DEACONESS HEALTH SYSTEM, INC. Evansville, Indiana

Policy and Procedure No. 50-29 S

CONSENT FOR TREATMENT & INFORMED CONSENT INDIANA

I. SCOPE: This policy and procedure applies to the system entities in which Deaconess has at least 50% or greater ownership including but not limited to those marked below:

X	Deaconess Health System, Inc.
X	Deaconess Hospital, Inc.
X	Deaconess Clinic, Inc.
	Deaconess EMS, LLC
Χ	Deaconess Gibson Hospital (Gibson General Hospital, Inc.)
	Deaconess Health Kentucky, Inc.
	Deaconess Henderson Hospital (Methodist Health, Inc.)
Χ	Deaconess Specialty Physicians, Inc.
	Deaconess Union County Hospital, Inc.
Χ	Deaconess Women's Hospital of Southern Indiana, LLC d/b/a The Women's Hospital
	Deaconess Illinois Clinic, Inc
	Deaconess Illinois Specialty Clinic, Inc.
	Deaconess Regional Healthcare Network Illinois, LLC
Χ	Deaconess VNA Plus, LLC
	DCI Commercial ACO, LLC
	Deaconess Health Plans, LLC
	Deaconess Care Integration, LLC
	Healthcare Resource Solutions, LLC
	Mainspring Managers, LLC
	One Care, LLC
	OrthoAlign, LLC
	Progressive Health of Indiana, LLC
	Transcare Medical Transport and Logistics, Inc. dba Deaconess EMS
	Tri-State Radiation Oncology Centers, LLC
	Tri-State Healthcare Consultants, LLC
	VascMed, LLC

- I. PURPOSE: It is important that patients are involved in all decisions concerning procedures and/or recommended treatment. This policy provides definitions, guidelines and procedures to be used in obtaining and documenting patient consent for treatment and informed consent.
- II. DEFINITIONS (Based on Indiana Code):
 - A. Adult: An individual who is at least eighteen (18) years of age.
 - B. Minor: An individual who is not an adult.
 - C. <u>Emancipated Minor</u>: At least fourteen (14) years of age, is not dependent on a parent for support, is living apart from the minor's parent or from an individual acting *in loco parentis*, and is managing the minor's own affairs (IC I6-36 Health Care Consents). (NOTE: Married minors or U.S. military service persons are considered emancipated.)
 - D. <u>Health Care:</u> Any care, treatment, or procedure to maintain, diagnose, or treat an individual's physical or mental condition.

- E. <u>Health Care Representative</u>: A written declaration by a person of sound mind and who is at least 18 years of age, appointing someone else to make health care decisions when the appointer is no longer capable of providing consent.
- F. <u>Loco Parentis</u>: A person aged eighteen (18) or over who is acting in the place of a minor's parents.
- G. <u>Competence:</u> is a legal determination made by court of law that a person is not legally capable of making healthcare or other decisions. Court appoints a guardian to act on behalf of incompetent person.
- H. <u>Capacity:</u> Is a medical determination made by a physician and requires a patient to have the ability to comprehend, deliberate, and communicate. Capacity may change due to factors such as illness, sedation or stress.
 - 1. The question of capacity should be approached from a functional standpoint that recognizes that regardless of the decision the patient ultimately makes, or the clinical label attached to the patient, the key element is whether the patient is able to engage in rational decision-making.
 - 2. An individual person who otherwise would be legally able to consent in accordance with Indiana Code § 16-36, may lack capacity if in the good faith opinion of the attending physician the person is incapable of making a decision regarding proposed healthcare. (IC 16-36-1-4)
- I. <u>Emergent condition:</u> constitutes a threat to health or life or requires immediate action to prevent permanent bodily harm or death. If a patient has an emergent condition and it is <u>NOT</u> possible to obtain the consent of either the patient or someone legally authorized to consent for the patient, the required procedure may be performed with physician documentation of rationale for immediate action.
- **III. POLICY:** It is the policy of Deaconess that patients have the right to participate in their healthcare decisions and to sign their own consent unless they are incapable by virtue of age or physical/mental incapacity.

IV. RESPONSIBILITIES:

- **A. Medical Records Committee:** The Medical Records Committee will review and approve all consent forms proposed for use within the Hospital.
- **B. Risk Management**: The Risk Management office will provide support in the form of obtaining legal interpretations and research into state law and other requirements governing the consent process.
- **C. Case Management Department**: The Case Management/Social Work Department will assist in the process to obtain court assistance for guardianship cases.

