

SOP 014: Human Subjects Protection Program

TITLE: Investigations

PURPOSE: Investigations are conducted when HSPP staff and the IRB Chair cannot

address the questions as required by SOP-013: Reportable Items.

RESPONSIBILTIES: Organizational Official

HSPP Staff

PROCEDURES:

The Organizational Official may convene an ad hoc investigative committee, with members chosen from University of Arizona staff and faculty based on the suitability of their expertise and background. Investigative committee decisions are made by simple majority vote. The Organizational Official appoints the chair of this committee.

Alternatively, the Organization Official may retain an external consultant based on the expertise needed to answer the questions posed, if such expertise does not exist within the University, or to avoid any potential conflict of interest.

The Organizational Official charges the investigative committee or consultant with the question(s) to be answered. The committee/consultant:

- Reviews information gathered by HSPP staff
- Interviews individuals with knowledge regarding the question. These individuals may have counsel present; however counsel cannot address the committee/consultant. If deemed disruptive by the committee/consultant, counsel may be excluded.
- Makes decisions on the preponderance of the evidence
- Provides a written report of findings and recommendations to the Organizational Official
- Completes this process in a within a specified time

HSPP staff is to assist the committee/consultant as requested.

- If appropriate, notify the investigator that an investigation is being conducted, and inform the
 investigator of the question to be answered, and the time frame for the investigation's
 completion.
- Gather applicable information
- Interview appropriate individuals
 - If requested by the committee/consultant, arrange for a court stenographer to record the interviews.

MATERIALS:

- SOP-013: Reportable Items
- Operations Manual

REFERENCES:

None



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REVIEW/REVISIONS:

From 10/01/10 version: Updated references; Clarified that outside consultants also might be utilized when the organization needs additional expertise or to remove any potential conflict of interest.

From 01/2014 version: Renumbered from P&P-025; Materials P&P-025 revised to SOP-014 to reflect new numbering system.