Department	**Title**	**Dates**
Research Integrity and Protection	Suspension or Termination of IRB Approval	Effective: 2/19/2018
		Approved: 2/12/2018
SOP ID		Last Revised: n/a
IRB-SOP-604		Expiration: n/a

SOP

PURPOSE

This procedure establishes the process for someone other than the convened IRB to institute a Suspension of IRB Approval or a Termination of IRB Approval.

SCOPE

This procedure applies to research conducted at Ascension Wisconsin or any research reviewed by an Ascension Wisconsin IRB.

DEFINITIONS

Suspension of IRB Approval An action of the IRB, IRB designee, Institutional Official, or designee of the Institutional Official to temporarily or permanently withdraw IRB approval of some or all research procedures short of a Termination of IRB Approval. Suspended studies remain open and are subject to continuing review. This action may be reportable to federal agencies.

Termination of IRB Approval An action of the IRB, IRB designee, Institutional Official, or designee of the Institutional Official to permanently withdraw IRB approval of all research procedures. Terminated studies are permanently closed and no longer require continuing review. This action may be reportable to federal agencies.

Hold

PROCESS

1. **Authority**
   - **1.1.** The Institutional Official or designee may institute a Suspension of IRB Approval or Termination of IRB Approval for any reason.
   - **1.2.** The IRB Chair or Director of Research Integrity and Protection may institute a Suspension of IRB Approval when in their opinion, subjects may be at risk of adverse effects on their rights and welfare before action may be considered by the convened IRB.
   - **1.3.** Suspension or Termination of IRB Approval not initiated by the IRB must be reported to and reviewed by the convened IRB.

2. **Considerations**
   - **2.1.** The Institutional Official, IRB Chair or Director of Research Integrity and Protection will consider whether any of the following additional actions are required to protect those or other subjects rights and welfare or to eliminate an apparent immediate hazard:
     - Transferring subjects to another investigator.
     - Making arrangements for clinical care outside the research.
     - Allowing continuation of some research activities under the supervision of an independent monitor.

- Requiring or permitting follow-up of subjects for safety reasons.
- Requiring adverse events or outcomes to be reported to the IRB and the sponsor.
- Notification to current or former Human Subjects.
- Other actions, if any, that may be needed to protect the rights and welfare of currently enrolled subjects.

3. Notification and Reporting

3.1. The Institutional Official, IRB Chair or Director of Research Integrity and Protection will notify the investigator of the Suspension of IRB Approval or Termination of IRB Approval along with the reasons for the decision. Whenever possible, communication with investigators orally and in writing.

3.2. The Institutional Official, IRB Chair or Director of Research Integrity and Protection will refer the review to IRB staff to place on the agenda for a convened IRB meeting as an item of Suspension of IRB Approval or Termination of IRB Approval.

3.2.1. IRB staff may request additional information or completion of an IRB report form be submitted in Mentor, as appropriate from the event.

3.2.2. IRB staff will notify the Investigator of the Suspension and Termination through Mentor.

REFERENCES

21 CFR §56.108(b)(3), 21 CFR §56.113
45 CFR §46.103(b)(5)(ii), 45 CFR §46.108(a), 45 CFR §46.113

RELATED MATERIALS

SOP: IRB Meeting Conduct (SOP-402)

REVISION HISTORY

Version #	Date Revised	Reason for/Brief Description of Change	Revised By
01	12/6/2017	New- Initial Integration Update	J. Blundon