V. PROCEDURES:

TYPES OF CONSENT and PATIENT & PROVIDER DISCUSSION

- A. General Consent for Treatment is agreement to receive care and treatment from a Deaconess facility. Consent is provided by the patient or someone legally authorized to consent for patient and is obtained at the time a patient presents to the hospital or outpatient locations.
- **B. Informed Consent** is agreement to a proposed procedure or course of treatment after patient has been provided an explanation of the condition and procedure including:
 - 1. Nature of patient's condition,
 - 2. General and specific risks,

- Benefits
- Anticipated outcomes,
- Alternatives available
- 6. Risk of not having surgery or procedure and any timing considerations.
- 7. Inform when other physicians, providers (including advanced practice providers APP), residents, or students will participate in any important tasks of the surgery or procedure or administering anesthesia.
 - a. Important tasks include:
 - 1) Opening and closing
 - 2) Dissecting tissue
 - 3) Removing tissue
 - 4) Harvesting grafts
 - 5) Transplanting tissue
 - 6) Administering anesthesia
 - 7) Implanting Devices
 - 8) Placing invasive lines
- 8. Discussion related to intimate or sensitive exams and participation of other physicians, providers (including APPs), students in these exams or surgeries

VI. INFORMED CONSENT

A. Responsibility for obtaining and documenting Informed Consent:

- Physicians will obtain and document informed consent for procedures they will perform.
- 2. Advanced practice providers will obtain and document the elements of informed consent for the procedures they will perform.
- 3. Nurses may obtain patient consent for:
 - a. administration of influenza or pneumococcal vaccines provided the relevant Vaccine Information Sheet has been provided to the patient or patient's representative and questions have been answered.
 - b. PICC line placement, if they are responsible for placement.

B. Documentation that Informed Consent discussion was completed with person authorized to provide consent.

The physician or provider will document the informed consent process prior to the surgery or procedure in the patient's medical record. The following are acceptable methods of documentation in addition to completion of the appropriate and approved hospital consent:

- 1. Entering a progress note, consult note or documentation in the History & Physical which is maintained as part of the medical record.
- 2. Providing notes from the office, which become part of the medical record.

C. Procedures requiring Informed Consent:

1. Major or minor surgery involving entry into the body, either through an incision or through a natural body opening.

- 2. All procedures in which general or regional anesthesia is used, regardless of whether an entry into the body is involved.
- 3. Non-surgical procedures that involve more than a slight risk of harm to the patient including invasive diagnostic procedures such as myelograms, arteriograms, etc.
- 4. All forms of radiation therapy.
- 5. All experimental procedures (after approval by an Institutional Review Board and in accordance with their requirements.)
- 6. Any procedure that the physician determines to require a specific explanation to the patient.
- 7. Whenever there is uncertainty regarding the need for informed consent, the physician or provider will resolve the uncertainty by obtaining informed consent.

D. Emergent Conditions

If a patient has an emergent condition and it is <u>NOT</u> possible to obtain the consent of either the patient or someone legally authorized to consent for the patient, the required procedure may be performed with physician documentation of the rationale for immediate action.

E. Health Care Consent

- 1. The following individuals with decision-making capacity: Unless the attending physician in good faith believes that the patient is incapable of making a decision regarding proposed health care, any individual listed below can give effective consent for his or her own treatment
 - a. Adults
 - b. Emancipated minors
 - c. Unemancipated minors for the following limited purposes:
 - 1) Unemancipated minors seeking treatment for sexually transmitted diseases (IC 16-36-1-3)
 - 2). Unemancipated minors seeking treatment for substance/alcohol abuse disorders (IC 12-23-12-1)
 - 3) Any minor age 17 or older seeking to donate blood (IC 16-36-1-3)

2. For Adults without decision-making capacity

- a. If an individual does not have capacity to consent, the individual's appointed health care representative has the authority to make health care decisions for that individual.
- b. If an individual does not have capacity to consent and does not have an appointed health care representative or their health care representative is unable or unwilling to act, Indiana Code § 16-36-1-5 governs who has the authority to make health care decisions for that individual. In that situation, the following individuals, in the following order of priority, have the ability to consent:
 - 1) A judicially appointed guardian or court appointed representative.
 - 2) A spouse
 - 3) An adult child
 - 4) A parent

