HRP-021 | 11/26/2024 | Author: T. Bechert | Approver: J. Opalesky

# SOP: Pre-Review

1. **PURPOSE**

This procedure establishes the process to pre-review a request for approval (approval of new research, approval to rely on an external IRB, humanitarian use device (HUD), continuing review of research, or modification to previously approved research) or a determination whether an activity is exempt Human Research or is not Human Research.

* 1. The process begins when the IRB receives a request for local IRB approval, including requests from other institutions when this institution is the IRB of record, e.g., for a Collaborative Study or Multi-Site Study, or a request to rely on an external IRB.
  2. The process ends when the information has been placed on the agenda for an IRB meeting or will be handled by Non-Committee Review, or the information is sent to the Reliance Coordinator or IRB staff to review the request to rely on an external IRB.

1. **REVISIONS FROM PREVIOUS VERSION**
   1. Revised the workflow to incorporate DUA review; 10/2/23.
   2. Revised to incorporate HRP-803 - SOP - Reliance Pre-Review content per Huron HRPP Toolkit v5.1 release; 2/1/24.

* 1. Updated federal debarment link; additional administrative updates for clarity; added reference to HRP-815 - FORM - Institutional Profile; added process step for IIA, revised workflow for expanded access; 11/26/24.

1. **POLICY**
   1. The assigned IRB Coordinator will conduct pre-review within 10 business days of assignment. The IRB Coordinator will consult with their supervisor when review exceeds turnaround expectations.
   2. Any institution located in the United States that is engaged in federally-funded cooperative research must rely upon approval by a single IRB for that portion of the research that is conducted in the United States. The reviewing IRB will be identified by the Federal department or agency supporting or conducting the research or proposed by the lead institution subject to the acceptance of the Federal department or agency supporting the research.
   3. An NIH funded study being conducted at more than one U.S. site involving non-exempt human subjects research may be subject to the [NIH Single IRB policy](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-094.html) and/or the revised Common Rule cooperative research provision ([§46.114](https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML#se45.1.46_1114)  Link to Non-U.S. Government Site - Click for Disclaimer ).
   4. The VCU Post Approval Monitoring and Education program (PAM&E), when applicable, performs routine or for-cause audits on studies relying on an external IRB.
   5. VCU evaluates requests for VCU IRB to serve as sIRB for federally funded or non-industry funded multi-site/collaborative research on a case-by-case basis.
   6. The addition of a participating site to a previously approved protocol for which the IRB will serve as the IRB of record for that participating site is considered a modification to previously approved research.
   7. Single subject protocol exceptions are reviewed as modifications to previously approved research. [[1]](#footnote-1)
   8. A new HUD protocol submission must be reviewed at a convened IRB meeting. Continuing review of a HUD can be handled by Non-Committee Review.
2. **RESPONSIBILITIES**
   1. IRB staff members carry out these procedures.
3. **PROCEDURE**
   1. If the submission is a response to modifications required to secure approval received within 30 calendar days (RAMS-IRB will auto-withdraw the submission if not returned within 30 calendar days of the IRB review date):
      1. Evaluate whether the investigator made the required modifications.
      2. If the investigator made the required modifications, follow HRP-052 - SOP - Post-Review to issue an approval.
      3. If the investigator did not make the required modifications or made unrequested modifications, execute the “Changes Requested by IRB staff” activity and offer the investigator the opportunity to correct the submission.
         1. If the investigator will correct the submission, have the investigator make changes then execute the “Submit Changes” activity and stop processing the current submission until changes are received.
         2. If the investigator will not correct the submission, have the investigator execute the “Submit Changes” activity to resubmit and continue processing.
   2. If the request is for this institution to rely on an external IRB:
      1. Refer to HRP-806 - SOP - Review Request to Rely on External IRB.
   3. If the request includes review of a pSite submission:
      1. Determine if the pSite is engaged in the non-exempt human subjects research using HRP-311- WORKSHEET - Engagement Determination.
