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Columbia St. Mary's
A Passion for Patient Care™

Effective: 12/2017
 Approved: 12/2017
 Last Revised: 12/2017
 Expiration: 12/2020
 Owner: Lynn Schuster: Regional Risk Officer
 Department: Risk Management
 References:
 Applicability: Ascension Wisconsin

Informed Consent, AW

SCOPE

This policy applies to all health care facilities wholly owned, and/or controlled directly or indirectly managed by Ascension Wisconsin. See Exhibit A for list of entities.

PURPOSE/RATIONALE

The purpose of this policy is to ensure that an appropriately obtained informed consent conversation is conducted with the patient* before undergoing a surgical/ invasive procedure and other specific procedures and circumstances as described throughout the policy. The informed consent conversation between the physician* and his or her patient* is crucial in order to respect the inherent dignity of all patients. . This policy is consistent with the Ethical and Religious Directives for Catholic Healthcare Services and applicable state and federal regulations.

In accordance with the Ethical and Religious Directives for Catholic Health Care Services the following directives are applicable to the policy:

26. The free and informed consent of the person or the person's surrogate is required for medical treatments and procedures, except in an emergency situation when consent cannot be obtained and there is no indication that the patient would refuse consent to the treatment.

27. Free and informed consent requires that the person or the person's surrogate receive all reasonable information about the essential nature of the proposed treatment and its benefits; its risks, side-effects, consequences, and cost; and any reasonable and morally legitimate alternatives, including no treatment at all.

28. Each person or the person's surrogate should have access to medical and moral information and counseling so as to be able to form his or her conscience. The free and informed health care decision of the person or the person's surrogate is to be followed so long as it does not contradict Catholic principles.

(Ethical and Religious Directives for Catholic Healthcare Services, Fifth Edition, directives 26-28).

POLICY

It is the policy of Ascension Wisconsin to support the patient or their authorized representative in making informed decisions regarding the patient's care while following all applicable laws and regulations regarding the consent process. **The informed consent conversation with the patient or authorized decision-maker is the responsibility of the physician* that will be performing the Medical intervention. It is also the**

responsibility of the physician* to document in the medical record that the informed consent conversation occurred.

DEFINITIONS

Activated Power of Attorney for Healthcare Agent: When a patient has a valid healthcare power of attorney document and is determined to lack decision-making capacity, the power of attorney document may be triggered. Activation allows the agent identified in the healthcare power of attorney document to act as the authorized decision-maker for the non-decisional patient. This can be deactivated should the patient regain decision-making capacity.

Authorized Decision-Maker A broad term that refers to the person who is considered to speak on behalf of a patient who lacks decision-making capacity. This ability may be permanent or temporary. Examples include, but are not limited to an activated Power of Attorney for Healthcare Agent, legal guardian, or family member.

Decision-Making Capacity: The ability to receive and evaluate information effectively, to process that information in accordance with one's own value system, and to make and communicate decisions.

Decisional Patient: An adult patient who is eighteen years old (18) or more and possesses the decision-making capacity to understand the nature and consequences of his or her healthcare decisions.

Emergency: Means a circumstance in which there is an immediate risk to a patient's life, body part, or function which demands prompt action by a physician*.

Incompetent Patient: A patient that has been adjudicated to be non-decisional by a court of law.

Implied Consent: When a patient submits him or herself to anticipated care. Examples include when a patient holds out an arm to receive a shot or presents to the emergency department but lacks the ability to verbalize consent.

Informed Consent: The conversation between a physician* and a patient* in which the patient* is informed by the physician* with sufficient information regarding a specific treatment or procedure in order to make a prudent treatment choice.

Legal Guardian: Someone appointed by a court to represent the patient and make decisions on behalf of the patient. The legal guardian does not have absolute authority and is bound by constraints found in the court order granting the guardianship and Wisconsin statutes.

Minor: Any individual who is under the age of eighteen (18).

Patient*: This term as used throughout this policy refers to the patient or the authorized decision-maker as determined by the patient's decision-making capacity.

Permit: The physical paper form which, when signed by the patient*, confers permission upon the physician* facilitating the informed consent conversation to perform the proposed and agreed-upon treatment or procedure. In surgical cases, the signed permit must be placed in the patient's medical record prior to surgery.

Physician*: This term as used throughout this policy refers to a licensed physician, podiatrist, dentist, or advanced practice allied health professional operating within his or her authorized clinicians scope of practice (i.e. advanced practice nurses with prescriptive authority, physician assistants, and anesthesiologist assistants).

