration Form on 1 Aug 2024, this declaration would be valid only from 1 Aug 2024 to 31 Dec 2025.

## **3. There are changes to my Financial Interest status. How do I update DSRB?**

Do submit an updated FCOI Declaration Form within 30 days on ECOS for the FCOI Secretariat and/or DSRB to review. If any changes are required (e.g. update to the Informed Consent Form), please submit a Study Amendment.

## **4. How do I submit the FCOI Declaration Form?**

You should submit your FCOI Declaration on ECOS via the FCOI Module.

You may refer to the ECOS User Guide for FCOI Module which can be downloaded [here](#).

## **5. Can I submit FCOI Declaration Forms on behalf of my department/study team?**

No, every individual will be required to submit his/her personal FCOI Declaration on ECOS.

## **6. What do I need to do during the submission of new studies and study amendments to DSRB?**

If you are a Principal Investigator/Site Principal Investigator, please ensure that minimally you and all the investigators listed in the ECOS IRB Application Form have submitted your/their FCOI Declarations in ECOS.

If you are a Co-Investigator, please ensure that you have submitted your FCOI Declaration in ECOS.

The Principal Investigator will not be allowed to submit new applications and study amendments until this is completed as the DSRB will need to review this information.

## **Part 3 – FCOI Declaration Form FAQs**

### **1. Who are considered to be involved in the design, conduct or reporting of research?**

Individuals who have a sufficient level of responsibility that they could have a meaningful impact on the results of the study have to declare FCOI. This includes individuals who have a substantial role in the research design, in the recruitment and enrollment of subjects, or direct control over the collection and/or analysis of data.

Individuals involved in any of the following are usually considered to be “responsible for the design, conduct or reporting” of research:

- Making a substantial contribution to or key decisions about the design of the research
- Recruiting, enrolling, or consenting research subjects
- Recording primary study data in a system without quality control mechanisms
- Independently operating or calibrating laboratory or technical equipment or processes that capture primary study data
- Analysing or manipulating data
- Expected to be an author on publications resulting from the research
- Presenting research results at conferences, seminars, or in public settings
- Reporting adverse events to an agency or sponsor
- Auditing or data monitoring of the study

Individuals are generally not considered to be "responsible for the design, conduct or reporting" of research if they are only engaged in one or more of the following:

- Provide limited technical support or those who are in a purely advisory capacity
- Conducting literature reviews
- Preparing or editing protocol summaries, consent documents, brochures, questionnaires and other study materials if the scientific decisions are made by other members of the research team
- Recording study data in a system with quality control mechanisms such as duplicate entry or random data checks
- Assisting with laboratory or technical equipment or processes under the direction of an investigator
- Administrative tasks such as scheduling appointments or investigator meetings, or maintaining financial records for the project

Special Considerations - For studies that are at the data analysis stage (i.e. the study status on ROAM is “Last Participant, Last Visit Over, Only Data Analysis Ongoing”), study team members who were previously involved in the design and/or conduct of the research, and are currently not involved in the reporting and analysis of study data, are not required to declare FCOI.

## **2. What types of Financial Interests should be declared?**

The following financial interests, arrangements, and payments must be disclosed:

- a. Any compensation by any commercial sponsor of the study in which the value of compensation could be affected by study outcome.
- b. A proprietary interest in the tested product including, but not limited to, a patent, trademark, copyright or licensing agreement.
- c. Any equity interest in any commercial sponsor of the study, i.e., any ownership interest, stock options, or other financial interest whose value cannot be readily determined through reference to public prices. The requirement applies to interests held during the time the investigator or study team member is carrying out the study and for one year following completion of the study.
- d. Any equity interest in any commercial sponsor of the covered study if the commercial sponsor is a publicly held company and the interest exceeds \$10,000 in value, or more than 10% voting stock or controlling interest of the commercial sponsor (whichever is lower). The requirement applies to interests held during the time the investigator or study team member is carrying out the study and for one year following completion of the study.
- e. Significant payments of other sorts (SPOOS) are payments that have a cumulative monetary 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.

## **3. What is the difference between "Any equity interest in any commercial sponsor of the study" (Point c above) and "Any equity interest in any commercial sponsor of the covered study if the commercial sponsor is a publicly held company and the interest exceed \$10,000 in value, or more than 10% voting stock or controlling interest of the commercial sponsor (whichever is lower)" (Point (d) above) above?**

Point c refers to having an interest in a Sponsor either by owning shares in the Sponsor (i.e. as a Director) or through owning stock options or other ownership methods excluding shares. Point (d) refers specifically

to having an interest in a Sponsor by owning shares in the Sponsor which are listed in a public stock exchange such as the Singapore Exchange.

**4. For equity interest in any commercial sponsor of the study, should fluctuations above and below the \$10,000 level, or 10% voting stock or controlling interest level of the commercial sponsor (whichever is lower) during the course of the investigation and one year after completion of the study be reported?**

DSRB recognizes that the dollar value of an equity holding in a sponsoring company is likely to fluctuate during the course of a study. FCOI should be reported when the investigator becomes aware that the equity interest has exceeded \$10,000 or exceeded 10% voting stocks or controlling interest of the commercial sponsor (whichever is lower). DSRB does not expect the investigator to report when an equity interest fluctuates below that threshold.

**5. How do significant payments of other sorts (SPOOS) relate to the variety of payments the sponsor might make to an individual or institution for various activities?**

The term "significant payments of other sorts" was intended to capture substantial payments or other support that has a value of more than \$10,000, provided to an investigator or institution that could create a sense of obligation to the sponsor.

These payments do not include payments for the cost of conducting the clinical study of the product under consideration or clinical studies of other products, under a contractual arrangement, but do include other payments made directly to the investigator or to an institution for direct support of the investigator. E.g. Payments made to the institution that are not made on behalf of the investigator and are not specifically targeted towards the investigator generally would not need to be reported. However, a grant made to an institution is worded in such a way that only the investigator could fulfill it, it would be reportable.

Examples of SPOOS include

- Payments, retainers and honoraria from a sponsor to a clinical investigator for activities such as participating on committees, providing consultation, or serving as a preceptor.
- Grants to fund ongoing research not related to the conduct of the clinical study, including laboratory activities and equipment, and compensation in the form of actual equipment for the laboratory/clinic. However, if the investigator was provided with computer software or money to buy software needed for use in the clinical study, that payment would not need to be reported.

**6. Are payments made to investigators to cover travel expenses (such as transportation, lodgings and meal expenses) reportable as significant payments of other sorts (SPOOS)?**

Generally, reasonable payments made to investigators to cover reimbursable expenses such as transportation, lodgings and meals do not fall within the definition of SPOOS and would not need to be reported. Payment for other expenses that are generally considered outside of normal reimbursable expenditures and not expenses necessary to conduct the study would be considered SPOOS. For example, entertainment costs, travel costs associated with transporting and/or providing lodgings and meals for family members, and other payments that exceed reasonable expectations (for example, if an investigator was flown to a resort location for an extra week of vacation). These types of expenses are reportable and should be tracked as SPOOS.