

**SOP: 601**  
**IRB COMMUNICATION AND NOTIFICATION**

**1. POLICY**

The IRB shall notify the Institutional Officials in the Offices of the Senior Vice President and Provost and investigators in writing of all decisions made by the IRB. Open and frequent communication shall be maintained among the IRB, the Institutional Officials in the Offices of the Senior Vice President and Provost, the investigator, and the investigator's research team.

The IRB shall foster open communication with the investigator regarding questions, concerns, and suggestions that pertain to the HRPP program. The IRB shall answer questions as promptly as possible. Concerns and suggestions that cannot be satisfactorily addressed by HRPP or IRB staff shall be addressed in a meeting with the appropriate administrative individuals.

Opportunity for improvement in the IRB review process is based upon voluntary feedback of investigators and, as such, investigators are encouraged to offer suggestions and discuss concerns regarding the HRPP program and IRB review process.

**Specific Policies**

**1.1 New Research Projects**

- 1.1.1 All submissions shall be processed per SOP 301, Research Submission Requirements; and SOP 302, Administrative Review and Distribution of Materials.
- 1.1.2 Once a research project is reviewed by the convened IRB, the IRB shall forward a letter to the investigator regarding the decision of the IRB to approve, contingently-approve, defer, or disapprove the project.
- 1.1.3 After the IRB Chair reviews and approves research projects meeting one of the Expedited Review Categories, the IRB Administrator shall forward a letter to the investigator regarding the approval of the project. If the IRB Chair requires revisions or submission to the convened IRB, the IRB Administrator shall notify the investigator via email or telephone.
- 1.1.4 If the research project receives a contingent approval status and is pending receipt and review of requested revisions and/or information from the investigator or sponsor, the IRB shall receive a response within 60 calendar days of the date of notification; however, this period may be extended if the investigator/sponsor communicates a need for an extension. If the investigator does not respond within 60 calendar days, the IRB staff shall inform the investigator that the research project is being administratively withdrawn.
- 1.1.5 HSC Campus IRB: If the research project is deferred or disapproved by the convened IRB, the IRB Chair shall notify the investigator by telephone of the IRB's decision immediately following the IRB meeting, followed by written notice per 1.1.2.

1.1.6 Norman Campus IRB: If the research project is deferred or disapproved by the convened IRB, the IRB Chair shall notify the investigator via email of the IRB's decision immediately following the IRB meeting, followed by written notice per 1.1.2.

## **1.2 Submissions Involving On-Going Research Projects**

For submissions related to on-going research projects, the IRB shall notify the investigator of all review decisions. These decisions may include:

- All revisions, additions, or deletions to a research project.
- Notification of an impending continuing review and the outcome of the project once it has been reviewed.
- Actions to withdraw or inactivate a research project and the reason such action is being taken.
- Status of all adverse events submitted for review.
- Necessity to conduct an audit as described in SOP 903, Non-compliance/Scholarly Misconduct.

## **1.3 Appeal of IRB Action**

An investigator may appeal the revisions required by the IRB in the protocol and/or informed consent form. This appeal shall be in writing and submitted to the IRB office. Investigators may also appeal an IRB decision to disapprove a study. Any such appeal shall be in writing or in person and shall be reviewed by the convened IRB. If the IRB denies the appeal and disapproves the study, the Investigator's institution shall not override the IRB's decision.

## **1.4 Pending Items Over 60 Days**

The IRB Administrator shall send a pending withdrawal letter to the investigator after the study or amendment has been in pending status for 60 days.

## **1.5 Notification to Institutional Offices and Officials**

The HSC IRB shall notify the HSC Office of the Senior Vice President and Provost as the Institutional Official of IRB findings and actions. The Institutional Official shall receive a copy of the approved IRB meeting minutes for each IRB.

The Norman Campus IRB shall notify the Norman Campus Office of the Senior Vice President and Provost as the Institutional Official of IRB findings and actions. The Institutional Official shall receive a copy of the approved IRB meeting minutes for each IRB.

## **1.6 Questions, Concerns, and Suggestions Regarding the Human Research Participant Protection Program**

Investigators can direct questions, concerns, and suggestions regarding the Human Research Participant Protection Program to the HRPP Director. Investigators can direct questions, concerns, and suggestions regarding the Human Research Participant Protection Program that are not satisfactorily addressed by the HRPP Director to the Director of Compliance or the Institutional Official.

## **2. SCOPE**

These policies and procedures apply to all research submitted to the IRB.

## **3. RESPONSIBILITY**

The HRPP Director or designee is responsible for overseeing all IRB communications.