- 5) An adult sibling
- 6) A grandparent
- 7) An adult grandchild
- 8) Nearest other adult relative in the next degree of kinship, not listed above
- 9) A friend who is
 - a, an adult;
 - b. has maintained regular contact with the individual; and
 - Is familiar with the individual's activities, health, and religious or moral beliefs.
- 10) The individual's religious superior, if the individual is a member of a religious order
- c. If there are multiple individuals at the same priority level, such as multiple adult children, those individuals must make a reasonable effort to reach consensus as to the health care decisions of the individual incapable of consenting. If the individuals disagree on the health care decisions, a majority of the available individuals at the same priority level controls.
- d. Even if an individual has priority as listed above and would be authorized to consent on behalf of an incapable adult, he or she <u>cannot</u> act to make decisions on behalf of the incapable adult if any of the following apply:
 - a. The individual has been disqualified from consenting to health care for the adult, as signed and in writing by the adult when he or she had capacity to make decisions.
 - b. If the individual is:
 - a spouse who is legally separated or has a petition for dissolution, legal separation, or annulment of marriage that is pending in court, from the adult who is incapable of consenting
 - Subject to a protective order or other court order that directs the individual to avoid contact with the adult who is incapable of consenting.
 - c. Subject to a pending criminal charge in which the adult who is incapable of consenting was the alleged victim.
- 3. Health care providers are required to make reasonable inquiry as to the availability of individuals who are able to provide consent (IC 16-36-1-17).

Reasonable inquiry includes:

- a. Examining medical records and personal effects of individual incapable of consenting.
- b. The provider must attempt to contact individuals who are high in the priority level by telephone or other means after the provider has determined the individual is incapable of consent.
- E. If a lawful representative is not known, available or willing to act on the patient's behalf:
 - 1. In each case when a patient is not able to consent and the first designated lawful representative is not available to act on his or her behalf, the next designated lawful representative should be contacted. If that party is unable or unwilling to

- act on the patient's behalf, then the third designated representative should be contacted.
- 2. In non-emergency situations, the hospital through the Case Management Department may petition the courts to appoint a guardian for a patient when the patient is not lawfully able to consent and those person(s) having the lawful authority to consent are not known to us, or are not reasonably available, or are unwilling to act on behalf of the patient.
- 3. In emergency situations where a person cannot consent for themselves and no other consenting authority is known or available, the physician may proceed with treatment under the doctrine of implied consent if it is necessary to save life or prevent serious harm.
- **For Minors**: Consent to health care for a minor not authorized to consent by special statute on their own may be given by any of the following:
 - 1. A judicially appointed guardian or a properly appointed Health Care Representative.
 - 2. A parent or an individual in loco parentis if:
 - a. There is no guardian or other representative described in F1;
 - The guardian or representative is not reasonably available or declines to act;
 or
 - c. The existence of the guardian or other representative is unknown to the healthcare provider
 - 3. An adult sibling of the minor if
 - a. There is no guardian or other representative described in F1;
 - A parent or individual in loco parentis is unavailable or is not reasonably available or declines to act; or
 - c. The existence of the parent or individual in loco parentis is unknown to the healthcare provider after reasonable efforts are made by the healthcare provider to determine whether the minor has a parent or an individual in loco parentis who is able to consent to the treatment of the minor.
 - 4. A grandparent of the patient.
 - a. there is no guardian or other representative described in F1;
 - b. a parent, an individual in loco parentis, or an adult sibling is not reasonably available or declines to act; or
 - c. the existence of the parent, individual in loco parentis, or adult sibling is unknown to the health care provider after reasonable efforts are made by the health care provider to determine whether the minor has a parent, an individual in loco parentis, or an adult sibling who is able to consent to the treatment of the minor.
 - 5. Attempts to contact the parent and make them aware and involve them if available for situations where consent is provided by in loco parentis, an adult sibling or grandparent.
 - a. Attempts to contact parent(s) should be documented in the medical record
 - b. If parent refuses treatment of a minor child. The refusal of medical or mental health care to a minor by the minor's parent, loco parentis, guardian or other health care decision maker could rise to the level of reportable abuse or neglect if the refusal of treatment could make the minor a Child and Need of

Services (CHINS) as defined in DHS Policy 40-03 S Abuse/Neglect/Domestic Violence.