Invasive Procedures or Treatment: Any medical procedure or treatment that invades the body by cutting or puncturing the skin or by inserting instruments into the body except for those procedures that are duly

authorized to be performed by medical experts other than a physician*.

Non-Decisional Patient: An adult patient who is eighteen years old (18) or more but lacks decision-making capacity due to either temporary or permanent incapacity or a patient that has been adjudicated to be incompetent by a court of law. A non-decisional patient is not necessarily incompetent because a competency determination must be made by a court of law. All incompetent patients are non-decisional, but not all non-decisional patients are incompetent.

Routine Treatment: Addressed in the Inpatient and Outpatient Consent for Treatment and Financial Agreement. Examples include, but are not limited to: placement of Foley catheters, placement of a peripheral IV, placement of nasogastric tubes, administration of medications, and collection of blood by phlebotomy.

Surgical Procedure: Procedures which involve entry into the body through an incision.

Witness: A witness is the person who observes a person signing a procedural permit. A witness is not responsible for attesting to the adequacy of the informed consent conversation conducted between physician* and patient*.

PROCEDURE

- A. **Elements Required for Informed Consent:** The physician* performing the procedure or treatment is responsible for ensuring informed consent of the patient* before performing the procedure or treatment. Other health care personnel may be utilized to help provide additional information such as educational material to the patient*. The information includes the following:
1. Indications for the proposed care, treatment, services, surgery, or invasive procedure;
 2. A description of the contemplated surgery or invasive procedure including the type of anesthesia to be used;
 3. The prognosis (i.e., the prospects for success) of the contemplated surgery or invasive procedure;
 4. The material benefits, risks, and possible complications of the contemplated surgery or invasive procedure, care, treatment, or service;
 5. The reasonable alternatives to surgery or invasive procedures, care, treatment, or service;
 6. The likely effect of no intervention;
 7. The likelihood of achieving the patient's and/or clinical goals;
 8. For surgical procedures, information as to whom will actually perform the contemplated surgical intervention. When practitioners other than the primary surgeon will perform important parts of the surgical procedures even when under the primary surgeon's supervision, the patient* must be informed of the other practitioners and what important tasks each will conduct;
 9. HIV Informed consent –Additional elements of informed consent are required for HIV testing - Wis. Stat. § 252.15(2m).
 - a. Patients must be notified that the test will be performed and that they may decline it.
 - b. The provider must offer the patient a brief oral or written explanation or description of the HIV infection, HIV test results, requirements for reporting HIV test results, treatment options for a person who has a positive result, and services provided by AIDS service organizations and other community based organizations for persons who have a positive HIV test result.
 - c. If the patient declines the test, the provider may not use this fact as a basis for denying services

or treatment to the patient.

B. Elements Not Required for Informed Consent: As established by Wisconsin Statute § 448.30, the physician's* duty to inform the patient* of alternate modes of treatment does not require disclosure of:

1. Information beyond what a reasonable well-qualified physician* in a similar medical classification would know;
2. Detailed technical information that in all probability a patient* would not understand;
3. Risks apparent or known to the patient*;
4. Extremely remote possibilities that might falsely or detrimentally alarm the patient*;
5. Information in emergencies where failure to provide treatment would be more harmful to the patient than treatment;
6. Information in cases where the patient is incapable of consenting; and
7. Information about alternate medical modes of treatment for any condition the physician* has not included in his or her diagnosis at the time the physician* informs the patient*.

C. Permit: The permit must contain the following elements:

1. Name of facility where the treatment or procedure is to take place.
2. Name of specific treatment or procedure for which consent is being given.
3. Name of responsible practitioner who is performing the surgery, invasive procedure, or treatment. (EXCEPTION: The blood consent permit does not require the name of the ordering practitioner).
4. Statement that the anticipated benefits, material risk and alternative therapies related to the planned treatment or procedure was explained to the patient*.
5. Signature of the patient*.
6. Date and time the permit is signed by the patient*.

D. Witnessing the Patient's* Signature on the Permit

1. Only the physician* can carry out the informed consent process. Non-physician* associates may assist the physician* in obtaining documentation of the process but may not take responsibility for informing the patient* of the required elements. In instances in which a non-physician is assisting with documentation of an informed consent and the patient* expresses concern about the procedure or exhibits an unwillingness to sign the permit, the physician* should be contacted immediately.
2. If the physician* has not obtained the patient's* signature on the permit at the time of the informed consent conversation, the patient's* signature may be obtained and witnessed by another member of the care team. Any member of the care team acting as a witness merely attests to the fact that the patient* signed the permit; the witness is not attesting to the adequacy of the informed consent conversation between physician* and patient*.