The IRB Administrator is responsible for generating appropriate correspondence in response to IRB meetings and decisions and for distributing IRB correspondence to appropriate parties.

The IRB Chair is responsible for contacting the investigator in the event of an IRB action of deferral or disapproval and for drafting the letters for the IRB Administrator.

The HRPP Director is responsible for all communication with OHRP, FDA, and University officials.

## **4. APPLICABLE REGULATIONS AND GUIDELINES**

21 CFR 56.109, 56.113

45 CFR 46.109, 46.113

## **5. REFERENCES TO OTHER APPLICABLE SOPS**

SOP 301, Research Submission Requirements

SOP 302, Administrative Review and Distribution of Materials

SOP 304, Documentation and Document Management

SOP 401, Research Exempt from IRB Review

SOP 402, Expedited Review

SOP 403, Initial Review – Criteria for IRB Approval

SOP 404, Continuing Review

SOP 409, Categories of Action

SOP 903, Non-compliance/Scholarly Misconduct.

## **6. ATTACHMENTS**

601-A	Protocol Pre-Review
601-B	Protocol Contingent Approval - Full Board
601-C	Protocol Final Approval – Full Board, Expedited, Exempt
601-D	Protocol Deferral – Full Board
601-OS-D	Protocol Disapproval – Full Board
601-F	Protocol Form 310
601-G	Protocol Inactivation by Board, PI, Sponsor
601-H	Protocol Pending Withdrawal

601-I	Protocol Withdrawal Request by PI, Admin.
601-OS-I	Not Human Research Determination
601-OS-J	Human Research Determination
601-J	Protocol Exempt Status
601-K	Protocol Development Approval
601-L	Protocol Emergency Use Approval
601-M	Amendment Pre-Review
601-N	Amendment Contingent Approval
601-O	Amendment Final Approval – Full Board & Expedited
601-OS-E	Amendment Disapproval
601-Q	Amendment Pending Withdrawal
601-R	Amendment Withdrawal – PI, Admin.
601-S	Continuing Review Contingent Approval
601-T	Continuing Review Approval – Active & Closed Enrollment
601-OS-U	Miscellaneous Approval
601-OS-A	Continuing Review Deferral
601-V	Continuing Review Periodic Report Request
601-W	Protocol-Deviation
601-OS-X	Unanticipated Problem
601-OS-B	HIPAA, No PHI
601-OS-C	Notice of Study Expiration
601-OS-F	QI Routine Evaluation Letter
601-OS-G	QI For-Cause Evaluation Letter
601-OS-H	QI Evaluation Report
602C-A	Contract-Hold Notification Email

## 7. PROCESS OVERVIEW

- 7.1 The IRB Administrator shall process new research projects, revisions to currently approved research, and continuing review of research documents per SOP 301, Research Submission Requirements; and SOP 302, Administrative Review and Distribution of Materials.
- 7.2 The IRB review is conducted as per SOP 401, Research Exempt from IRB Review; SOP 402, Expedited Review; or SOP 403, Initial Review – Criteria for IRB Approval, as appropriate.
- 7.3 The Investigators shall submit requested revisions within 60 calendar days of receiving written IRB notification.

- 7.4 The IRB Administrator shall conduct periodic review of outstanding items, including telephone calls and/or emails to investigator regarding outstanding issues.
- 7.5 IRB Administrator shall consult with the HRPP Director or designee for items outstanding greater than 60 calendar days; a pending withdrawal notification shall be drafted and presented to the IRB Chair or designee for signature.
- 7.6 After the IRB Chair's signature is obtained, pending withdrawal notification shall be sent to the investigator for new projects and protocol modifications/ amendments.
- 7.7 In the case of outstanding continuing review items, SOP 404, Continuing Review, is followed.
- 7.8 The IRB Administrator shall forward Investigator appeals of requested revision(s) to the IRB (for the next available meeting agenda) or the IRB Chair for review.
- 7.9 Final IRB determinations shall be adhered to by the investigator; final determinations cannot be overruled by the Institution.
- 7.10 All documentation shall be retained per SOP 304, Documentation and Document Management.
- 7.11 Investigators who have questions, suggestions, or concerns may utilize the web form to communicate with the IRB.
- 7.12 IRB staff will provide a copy of the approved IRB meeting minutes for each IRB to the Institutional Officials.

**APPROVED BY:** \_\_\_\_\_ **DATE:** 09/01/2009

**NEXT ESTABLISHED REVIEW DATE:** MAY 2012