RUTGERS UNIVERSITY
Office for Research

SOP: Exit Interview Routine and For-Cause Review		
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1 PURPOSE

1.1 This SOP ensures that the Quality Assurance and Evaluation (QA&E Team provides a summary of their visit and allows the Principal Investigator to ask questions, clarify, and provide missing information. This assures the Principal Investigator that accurate information is communicated to the IRB Executive committee representing how the IRB approved study is being conducted.

2 REVISIONS FROM PREVIOUS VERSION

2.1 None.

3 POLICY

3.1 This SOP applies to the audit team and pertains to providing clear and concise communication regarding their findings at the time of the audit review. It also pertains to the Principal Investigator and the study team allowing time to hear the concerns and observations and allowing time for discussion and comments.

4 RESPONSIBILITIES

4.1 During the Exit Interview the QA&E team member is responsible for notifying the Principal Investigator (PI) of any potential or significant findings discovered during the Post Approval Monitoring (PAM) review.

4.2 During the PAM review process, both the QA&E team member and the PI have the opportunity to clarify and address any findings, observations, or misunderstandings.

4.3 The QA&E team member must also ensure that an accurate report is prepared and presented to the IRB Executive Committee

5 PROCEDURE

5.1 Exit Interview

5.1.1 The exit interview will ideally occur within 72 working hours of the completion of the audit.

5.1.2 The Principal Investigator is required to be present during the exit interview.

5.1.2.1 The co-investigator and/or study team members are also strongly recommended to attend.

5.1.3 The QA&E Team presents the audit findings and responds to any questions from the Principal Investigator and study team.

5.1.4 It is important at this point to discuss all questionable issues and provide opportunities for clarification.

5.1.4.1 Any missing, incomplete, or incorrect data should be given to the QA&E Team member within three (3) business days of the exit interview unless the finding(s) may impact the safety of subjects or otherwise the integrity of the research.

5.1.4.2 If no communication is received regarding the missing, incomplete, or incorrect data, then the finding/deviation will be cited in the final report.

6 MATERIALS

6.1 1.001 (HRP-101) – Human Research Protection Program Plan.

6.2 12.102 (HRP-430a) - CHECKLIST - Investigator Quality Improvement Assessment - Drug, Devices, Clinical Trial.

6.3 12.103 (HRP-430b) – CHECKLIST – Investigator Quality Improvement Assessment – Participant File.

6.4 12.104 (HRP-430c) – CHECKLIST – Investigator Quality Improvement Assessment – Biomedical Research.

6.5 12.105 (HRP-430d) – CHECKLIST – Investigator Quality Improvement Assessment – Social Behavioral Research.

6.6 12.106 (HRP-430e) – CHECKLIST – Investigator Quality Improvement Assessment –Humanitarian Use Device.

7 REFERENCES

7.1 None.