E. Limited English-Proficient Patients*: For patients* with limited English language proficiency, a medical interpreter should be used to assure effective communication during the informed consent process. The medical interpreter's role is to facilitate the communication between the limited English proficient (LEP) patient* and the provider during the informed consent conversation. Whether the interpreter resource used is in-person, telephonic, or video remote interpreting, the medical interpreter's name and/or interpreter number should be added to the permit to document that an interpreter was provided during the informed consent conversation. It is outside the scope of the interpreter's role to act as a witness to the

patient's* signature on the permit.

F. Process for Obtaining and Documenting Informed Consent

1. **Written Consent:** For all surgical and invasive procedures, the decisional patient's* signature or the authorized decision maker for non decisional patients should be obtained on a permit Ideally .the informed consent conversation should occur in a face to face conversation between the physician* and the patient*. The exact time the consent permit was executed should be noted. The physician* is responsible for noting in the patient's medical record that the informed consent conversation occurred. 42 C.F.R. § 482. 51(b)(2).
2. **Verbal/Telephone Consent:** In circumstances where the decisional patient* or the authorized decision maker for non decisional patients is not present to sign the consent permit or have the face to face conversation with the physician*, it may be permissible to obtain verbal consent, There should be documentation on the patient's signature line that patient is unable to sign, verbal consent given
3. **Treatment without Informed Consent:** In an emergency, consent for the necessary procedure or treatment is implied, unless there is visual documentation (e.g., community DNR bracelet, etc.) or prior knowledge of a patient's wish to the contrary. The need to proceed with emergency procedures or treatments must be documented by the attending physician* making the decision. *Refer to Definitions: Emergency*
4. **Sedation:** Informed consent should be obtained before sedation is given. However, a patient who has received sedation can sign the permit if in the judgment of the physician*, the patient retains decision-making capacity.
5. **Consent Prior to Hospitalization:** Optimally, the physician* that is to perform the surgical or invasive procedure will have the informed consent conversation with the patient* and obtain the patient's* signature in the physician's* office prior to the patient's arrival at the facility for a procedure. In that case, the physician* who is to perform the surgical or invasive procedure should document that the informed consent conversation occurred by documenting that information in the medical record as instructed by the Medical Staff Council. A copy of any signed permit obtained by the physician* should be included in the patient's medical record.

G. Duration of Informed Consent

1. **Surgical Procedural Permits:** Signed consent permits and documentation of the informed consent conversation are valid for 30 days as long as the reason for the treatment remains the same and the patient's condition has not changed.
2. **Administration of Blood and Blood Products:** Consent for the administration of blood and blood products is valid for the entire duration that a patient is initially in a facility and the entire length of stay for inpatients. Should the administration of blood or blood products be necessary on a recurring basis, the signed permit is valid for one year from the date of signing. *(Also refer to legacy ministry Blood Administration policy and Refusal of Blood Transfusion Policy*
3. **Recurring or Series Outpatient Procedures:** An informed consent permit must be obtained prior to the first treatment. The consent permit for recurring or series outpatient procedures is valid for one year; a new permit is not necessary for each treatment. For example, the yearly limit applies, but is not necessarily limited, to recurring treatment such as radiation therapy, chemotherapy, and epidural pain management.as long as the reason for the treatment remains the same and the patient's condition has not changed.

4. **Discharge:** All permits shall be considered revoked after the patient has been discharged from the facility except in the case of consent permits authorizing recurring or series outpatient procedures.

H. Who May Consent

1. Adult patients (18 years of age or older)

- a. **Decisional Patients:** Adult patients that possess decision-making capacity have the right to consent to treatment. Decisional adult patients also have the right to refuse treatment. The presumption is that an adult patient has decision-making capacity unless the patient has been found clinically non-decisional or has been declared incompetent by a court of law.
- b. **Non-Decisional Patient:** If an adult patient is unable to give consent because he or she lacks decision-making capacity, and the patient's condition is not an emergency, consent should be obtained from the patient's authorized decision-maker. Authorized decision-makers include:
 1. Court Appointed Legal Guardians;
 2. Activated Healthcare Power of Attorney Agents
 3. In absence of Court Appointed Legal Guardian or Activated Health Care Power of Attorney:
 4. Consensus of patient's family and significant others to include spouse, domestic partner, adult children, parent, adult sibling or significant others
 5. The intent of the consensus is to gather information that would reflect the patient's likely treatment preferences under the circumstances.. If there is a conflict, please consult with Risk Management. Case Management and/or Ethics may provide additional guidance.
- c. **Temporarily non-decisional Adult**
 1. Procedures requiring consent in non-life threatening clinical situations should be delayed until either the patient regains decision-making capacity or the patient's condition becomes an emergency. Even if a patient signed a consent form within 30 days of the procedure, the consent is no longer valid if the patient's status has changed.
 2. When a non-decisional patient is in a non-emergency situation, but regaining of decision-making capacity is not foreseeable, consent for treatment must be obtained from the authorized decision-maker.

