1 PURPOSE
1.1 This procedure establishes the process to conduct investigations into new information that may represent Non-Compliance or Unanticipated Problems Involving Risk to Participants or Others.
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 or designee.

2 REVISIONS FROM PREVIOUS VERSION
2.1 Updated logo and date in header.
2.2 Minor editorial revisions; replaces version dated 12/27/2012.

3 POLICY
3.1 None

4 RESPONSIBILITIES
4.1 The Organizational Official or 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.
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 and cannot be overturned by the Organizational Official.
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 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.
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 Organizational Official.
5.7 The IRB staff will use the investigative committee’s decision to inform the remainder of the processes outlined in the “SOP: New Information”.

6 MATERIALS
6.1 SOP: New Information

7 REFERENCES
7.1 None