



Department	Title	Dates
Research Integrity and Protection	Research Covered by the Human Research Protection Program	Effective: 10/23/2017
<b>SOP ID</b>		Approved: 7/25/2017
RI&P-SOP-005		Last Revised: 12/05/2017
		Expiration: n/a

**PURPOSE**

The Ascension Wisconsin Human Research Protection Program (HRPP) is responsible for the oversight of all research that involves human subjects. This policy explains the jurisdiction of the Ascension Wisconsin HRPP, including IRB and quality/compliance oversight.

**SCOPE**

All human subject research conducted at Ascension Wisconsin or by Ascension Wisconsin’s employees or agents.

**DEFINITIONS**

**Associate** refers to an individual who is an employee of Ascension Wisconsin.

**Agents** include associates of Ascension Wisconsin for purposes of engagement in human research when that individual is on-duty in any capacity as an employee of this Ministry. An individual who is not an employee is considered an agent when that individual has been specifically authorized to conduct human research under the auspices of Ascension Wisconsin. Legal counsel has the ultimate authority to determine whether someone is acting as an agent of this Ministry.

**Engagement in Research** applies when employees or agents interact or intervene with human subjects or their private identifiable information for the purpose of conducting non-exempt human subject research. Ascension Wisconsin follows OHRP guidance on "Engagement of Institutions in Research" to apply this definition.

**Intervention** includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject’s environment that are performed for research purposes.

**Interaction** includes communication or interpersonal contact between the researcher and subject.

**Private information** includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

**PROCEDURES**

**1. Covered Research**

Any activity that is considered human subject research, as defined in SOP Determination of Human Subjects Research, whether funded or not funded, that falls into one of the categories below is subject to oversight of the Ascension Wisconsin HRPP:

- Ascension Wisconsin, or its employees or agents, is engaged in conducting the research, in accordance with the OHRP guidance Engagement of Institutions in Human Subjects Research.
- Research that Ascension Wisconsin assumes jurisdiction over per written agreement.
- All non-Ascension Wisconsin investigators involved in human subjects research not falling under the categories above that access any Ascension Wisconsin facilities, patients or personnel must submit an application for Administrative Review to the Ascension Wisconsin IRB staff for a determination by an IRB Chair or Designee of whether or not the proposed research involving human subjects falls within the IRB jurisdiction and requires Ascension Wisconsin IRB review and approval or a certification of exemption from IRB review.

**2. Process for Determining Whether an Activity is Covered Research**

- 2.1.** Researchers who have a question about whether or not their human subject research requires oversight by the Ascension Wisconsin IRB may contact IRB staff with the details of their project.
- 2.2.** The Determinations are made in a timely manner by designated RI&P staff who may consult with the IRB Chair, Director or other experts on the decisions. All determinations will be made in a timely manner in accordance with the applicable federal regulation and guidance. Each determination and its basis will be documented and communicated to the researcher via the electronic IRB system or email.
- 2.3.** If the RI&P staff determines that the project requires additional IRB review, the researcher will be guided to submit the appropriate application for a new study or other determination.

**REFERENCES**

None

**RELATED MATERIAL**

Ascension Wisconsin Policy: Human Subject Research

**REVISION HISTORY**

Version #	Date Revised	Reason for/Brief Description of Change	Revised By
01	4/11/2017	New- Initial Integration Update	J. Blundon
02	7/25/2017	Minor grammar corrections	J. Blundon
03	10/23/2017	Addition of Related Material, References and Revision History sections.	J. Blundon
04	12/5/2017	Change SOP # from 001 to 005	J. Blundon