2. Minor Patients (under 18 years of age)

- a. **General Rule:** Minor patients should not be treated without obtaining the consent of the parent or legal guardian unless a specific exception applies.
- b. **Exceptions for Minor Consent:** The following exceptions exist in **Wisconsin**
 1. In case of a medical emergency.
 2. Patient is an emancipated minor when at least 16 years of age and married. This exception also includes court-ordered emancipation. Wis. Stat. § 765.02.
 3. Pregnancy, Labor, and Delivery: In case of a pregnant minor, the patient must consent to treatment related to the pregnancy, labor, and delivery. Parental consent of the pregnant minor should be attempted, if possible. However, medical care related to the minor's pregnancy, labor, and delivery may be provided without the consent of the minor's parent or guardian if the minor appears to have good cause for refusing parental involvement. In addition:

- a. The minor has the right to pain control (such as an epidural).
 - b. Consent of the minor must be documented.
4. Minors must consent to treatment of their dependent children without requiring consent of the minor's parents or legal guardian.
 5. All Minors may consent to STD testing and treatment.
 6. Minors 14 years of age or older may consent to HIV testing and treatment.
 7. Minors 12 years of age or older may consent to alcohol or other drug-abuse testing and treatment.
 8. Consent of a minor 14 years of age or older is required for inpatient and outpatient mental health treatment.
- c. **Exceptions for Minors Consent – the following exceptions exist in Minnesota**
1. In the case of an emergency
 2. Patient is married
 3. Patient lives apart from his or her parents or guardians and is managing his or her own financial affairs.
 4. Any minor may give effective consent for medical, mental and other health care services to determine the presence of or treat pregnancy and conditions associated therewith, venereal disease, alcohol and other drug abuse and the consent of no other party is required. (Minn Stat 144.343)
 5. A minor 16 years of age or older may consent to hospitalization, routine diagnostic evaluation and emergency or short term acute care in a mental health treatment facility (Minn Stat 253B.03 Subd 6 (d)
- d. **Minors with Divorced Parents:** If the child's parents are divorced or legally separated, consent shall be obtained from the parent having legal custody. If parents share legal custody, consent from only one (1) parent is necessary. A stepparent may not consent to treatment unless they are the legal guardian or if there is evidence that the legal guardian provided the stepparent with authority to consent.
- e. **Minors in Foster Care:** Unless parental rights have been legally terminated and the foster parents have been granted guardianship or legal custody of the child (distinct from physical custody), parental consent is required unless treatment falls under one of the stated "Exceptions for Minor Consent."
- f. **Adoption Agencies:** A licensed adoption agency having legal custody of a minor may, upon termination of the biological parents' rights, supply the necessary consent. If parental rights have not been terminated, consent should be obtained from the biological parent unless treatment falls under one of the stated "Exceptions for Minor Consent."
- g. **Substitute Consent:** Written consent may be provided by any competent adult to whom the responsible parent has given authority in writing to consent to the treatment of the minor unless treatment falls under one of the stated "Exceptions for Minor Consent.". A copy of the substitute consent authorization should be maintained in the minor's medical record.
- h. **Persons in Legal Custody:** A person in the custody of law enforcement must still give their consent for medical examination, operation, or such treatment before procedures are performed

regardless of law enforcement request. Some exceptions apply such as when testing for alcohol or controlled substances pursuant to Wisconsin's Implied Consent Statute as discussed in Section J(3) below.

