SOP		
Department	**Title**	**Dates**
Research Integrity and Protection	Lapse (Expiration) of IRB Approval	Effective: 11/01/2017
		Approved: 10/25/2017
SOP ID		Last Revised: 11/08/2018
IRB-SOP-603		Expiration: n/a

PURPOSE

Per federal regulations and Ascension Wisconsin policy, research must maintain current IRB approval and may not involve subjects or their identifiable data in research where there is not current IRB approval. This procedure establishes the process for determining circumstances and implementing procedures where IRB study approval has lapsed.

SCOPE

This SOP applies to IRB approval expirations which occur due to failure of the PI to provide a Continuing Report or Study Closure Notice (and all other required documents) to the Ascension Wisconsin IRB and/or when the information is not submitted in sufficient time for the IRB to review and approve a research study by the approval expiration date specified by the IRB. If research is granted "Conditional Approval Pending Modifications" and expires before responsive materials are reviewed and approved, these procedures apply.

DEFINITIONS

Lapsed/Expired A research study status is considered lapsed if the IRB has not reviewed and approved the study by its expiration date.

PROCEDURES

1. The Principal Investigator (PI) is responsible for ensuring that IRB approval does not expire. For a student led research study, the mentor/advisor listed is also held responsible.

2. The IRB is responsible for maintaining records of the status of all approved studies and will monitor expiration dates on a regular basis to ensure continuing reviews are scheduled to avoid lapses in IRB approval; this is managed through the electronic IRB system.

3. The IRB will send a notification to the PI to inform the investigator that all research activity must cease as of the IRB approval expiration date. Additionally, the IRB will instruct the PI that:
   - All research activities (including recruitment, enrollment, treatments, follow-up, and data collection/analysis) must cease when a study approval period has lapsed.
   - The PI must immediately submit a written request to continue interventions for any research subjects for whom discontinuation of the research would cause harm and continuation in the research would be in the best interest of the individual participant. Requests to allow continued participation should be submitted via appropriate submission processes.
   - The PI should notify the Sponsor, if any, of the lapse immediately.
   - The IRB will not accept or review any submission from the PI until they have submitted a continuing report or closure notice to the IRB, including an explanation for the lapse and a Corrective Action Plan to prevent any repetitions; and the IRB has reviewed and approved that submission.

3.1. Copies of the notification may be issued to the IRB Chair, Research Integrity and Protection Director or the PI's manager or department/area leader.

3.2. The notification will be sent using Mentor or uploaded to Mentor, if sent via email.

4. The PI must immediately submit a written request to continue interventions for any research subjects for whom discontinuation of the research would cause harm and continuation in the research would be in the best interest of the individual participant.

4.1. The PI must include what subjects need to continue in the expired research, what procedures are being requested to continue, and why.

4.2. The IRB Chair, Vice Chair or designated reviewer will determine if the subject(s) may continue in the research and this determination may be reviewed through an expedited process. Requests to allow continued participation should be submitted via appropriate submission processes (containing the signature of the PI).

4.2.1. Determine which subjects can continue in the research based on these principles:

- In general, research procedures should be safely discontinued.
- In general, the only research procedures that should continue are those that are not available outside of the research context. If the required procedures can be provided as standard of care, these should be provided as such.
- In general, research procedures conducted to collect data with no direct benefit to the subject should not continue.
- In some cases, an ethical issue may be raised where the above general principles may not be followed.

4.2.2. In the case of Veterans Administration (VA) research, have the IRB chair consult with the Veterans Administration (VA) Chief of Staff to make a final determination within 2 business days whether participants may continue participating in the research interventions or interactions.

5. The IRB will notify the PI and other key personal of the decision and will provide further instructions as applicable.

5.1. Staff will make every reasonable attempt to contact the PI, and study staff if applicable, to obtain a complete set of continuing/reactivation or closure documents. If the documentation is completed, the study participants, the study may be reactivated via the standard continuing review process.

5.2. If after three months, complete paperwork is not submitted, the study will be administratively closed. For studies that are administratively closed, a new project submission will be required for review and approval going forward.

6. For studies with Investigators who leave the institution prior to submitting a close out study report or having a change in PI approved, a letter will be sent to the Department Chair/ leader informing him/her, and providing instruction on how to resolve the matter.

7. If non-compliance issues have not been resolved, including but not limited to having a study with lapsed status, the IRB will not process submissions from that PI until those issues have been resolved.

7.1. Additionally, the IRB may rule that no new studies be accepted from the PI until issues are resolved and official notification of study reactivation or documentation of study closure is issued.

7.2. With a second occurrence of any study expiration under the PI, the PI will be notified in writing that this is a second occurrence of non-compliance with regard to study expirations; the department chair and others as applicable will also be notified.

7.3. With the third or greater occurrence of a study lapse under a PI, the PI, department chair, and others will be notified in writing of the pattern of study lapses and a fully convened IRB review will be conducted to determine if the non-compliance is actionable.

REFERNCES

- 45 CFR 46, subpart E
- FDA: "Guidance for Institutional Review Boards (IRBs) - Frequently Asked Questions - IRB Registration"

RELATED MATERIAL

- Ascension Wisconsin Policy: Human Subject Research

REVISION HISTORY

Version #	Date Revised	Reason for/Brief Description of Change	Revised By
01	10/23/2017	New- Initial Integration Update	J. Blundon
02	11/27/2017	Updated SOP number from 304 to 604; added bullet format to references	J. Blundon
03	11/8/2018	Updated to state that the eIRB system is used for tracking of IRB approval expiration. Other minor editing corrections.	J. Blundon-Kirchen