



## SOP: Non-Committee Review Preparation

NUMBER	DATE	PAGE
3.004 (HRP-031)	6/4/2024	1 of 1

### 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 HRPP maintains official IRB rosters for the OHRP/FDA Registration. IRB rosters are also maintained in eIRB+ using in the 2.306 (HRP-601) -DATABASE - IRB Committee Member Profile (in eIRB+).
- 3.2 In order to prepare for a non-committee review, individuals access materials through an electronic system or are provided all submitted materials. Those individuals are expected to review the materials listed in 3.203 (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 The IRB Staff will select the appropriate checklist from the 3.203 (HRP-301) – WORKSHEET – Review Material and additional worksheets that need to be considered during a non-committee review.
- 5.2 Add to the review materials:
  - 5.2.1 3.101 (HRP-402) - CHECKLIST - Non-Committee Review.
  - 5.2.2 Any relevant minutes or correspondence.
- 5.3 Refer to 2.306 (HRP-601) – DATABASE - Committee Member Profile (in eIRB+) and select a Designated Reviewer.
  - 5.3.1 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 more timely review, schedule the protocol to be reviewed by the convened IRB.
  - 5.3.2 Use the "Forward to Expedited Reviewer" activity and select a Designated Reviewer upon receipt of a complete submission.

### 6 MATERIALS

- 6.1 2.306 (HRP-601) – DATABASE - IRB Committee Member Profile (in eIRB+).
- 6.2 3.101 (HRP-402) - CHECKLIST - Non-Committee Review.
- 6.3 3.203 (HRP-301) - WORKSHEET - Review Materials.

### 7 REFERENCES

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