HRP-071 | 10/9/2024| Author: T. Bechert | Approver: J. Opalesky

**SOP: Toolkit Management**

1. **PURPOSE**
   1. This procedure establishes the process to create and update standard operating procedures and associated checklists and worksheets.
   2. The process begins when the HRPP Director or Institutional Official/ Deputy Institutional Official (IO/DIO) or designee determines that a Toolkit document needs to be created or modified.
   3. The process ends when the new or revised standard operating procedure has been approved and filed.
2. **REVISIONS FROM PREVIOUS VERSION**
   1. Expanded on procedures for the Toolkit evaluation and revision process; 2/1/24.
   2. Removed unnecessary footer and image; 10/1/24.
3. **POLICY**
   1. For all new or revised standard operating procedures, review is conducted of all associated Toolkit documents and if additional changes are warranted, each document is updated per the procedures below.
   2. Substantive HRPP Toolkit revisions are reviewed and approved by the HRPP Director, or designee.
4. **RESPONSIBILITIES**
   1. The HRPP Director or designee carries out these procedures.
5. **PROCEDURE**
   1. For a new Toolkit document:
      1. Assign a number.
      2. Assign an author and approver.
      3. Toolkit documents will be created following HRP-505 - TEMPLATE SOP for a new SOP, or through creation of an associated document.
         1. The proposed draft version will be filed in the “*Toolkit Change Control\_Tracked Changes Submitted*” subfolder of the *HRPP Toolkit (Change Control)* folder on the VPR\_IRB shared Google drive.
      4. Have the approver review and approve the document.
      5. Once approved by the approver:
         1. Update the approval/effective date within the proposed document maintained in the “*Toolkit Change Control\_Tracked Changes Submitted*” subfolder.
         2. Create a copy of the newly approved document.
         3. File and maintain this approved version of the document in the Clean Document Archive sub-folder on the HRPP Toolkit (Change Control) folder on the VPR-IRB shared Google drive.
         4. Create a duplicate of the approved document referenced in 5.2.5.2.
         5. File and maintain this final approved version of the document in the “*Section D*” subfolder in the VPR-HRPP Toolkit shared Google drive.
         6. Documents in Section D of the VPR-HRPP Toolkit shared drive are the final approved documents.
         7. Move and retain the track changes document into the “*Tracked Change Archive*” subfolder.
   2. For a revised Toolkit document:
      1. Toolkit documents will be revised from the most recent version on the VPR-HRPP Toolkit shared drive.
      2. Create a track changes version which is used to document the proposed changes
         1. If a track changes version was provided with the proposed change, confirm the currently approved document was used as the basis for the track changes.
         2. If a track changes version was not provided, create a new document by copying the currently approved document from the VPR-HRPP Toolkit shared drive, then track the proposed changes.
      3. For revisions to SOPs, update Section 2 (Revisions from Previous Version) and include:
         1. A short summary of changes,
         2. The date of the most recent previous approval.
      4. The proposed track changes version will be filed in the “*Toolkit Change Control\_Tracked Changes Submitted*” subfolder of the HRPP Toolkit (Change Control) folder in the VPR\_IRB shared folder on Google Drive while pending approval.
      5. Have the approver review and approve the document.
      6. Once approved by the approver:
         1. Update the approval/effective date on the track changes version in the “Toolkit Change Control\_Tracked Changes Submitted” subfolder.
         2. Create a “clean” version from the newly approved track changes document.
            1. File and maintain the clean approved version in the *Clean Document Archive* subfolder on the *HRPP Toolkit (Change Control)* folder on the VPR-IRB shared Google drive.
         3. Create a duplicate of the clean approved version referenced in 5.3.4.2.
            1. File and maintain this final approved version of the document in the “*Section D*” subfolder in the VPR-HRPP Toolkit shared Google drive.
            2. Documents in *Section D* of the VPR-HRPP Toolkit shared drive are the final approved documents.
         4. Move and retain the track changes document into the “*Tracked Change Archive*” subfolder.
   3. Website Update:
      1. Post or replace the approved toolkit document on the Human Research Protection Program Web site through submission of a VITALS ticket.
         1. Update the version date (rev. date) on the HRPP Toolkit page.
   4. Communicate changes and necessary training to affected individuals.
   5. Update status on HRPP Toolkit Change Control Tracking Log.
6. **MATERIALS**
   1. HRP-505 - TEMPLATE SOP
7. **REFERENCES**
   1. AAHRPP elements I-9, II.5.A