

Principal Investigator (PI) Self-Assessment Programme

Frequently Asked Questions (FAQs)

1. What is the PI Self-Assessment Programme?

First launched in 2009, the PI Self-Assessment Programme is a quality assurance component under the NHG OHRPP Research Quality Management (RQM) framework. In this programme, investigators perform a Self-Assessment as a form of self-monitoring during their annual study renewal process.

2. How is the PI Self-Assessment Programme helpful to me?

The programme aims to familiarize investigators with current ethical and regulatory requirements and identify potential issues in research conduct through the use of the self-assessment tool.

3. What are the changes to the revised PI Self-Assessment Programme?

Previously, participation in this program is mandatory for all PIs. Effective March 2017, it will be mandatory for only a selected group of PIs to participate in the self-assessment programme using the PI Self-Assessment Form (PISAF). All other PIs may continue to access the PISAF to perform self-monitoring of their studies on a voluntary basis. The PISAF is a question-based checklist which takes approximately 15mins to complete.

4. Who will be selected to complete the PISAF?

4.1. For NHG PIs, you will need to complete the PISAF if you meet the following

criteria:

- 1) You are a first time PI, i.e. no prior studies approved by DSRB in ROAM.
- 2) Your study was reviewed via Expedited Review.
- 3) Your study is a PI-initiated study
- 4) Your study involves consent taking.
- 5) Your study is / will be undergoing its first study renewal

4.2. For other NHG PIs and non-NHG PIs, you will be invited to complete the PISAF if you meet the following criteria:

- 1) You are a first time PI, i.e. no prior studies approved by DSRB in ROAM.
- 2) Your study was reviewed via Full Board/Expedited Review.
- 3) Your study is a PI-initiated study
- 4) Your study is / will be undergoing its first study renewal.

5. How often would I need to submit the PISAF?

Each investigator will be selected to perform no more than 1 Self-Assessment per year. If the study has been terminated / completed at the time of the request, an alternative study will be chosen for self-assessment.

6. How should the PISAF be submitted?

The RQM team will send you the link to the online PISAF. Once you have completed the self-assessment, simply click the submit button.

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

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

8. 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 response and send you the final outcome email if it is satisfactory.

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

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