SOP

Department	Title	Dates
Research Integrity and Protection	Post-Review Approval Completion	Effective:2/19/2018
		Approved: 2/12/2018
Policy ID		Last Revised: 11/08/2018
IRB-SOP-503		Expiration: n/a

PURPOSE

This procedure establishes the procedures for the administrative completion of the IRB approval/ disapproval process and communications after a protocol is reviewed.

SCOPE

This procedure applies to non-exempt human subject research reviews, including initial applications, continuing review, modifications, and all other types of IRB review activities. It is not applicable for other processes, such as closures or exempt determinations.

DEFINITIONS

Approval In this document, "approval" refers to full unconditional, approval. It does not include conditional approval ("Approval Pending Required Revisions"). Additionally, while the term "approval" is used throughout this document, same procedures are followed for IRB disapprovals, except as noted below.

PROCESS

1. **Completion of Approval**
   - **1.1.** The administrative completion of approval is done by Research Integrity and Protection (RI&P) staff after the completion of the IRB review (including the verification of any conditions).
   - **1.2.** Verification and updating IRB Records: Staff review the IRB file and verify and/or update the following:
     - **1.2.1.** Reviewer checklists are complete and signed.
     - **1.2.2.** Final, clean version of any consent/HIPAA material is uploaded.
     - **1.2.3.** All general study information and administrative tracking entered into Mentor are complete and consistent with approved materials.
     - **1.2.4.** Staff completes the approval process in Mentor to update the final approval status, regulatory categories, approval date and assignment to the IRB minutes reports.
   - **1.3.** Approval Dates
     - **1.3.1.** The date of IRB approval is the date when the IRB granted approval, including conditional approval (not the date when conditions were met). This includes the effective date of the initial approval.
     - **1.3.2.** The date of the next Continuing review is calculated using the electronic IRB system, based on the approval date and frequency of review determined by the IRB. For example, if the IRB determined a review frequency of one year, the latest permissible date of the next continuing review would be 365 days from the IRB approval date.
   - **1.4.** Stamping documents:
     - **1.4.1.** All materials are "stamped" electronically through Mentor.
     - **1.4.2.** Documents that are stamped include the following:
       - All types of consent, assent and permission forms for studies and sub-studies.

- Verbal consent scripts or consent documents where the requirement for signed consent documentation was waived.
- HIPAA authorization forms.

1.4.3. For translated consent materials, the approval stamp means that (1) the IRB has approved the English version, and (2) the IRB approved of the translation method proposed by the researcher.

1.4.4. Items are stamped when the IRB review process is completed, including verification of any conditions. Consent materials are stamped at the time of initial approval or approval of changes; they do not receive a new approval stamp at the time of continuing review.

1.4.5. Materials will be stamped with the date when the IRB granted conditional approval (not the date when conditions were met).

2. Investigator Notification

2.1. Ascension Wisconsin IRBs comply with federal human subject regulations which require the IRB to notify the researcher in writing of the IRB's decision to approve or disapprove the proposed research activity.

2.2. If the IRB decides to disapprove a research activity, it is required to include in its written notification a statement of the reasons for its decision and to give the researcher an opportunity to respond in person or in writing.

2.3. Correspondence with the Investigator is sent through Mentor and maintained in the IRB file.

2.4. Communication of review results to investigators are to be completed within 10 business days of the review determination (at an IRB meeting or through expedited procedures).

REFERENCES

- 45 CFR 46.109 (d), 45 CFR 46.115
- 21 CFR 56.109(e), 21 CFR 56.115

RELATED MATERIAL

- SOP: IRB Records, Storage and Retention (SOP-104)
- SOP: Human Subject Research Exempt from IRB Review (SOP-302)
- SOP: Expedited Review (SOP-303)
- SOP: IRB Meeting Conduct (SOP-402)

REVISION HISTORY:

Version #	Date Revised	Reason for/Brief Description of Change	Revised By
01	12/13/2017	New- Initial Integration Update	J. Blundon
02	11/8/2018	1.3 Added to detail the determination of the effective date of the initial approval and subsequent continuing reviews.	J. Blundon-Kirchen