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