SOP		
Department	**Title**	**Dates**
Research Integrity and Protection	Intake and Processing of Submitted Items	Effective: 1/12/2018
		Approved: 1/3/2018
Policy ID		Last Revised: n/a
IRB-SOP-201		Expiration: n/a

PURPOSE

This document describes the procedures for the initial intake and processing of items submitted to Research Integrity and Protection or the Ascension Wisconsin Institutional Review Board (IRB).

SCOPE

This policy applies to all items submitted by investigators intended for review by Research Integrity and Protection or the Ascension Wisconsin Institutional Review Board (IRB).

DEFINITIONS

None

PROCESS

1. **Initial Intake**
   - **1.1.** All information is generally submitted through the electronic IRB system, Mentor. The Research Integrity and Protection (RI&P) staff assess new submissions through Mentor daily.
     - **1.1.1.** RI&P does not regularly accept submissions by email or fax, though staff may grant exceptions in some circumstances. Items not submitted though Mentor will include a submission date, such as a dated email or fax, and will be added to Mentor by staff.
   - **1.2.** The submission will first go through an intake process where RI&P staff assesses the submission for basic elements, such as the submission application, accuracy of information in Mentor, required signatures, status of PI compliance, current expiration date if already approved, etc.
     - **1.2.1.** RI&P staff confirms the appropriate review type as selected by the researcher.
     - **1.2.2.** If there are missing or incomplete items, RI&P staff contact the investigator or study contact person to obtain the items needed to complete the submission.

2. **Intake Actions**
   - **2.1.** Certain administrative submissions can be completed by RI&P staff at time of intake review, as described below:
     - **2.1.1.** Request to withdraw a submission from further consideration: the submission status is changed to withdrawn in Mentor.
     - **2.1.2.** Study closure requests:
       - Requests that meet closure criteria: RI&P staff follows the Post-Review policy and procedure to close the study.
       - Requests that do not meet closure criteria: RI&P staff contact the investigator to explain the issue and offer the investigator and opportunity to withdraw or correct the submission. If the investigator withdraws the submission, stop processing; if the investigator will not withdraw the submission, the submission requires review by a convened IRB.

2.1.3. Staff updates amendments/changes that do not require IRB review and are approved administratively:
- New or modified contact information for current staff: information is updated by RI&P staff or researchers are instructed to update their Mentor account, as applicable.
- Addition of new study personnel that have required training, fCOI disclosures without a reported significant financial conflict, except for the PI (change is PI is processed as an amendment).
- Removal of study staff: RI&P staff updates the protocol staff list in Mentor.
- Removal of a research location (addition of a location is processed as an amendment).

2.1.4. Research that the institution does not conduct or oversee: staff contacts the investigator for additional details and provides guidance as appropriate.

2.1.5. Actions completed at intake are documented in Mentor and, when applicable to the review type, assigned in Mentor to the administrative/expedited actions list provided to IRB members.

2.2. Items requiring additional review

2.2.1. Request is for IRB reliance or transfer of IRB oversight: submission is forwarded to the RI&P Director, or designated staff, and completed per applicable SOPs.

2.2.2. Request for non-human subject research or engagement in research determinations: assigned to an RI&P staff person for pre-review.

2.2.3. Notification of an emergency use of a test article: assigned to an IRB Chair or designated reviewer follow SOP: Treatment use of Investigational Drug, Biologic or Device, including Emergency Use

2.2.4. New or ongoing review of human subject research:

2.2.4.1. Should IRB approval for a project that requires ongoing oversight be expired (lapsed), RI&P staff will follow procedures described in "SOP: Lapsed (Expired) IRB Approval (SOP-603)".

2.2.4.2. Staff ensures completion of Researcher Documentation in Mentor for all research staff identified, including CV of Investigators and physician researchers, human subject protection training and financial conflict of interest disclosures. RI&P staff work with the investigator or study contact person until all Researcher Documentation items are complete for all required staff.

2.2.4.3. Exemption requests are assigned to an RI&P staff person and completed per the applicable SOPs.

2.2.4.4. Protocols requesting Expedited or Convened IRB review are forwarded as to an RI&P staff person to conduct the IRB pre-review before assigning submissions to a reviewer.

2.2.5. Question, concern, or complaint: Document the nature of the question, concern, or complaint and the contact information of the person contacting the IRB. Respond to any questions or concerns. When appropriate, tell the person that you will call/email him/her once you have been able to find additional information. Continue per described in "SOP: Managing Concerns and Complaints Regarding Human Subject Research (SOP-004)."

REFERENCES

- SOP: Managing Concerns and Complaints Regarding Human Subject Research (SOP-004)
- SOP: Lapsed (Expired) IRB Approval (SOP-603)

RELATED MATERIAL

- SOP: Treatment use of Investigational Drug, Biologic or Device, including Emergency Use
- SOP: Lapse (Expiration) of IRB Approval
- SOP: Financial Conflicts of Interests in Research
- SOP: IRB Pre-Review

- SOP: IRB Reliance

REVISION HISTORY

Version #	Date Revised	Reason for/Brief Description of Change	Revised By
01	10/23/17	New- Initial Integration Update	J. Blundon