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 IRB manager or Institutional Official / Organizational Official (IO/OO) or designee determines that a standard operating procedure 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. None
3. POLICY
   1. None
4. RESPONSIBILITIES
   1. The IRB manager carries out these procedures.
5. PROCEDURE
   1. For a new standard operating procedure, assign a number.
   2. Assign an author and approver.
   3. Have the author create or update the standard operating procedure following the “TEMPLATE SOP (HRP-505)” or update the associated checklist or worksheet.
   4. Have the approver review and approve the document.
   5. Once approved by the approver:
      1. Update the approval/effective date.
      2. File and maintain the approved new or revised document in the standard operating procedure files.
      3. Post the approved procedure on the Human Research Protection Program Web site.
      4. File and retain the previous version in the standard operating procedure files.
      5. Send an email to affected individuals informing them of the change.
6. MATERIALS
   1. TEMPLATE SOP (HRP-505)
7. REFERENCES
   1. None