

DEACONESS HEALTH SYSTEM, INC.
Evansville, Indiana

Policy and Procedure No. 50-51 S

CONSENT FOR TREATMENT & INFORMED CONSENT
KENTUCKY

- I. SCOPE:** This policy and procedure applies to all system entities for care and services provided in **Kentucky** and listed below:

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

- II. 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 in the Commonwealth of Kentucky.

III. 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.

IV. DEFINITIONS:

- A. Adult: An individual who is at least eighteen (18) years of age.
- B. Minor: An individual who is less than eighteen (18) years of age.
- D. Health Care: Any care, treatment, or procedure to maintain, diagnose, or treat an individual's physical or mental condition.
- E. Health Care Representative: 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.
- G. Competence: 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 individuals who are not competent.
- H. Capacity: Ability to make and communicate a health care decision. Treating provider responsible for the care of the patient or performing a procedure is responsible for determining if a patient lacks capacity to provide consent.
- I. Emergent condition: 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 NOT 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.

- V. 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.

VI. PROCEDURES

TYPES OF CONSENT and Patient & Provider Discussion:

- A. **General Consent for Treatment** is agreement to receive care and treatment from Deaconess. 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,
 - 3. Benefits
 - 4. Anticipated outcomes,
 - 5. 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:**

1. 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 will resolve the uncertainty by obtaining informed consent.

D. Emergent Conditions

If a patient has an emergent condition and it is NOT 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. **Only the patient may provide consent for treatment**
 - unless the patient is a minor or

- attending physician in good faith believes that the patient lacks capacity to make decisions regarding proposed health care
- 2. Adults without decision-making capacity**
- A. 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, the following individuals, *in the following order of priority*, have the ability to consent:
1. Legally appointed guardian or court appointed representative and decisions are within the scope of the guardianship.
 2. Durable Power of Attorney if the durable power of attorney specifically includes authority for healthcare decisions.
 3. Spouse of the patient
 4. An adult child(ren) of the patient
 5. Parent(s) of patient
 6. Nearest other adult relative in the next degree of kinship, not listed above.
- 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.
- E. If a lawful representative is not known for adults lacking decision making capacity, 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 that 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.
- F. Minors:** If the patient is a Minor and is living with his/her parent or legal guardian, either parent or the legal guardian may provide consent on the Minor's behalf.
1. Consent can be providing by the following methods:
 - a. The parent(s) or legal guardian may provide written, signed authorization designating another individual who may consent on behalf of the Minor.
 - b. If the Minor patient presents for a non-emergency service, the parent or legal guardian's consent may be obtained verbally; it must be documented and signed by two witnesses. *KRS 2.015; KRS 214.185*
 - c. If the parents of the Minor are divorced, only the custodial parent may provide consent on the Minor's behalf. If the divorced parents share joint custody, either parent may provide consent on the Minor's behalf.

- d. A relative caring for a Minor or a stepparent of a Minor, who does not have legal guardianship or has not been granted authority through a written, signed authorization as noted above, may **not** provide consent on the Minor's behalf.
- e. If a situation presents that is not addressed in this policy regarding consent on behalf of a Minor then contact Administrator On-Call or Risk Management for further assistance.

2. Exceptions to Parental Consent for minors include:

a. Emergencies

Medical care may be rendered to Minors of any age without the consent of a parent or legal guardian when, in the professional's judgment, the risk to the Minor's life or health is of such a nature that treatment should be given without any delay and the requirement of consent would result in delay or denial of treatment. *KRS 214.185(4)*

b. *Emancipation*

If the patient is under the age of 18, is self-supporting, and living apart from the parent's residence, the patient, though a Minor, may give consent provided the services are fully explained and he/she seems to understand the associated risks. The patient may be adjudicated emancipated by court order or by agreement between the parents and the child.

c. *Marriage*

If the patient is under 18 years of age and contracted a lawful marriage, he/she is then considered emancipated for the purpose of giving valid consent for the services to be provided to his/her self or his/her child.. A subsequent annulment of the marriage or a divorce does not deprive the Minor of his/her Adult status once it has been obtained. *KRS 214.185(3)*

d. *Borne a Child*

If the patient is under 18 years of age, unmarried, and has borne a child she may give consent for services for her child or herself without consent of her parent(s) or guardian. *KRS 214.185(3)*

e. *Treatment for STD, Pregnancy, Alcohol Abuse/Addiction, Drug Abuse/Addiction*

If the patient is under 18 years of age and seeks diagnosis and/or treatment for sexually transmitted (venereal) disease, pregnancy, alcohol, and/or drug abuse or addiction, or emotional disturbance from the effects of a family member or legal guardian's alcohol or other drug abuse problem, the physician may advise, prescribe for and treat such Minor for sexually transmitted disease, alcohol and other drug abuse or addiction, contraception, pregnancy, or childbirth upon the consent of the Minor, all without the consent of or notification to the parent(s), guardian, or any other person having custody of the Minor patient. Treatment does not include the inducing of an abortion or the performance of a sterilization operation. *KRS 214.185(1); KRS 222.441(1)*

f. *Victim of Sexual Offense*

If the patient is under 18 years of age and a victim of a sexual offense, he/she, even though a minor, may consent to examination by a physician such consent is not subject to disaffirmance because of minority. The consent of his/her parent(s) or guardian is not required for such an examination. *KRS 216B.400(7)*

g. *Victim of Alleged Abuse or Neglect*

Photographs, x-rays, or other appropriate medical diagnostic procedures may be taken without the consent of the parent(s) or guardian as a part of a medical evaluation or investigation resulting from a report of suspected child abuse or neglect. *KRS 620.050(14)*

h. *Mental Health*

If a patient 16 years or older presents for outpatient mental health counseling, the patient may consent to examination by a physician without consent of a parent(s) or guardian. *KRS 214.185(2)*

An authorized staff physician may admit a patient 16 years of age or older for inpatient treatment of mental illness upon written application by the patient without the consent of a parent(s) or guardian. The hospital must give notice within 24 hours to the parent(s) or guardian exercising custodial control for the Minor. *KRS 645.030; KRS 645.220 See also the BH policy, "Involuntary Hospitalization (72-Hour Hold)" for additional guidance.*

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.
4. **Verbal Consent:**
 - a. It is preferable for physicians to obtain written consent and document the elements in the medical record.
 - b. In the event that 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.
 - b. The patient's condition has had such a major change that a good faith question arises as to whether the circumstances under which the consent was originally given still exist.

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 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."
 - 5. 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.
 - 6. Questions about the procedure or differences between the scheduled procedure and the patient description should be redirected to the physician.
 - 7. The individual attesting to the informed consent process has been completed by physician or provider performing the procedure will sign with date and time it was documented at the bottom of the form.
- C. 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.

- D. The **Consent for Treatment or Minor Procedure (F8765)** should be completed by physician or provider ordering/performing the treatment or designated clinical staff.
- E. 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

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