HRP-025 09/01/2025 | Approver: B. Alberola

# **SOP: Investigations**

## 1 PURPOSE

- 1.1 This procedure establishes the process to conduct investigations.
- 1.2 The process begins when the IRB staff members and chair cannot answer a question required by HRP-024 SOP New Information.
- 1.3 The process ends when the investigation is complete and the answer has been provided to the <u>Institutional Official/Organizational Official (IO/OO)</u> or designee.

### 2 REVISIONS FROM PREVIOUS VERSION

2.1 None

#### 3 POLICY

3.1 None

### 4 RESPONSIBILITIES

- 4.1 The <u>IO/OO</u> or designee:
  - 4.1.1 Appoints the members of the investigative committee based on the expertise and background needed to answer the question.
- 4.2 Appoints a chair of the investigative committee.
  - 4.2.1 Charges the investigative committee with the question to be answered.
- 4.3 The investigative committee carries out these procedures within 60 days.
- 4.4 Investigative committee members make their decisions based on a preponderance of the evidence.
- 4.5 Investigative committee decisions are made by majority vote.
- 4.6 Individuals being interviewed may have counsel present. However, counsel cannot address the investigative committee. The investigative committee by a vote of the majority may exclude counsel when in the opinion of the investigative committee that person's presence is disruptive.

## 5 PROCEDURE

- 5.1 Notify the investigator that an investigation is being conducted, the question to be answered, and the time frame for completion.
- 5.2 Determine what information to gather and what individuals to interview.
- 5.3 Gather information and interview individuals.
- 5.4 If the investigative committee believes that a transcription of the interviews will be required to make a proper decision, the investigative committee may record the interviews and obtain a transcript.
- 5.5 Repeat information gathering and interviews until a decision can be made.
- 5.6 The investigative committee provides a written report of the investigative committee's decision to the IO/OO or designee.

#### 6 MATERIALS

6.1 HRP-024 - SOP - New Information

# 7 REFERENCES