

SOP: Investigations

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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 "SOP: New Information."
- 1.3. The process ends when the investigation is complete and the answer has been provided to the [Organizational Official].

2. POLICY

- 2.1. None.

3. RESPONSIBILITY

- 3.1. The [Organizational Official] or designee:
 - 3.1.1. Appoints the members of the investigative committee based on the expertise and background needed to answer the question.
 - 3.1.2. Appoints a chair of the investigative committee.
 - 3.1.3. Charges the investigative committee with the question to be answered.
- 3.2. The investigative committee carries out these procedures within 60 days.
- 3.3. Investigative committee members make their decisions based on a preponderance of the evidence.
- 3.4. Investigative committee decisions are made by majority vote.
- 3.5. 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.

4. PROCEDURE

- 4.1. Notify the investigator that an investigation is being conducted, the question to be answered, and the time frame for completion.
- 4.2. Determine what information to gather and what individuals to interview.
- 4.3. Gather information and interview individuals.
- 4.4. If the investigative committee believes that a transcription of the interviews will be required to make a proper decision, the investigative committee may request a court stenographer to record all interviews.
- 4.5. Repeat information gathering and interviews until a decision can be made.
- 4.6. The investigative committee provides a written report of the investigative committee's decision to the [Organizational Official].

5. REFERENCES

- 5.1. None