



Department	Title	Dates
Research Integrity and Protection	Research Integrity and Protection and IRB Resources	Effective: 10/23/2017
		Approved: 3/1/2017
<b>Policy ID</b>		Last Revised: 10/23/2017
RI&P-SOP-002		Expiration: n/a

**PURPOSE**

This document describes how Ascension Wisconsin assures that it has a sufficient number of Institutional Review Boards (IRBs) to review studies in a thorough and timely manner and that it’s Human Research Protection Program (HRPP) has adequate resources for conducting the activities under its jurisdiction.

**SCOPE**

This policy applies to the Ascension Wisconsin IRB and all components of the Research Integrity and Protection (RI&P) program at Ascension Wisconsin. Other components of the Human Research Protection Program have similar budget and review processes.

**DEFINITIONS**

None

**PROCESS**

1. Ascension Wisconsin has made a commitment, under its Federalwide Assurance (FWA) to ensure that each IRB designated under the FWA has meeting space and sufficient staff to support the IRB’s review and recordkeeping duties.
  - 1.1. The Ascension Wisconsin Institutional Official (IO), along with the Ascension Wisconsin Research Institute Research Advisory Board (RAB) and IRB Chair(s), is charged with assessing the appropriateness of the number of IRBs, level of IRB staffing and making additions to Ascension Wisconsin human research review program as needed based on measures of the quality and timeliness of review and staff workload.
2. The Research Integrity and Protection (RI&P) Director, along with Finance and the Chief Medical Officer, prepare an annual budget. This budget supports the following:
  - Adequate number of IRBs
  - Adequate staffing
  - Adequate technology support, including electronic study management and submission systems, policy storage and related online training
  - Adequate funds for educational opportunities for IRB members and RI&P staff, including off-site conferences
  - Adequate funds to provide on-going office and logistic support
  - Adequate funds to carry out agreed-upon special projects
3. When unanticipated needs arise, they are communicated by the RI&P Director to the Chief Medical Officer. These needs are considered in light of their urgency and fiscal implications.

**REFERENCES**

None

**RELATED MATERIAL**

Ascension Wisconsin Policy: Human Subject Research

OHRP Federalwide Assurance (FWA) for the Protection of Human Subjects

**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