Principal Investigator (PI) Self-Assessment Programme Frequently Asked Questions (FAQs)

1. What is the PI Self-Assessment Programme?

The PI Self-Assessment Programme is a quality assurance component under the NHG OHRPP Research Quality Management (RQM) framework. In this programme, selected Principal Investigators (PIs) will be asked to complete a PI Self-Assessment Form (PISAF), which is a tool developed by NHG Research Quality Management (RQM) Unit for PIs to conduct self-monitoring.

2. Who will be selected to complete the PISAF?

For **NHG** PI(s), it is **mandatory** for you to complete the PISAF if you meet the following criteria:

- 1) You are a first time PI whose studies have been approved by DSRB
- 2) Your study was reviewed via Expedited Review
- 3) Your study is a PI-initiated study
- 4) Your study is a Human Biomedical Research Act (HBRA) regulated study that involves consenttaking
- 5) Your study is / will be undergoing its first study renewal

For other **NHG** PI(s), you will be invited (voluntary) to complete the PISAF if you meet the following criteria:

- 1) You are a first time PI whose studies have been approved by DSRB
- 2) Your study was reviewed via Full Board/Expedited Review
- 3) Your study is a PI-initiated study
- 4) Your study is <u>either</u> a non-HBRA regulated study or is a HBRA regulated study that <u>does not</u> involve consent taking
- 5) Your study is / will be undergoing its first study renewal

For other **non NHG** PI(s), you will be invited (voluntary) to complete the PISAF if you meet the following criteria:

- 1) The PI is a first time PI whose study has been approved by DSRB
- 2) The study was reviewed via Full Board/Expedited Review
- 3) The study is a PI initiated study
- 4) The study is/will be undergoing its first study renewal

3. When do I need to submit the PISAF?

Selected PI(s) will be asked to perform a <u>one-time</u> Self- Assessment during their first annual study renewal.

4. How do I go about completing the PISAF?

The RQM team will email the selected PI(s) 3 months before the first study renewal to request for the completion of the PISAF. PI(s) should respond to the notification and complete the PISAF accordingly.

5. How much time am I given to complete the PISAF?

You will be given **2 weeks** to complete the PISAF.

6. What should I expect after I have submitted the PISAF?

Your completed PISAF will be reviewed by the RQM team within 2 weeks. You will receive an email notification regarding the outcome of the review.

There are 3 types of outcome:

- (1) Closed with satisfaction
- (2) Closed with comment
- (3) Queried

If there are queries, you would be requested to respond within 2 weeks. The RQM team will review your responses and notify you of the final outcome.

7. Who can I contact if I have questions about PISAF?

You may contact the RQM team at researchquality@nhg.com.sg.