



AW IRB and Local Context Information

The form should be provided to the main PI and IRB of record when requesting AW rely on an External IRB for review. If you have any questions, contact the IRB at IRB@ascension.org or 414-465-3134.

IRB Reliance Contact	Jackie Kirchen, MS, CIP 414-465-3134; Jackie.Kirchen@ascension.org
FWA Information	Wheaton Franciscan Healthcare- Southeast Wisconsin FWA 00011154 Columbia St. Mary's, Inc. FWA 00005861 Ministry Health Care, Inc. FWA 00024776
Institution Names	The above named legal entities are part of the Ascension Wisconsin market. Names of individual campus/ locations may include the name "Ascension", rather than the legal names listed above.
Institutional Official	Douglas Reding, MD, MPH, FACP Chief Academic Officer, VP- Research, Ascension Wisconsin
IRB	Ascension Wisconsin IRB #1 IRB 00006687; Ascension Wisconsin IRB #2 IRB 00011482
Post Approval Monitoring	Ascension Wisconsin Research Integrity & Protection has a post approval monitoring program – called Research Education and Quality Management (REQM). REQM monitors studies that have been deferred to external IRBs.
State Laws (and interpretation/ requirements at Ascension Wisconsin)	<p><u>Legally Authorized Representative (LAR)</u> An LAR must be a court appointed guardian or a health care agent designated under a power of attorney for health care. Investigators are to be clear on the terms of the guardian's authority (a guardian should be able to readily produce a copy of the pertinent court order); are to consult with the Office of General Counsel; and are to recognize that a court is most likely to approve such authority in situations where the research is "therapeutic," where it offers care not available outside of the research, or where it presents care alternatives for which there is genuine equipoise concerning which treatment is preferred.</p> <p>Wisconsin law prohibits a health care agent from agreeing to experimental mental health research or to psychosurgery, electroconvulsive treatment, or drastic mental health treatment procedures for an adult subject lacking capacity to consent. [WSA 155.20(3)]</p> <p>Wisconsin has no statute that broadly encompasses human subjects research. However, the Guardianships and Conservatorship statute, WSA Chapter 54, addresses the power of a court appointed guardian of the person to authorize an incompetent ward's participation in research. Ascension Wisconsin does not apply WSA. §50.06 regarding priority of surrogates for consent to research.</p> <p><u>Wards of the State</u> WSA Chapter 54 describes powers of a guardian regarding a Ward's participation in research.</p> <p><u>Age of Majority/ legal age for consent</u> In Wisconsin, to be an adult, a person must be 18 years old or older [WSA 48.02(1d), 48.02(2)] or an emancipated minor. An emancipated minor, under Wisconsin law, includes (1) a married, widowed or divorced person who is at least 16 years old, (2) a minor who has given birth, (3) a minor emancipated by court order, (4) a minor emancipated by parental consent, and (5) a minor living on his or her own who is not supported by parents. [WSA 48.375(2)(e), 765.02(2), 54.46(6), 895.037(1)(c)]. Emancipated minors are considered able to give legal consent to treatments or procedures involved in research.</p> <p><u>Mandatory reporting</u></p>

