



Department	Title	Dates
Research Integrity and Protection	Assurance of Compliance and IRB Registration	Effective: 10/23/2017
SOP ID		Approved: 3/1/2017
IRB-SOP-101		Last Revised: 10/23/17
		Expiration: n/a

PURPOSE

This SOP explains how and when the institution applies the terms of the Federalwide Assurance (FWA) and defines administration and oversight of the institution's FWA(s).

SCOPE

This SOP applies to all IRBs established within Ascension Wisconsin.

DEFINITIONS

Federalwide Assurance (FWA): The Federalwide Assurance (FWA) is a written agreement between the institution and OHRP where the institution commits to HHS that it will comply with the requirements set forth in 45 CFR 46, as well as the Terms of Assurance. An FWA is the only type of assurance of compliance accepted and approved by OHRP for institutions engaged in non-exempt human subject research conducted or supported by HHS.

PROCESS

1. Assurance and IRB Registration

- 1.1.** Ascension Wisconsin and its affiliates maintain Federalwide Assurances under OHRP. The following are the Ascension Wisconsin legal entities who are involved in the conduct of human subject research:
 - Affinity Health System (FWA00004789); Columbia St. Mary's, Inc. (FWA00005861); Ministry Healthcare, Inc. (FWA00024776); Wheaton Franciscan Healthcare – Southeast Wisconsin (FWA00003758); Wheaton Franciscan Medical Group (FWA00011154)
- 1.2.** All Ascension Wisconsin entities rely on an IRB at an Ascension Wisconsin site as the internal IRB.

2. Applicability

- 2.1.** Regardless of the funding source, Ascension Wisconsin provides protections equal or greater to those under the federal Common Rule (45 CFR Part 46, Subpart A) to all non-exempt human participants research conducted or supported by any federal department or agency that has adopted the Common Rule, unless a department or agency conducting or supporting the research determines that the research shall be conducted under a separate assurance.
- 2.2.** Ascension Wisconsin applies Subparts B, C and D of the federal Common Rule to non-exempt human subject research funded by the U.S. Department of Health and Human Services.

3. Maintenance of Assurance and IRB Registration

Research Integrity and Protection staff is responsible for maintaining and updating the assurance(s) and IRB/Organization Registration.

REFERENCES

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	4/11/2017	New- Initial Integration Update	J. Blundon
02	10/23/2017	Addition of Related Materials, References and Revision History	J. Blundon