



IRB Information & Compliance Statement

September 10, 2018

Federal Wide Assurances

Ascension Wisconsin holds the following Federal Wide Assurances approved by the DHHS Office for Human Research Protection.

- Columbia St. Mary's, Inc. (FWA00005861)
- Ministry Healthcare, Inc. (FWA00024776)
- Wheaton Franciscan Healthcare – Southeast Wisconsin (FWA00006568)

Under each assurance, Ascension Wisconsin complies with 45 CFR 46 for federally funded research; however, the regulations under 45 CFR 46, including all of Subparts B, C, and D, provide the practical basis for the review and approval of all research at Ascension Hospitals and Clinics regardless of funding.

Ascension Wisconsin policy requires all research that involves human subjects, whether or not supported by external funding, to be reviewed and approved by the Institutional Review Board (IRB).

IRB Registration

The following IRB(s) are registered with OHRP and are designated in all FWAs listed above to conduct reviews of research involving human subjects at all Ascension Wisconsin sites and all institutions that cede IRB review:

- Ascension Wisconsin IRB, registered as: Wheaton Franciscan Healthcare IRB #1 (IRB 00006687);
Wheaton Franciscan Healthcare IRB #2 (IRB 00011482)

Food and Drug Administration Regulations

Ascension Wisconsin Hospitals and Clinics participate in clinical research that falls under the jurisdiction of the Food and Drug Administration. WFH complies with the regulations found under 21 CFR 50; 21 CFR 56; 21 CFR 312; 21 CFR 361; 21 CFR 612; and 21 CFR 812.

Statement of GCP Compliance

The Ascension Wisconsin IRB is in compliance with Good Clinical Practice Guidelines insofar as those guidelines are consistent with the Food and Drug Administration regulations (21 CFR Parts 50 and 56) and the Department of Health and Human Services regulations (45 CFR 46) pertaining to the protection of human subjects in research.

Electronic systems

The Ascension Wisconsin IRB uses various electronic record systems for treatment, payment, and health care operations. Based on these systems and current regulations, Ascension believes that it is compliant with the HIPAA Standards outlined in 45 CFR Part 164 Subpart C. As to its system that Ascension considers its legal record, Ascension believes that these electronic systems are trustworthy, reliable and generally the equivalent to paper records and handwritten signatures executed on paper. However, these systems have not been certified pursuant to 21 CFR Part 11.

Mentor eIRB

Record Archiving. Ascension Wisconsin's eIRB system facilitates record archiving by the comprehensive logging of every action taken within the eIRB system. Within these logs is a record of each action, the identity of the individual performing the action, and the date and time the action occurred.

Electronic Signatures & Security Controls. The eIRB system addresses the requirements for electronic signatures and security controls by including the following.

- Controls for identification: Every eIRB user must have a registered account with a unique name and password and a specified level of system authority.
- System access is limited to authorized individuals: Action in the eIRB is only allowed by users with a registered account and system privileges vary depending on assigned authority.
- Written policies that hold individuals accountable and responsible for actions initiated under their electronic signatures: WFH has written policies which prohibit the sharing of passwords.
- Controls for a closed system: eIRB is a closed system meaning all of the information associated with research proposals and reviews is maintained entirely by WFH and is governed by WFH policies and procedures for data security.

If you have any questions about this statement, please contact the IRB office at IRB@ascension.org or 414-465-3059.



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Director, Research Integrity and Protections

Ascension- Wisconsin