	<ul style="list-style-type: none"> - Any medical or mental health professional that has reasonable cause to suspect child abuse is required to report the suspected abuse under Wisconsin statutes. - Wisconsin law also requires any health care provider to report the appearance of a communicable disease or a death caused by such a disease to the local health officer. - Research related radiation exposure: Prior authorization from the State of Wisconsin Division of Public Health is required prior to conducting research that involves exposing subjects to radiation. Specifically, Wisconsin Administrative Code, Radiation Protection, DHS157.74 (2)(f), prohibits the use of x-ray devices for screening purposes without Department permission. Screening is defined as ". . . an exposure of a person without prior examination disclosing a need for x-ray study and prescription for such a study by a licensed practitioner." Current interpellation by the state is that any research related X-ray required prior DPH authorization.
<p style="text-align: center;">Other Local Consideration (s)</p>	<p>As a Catholic Healthcare Institution all human research conducted at Ascension WI must conform to the "Ethical and Religious Directives for Catholic Health Care Services". Pertinent excerpts (not all inclusive) from the Ethical and Religious Directives for Catholic Healthcare Services that apply to research:</p> <ul style="list-style-type: none"> • A Catholic Healthcare Institution, especially a teaching hospital, will promote medical research consistent with its mission of providing health care and with concern for the responsible stewardship of health care resources. Such medical research must adhere to Catholic moral principles. <i>Directive #4</i> • Nontherapeutic experiments on a living embryo or fetus are not permitted, even with the consent of the parents. Therapeutic experiments are permitted for a proportionate reason with the free and informed consent of the parents or, if the father cannot be contacted, at least of the mother. Medical research that will not harm the life or physical integrity of an unborn child is permitted with parental consent. <i>Directive #51</i> • Catholic Healthcare Institutions should not make use of human tissue obtained by direct abortions even for research and therapeutic purposes. <i>Directive #66</i> • No one should be the subject of medical or genetic experimentation, even if it is therapeutic, unless the person or surrogate first has given free and informed consent. In instances of nontherapeutic experimentation, the surrogate can give this consent only if the experiment entails no significant risk to the person's wellbeing. Moreover, the greater the person's incompetency and vulnerability, the greater and vulnerability, the greater the reasons must be to perform any medical experimentation, especially nontherapeutic. <i>Directive #31</i>
<p style="text-align: center;">Consent Considerations</p>	<p><u>Short Form and Safe Harbor Languages</u> Institutional policy defines a research consent form that includes care or treatment to be a "vital document" under language access law. Therefore, research consent forms are required to be translated into the institution's safe harbor languages- Spanish and Hmong- prior to approaching subjects who are non-English speakers for which the safe harbor language is their native language. The short form consent process is not allowed to be used in these cases.</p> <p><u>Consent Form Language Requirements</u> The AW IRB requires the topics below be addressed in the consent and recommends the following language. The language may be modified to fit the tone and style of the consent, but the meaning cannot be changed. The AW IRB must approve the consent language during the deferral review.</p> <p><u>Pregnancy and Use of Contraceptives</u> Consent form language that explicitly mandates the use of contraceptives by study participants would constitute Formal Cooperation (or, at least, Implicit Formal Cooperation) with an act that is considered to be intrinsically immoral by Catholic Church teaching. To address this, the Ascension Wisconsin consent form template language regarding the use of contraceptives in research must be used; the only modifications allowed are to adjust the language to match the voice or style of writing or to add study specific information where indicated.</p> <p style="padding-left: 40px;"><i>The study drug or procedures performed during this study may include unknown risks to an unborn child if a woman is already pregnant or becomes pregnant during the study. Since the effects of the investigational drug on the female [and male] reproductive systems are still unknown, you and your partner MUST take appropriate precautions to avoid becoming pregnant [or fathering a child] throughout the study until your follow-up visit.</i></p>

Consent Considerations (cont.)

If you are pregnant or currently breast feeding, you cannot be in this in this study. Women are able to be part of the study if they are:

- *post-menopausal for at least 1 year, or*
- *surgically sterile (had a hysterectomy or bilateral oophorectomy (removal of ovaries)) for at least 3 months, or*
- *able to have children and agree to take actions to avoid becoming pregnant*

To check that you are not pregnant, you will need to agree to have a pregnancy test done [within the screening period and before you start the first dose of the drug. You will also have a blood or urine pregnancy test before each dose of study drug is given. If the urine test is positive, you will have a blood test done. If the blood test is positive, you will not receive any more doses of study drug.]

If you are able to become pregnant [or father a child] you must agree to take precautions that are at least 99% effective in preventing pregnancy while you are in this study [and for 3 months after your last dose of study drug]. The following methods have been identified in the medical literature as being at least 99% effective in preventing pregnancy:

- 1) *Complete abstinence from sexual intercourse*
- 2) *Use of two of the following methods in combination (a+b or b+c or a+c)*
 - a. *Condom or occlusive cap (diaphragm or occlusive/vault caps) with spermicide*
 - b. *Oral, injectable, or implanted hormonal contraceptives*
 - c. *Tubal ligation or vasectomy (surgical sterilization) or intrauterine device or intrauterine system*

You should discuss this matter thoroughly with your physician so that you are able to make an informed decision, and so you and your physician agree that you are taking appropriate precautions.

Subject Compensation

If subjects will receive compensation for their participation in the study through Ascension Wisconsin, please make sure that the section of the consent form that discusses compensation includes the following language:

Because you will be paid, we will collect your name, address, telephone number, and social security number and you will be asked to complete an IRS Form W-9. We will give this information to the Ascension Wisconsin office that processes the payments. The payments you receive may be reportable as income on your taxes. If you are paid \$600 or more in a calendar year by any Ascension Wisconsin owned location, you will be sent a Form 1099 to use when preparing your tax forms.

Communicable Disease Testing

If the study involves testing for communicable diseases, include the following:

As part of this study you will be tested for [identify the reportable disease being tested for]. Wisconsin state law requires the study doctor or study staff to report positive test results, including to the local health department. These reports are required to identify you by name.