SOP 601: IRB Communication and Notification

1. POLICY

The IRB shall notify the Institutional Officials 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 or IRB designee 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 or IRB designee requires revisions to or submission of the research project to the convened IRB, the IRB Administrator shall notify the Investigator via the IRB’s electronic information system.

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 from the Investigator within 60 calendar days of the date of notification; however, this period may be extended by the IRB Chair or IRB designee if the Investigator/Sponsor communicates a need to the IRB for an extension. If the Investigator does not respond to the requested revisions and/or information within 60 calendar days, the IRB staff shall inform the investigator that the research project may be administratively withdrawn.

1.1.5 If the research project is deferred or disapproved by the convened IRB, the IRB Chair shall notify the investigator (by telephone and/or by electronic communication) 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.
- An impending continuing review and the outcome of the research 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 reports 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 to the human research protocol and/or informed consent documents. This appeal shall be in writing and submitted to the IRB office via email. Investigators may also appeal an IRB decision to disapprove a research project. 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 research project, the University 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 submission has been in pending status for 60 days.

1.5 Notification to Institutional Offices and Officials
The IRB shall make available, IRB minutes, including findings and actions to the Office of the Senior Vice President and Provost as the Institutional Official.

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 for the NC or the HSC VPR for HSC or the Institutional Official.

1.7 Determination of Human Research and Protocol Development
Determination of Human Research or Protocol Development submissions are reviewed according to SOP 406: Determination of Human Research and Protocol Development. The outcome of each determination is communicated to the investigator via the IRB electronic information system.
2. SCOPE
   This SOP applies to all research submitted to the IRB.

3. RESPONSIBILITY
   3.1 The HRPP Director or designee is responsible for overseeing all internal and external IRB communications.
   3.2 The IRB Administrator is responsible for generating appropriate correspondence in response to IRB meetings and decisions and for distributing IRB correspondence to appropriate parties.
   3.3 The IRB Chair or IRB designee 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 to send to the Investigator.
   3.4 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 903: Non-compliance/Scholarly Misconduct

6. ATTACHMENTS
   BEGIN ANEW HERE!

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 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 IRB requested revisions to the IRB within 60 University business 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 more than 60 University business days; a pending withdrawal notification shall be sent to the investigator for new research project submissions and protocol modifications.

7.6 In the case of outstanding continuing review items the IRB shall follow, SOP 404: Continuing Review.

7.7 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.

7.8 The Investigator shall adhere to final IRB determinations; the University cannot overrule final IRB determinations.

7.9 All documentation shall be retained per SOP 304: Documentation and Document Management.

7.10 Investigators who have questions, suggestions, or concerns should visit the contact page of the IRB website.

7.11 IRB staff will make available the approved IRB meeting minutes for each IRB to the Institutional Officials.

APPROVED BY: __________________________ DATE: 08/31/2014

NEXT ESTABLISHED REVIEW DATE: AUGUST 2016