HRP-052 | 11/26/2024 | Author: T. Bechert | Approver: J. Opalesky

**SOP: Post-Review**

1. **PURPOSE**
   1. This procedure establishes the process for communications after a protocol is reviewed.
   2. The process begins when:
      1. A Designated Reviewer has completed a Non-Committee Review and provided completed materials to the IRB staff; OR
      2. An IRB meeting has adjourned, and the IRB chair or IRB manager has approved the minutes; OR
      3. An IRB staff member has verified that modifications required to secure approval have been made.
   3. The process ends when all correspondence related to IRB determinations and actions have been sent and additional tasks have been completed.
2. **REVISIONS FROM PREVIOUS VERSION**
   1. Clarification to procedure 5.3.1.2 to set an approval interval for exempt determinations and expedited studies reviewed under the 2018 Common Rule regulatory authority.
   2. Clarified process steps in section 5.3 and 5.4 for notification when lifting a suspension and 5.5 for reportable findings.
   3. Removed reference to HRP-526 and added process steps to remove a Suspension of IRB Approval; removed reference to direct reporting to the Chief Ethics and Compliance Officer via the University Integrity and Compliance Office reporting system as this process is managed within OVPRI; 2/1/24.
   4. Updated to clarify grant review status update interval, processing turnaround expectations, NHSR and finalize and stamp document processes, prisoner certification record retention, and to clarify OHRP incident report submission types; 11/26/24.
3. **POLICY**
   1. The IRB reports its findings and actions to the investigator.
   2. The IRB reports its findings and actions to the institution.
   3. When the IRB disapproves research, it provides the investigator with a statement of the reasons for the decision and gives the investigator an opportunity to respond in person or in writing.
   4. Communication of review results to investigators are to be completed within 2 business days of receipt of the completed Non-Committee Review materials or outright IRB meeting approvals, or within 5 business days of the IRB meeting.
   5. Reporting of Serious Non-Compliance; Continuing Non-Compliance; Suspension of IRB Approval; Termination of IRB Approval; and Unanticipated Problem Involving Risks to Subjects or Others to outside agencies is to take place within 30 business days from the determination of a reportable problem.
      1. For Veterans Affairs (VA) research:
         1. An Unanticipated Problem Involving Risks to Subjects or Others that is a local research death, notification to the VA facility Director, the Research Compliance Officer (RCO) and the Associate Chief of Staff/R&D must occur within 5 business days of the convened IRB’s determination(s).
         2. Information determined by the IRB to constitute an Unanticipated Problem Involving Risks to Subjects or Others, Serious Non-Compliance or Continuing Non-Compliance, notification to the VA facility Director, the Research Compliance Officer (RCO) and the Associate Chief of Staff/R&D must occur within 5 business days of the convened IRB’s determination(s).
            1. If the IRB is unable to make a determination on the apparent Unanticipated Problem Involving Risks to Subjects or Others within 30 calendar days of the convened IRB’s initial review due to insufficient information or due to a lack of sufficient time to complete its review, the IRB must notify the VA medical facility Director, the Research Compliance Officer (RCO), and the ACOS/R&D in writing no later than five (5) business days after the determination was due.
   6. When a modification is reviewed to lift a suspension for a previous Suspension of IRB Approval, the state of the study will be changed from “Suspended” to “Approved” when the modification is approved.
4. **RESPONSIBILITIES**
   1. IRB staff members carry out these procedures.
5. **PROCEDURE**
   1. If the Non-Committee Review indicated a Conflicting Interest or a lack of expertise, follow HRP-031 - SOP - Non-Committee Review Preparation.
   2. Confirm final CHECKLISTS are uploaded in Administrative Documents.
   3. For initial reviews, continuing review, or modification:
      1. If the communication is an IRB determination of Approved (advance to step 5.3.1.3 for NHSR unless otherwise noted):
         1. Refer to HRP-302 - WORKSHEET - Approval Intervals to calculate approval intervals (if applicable).
         2. Execute the applicable “Set Amendment Approval Date” or “Set Approval and Expiration Date” activity.
            1. For expedited studies reviewed under the 2018 Common Rule regulatory authority, enter an expedited anniversary date to facilitate an automated RAMS-IRB status update request.
            2. For Center or Institute Administrative Grant Review submissions with NHSR determination, set a 1-year approval interval to facilitate the status update process.
         3. Reference HRP-303 - WORKSHEET - Communication of Review Results to determine the appropriate letter template.
         4. Execute the “Prepare Letter to Study Team” activity and modify the system or paper-based letter as needed.
         5. Execute the “Send Correspondence Letter” activity.
            1. If reviewed at a convened meeting, “Send Correspondence Letter for Review” to the Chair or Vice Chair to approve the correspondence letter. The Chair/Vice Chair will complete the “Edit or Approve Correspondence Letter” activity and execute the “Send to Study Team” activity.
            2. If reviewed by non-committee review, “Send Correspondence Letter for Review” to the assigned IRB Coordinator to complete the “Edit or Approve Correspondence Letter” activity.
            3. Execute the “Send Correspondence to Study Team” activity.

For NHSR, processing concludes with this step.

