

Updates on the Principal Investigator Self-Assessment Program

Purpose of the Principal Investigator Self-Assessment Program

The Principal Investigator Self-Assessment Program is a quality assurance component under the Research Quality framework at OHRPP and functions as a supplement to the study review program. The Program seeks to:

- Familiarize investigators with current ethical and regulatory requirements &
- Help investigators identify potential issues in research conduct

Changes in Practice

Since 2009, a self-assessment was required at every continuing review through the completion of the ROAM RQA Self-Assessment Checklist.

Effective July 2016, only selected PIs will be required to complete a mandatory self-assessment via a shorter online form (PISAF – PI Self-Assessment Form). The PISAF is a question-based checklist which takes approximately 15mins to complete.

While the priority is to select new investigators to educate and familiarize them on research conduct requirements, a random number of other PI-initiated Full Board or expedited studies may also be selected for this self-assessment exercise.

Investigators will be informed by the Research Quality Management (RQM) team if they are selected to participate in the self-assessment exercise, and given 2 weeks to complete the online PISAF.

Once the completed PISAF is received, the RQM team will review and update investigators of the review outcome within 2 weeks.

A copy of the updated PISAF can be located via the research website www.research.nhg.com.sg. For clarifications, please write to us at researchquality@nhg.com.sg.

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Summary of the Revised Process

The following table summarises key revisions to the self-assessment program:

Summary	As is	Effective July 2016
Who is impacted?	All PIs are required to perform a self-assessment & submit the RQA Assessment Form at the point of study renewal.	Only PIs with a PI-initiated FB/ Expedited study may be selected to do self-assessment.
What types of Studies are subjected to Self-Assessment?	All studies.	Only PI-initiated studies reviewed via FB/Expedited review.
How often is Self-Assessment needed?	At every continuing review for all studies.	No more than once per year per PI
What are the Self-Assessment tools?	RQA Self-Assessment Checklist in ROAM.	Online PISAF