         1. If the pSite is not engaged in the non-exempt human subjects research, execute the “Submit Invitation Decision” activity to notify the lead investigator using HRP-850 - LETTER - Decline to Serve that this IRB will not serve as the IRB of Record for the pSite.
      2. If the pSite is engaged, click on the Institutional Profile area in the IRB system and:
         1. Confirm that the pSite has an active profile. If not, see 5.3.2.2.1.
         2. Determine whether an existing Authorization Agreement covers the study activities for the pSite.
            1. If not, follow HRP-801 - SOP - Establishing Authorization Agreements to collect the information needed to confirm reliance and create a new or updated HRP-815 - FORM - Institutional Profile in the IRB system.
      3. Execute the “Submit Invitation Decision” activity to notify the pSite using HRP-851 - LETTER - Invitation Decision or HRP-850 - LETTER - Decline to Serve that this IRB will or will not serve as the IRB of Record for their participation in the study.
      4. If the IRB will serve as the sIRB for the pSite, after all site materials are submitted, proceed to next section.
   4. If the request includes review of a collaborating independent investigator or collaborating institutional investigator, follow HRP-801 - SOP - Establishing Agreements to establish an Individual Investigator Agreement.
   5. For all other submissions, complete HRP-401 - Checklist - Pre-Review or review the previously completed checklist and revise as needed, considering the items on HRP-308 - WORKSHEET - Pre-Review and note all remaining contingencies in the “Notes” section.
      1. Perform the “Upload Administrative Documents” Activity to attach applicable documents:
         1. HRP-401 - Checklist - Pre-Review.
            1. Layer the revised pre-review checklist, when applicable, to the previous version.
         2. All applicable special determination checklists for completion by the assigned reviewer(s).
   6. When assigning to an IRB member for review, include HRP-314a - WORKSHEET - Criteria for Approval Reviewer Summary.
   7. If the information is not complete, contact the investigator by selecting the “Changes Requested by IRB Staff” Activity. Offer the investigator the opportunity to provide additional information.
      1. Continue processing once the investigator responds to the request for additional information.
   8. If the request is for an initial approval, use HRP-308 - Worksheet - Pre-Review to assess the completeness of the submission, identifying any incomplete responses or missing materials (e.g., missing informed consent process information). Also assess the following as it relates to the submission:
      1. Search the RAMS-IRB system for all of the Principal Investigator’s open studies to determine if they have any studies requiring continuing review in a lapsed state. If the Principal Investigator has any lapsed studies, note in the “Notes” section of HRP-401 - Checklist - Pre-Review.
         1. Request the Principal Investigator submit a continuing review or closure for any lapsed studies and determine whether any research activities have taken place during the lapse in IRB approval; if research has been conducted, request a Report to the IRB and refer the identified lapsed studies to the PAM&E Monitor.
      2. If the study is FDA-regulated, and involves a new or unfamiliar investigator, search the [FDA debarment list](https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/compliance-actions-and-activities/fda-debarment-list-drug-product-applications) to see if the Principal Investigator is listed.
         1. If the Principal Investigator is listed, note in the “Notes” section of HRP-401 - Checklist - Pre-Review.
      3. If the study involves clinical elements being performed at a VCUHS site by clinicians who require VCUHS privileges, search the “Privileged Personnel List” on the VPR-IRB shared drive to confirm that they hold appropriate, current hospital privileges.
         1. If personnel are not listed, note in the “Notes” section of HRP-401 - Checklist - Pre-Review.
      4. Initiate COI ancillary review for COI Investigators by executing the “Create AIRS Review Request” activity. Select the checkbox for each name and click “OK” to complete the process.
         1. Confirm the COI Status tab contains a Disposition Date and a final Disposition state (e.g., Complete - No COI, or where a management plan has been established) to proceed with review assignment or consult with the supervisor to determine whether review assignment may proceed concurrent to IRB review.