I. Drug and/or Alcohol Screens – Wis Stat 146.02555 (2) and 146.0255 (3) (b)

1. **Expectant Mothers:** Prior to performing the drug test, the physician* must secure the patient's* informed consent and disclose to them that the test results may be disclosed to the county agency if the results are positive in an expectant mother.
2. **Newborns:** Any hospital social worker or employee who provides healthcare may refer an infant to a physician* for drug testing, if he or she suspects that the infant has been exposed to controlled substance abuse by the mother while pregnant. In these circumstances, the physician* does not need parental consent, but the physician* must:
 - a. Inform the infant's mother that the drug test was performed and the date of the test;
 - b. Disclose the test results; and
 - c. Inform the infant's mother that a positive test result must be disclosed to the county agency. Wis. Stat. § 164.0255(2).
3. **Blood Alcohol Tests Required by Law Enforcement: (Wis Stat 343.305)**
 - a. Hospital personnel must administer a blood alcohol test and report results at the request of an officer subject to the penalty under state law. However, if a patient refuses, staff may not restrain the patient. Law enforcement may restrain the patient.
 - b. Any person who drives or operates a motor vehicle is deemed to have given consent to one or more tests of his or her breath, blood, or urine for the purpose of determining the presence or quantity of alcohol or controlled substances when requested to do so by a law enforcement officer.
 - c. Any person withdrawing blood at the request of law enforcement is immune from any civil or criminal liability for the act, except for civil liability for negligence in performing the act. Wis. Stat. § 895.53(2).
4. **Chemical Tests for Intoxication (Minn Stat 169A.51)**
 - a. Any person who drives, operates, or is in physical control of a motor vehicle consents to a chemical test of that person's blood, breath or urine for the purpose of determining the presence of alcohol, a controlled substance or its metabolite or a hazardous substance. The test must be administered at the direction of a peace officer
 - b. A person who is unconscious or who is otherwise in a condition rendering the person incapable of refusal is deemed not to have withdrawn the consent provided and the test may be given
 - c. Any person withdrawing blood at the request of a peace officer for the purpose of determining the concentration of alcohol, a controlled substance or its metabolite, or a hazardous substance is in no manner liable in any civil or criminal action except for negligence in drawing the blood.

Circumstances Not Covered under Policy: For all circumstances that are not covered or are unclear as described in this policy, contact Risk Management.

REFERENCES

Local Ministry HIV Testing policies

Local Ministry Blood Administration policies

Departure Against Medical Advice (AMA) Unauthorized Departure

Refusal to Permit Procedure Site-based Patient Rights and Responsibilities

Ethical and Religious Directives for Catholic Healthcare Services Fifth Edition (sections 26-28)

42 C.F.R. 482.51 – Condition of Participation: Surgical Services

Wis. Stat. 448.30,

Wis. Stat 146.02555 (2)

Wis. Stat 146.0255 (3) (b)

Wis. Stat 164.0255 (2)

Wis Stat 343.305

Wis Stat 895.53 (2)

Minn Stat. 144.651

Minn Stat. 144.343

Minn. Stat. 253B.03

Minn 169A.51

Attachments:

[Exhibit A Ascension sites 12-2017.doc most current - 12-18-17.doc](#)

Approval Signatures

Step Description	Approver	Date
	Lynn Schuster: Regional Risk Officer	12/2017

Exhibit A

This policy is adopted for the following entities and its wholly owned and managed subsidiaries, including but not limited to the following providers:

Hospitals

Wheaton Franciscan, Inc.

- Wheaton Franciscan – St. Joseph Campus
- Wheaton Franciscan – Elmbrook Memorial Campus
- Wheaton Franciscan – Wauwatosa Campus
- Wheaton Franciscan – Brown Deer Campus
- Wheaton Franciscan – Rehabilitation Unit

Wheaton Franciscan Healthcare – St. Francis

Wheaton Franciscan Healthcare – Franklin

Midwest Orthopedic Specialty Hospital

Wheaton Franciscan Healthcare – All Saints

Columbia – St Mary's, Inc.

- Milwaukee Campus
- Ozaukee Campus
- Sacred Heart Rehabilitation Hospital

Mercy Medical Center of Oshkosh, Inc. d/b/a
Ascension NE Wisconsin Mercy Hospital, Inc.

St Elizabeth's Hospital, Inc. d/b/a Ascension NE
Wisconsin St Elizabeth's Hospital, Inc.

Ascension Calumet Hospital, Inc.

St Michaels Hospital of Stevens Point, Inc.

Howard Young Medical Center, Inc.

Eagle River Memorial Hospital, Inc.

Good Samaritan Health Center of Merrill Wisconsin, Inc.

Our Lady of Victory Hospital, Inc.

Sacred Heart – Saint Mary's Hospitals, Inc.

St Clare's Hospital of Weston, Inc.

St. Elizabeth's of Wabasha, Inc.

Medical Group

Wheaton Franciscan Medical Group

- Metro Physicians
- WFMG – Sussex
- Ministry Medical Group
- Network Health System, Inc. d/b/a Affinity Medical Group

Other Providers

Wheaton Franciscan Laboratories