* + - 1. Execute the “Finalize Approved Documents” activity.
         1. Click “Update” and mark as Approved all new or changed documents, where applicable.
         2. “Stamp” relevant documents (“yes” for consent forms and information sheets; recruitment materials where stamping is requested by the study team). Stamps do not expire and are applied at the time of initial review or once a document is revised. Stamps must be applied to clean drafts free of previous stamps.

To update a document with a previously applied stamp, update the “Stamp” to “No,” select “OK;” update the “Stamp” to “Yes.”

* + - * 1. Click “OK” to exit Update Document activity.
      1. Complete the “Send to Approved” activity.
      2. “Log Private Comment” to the parent submission for studies under Committee Review where the IRB determined the study is minimal risk and therefore eligible for expedited continuing review.
      3. Execute the Lift Suspension activity on the parent submission to move the study status from Suspended to Approved, when applicable.

5.3.1.10 “Reassign Ownership” to the appropriate team lead if the submission received a different level of review than anticipated during HRP-020 - SOP - Incoming Items. (e.g., An expedited submission that received Committee Review, or a full board submission determined to be minimal risk and eligible for expedited continuing review.)

* + 1. If the communication is an IRB determination other than Approved:
       1. Execute the “Send Correspondence Letter” activity and modify the letter as needed.
          1. If reviewed at a convened meeting, send to Chair or Vice Chair to approve the correspondence letter. The Chair/Vice Chair will complete the “Edit or Approve Correspondence Letter” activity and execute the “Send to Study Team” activity.
       2. Execute the “Send to Study Team” activity.
  1. Refer to HRP-303 - WORKSHEET - Communication of Review Results to determine if any additional paper-based letters need to be sent and send all applicable letters within 30 business days.
     1. Refer to HRP-303 - WORKSHEET - Communication of Review Results and send applicable letter to the Principal Investigator or other recipients within 5 business days.
        1. Have letter signed by the signatory in the template letter.
        2. Send the letter to the inside addresses and cc list as directed by the letter.
           1. For prisoner research funded, conducted or supported by DHHS: upload signed HRP-522 - LETTER - Cert Prisoner Research and copy of submitted online Subpart C Certification Form to submission under Admin Docs tab.
           2. Save copy of submitted online Subpart C Certification Form, finalized HRP-522 - LETTER - Cert Prisoner Research, and submitted attachments to the VPR-IRB drive in the applicable OHRP Prisoner certifications sub-folder.
  2. For determinations of Serious Non-Compliance; Continuing Non-Compliance; Suspension of IRB Approval; Termination of IRB Approval; or Unanticipated Problem Involving Risks to Subjects or Others:
     1. Execute the “Prepare Correspondence Letter” activity and modify HRP-519 - LETTER - Information Item.
     2. Send to the Chair or Vice Chair to approve the correspondence letter. The Chair/Vice Chair will complete the “Edit or Approve Correspondence Letter” activity and execute the “Send to Study Team” activity.
     3. Add to the Federal Reporting Tracking Log.
     4. The following steps are performed by the IRB Meeting Coordinator, or designee, in consultation with the HRPP Director or designee:
        1. When reporting to OHRP only, complete the *OHRP Incident Report Form[[1]](#footnote-1)* within 30 business days from the determination of a reportable problem.
           1. Select Full Report unless further actions will be taken in which case Initial Report submission type should be selected.

OHRP will require a Follow-up Report within 3 months of an Initial Report.

* + - 1. If reporting to both OHRP and any other outside agency concurrently, utilize the OHRP Incident Report Form email confirmation and HRP-520a - LETTER - External Report - OHRP and Other Agencies and send within 30 business days from the determination of a reportable problem.
      2. Modify HRP-520a - LETTER - External Report - OHRP and Other Agencies for VCU internal communication of the reportable problem; attach the OHRP Incident Report Form email confirmation, and when applicable, a copy of the HRP-520a letter sent to any other outside agency.

5.5.4.4 Save all materials to the VPR-IRB drive in the applicable Federal Correspondence sub-folder.

1. **MATERIALS**
   1. HRP-031 - SOP - Non-Committee Review Preparation
   2. HRP-302 - WORKSHEET - Approval Intervals
   3. HRP-303 - WORKSHEET - Communication of Review Results
   4. HRP-520a - LETTER - External Report OHRP and Other Agencies
2. **REFERENCES**
   1. 45 CFR §46.103(b)(4)(i), 45 CFR §46.207, 45 CFR §46.306(2)(C), 45 CFR §46.306(2)(D), 45 CFR §46.407, 45 CFR §46 Waiver of Informed Consent Requirements in Certain Emergency Research (November 1, 1996)
   2. 21 CFR §56.108(a)(1), 21 CFR §50.24(e), 21 CFR §50.54(b), 21 CFR §812.66
   3. VHA Directive 1058.01 October 22, 2020
   4. AAHRPP elements I.1.A, I.5.D, I-9, II.1.D, II.1.E, II.2.A, II.2.G, II.2.H, II.2.E-II.2.E.2, II.2.F-II.2.F.3, III.2.D

1. <https://oash.force.com/ohrpwebforms/s/incident-web-form> [↑](#footnote-ref-1)