

SOP 010: Human Subjects Protection Program

TITLE: Incoming Items Directed to the IRB

PURPOSE: Receive and process items directed to the IRB

RESPONSIBILTIES: HSPP staff

PROCEDURES:

All incoming correspondence, email, and telephone queries to the IRB are to be logged in the HSPP database.

Email is received via VPR-IRB@email.arizona.edu.

The HSPP Coordinator or designated staff member is responsible for reviewing incoming email messages and forwarding to the appropriate individual or folder. The mailbox is to be checked continuously.

Follow SOP-070, IRB Records" to update IRB records, as needed, based on the information received and documented response.

Specific Queries:

- <u>Notification of an emergency use of a test article:</u> Information concerning a prior notification of an emergency use of a test article in a life-threatening situation or a five-day notification after an emergency use of a test article is to be forwarded to the Director or designee.
- <u>Investigator's request to continue subjects in expired research</u>: Forward the request to the Director or designee immediately.
- Routine question: Answer as appropriate. For questions that you are unable to answer, consult with the Director or designee, and inform the investigator you will get back to them in a specified timeframe.
- Concern or complaint: Transfer the telephone call or forward the email to the HSPP Director or Designee. If you are unable transfer the telephone call, document the nature of the question, concern, or complaint and the individual's contact information and forward it to the HSPP Director or Designee when appropriate. Inform the individual that the information will be shared with the HSPP Director or designee. All information is considered confidential unless instructed differently the complainant.

MATERIALS:

- SOP-051: Emergency Use of a Test Article Review
- SOP-016: Continuation of Subjects in Expired Research
- SOP-070: IRB Records
- SOP-012: Changes Required to Secure Approval



SOP 010: Human Subjects Protection Program

SOP-013: Reportable Items

SOP-011: Pre-Review

Operations Manual

UAR Manual

REFERENCES:

None

REVIEW/REVISIONS: From 10/01/10 version: Incorporated changes to process due to electronic email submission and transition to UAccess Research (UAR); Clarified that the Director or their designee may be contacted as outlined below.

> From 01/2014 version: Renumbered from P&P-020; The following materials updated to reflect new numbering system: P&P-023 to SOP-051; P&P-061 to SOP-016; P&P-070 to SOP-070; P&P-022 to SOP-012; P&P-024 to SOP-013; P&P 021 to SOP-011.