SOP		
Department	**Title**	**Dates**
Research Integrity and Protection	IRB Pre-review of Human Subjects Research	Effective: 1/12/2018
		Approved: 1/3/2018
SOP ID		Last Revised: 12/10/2018
IRB-SOP-203		Expiration: n/a

PURPOSE

This procedure establishes the process to pre-review a request for approval (approval of new research, continuing review of research, or modification to previously approved research) or a determination whether an activity is exempt Human Research or is not Human Research, including requests from other institutions when this institution is the IRB of record, e.g., for a Collaborative Study or Multi-Site Study.

SCOPE

This policy applies to all human subject research requiring expedited or full board Institutional Review Board (IRB) review that is submitted by investigators intended for review by the Ascension Wisconsin IRB.

DEFINITIONS

See SOP: Definitions

PROCESS

1. Submissions are processed on a first-come first-served basis. Submissions may be processed more quickly at the discretion of RI&P staff (e.g. administrative reviews, studies approaching expiration, short funding time lines, etc.).

2. Pre-review consists of assessing the completeness of each submission, checking for all required documents and signatures, reviewing documents for consistency, as well as determining if sufficient information has been provided for IRB review of criteria at 45 CFR 46.111, 21 CFR 56.111 and/or other applicable federal regulations, laws or Institutional requirements.

3. If the submission is a response to modifications required to secure approval received within 60 days of the IRB review date:

3.1. Evaluate whether the investigator made the required modifications.

3.2. If the investigator made the required modifications, and did not make unrequested modifications, IRB SOP: Post-Review is followed to issue an approval.

3.3. If the investigator did not make the required modifications, or made unrequested changes, RI&P staff contacts the investigator and provide the opportunity for them to make the required modifications and resubmit for review.

3.3.1. If the investigator will correct the submission, have the investigator resubmit and stop processing the current submission.

3.3.2. If the investigator will not provide additional information, continue processing.

3.3.3. For Veterans Administration (VA) research the approval of minor conditions by the IRB chair or designated IRB voting member must be documented in the minutes of the first IRB meeting that takes place after the date of the approval of the minor conditions.

4. If the request is for an initial approval and principal investigator has not completed the requirements in "SOP: Human Subject Protection Education and Training for Researchers (SOP-804)" or has a protocol where IRB approval has Lapsed (Expired), staff contact the investigator to explain that the investigator may not submit a protocol until meeting the requirements, give the reasons, and indicate that if a new protocol goes to the IRB, the IRB policy is to disapprove the research. The Investigator will also have the opportunity to withdraw the submission pending completion of all requirements.

4.1. If the investigator does not withdraw the submission or complete all requirements within 30 days, continue processing.

5. RI&P staffs evaluate the most likely level of review.

5.1. If after review, RI&P staff confirms that the submission can be processed as outlined in SOP: Intake and Processing of Submitted Items (SOP-201), that SOP is followed.

5.2. If after review, RI&P staff confirms that the submission does not otherwise qualify for required submission or reporting to the IRB (i.e. a newsletter or memo the study Sponsor wants submitted to the IRB), and then RI&P staff may administratively acknowledge the submission in Mentor.

5.2.1. The Investigator is notified through Mentor of the acknowledgement.

5.3. IRB staff makes a preliminary risk assessment and assigns the project based on regulatory criteria and applicable SOP, degree of risk involved, and on the previously determined risk assessment and current status of the project, when applicable.

5.3.1. If the protocol was determined to be non-human subject research Not Human Research or Human Research staff follow "SOP: Determination of Human Subjects Research (IRB-207)" to complete the review.

5.3.2. If the protocol was determined to be Human Research for which Ascension Wisconsin is not Engaged, staff follow "SOP: Engagement in Human Subjects Research (IRB-206)" to complete the review.

5.3.3. If the protocol was determined to be exempt Human Research (including exempt Human Research that requires Limited IRB Review), staff follow "SOP: Exempt Review Conduct (IRB-208)" to complete the review.

5.3.4. If the submission was determining to require Expedited or Convened IRB review, staff complete the applicable pre-review checklist, as well as any applicable subpart checklists, in Mentor, considering the items on "WORKSHEET: Pre-Review (WRK-102)" and note all remaining contingencies in the notes section.

5.4. IRB staff make the determination of whether FDA regulations apply and documents the determination in the Mentor Checklist.

5.4.1. RI&P staff determine which FDA regulations, if any, apply to a research study during pre-review of the IRB application materials provided by the researcher, in the absence of specific information from the FDA. The assessment may require obtaining additional information from the researcher, the sponsor, and/or the FDA. Staff may refer to WORKSHEET: Human Research Determination.

5.4.2. This determination includes, but is not limited to:

- If the research is exempt from IRB review, as defined by the 21 CFR 56.104.
- If the activity considered investigational drug research that is governed by 21 CFR 312. (WORKSHEET Drugs and Biologics)
- If the activity considered investigational device research that is governed by 21 CFR 812 (WORKSHEET Devices; WORKSHEET: Non-Significant Risk Device)
- If the activity involves the use of a Humanitarian Use Device (HUD) that is governed by 21 CFR 814.

6. RI&P staff assigns a Designated Reviewer(s) for IRB review.

6.1. Staff selects a Designated Reviewer from the current roster, based on the protocol and reviewer expertise. Whenever possible, staff will assign a reviewer who has previously conducted reviews for the protocol.

6.2. Staff assigns a Primary Reviewer for all non-committee and Convened IRB reviews. For initial reviews requiring Convened IRB review, a Secondary Reviewer is assigned; at least one reviewer must have related subject matter expertise.

6.3. RI&P staff assigns the Designated Reviewer(s) and assigns the applicable reviewer checklist, as well as any applicable subpart checklists, through Mentor.

6.3.1. Typically the review is assigned to be completed within 7 calendar days for non-committee review or for 2 days prior to the assigned IRB meeting.

6.3.2. Notification is sent to the Reviewer(s) through Mentor when assigned.

6.4. Reviewer(s) can access the review and all material in Mentor, as outlined in the SOP: Materials for IRB Review (SOP-105); WORKSHEET: Review Materials (WRK-101) may be referenced.

6.5. If a reviewer declines a review, the IRB Coordinator will be notified and will re-assign the review to an appropriate Designated Reviewer.

6.6. If needed, a consultant may be assigned to complete a review at this time, as outlined in the SOP: Consultants, Observers and Guests (SOP-502).

REFERNCES

- SOP: Materials for IRB Review (SOP-105)
- SOP: Engagement in Human Subjects Research (IRB-206)
- SOP: Determination of Human Subjects Research (IRB-207)
- SOP: Exempt Review Conduct (IRB-208)
- SOP: Consultants, Observers and Guests (SOP-502)
- WORKSHEET: Review Materials (WRK-101)
- WORKSHEET: Human Research Determination
- WORKSHEET: Drugs and Biologics
- WORKSHEET: Devices
- WORKSHEET: Non-Significant Risk Device Determination

RELATED MATERIAL

- SOP: IRB Meeting Preparation (SOP-401)
- SOP: IRB Meeting Conduct (SOP-402)

REVISION HISTORY

Version #	Date Revised	Reason for/Brief Description of Change	Revised By
01	10/23/2017	New- Initial Integration Update	J. Blundon
02	10/17/2018	Section 6- clarifications to wording and process for assigning Designated Reviewer for consistency with other SOPs	J. Blundon-Kirchen