      5. Confirm the Principal Investigator (and Medically or Psychologically Responsible Investigator, and Lead Student/Trainee Investigator, if applicable) have completed the required CITI training by uploading their training completion certificate with the IRB submission. The PI is responsible for ensuring all other study staff have current CITI training.
      6. If training is not complete, note in the “Notes” section of HRP-401- Checklist - Pre-Review. Notify the investigator. Review may proceed but the final determination letter may not be issued until the training certificate is provided.
      7. If the study involves sharing a Limited Data Set (LDS) from VCU Health system to an internal entity, confirm a [Data Use Agreement for LDS](https://research.vcu.edu/media/office-of-research-and-innovation/documents/DataUseAgreementforUseofLimitedDataSet.docx) signed by investigator is provided. Send to HRPP Director for signature.
         1. Log in to [Docusign](https://account.docusign.com/oauth/auth?response_type=code&client_id=2CC56DC9-4BCD-4B55-8AB0-8BA60BAE1065&redirect_uri=https%3A%2F%2Fapp.docusign.com%2Foauth%2Fcallback&state=%7B%22authTxnId%22%3A%229546bf9b-94be-420b-b3ad-f44a3814ec77%22%7D) using VCU credentials.
         2. Upload PDF of the DUA for LDS to Docusign.
         3. Use Docusign to add fields for name, title, date, and signature.
         4. Send to HRPP Director for completion. Docusign will send the signed PDF back once complete.
         5. Upload finalized PDF to the “Admin Docs” tab in RAMS-IRB.
      8. If there are any materials listed above, or reviewed as part of HRP-308 - Worksheet - Pre-Review that are missing or incomplete add all information to HRP-401 - Checklist - Pre-Review and upload to the submission under the “Admin Docs” tab.
         1. Select the “Changes Requested by IRB Staff” Activity and inform them that they must address all missing or incomplete items before the new request for initial approval will be accepted.
      9. If the submission is complete and there are no outstanding items, proceed to the step 5. 10 below.
   9. If the submission is a continuing review, use HRP-308 - Worksheet - Pre-Review to assess the completeness of the submission, identifying any incomplete responses or missing materials. Also assess the following as it relates to the submission:
      1. Review Private Comments from the parent submission to identify content relevant to follow-on submissions.
      2. Initiate COI ancillary review for COI Investigators by executing the “Create AIRS Review Request” activity. Select the checkbox for each name and click “OK” to complete the process.
         1. Confirm the COI Status tab contains a Disposition Date and a final Disposition state (e.g., Complete - No COI, or where a management plan has been established) to proceed with review assignment or consult with the supervisor to determine whether review assignment may proceed concurrent to IRB review.
      3. Confirm the Principal Investigator (and Medically or Psychologically Responsible Investigator, and Lead Student/Trainee Investigator, if applicable) have completed the required CITI training by uploading their training completion certificate with the IRB submission. The PI is responsible for ensuring all other study staff have current CITI training.
         1. If training is not complete, note in the “Notes” section of HRP-401- Checklist - Pre-Review. Notify the investigator. Review may proceed but the final determination letter may not be issued until the training certificate is provided.
      4. If there are any materials listed above, or reviewed as part of HRP-308 - Worksheet - Pre-Review that are missing or incomplete add all information to HRP-401 - Checklist - Pre-Review and upload to the submission under the “Admin Docs” tab.
         1. Select the “Changes Requested by IRB Staff” Activity and inform them that they must address all missing or incomplete items before the new request for initial approval will be accepted.
      5. If the submission is complete and there are no outstanding items, proceed to section 5. 10 below.
   10. If the submission is a modification to previously approved research, use HRP-308 - Worksheet - Pre-Review to assess the completeness of the submission, identifying any incomplete responses or missing materials. Also assess the following as it relates to the submission:
       1. Review Private Comments or documents under the Admin Docs tab from the parent submission to identify content relevant to follow-on submissions (e.g., PAM&E monitoring reports resulting in study modification or requests with the modification to lift a suspension of IRB approval).
