OBJECTIVE
The objective of this guidance is to define the procedure for use of the self-assessment tool as a component of the post approval monitoring program.

RESPONSIBILITY
The post-approval monitor will be responsible for the oversight of the self-assessment procedures.

PROCEDURE
Investigator self-assessment
Submission of the Self-Assessment checklist in this case is not required. The Principal Investigator (and if applicable, the Faculty Advisor) will receive a Self-Assessment checklist when a full on-site assessment is scheduled. Investigators can use this tool to prepare for a full on-site assessment. The Self-Assessment checklist is not used by the monitor during the review.

Principal Investigators will also be encouraged to utilize the Self-Assessment checklist on an annual basis, and to contact the monitor if questions arise. The Self-Assessment checklist will be sent in an annual email to active investigators.

IRB-directed self-assessment
The self-assessment tool may also be used in a directed fashion. In this case, the Principal Investigator will receive a notice along with a self-assessment form, with instructions to complete and submit the form within 30 days. The PI will submit the form, which is reviewed by the monitor. Follow-up may include suggested educational activities, requirement for submission of a modification, or a full on-site assessment.

If the form is not received within 30 days of notification, a follow-up email will be sent, with copies to the IRB Chair and the Associate Vice President for Research, again with notification to submit the form within 30 days.

If the form is not submitted by the 2 month deadline, the study will be closed to enrollment until the form has been submitted. Notification of the protocol’s status will be sent via a letter from the Associate Vice President for Research.
If, at the end of a third month, the Self-Assessment form has not been submitted, an on-site assessment will be scheduled. Notification of the need for on-site assessment will be sent from the Associate Vice President for Research.

REFERENCES:
Self-assessment annual email 1-3A
Self-assessment process tracking 1-3B
Self-Assessment checklist 1-3C
Notification Letter 1-3D
No response letter 1 month 1-3E
No response letter 2 months 1-3F
No response letter 3 months 1-3G