

## **SOP: Non-Committee Review Preparation**

### **1 PURPOSE**

- 1.1 This procedure establishes the process to prepare for a Non-Committee Review.
- 1.2 The process begins when an IRB staff member identifies an application as being possibly eligible for Non-Committee Review.
- 1.3 The process ends when the IRB staff member provides the materials to a Designated Reviewer or Staff Reviewer for Non-Committee Review.

### **2 REVISIONS FROM PREVIOUS VERSION**

- 2.1 None

### **3 POLICY**

- 3.1 IRB rosters are maintained using HRP-601 - DATABASE - IRB Roster.
- 3.2 Staff Reviewer rosters are maintained using HRP-602 - DATABASE - Staff Reviewer Roster.
- 3.3 For individuals who access materials through an electronic system or are provided all submitted materials, those individuals are expected to review the materials listed in HRP-301 - WORKSHEET - Review Materials according to their role: "Documents Provided to All IRB Members and Alternate IRB Members," "Additional Items Provided to Primary Reviewer," and "Additional Items Provided to Scientific/Scholarly Reviewer."
- 3.4 Waiver or alterations of HIPAA authorization reviewed via Non-Committee Review must be completed by a Designated Reviewer or Privacy Board designee.
- 3.5 A reviewer is assigned to a submission within 5 business days of receipt of a complete submission.

### **4 RESPONSIBILITIES**

- 4.1 IRB staff members carry out these procedures.

### **5 PROCEDURE**

- 5.1 Refer to HRP-601 - DATABASE - IRB Roster and/or HRP-602 - DATABASE - Staff Reviewer Roster to identify an appropriate reviewer, based on the review level and/or required determination.
  - 5.1.1 All Non-Committee Reviews can be performed by Designated Reviewers.
    - 5.1.1.1 If no Designated Reviewer is available, or if available Designated Reviewers are unable to perform a Non-Committee Review in a timely manner such that review by the convened IRB would result in a timelier review, schedule the protocol to be reviewed by the convened IRB.
  - 5.1.2 Staff Reviewers are not Designated Reviewers and therefore are limited to making the determinations identified in the definition of Staff Reviewer in HRP-001 - SOP - Definitions.

### **6 MATERIALS**

- 6.1 HRP-001-SOP - Definitions
- 6.2 HRP-301 - WORKSHEET - Review Materials
- 6.3 HRP-601 - DATABASE - IRB Roster
- 6.4 HRP-602 - DATABASE - Staff Reviewer Roster

### **7 REFERENCES**

- 7.1 21 CFR §56.110(b)

- 7.2 45 CFR §46.110(b)
- 7.3 45 CFR §164.512(i)
- 7.4 AAHRPP elements I.1.A, I.1.F, I.6.B, I.7.A, I-9, II.2.A-C, II.2.F-II.2.F.3