OBJECTIVE
To define the procedure for post-approval monitoring notification.

RESPONSIBILITY
The Research Compliance Monitor will be responsible for the execution of this Administrative Guidance.

PROCEDURES
1. The monitor will prepare and send a letter via email one to four weeks prior to the anticipated review date, to the Principal Investigator (PI) and, if applicable, the Faculty Advisor or Lab Manager, notifying him/her that the study has been selected for on-site post-approval review. The letter will request a convenient date and time to meet with study personnel.

   If no response is received within approximately 2 weeks, a second email will be sent.

   If no response to the second email is received within 2 weeks, a phone call or third email may be attempted.

   If no response is received after approximately 4 weeks from the initial notification, the Associate Vice President for Research may send a letter via messenger mail to the investigator asking him/her to contact the Research Compliance Monitor. Failure to contact the monitor within approximately two weeks after the letter is sent may result in temporarily closing the protocol to enrollment.

2. The notification letter will include specific areas to be reviewed, as applicable:
   • All subject consent forms
   • Regulatory files (electronic or physical)
   • Adherence to IRB-approved protocol’s plans for data security and protection of confidentiality

3. If subject enrollment has not occurred at the time of initial notification of the PI, the monitor may defer the visit and contact the study team again every 6-12 months until subjects have been enrolled.
4. The monitor will track notification of on-site review in the Post-Approval monitoring record (1-1A) and On-Site Process Tracking form (1-4A).

REFERENCES:
On-Site Review – Process Tracking 1-4A
Notification of Review Letter 1-4B
No Response Letter 1-4C