Title: Investigations

SOP # HRP-025  |  Revision # 1  |  Effective Date 12/1/2014

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Approved: Richard Larson, MD PhD Vice Chancellor for Research

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1 PURPOSE

1.1 This procedure establishes the process to initiate and conduct investigations and for reporting the same.

1.2 The process begins when the HRPO staff members and HRRC chair cannot answer a question required by "SOP: New Information (HRP-024)," or when the Institutional Official or designee identifies or becomes aware of facts that may give rise to a potential human research compliance concern or issue that warrants investigation.

1.3 The process ends when the investigation is complete, the question has been answered, and a report has been provided to the Institutional Official, the Institutional Official’s designee and the convened HRRC, if applicable.

2 REVISIONS FROM PREVIOUS VERSION

2.1 Correction of spelling and grammatical errors throughout SOP.

2.2 Replaced all references to “IRB” with “HRRC.”

2.3 Updated purpose, responsibilities and procedures to clarify Institutional Official’s, Institutional Official’s designee’s, HRRC’s, and HRRC chair’s roles in regard to investigations.

2.4 Section 4.3.1.1: clarified that non-HRRC members may be appointed to investigative committee.

2.5 Section 5.4: replaced “court stenographer” with “administrative support.”

3 POLICY

3.1 None

4 RESPONSIBILITIES

4.1 The Institutional Official or designee, or the HRRC chair (with the approval of the convened HRRC) may initiate an investigation.

4.1.1 In the event the information then available to the HRRC chair suggests that a subject is at immediate risk for harm, the HRRC chair may initiate the investigation independently and upon his/her decision but must promptly report the HRRC chair’s decision to commence an investigation to the HRRC for ratification.

4.2 The Institutional Official, designee or the HRRC chair, depending upon who determined to commence an investigation):
4.2.1 Appoints the members of the investigative committee based on the expertise and background needed to answer the question.  
4.2.1.1 Non-HRRC members may be appointed to an investigative committee.  
4.2.2 Appoints a chair of the investigative committee.  
4.2.3 Charges the investigative committee with the question or questions to be answered.  
4.2.4 Charges the investigative committee with a deadline to complete the investigation.  

4.3 Investigative committee members make their decisions based on a preponderance of the evidence presented to the investigative committee.  
4.4 Investigative committee decisions are made by majority vote.  
4.5 Individuals being interviewed by the investigative committee may have legal counsel present during the interview. However, such legal counsel are not permitted to address the investigative committee. The investigative committee by a vote of the majority may exclude such legal counsel when in the opinion of the investigative committee that person’s presence is disruptive.  

5 PROCEDURE  
5.1 Notify the investigator (or other target of the investigation) that an investigation is being initiated and conducted, the question or questions to be answered by the investigative committee, and the time frame for completion.  
5.2 Determine what information needs to be gathered to answer the question or questions and determine what individuals need to be interviewed to answer the question or questions.  
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 administrative support to record all interviews.  
5.5 Repeat information gathering and interviews until a decision on the question or questions presented can be made.  
5.6 If the investigation was requested by the Institutional Official or the Institutional Official’s designee, the investigative committee provides a written report of the investigative committee’s decision on the question to the Institutional Official and Institutional Official’s designee.  
5.6.1 The Institutional Official and/or the Institutional Official’s designee, reviews the report of the investigative committee and determines what notice, if any, must be provided to federal authorities to ensure compliance with federal program requirements.  
5.6.2 The Institutional Official and/or the Institutional Official’s designee, provides the written report of the investigative committee to the HRRC chair and HRRC for such other and further action as the convened HRRC determines to be appropriate under federal program requirements.  
5.7 If the investigation was requested by the HRRC or HRRC chair, the investigative committee provides a written report of the investigative committee’s decision to the Institutional Official, Institutional Official’s designee and the convened HRRC.  

6 MATERIALS  
6.1 SOP: New Information (HRP-024)  

7 REFERENCES  
7.1 None