DEACONESS HEALTH SYSTEM, INC.
Evansville, Indiana

Policy and Procedure No. 50-29 S **Revised Date: August 9, 2011**
Reviewed Date: August 28, 2012

INFORMED CONSENT

* **I. PURPOSE:** It is important that patients are involved in any and all decisions concerning procedures and/or recommended treatment. This policy provides definitions, guidelines and procedures to be utilized in obtaining and documenting patient consent for treatment and informed consent.

* **II. 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 incapacitation.

III. SCOPE: The policy is applicable to Deaconess Hospital, all campuses, Deaconess Clinic, and the Heart Hospital.

IV. DEFINITIONS:

A. Adult: An individual who is at least eighteen (18) years of age.

B. Minor: An individual who is not an adult.

C. Emancipated Minor: 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 l6-36 Health Care Consents). (NOTE: Married minor or U.S. military service persons are considered emancipated.)

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.

F. Loco Parentis: A person age eighteen (18) or over who is acting in the place of a minor's parents.

G. Competence: The question of competence or capacity should be approached from a functional standpoint which 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.

H. Emergent condition: constitute a threat to health or life, or require immediate action to prevent permanent bodily harm or death.

* **V. TYPES OF CONSENT**:

A. General Consent for Treatment is documented on general consent for treatment form and is obtained at the time a patient presents to the hospital.

B. Emergency Conditions is used 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 documentation of rationale for immediate action.

C. Informed Consent is agreement to a proposed procedure after patient has been given proper and sufficient 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 procedure

* **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. Nurse practitioners (NP) will obtain and document elements of informed consent for those procedures they will perform.
3. Nurses may obtain informed 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 NP will document the informed consent process prior to the procedure in the patient's medical record. One of the following are acceptable methods of documentation:

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.
3. Signature from practitioner performing procedure on the consent form.

* **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. Required Elements of Informed Consent**

The following elements are discussed with the patient and the patient is given the opportunity to ask questions.

1. The general nature of the patient's condition.
2. The proposed care, treatment, service, procedure, medication or intervention.

3. The potential benefits, risks or side-effects including problems related to recuperation.
4. The likelihood of achieving the care, treatment or service goals.
5. The reasonable alternatives to the treatment, procedure, examination or test.
6. The relevant benefits, risks and side effects related to alternative treatments including the possible results of not receiving care, treatment or services.
7. Any limitations on the confidentiality of information learned from or about the patient.
8. Additional information that should supplement the above include:
   a. The identity and professional status of the primary physician and of assistants if indicated.
   b. Any professional, institutional or business relationship with other caregivers or institutions involved in the patient's care which might indicate a conflict of interest.

* **E.** **Informed Consent** may be provided by:

1. **Competent persons:** Unless the attending physician in good faith believes that the patient is incapable of making a decision regarding proposed health care, any individual within the categories below can give effective consent for his 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 Incompetent Adults**: For incompetent adults, consent may be given, in descending order, by:
   a. A judicially appointed guardian or health care representative.
   b. A person appointed by the patient as a health care representative or a person holding a durable power of attorney (POA) that specifically references the POA's authority to make health care decisions.
   c. The previously expressed wishes of the patient contained in a "Living Will" or "Life Prolonging Procedures Declaration".
   d. The spouse, adult child, parent, or adult sibling of the patient.

3. **For Incompetent Adults who are Members of Religious Orders:** Consent may be provided by the patient's religious superior if:
   a. There is no judicially appointed guardian or health care representative,
   b. The guardian or representative is not reasonably available or declines to act, or
   c. The health care provider does not know of the existence of the guardian or representative.

4. **For Minors:** Except for the limited circumstances noted above in IV(D)(1)(c), consent to provide treatment to unemancipated minors must be obtained from the following in descending order:

   a. A judicially appointed guardian or judicially appointed Health Care Representative.

   b. A parent or person acting as the parent (Loco Parentis).

   c. An adult sibling of the patient.

* **F. 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.

*** G. Other provisions of consent:**

1. **Withdrawal of Consent (Competent Adult):** After full disclosure of alternatives, consequences, etc., the competent adult has the right to decline or refuse health care or lifesaving treatment and the right to withdraw a prior informed consent.

   a. Competency is a legal conclusion based on observation of the patient's mental status. If the treating physician believes that the patient is competent, he or she MUST follow the patient's wishes.

   b. If the physician believes that the patient is incompetent but there is a dispute among observers, 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.

2. **Withholding Consent for Minors**: Parents may <u>NOT</u> legally refuse indicated medical treatment on behalf of their minor children.

   a. Failure to give consent for indicated medical treatment is child abuse according to Indiana Statute.

   b. 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.

3. **Emergency Consent:** If the treatment is required immediately to preserve the life of the patient or prevent an impairment of the patient's health, and it is impossible to obtain the consent of the patient or someone legally authorized to consent for him, a required procedure may be undertaken without any liability for failure to obtain such consent.

   Emergencies, the court usually speaks in terms of threat to life or health. Thus, an emergency exists when an immediate action is necessary to prevent permanent bodily harm or death.

4. **Verbal Consent**:
   a. It is preferable for physicians to get the consent in writing and document the elements 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.

* 5. **Consent by Telegram or E-Mail:** Telegrams or e-mail granting permission for treatment may be accepted. The email or telegram should become part of the patient's record as any other consent from the patient.

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 presumed to continue to be valid until:
   a. A competent patient or the Healthcare Representative of an incompetent patient 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.

VII. OTHER RESPONSIBILITIES

A. **Medical Records Committee:** The Medical Records Committee will review and approve all consent forms proposed for use within the Hospital.

B. **Safety/Risk Management**: The Safety/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.

VIII. PROCEDURE FOR COMPLETING CONSENT FORM

A. Consent and signatures on consent forms should be obtained from the patient at a time when he or she is clearly **not** under the influence of drugs, sedatives or anesthesia.

B. A consent form is to be prepared by the physician or by designated hospital personnel when the procedure has been documented in the physicians orders.

1. The consent form is used to verify with the patient or patient representative that informed consent was obtained by the physician.
2. 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.
3. Questions about the procedure should be redirected to the physician.

C. All blanks on the consent form should be filled in with the appropriate information or marked out with a straight or diagonal line.

D. If the patient/representative is not able to read the consent form, the form must be read to him or her.

E. The patient/representative should sign in the space provided. The representative should note their relationship to the patient (ex: guardian, POA, attorney)

F. The staff member administering the form should witness the signatures.

G. If consent is obtained by telephone, the consent form should be completed, marked as phone consent and witnessed by two persons who heard the consent.

H. 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 management will initiate the process of seeking a court-appointed guardian.

I. In emergency situations, if the patient is not able to consent and a lawful representative is not present or able to be found, the physician will document the decision to proceed under implied consent.

IX. REFERENCES

A. Medical Consent (IC l6-36) (1993).

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

* F, This policy and procedure is owned by the Manager Safety/Risk Management and is coordinated with the Director or Nursing Surgical/Medical and the System P&P Committee.

* G. This policy and procedure revises and rescinds Policy and Procedure No. 50-29 S dated May 2, 2011.

Linda E. White
President and CEO