

## SOP: Virtual QA&E Review

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### 1. PURPOSE

- 1.1 This SOP compliments the established HRPP QA&E [Routine Audit SOP](#), Directed [For-cause Audit SOP](#) and is based on the newly released [Returning to Research at Rutgers Guidelines](#) (RRRG).
- 1.2 RRRG states that Local (in-state) travel to field sites or other research facilities is permitted, provided that guidelines are followed to the extent possible.

### 2. REVISIONS FROM PREVIOUS VERSION

- 2.1 None. (This is the first version of this Standard Operating Procedure (SOP)).

### 3. POLICY

- 3.1 Personnel should remain at home to the extent their responsibilities allow. When an onsite task is unavoidable, we will abide by RRRG.
- 3.2 All review activities that can be done remotely, must be done remotely. Those activities that have to be done in person and on-site should be completed in the shortest amount of time possible.

### 4. RESPONSIBILITIES

- 4.1 The HRPP QA&E team member is responsible for informing the Principal Investigator (PI) about the type of review that needs to be conducted. They will explain the process and what is expected from the PI. The team member will also schedule a virtual meeting at a mutually agreed time and on a chosen platform.
- 4.2 Before the meeting, the QA&E team member will review all relevant study documents and lead the discussion during the interview. At the end of the call, they will request any necessary study documents to complete the Post-Approval Monitoring Review.
- 4.3 Additionally, an Exit Interview will be scheduled virtually to discuss any findings from the review.

### 5. PROCEDURE

- 5.1 Interview
  - 5.1.1 Notification to the PI of Routine or Directed (For-Cause) Post Approval Monitoring (PAM) Review.
  - 5.1.2 When scheduling the virtual interview, the QA&E team member will determine the Rutgers-provided video conferencing platform that the Principal Investigator is most comfortable with (Zoom, Teams, Skype, etc.) and schedule the interview.
  - 5.1.3 All scheduling will be done ahead of time at a mutually agreed upon time. Study-related documents (or other items viewable on a computer screen) referenced by any party during the interview, may be shown to all by sharing on screen.
- 5.2 Document Review
  - 5.2.1 When requesting documents to review virtually, the QA&E team member will discuss a secure way to share such documents can be shared using platforms such as email, Teams, Rutgers OneDrive, etc. In-Person Tasks
  - 5.2.2 If any tasks are required to be conducted in person, the QA&E team member will abide by the SOP for the in-person audit.
- 5.3 Follow-up
  - 5.3.1 Post-PAM procedures include a summary letter to the Principal Investigator detailing any findings.
  - 5.3.2 A virtual Exit Interview will be scheduled with the Principal Investigator to discuss any findings from the review or any additional questions or
  - 5.3.3 A final report will be submitted and presented to the IRB Executive Committee. The Principal Investigator may request a copy of the final report via email.

### 6. MATERIALS

- 6.1 12.002 (HRP-025) – SOP - Post Approval Monitoring (PAM) Routine and Directed (For-Cause) Post Approval Monitoring Review.

### 7. REFERENCES

- 7.1 [Returning to Research at Rutgers Guidelines](#) (RRRG).