G. Other provisions of consent:

1. Patient Disagreement with statements on the consent form:

Patients who disagree with any of the "I agree" statements listed on the Consent form may draw one line through each statement with which they disagree. Both the patient and the witness must initial *each* change, and both must sign the consent form itself.

- 2. Withdrawal of Consent (Adult with decision-making capacity): After full disclosure of alternatives, consequences, etc., an adult capable of making decisions has the right to decline or refuse health care or lifesaving treatment and the right to withdraw a prior informed consent.
 - a. If the treating physician believes that the patient is capable of making decisions, he or she MUST follow the patient's wishes.
 - b. If the physician believes that the patient lacks decision-making capacity but there is a dispute among providers, a court determination of the matter may be sought.
 - c. In all events, where the patient refuses or withdraws consent for treatment, this will be in writing and attested to by the patient and recorded in the medical record.
 - d. When the patient is physically incapable of providing written instruction, the patient's verbal declaration will be witnessed by two persons and documented in the medical record.

3. Withholding Consent for Minors:

- If a parent does not want his/her child to receive treatment that the treating physician believes is medically necessary, a court-appointed guardian may be appropriate.
- Parents may agree with a treating physician that medical treatment may
 be withdrawn or withheld for a child who can no longer be helped by
 medical care, but if the physician believes that the medical care is
 indicated, he or she may not be bound by the wishes of the parents to
 withhold that treatment. In such a case, the physician MUST seek the
 court appointment of a guardian for the child.

4. Verbal Consent:

- a. It is preferable for physicians to obtain written consent and document the discussion with the patient in the medical record.
- b. If verbal consent has been given, the circumstances of the verbal consent will be documented in the medical record.
- c. The appropriate consent form will be utilized to document that verbal consent has been received. The consent form will include the patient's name, procedure they are consenting to, the physicians name (when applicable), the indication that this is a verbal consent, the signatures of two people who witnessed the verbal consent being given, the date and the time consent was given.

6. Consent by Telephone:

a. The appropriate consent form will be utilized to document that the telephone consent has been received. The consent form will include the patient's name, the procedure the consent is for, the physicians name

(when applicable), the indication that this is a telephone consent, the name of the person who is giving the consent and their relationship to the patient, the signatures of two witnesses to the consent being given over the telephone, the date and time consent was given.

- b. Whenever possible, written confirmation should be obtained.
- 7. **Consenter signs with an "X":** In the event that a patient or authorized Healthcare representative uses an "x" to sign their name, the appropriate consent form will be completed and two persons will be required to witness and sign the form.
- 8. Time Limitation on Consent: Signed consent forms are valid until:
 - a. The patient or the patient's Healthcare Representative who signed the form communicates to the hospital that he/she has withdrawn the consent.
 - The patient's condition has changed, or a question arises as to whether the circumstances under which the consent was originally given still exist.
 - c. Outpatients undergoing a series of treatments (not procedures) to continue for the timeframe of the treatment and expires and should be re-signed if treatment extends past one year.

VIII. PROCEDURE FOR COMPLETING CONSENT FORM

Consent and signatures on consent forms should be obtained from the patient at a time when he or she is capable of understanding, and not incapacitated due to the influence of drugs, sedatives or anesthesia.

- A. The **Consent for Surgery or Procedure form (F-7303)** is to be prepared by the physician or by designated hospital personnel when the procedure has been documented in the physician's orders.
 - 1. The consent form verifies with the patient or patient representative informed consent was provided by the physician or provider.
 - 2. On the first page of the form, the first bullet will list who the doctor or provider is and what date and time he or she talked with the patient about their medical condition and different ways it can be treated. This can be completed as the conversation is occurring. Or if the form is being completed retrospectively, the date/time of the informed consent note can be used.
 - 3. On the first page of the form, the scheduled procedure as ordered by the physician or provider will be written by the second bullet that states "My doctor or provider listed above described the scheduled surgery or procedure:"
 - 4. On the first page of the form, the 3rd bullet will include any advanced practice providers, residents or students that may perform in important tasks listed under Procedures B. Another provider not listed may join the surgery or procedure to assist or relieve providers during the case. This may occur after the consent form is signed or after the surgery has started.
 - 5. On the second page of the consent form, the procedure as described by the patient will be written by the statement "I agree to have this procedure which I understand in my own words to be."
 - 6. Hospital personnel may reinforce information that has been provided to the patient/representative by the physician and may answer questions about the consent form itself.

