

	<b>SOP: Investigations</b>		
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## 1 PURPOSE

- 1.1 This SOP establishes the process to conduct investigations when the investigation is not carried out by the HRPP PAM staff in accordance with the HRPP Post Approval Monitoring & Quality Assurance Plan.
- 1.1 The process begins when the IRB staff members and chair or designee cannot answer a question required by HRP-024 - SOP - New Information
- 1.2 The process ends when the investigation is complete and the answer has been provided to the IRB Chair or designee, Institutional Official/Organizational Official (IO/OO) or designee.

## 2 REVISIONS FROM PREVIOUS VERSION

- 2.1 Revised from the 5/30/2017 version.

## 3 SOP Statement

- 3.1 None

## 4 RESPONSIBILITIES

- 4.1 The IRB Chair or designee, Institutional Official or IO Designee:
  - 4.1.1 Appoints the members of the investigative committee based on the expertise and background needed to answer the question.
  - 4.1.2 Appoints a chair of the investigative committee.
  - 4.1.3 Charges the investigative committee with the question to be answered.
- 4.2 The investigative committee carries out these procedures within 60 days or as otherwise stipulated.
- 4.3 Investigative committee members make their decisions based on a preponderance of the evidence.
- 4.4 Investigative committee decisions are made by majority vote.
- 4.5 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 Consult with Office of General Counsel, as needed.
- 5.5 If the investigative committee believes that a transcription of the interviews will be required to make a proper decision, the investigative committee may request to record all interviews.
- 5.6 Repeat information gathering and interviews until a decision can be made.
- 5.7 The investigative committee prepares a written report of the investigative committee's decision.
- 5.8 Send written report to Office of General Counsel for review, as directed.
- 5.9 Provide final report to IO/OO or IO designee.

## 6 MATERIALS

- 6.1 HRP-024 - SOP - New Information
- 6.2 HRP-005 - SOP - HRPP Post Approval Monitoring & Quality Assurance Plan

## 7 REFERENCES

- 7.1 AAHRPP elements I.5.D, I-9, II.2.G