       2. Newly added Principal Investigator (and Medically or Psychologically Responsible Investigator, and Lead Student/Trainee Investigator, if applicable): initiate COI ancillary review by executing the “Create AIRS Review Request” activity. Select the checkbox for each name and click “OK” to complete the process.
       3. Confirm the COI Status tab contains a Disposition Date and a final Disposition state (e.g., Complete - No COI, or where a management plan has been established) to proceed with review assignment or consult with the supervisor to determine whether review assignment may proceed concurrent to IRB review.
       4. Confirm the newly added Principal Investigator (and Medically or Psychologically Responsible Investigator, and Lead Student/Trainee Investigator, if applicable) have completed the required CITI training by uploading their training completion certificate with the IRB submission, if applicable. The PI is responsible for ensuring all other newly added study staff have current CITI training.
          1. If training is not complete, note in the “Notes” section of HRP-401- Checklist - Pre-Review. Notify the investigator. Review may proceed but the final determination letter may not be issued until the training certificate is provided.
       5. If there are any materials listed above, or reviewed as part of HRP-308 - Worksheet - Pre-Review that are missing or incomplete add all information to HRP-401 - Checklist - Pre-Review and upload to the submission under the “Admin Docs” tab.
          1. Select the “Changes Requested by IRB Staff” Activity and inform them that they must address all missing or incomplete items before the new request for initial approval will be accepted.
       6. If the submission is complete and there are no outstanding items, proceed to section 5. 10 below.
   11. Evaluate the most likely level of review using HRP-310 - WORKSHEET - Human Research Determination, HRP-311 - WORKSHEET - Engagement Determination, HRP-312 - WORKSHEET - Exemption Determination, HRP-313 - WORKSHEET - Expedited Review, and/or HRP-323 - WORKSHEET - Criteria for Approval HUD as references:
       1. If the request can be handled as a Non-Committee Review and the Principal Investigator does not have any lapsed studies (applicable for initial review for approval only) and is not on the FDA debarment list (for FDA-regulated projects only), follow HRP-031 - SOP - Non-Committee Review Preparation.
       2. If the request cannot be handled as a Non-Committee Review, including requests to lift a suspension of IRB approval, reassign the IRB Owner to the IRB meeting coordinator for the next available meeting and include a Reassign Owner Comment with any relevant review findings to facilitate selection of an IRB reviewer (e.g., vulnerable population inclusion, drug/device trial, lifting of a suspension). (Do not assign a Veterans Administration (VA) protocol to a commercial IRB unless it has been specifically designated by the VA Office of Research and Development to serve as an IRB for cooperative research.[[2]](#footnote-2))
       3. If the request is a non-emergency individual patient expanded access use of an investigational drug, for which an IRB waiver is requested or device compassionate use, follow HRP-023 - SOP - Emergency Use, Compassionate Use, Indiv Patient Expanded Access and HRP-031 - SOP - Non-Committee Review Preparation.
4. **MATERIALS**
   1. HRP-023 - SOP - Emergency Use, Compassionate Use, Indiv Patient Expanded Access
   2. HRP-024 - SOP - New Information
   3. HRP-031 - SOP - Non-Committee Review Preparation
   4. HRP-040 - SOP - IRB Meeting Preparation
   5. HRP-052 - SOP - Post-Review
   6. HRP-308 - WORKSHEET - Pre-Review
   7. HRP-310 - WORKSHEET - Human Research Determination
   8. HRP-311 - WORKSHEET - Engagement Determination
   9. HRP-312 - WORKSHEET - Exemption Determination
   10. HRP-313 - WORKSHEET - Expedited Review
   11. HRP-314a - WORKSHEET - Criteria for Approval Reviewer Summary
   12. HRP-323 - WORKSHEET - Criteria for Approval HUD
   13. HRP-401 - CHECKLIST - Pre-Review
   14. HRP-801 - SOP - Establishing Agreements
   15. HRP-806 - SOP - Review Request to Rely on External IRB
   16. HRP-815 - FORM - Institutional Profile
   17. HRP-850 - LETTER - Decline to Serve
   18. HRP-851 - LETTER - Invitation Decision
   19. HRP-861 - WORKBOOK - Institutional Profiles
5. **REFERENCES**
   1. AAHRPP elements I.1.A, I-2, I.6.B, I.7.A, I-9, II.2.A-D, II.2.E-II.2.E.2, II.2.F-II.2.F.3

1. Per OHRP correspondence dated 07/22/2011, protocol exceptions are considered changes to previously approved research and eligible for review via expedited procedure. [↑](#footnote-ref-1)
2. Refer to the VA application process for the use of a commercial IRB approved by ORD: https://www.research.va.gov/programs/orppe/single\_irb.cfm [↑](#footnote-ref-2)