1 PURPOSE

1.1 This procedure establishes the process to complete tasks required to monitor the research review process.

1.2 The process begins each day.

1.3 The process ends when the tasks have been completed.

2 REVISIONS FROM PREVIOUS VERSION

2.1 03/24/2021.

3 POLICY

3.1 None.

4 RESPONSIBILITIES

4.1 Some procedures that follow are completed automatically by electronic systems; some procedures are completed by IRB staff members.

5 PROCEDURE

5.1 The following steps are completed automatically by electronic systems as follows:

5.1.1 CITI tracks Rutgers'-affiliated individuals' completion of required training modules. It automatically sends reminders to individuals when training will lapse in 90 days. A Failure to Submit correspondence is automatically sent by CITI when an individual fails to complete required training before the expiration date. CITI interacts with Rutgers electronic IRB system (eIRB+) downloading timely data about individuals training status.

5.1.2 eIRB+ tracks schedule of continuing review progress reports and status reports and automatically issues 60-day and 30-day reminders to the principal investigator to submit reports by their due date and study expiration notices, as applicable. eIRB+ automatically sends A Failure to Submit correspondence and Expiration of IRB Approval, as applicable, to the PI if the report is not submitted to eIRB+ by the due date.

5.2 The following steps are completed by IRB staff:

5.2.1 Check for emergency uses where the IRB has not received a progress report, within 5 business days:

5.2.1.1 Complete and send 8.301 (HRP-551) - LETTER - Failure to Submit Emergency Use Report through eIRB+.

5.2.1.2 Send a reminder email to PI to follow up with submission of progress report.

5.2.1.3 At the direction of the Executive Committee process the failure to submit as a Finding of Non-Compliance under 10.001 (HRP-024) - SOP - Reportable New Information

5.2.1.4 At the direction of the Executive Committee, the principal investigator's name will be placed on the Restricted Status list.

5.2.2 For individuals whose training has lapsed:

5.2.2.1 At the direction of the Executive Committee, a principal investigator's name will be placed on the Restricted Status list.

5.2.2.2 At the direction of the IO or designee, an IRB member's appointment to the IRB will be suspended or revoked. If revoked, follow 2.004 (HRP-083) - SOP - IRB Membership Removal.

5.2.3 For protocols that have expired due to lack of continuing review report or status report:

5.2.3.1 Follow 3.013 (HRP-063) - SOP - Expiration of IRB Approval.

5.2.4 For protocols that have expired and are administratively closed:

5.2.4.1 Follow the standard office procedures. See guidance for Expired Studies.

6 MATERIALS

6.1 2.004 (HRP-083) - SOP - IRB Membership Removal.
6.2 3.302 (HRP-530) - LETTER - Continuing Review Reminder – Automatically generated by eIRB+.
6.3 3.303 (HRP-531) - LETTER - Training Reminder – Automatically generated by CITI.
6.4 3.304 (HRP-533) - LETTER - Expiration of IRB Approval – Automatically generated by eIRB+.
6.5 3.305 (HRP-535) - LETTER - Annual Reminder – Automatically generated by eIRB+.
6.6 3.306 (HRP-550) - LETTER - Failure to Submit Continuing Review Report – Automatically generated by e-IRB+.
6.7 3.307 (HRP-554) - LETTER - Failure to Undergo Training.
6.8 3.013 (HRP-063) - SOP - Expiration of IRB Approval.
6.9 8.301 (HRP-551) - LETTER - Failure to Submit Emergency Use Report.
6.10 8.302 (HRP-553) - LETTER - Failure to Submit Emergency Use Protocol.
6.11 10.001 (HRP-024) - SOP – Reportable New Information.

7 REFERENCES

7.1 None.