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 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 or designee 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 and Policy Committee review and approve the document.
   5. Once approved:
      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 IRB website.
      4. File and retain the previous version in the standard operating procedure files.
   6. Approved standard operating procedures will be reviewed no less than three years from the effective date to ensure alignment with current IRB Office procedures, and compliance with federal and state regulations, and Parkview Health System policies.
   7. Previous versions of standard operating procedures must be retained for at least three years after they have been replaced.
6. MATERIALS
   1. None
7. REFERENCES
   1. None