- 7. Questions about the procedure or differences between the scheduled procedure and the patient description should be redirected to the physician.
- 8. The individual attesting to the informed consent process being completed by physician or provider performing the procedure will sign with date and time it was documented at the bottom of the form.
- B. The **Anesthesia Consent form** should be prepared by the anesthesiologist, NP, CRNA, or designated hospital personnel.
 - a. The anesthesia provider reviewing the consent may be different than the provider administering the anesthesia.
- C. The **Consent for Treatment or Minor Procedure (F8765)** should be completed by physician or provider ordering/performing the treatment or designated clinical staff.
- D. Elements to be completed on any consent forms:
 - a. All blanks on the consent form should be filled in with the appropriate information or marked as "none" or marked out with a straight or diagonal line.
 - b. If there is a need to change any portion of the consent form either at the time or after it is signed, the addition or strikethrough should be initialed by the patient and witness with date and time noted.
 - c. If the patient/representative is not able to read the consent form, the form must be read to him or her.
 - d. The patient/representative should sign in the space provided. The representative should note their relationship to the patient (ex: guardian, POA, attorney)
 - e. The staff member administering the form should witness the signatures.
 - f. If consent form is completed by telephone, the consent form should be completed, marked as phone consent and witnessed by two persons who read the form to the patient.
 - g. In non-emergency situations, if the patient is not able to consent the physician or designee will contact the lawful representative.
 - 1. If the lawful representative is known but not reasonably available or declines to fulfill the role of personal representative, the physician will contact the next statutorily designated representative.
 - 2. If there is no known lawful representative, the physician and case manager will initiate the process of seeking a court-appointed guardian.

VIII. AUTHORITY:

- A. Policy Owner: Manager, Clinical Risk Management
- B. Coordinate with: Legal Counsel

IX. REFERENCES:

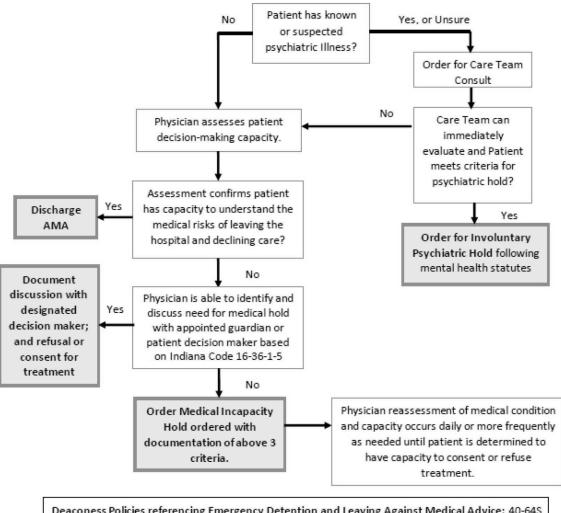
- A. Medical Consent (IC l6-36).
- B. Informed Consent (IC 34-18-12).
- C. System Policy and Procedure 40-14 S (Advance Directives)
- D. System Policy and Procedure 40-03 S (Abuse/Neglect/Domestic Violence).
- E. Revisions to the Hospital Interpretive Guidelines for Informed Consent, CMS, April 13, 2007

Exhibit A

Flowchart applies to patients who meet the following 3 criteria:

- . The patient is admitted to the hospital or has presented to Emergency Department, and
- . The patient is attempting or threatening to leave the hospital, or requesting AMA discharge, and
- . The patient would be at grave risk of harm, disability, or death if he/she leaves the hospital.

Physician documentation of the above three criteria in the medical record is required for Medical Incapacity Hold.



Deaconess Policies referencing Emergency Detention and Leaving Against Medical Advice: 40-64S
AGAINST MEDICAL ADVICE (AMA): REFUSAL OF OPERATION, PROCEDURE AND/OR TREATMENT

40-63 EMERGENCY DETENTION

MT Police/Security 812-450-7500
GW Police/Security 812-842-3900

40-64 S Against Medical Advice (AMA): Refusal of Operation, Procedure and/or Treatment (40-64 S)

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Description: It is important that patients are

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Internal Document Links:

40-03 S Abuse/Neglect/Domestic

Violence

/DHS Corporate/Deaconess Health System Policies/Patient Care/Case

Management

40-14 S Advance Directives /DHS Corporate/Deaconess Health

System

Policies/Administration/Corporate

Compliance

External Document Links:

50-29 S Exhibit A Kentucky 50-29 S Exhibit B Illinois