



Department	Title	Dates
Research Integrity and Protection	Authority and Independence of the IRB	Effective: 10/23/2017
		Approved: 3/1/2017
<b>SOP ID</b>		Last Revised: 10/23/2017
IRB-SOP-102		Expiration: n/a

**PURPOSE**

This SOP defines the purpose of the Ascension Wisconsin Institutional Review Board (IRB) and the institutional authority under which the IRB operates. There is no individual, group of individuals, or entity within or outside Ascension Wisconsin that can override a decision of the IRB, except to add restrictions or to disapprove an already approved activity. The IRB must function independently of other entities in the organization.

**SCOPE**

This SOP applies to all IRBs established within Ascension Wisconsin.

**DEFINITIONS**

None

**PROCEDURES****1. Authority**

- 1.1 The IRB derives its authority from both federal regulatory and institutional sources.
- 1.2 Institutional authority is conveyed by the Senior Vice President of Ascension Wisconsin Ministry Market Executive through approval of this procedure.
- 1.3 On a day-to-day basis, the IRB reports to the Chief Medical Officer of Ascension Wisconsin, through the Director or Research Integrity and Protections.
- 1.4 The IRB has the statutory and institutional authority to:
  - Approve, require modifications to secure approval, or disapprove all research activities overseen and conducted by the organization.
  - Suspend or terminate approval of research that is not being conducted in accordance with IRB requirements or that is associated with unexpected serious harm to participants.
  - Observe or monitor any human subject research to whatever extent it considers necessary to protect research participants.

**2. Independence of the IRB**

- 2.1 No individual or group of individuals may inappropriately try to influence the deliberations and decisions of the IRB.
- 2.2 Officials may not approve any research that has been disapproved by the IRB. The institution may require additional reviews or approvals of studies approved by the IRB.
- 2.3 An IRB member may report any attempt to influence the decision of the IRB to the IRB staff or the Institutional Official. The IRB staff and the Institutional Official will investigate and resolve the incident so there is no undue influence placed on the IRB activities and determinations.

**REFERENCES**

None

**RELATED MATERIAL**

Ascension Wisconsin Policy: Human Subject Research

**REVISION HISTORY**

<b>Version #</b>	<b>Date Revised</b>	<b>Reason for/Brief Description of Change</b>	<b>Revised By</b>
01	4/11/2017	New- Initial Integration Update	J. Blundon
02	10/23/2017	Addition of Related Material, References and Revision History sections.	J. Blundon