

## **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 the Designated Reviewer.

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

- 2.1 None

### **3 POLICY**

- 3.1 IRB rosters are maintained using HRP-601 - DATABASE - IRB Roster.
- 3.2 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."

### **4 RESPONSIBILITIES**

- 4.1 IRB staff members carry out these procedures.

### **5 PROCEDURE**

- 5.1 Use the "Assign Designated Reviewer" activity and select a Designated Reviewer.
  - 5.1.1 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 Execute the "Assign Designated Reviewer" activity.
- 5.2 Execute the "Assign Designated Reviewer" activity to send to the Designated Reviewer within ten business days of receipt of a complete submission.
- 5.3 Protocols eligible for a self determination of exemption or a self-determination of non-human subject research are not assigned a Designated Reviewer. They remain in "Pre-Review" status as part of the self-determination process.

### **6 MATERIALS**

- 6.1 HRP-301 - WORKSHEET - Review Materials
- 6.2 HRP-601 - DATABASE - IRB Roster

### **7 REFERENCES**

- 7.1 21 CFR §56.110(b)
- 7.2 45 CFR §46.110(b)