OREGON HEALTH & SCIENCE UNIVERSITY

OHSU HEALTHCARE

Policy # HC-RI-102-RR	Title: **Consent**	
Effective Date: 8/27/2014	Category: Rights and Responsibilities	
Origination Date: 5/21/1998	Next Review Date: 8/27/2017	Pages 1 of 9

PURPOSE:

The purpose of this policy is to ensure that all aspects of OHSU Healthcare's informed consent process comply with state law and the standards of the Centers for Medicare & Medicaid Services and The Joint Commission.

PERSONS AFFECTED:

All OHSU Healthcare workforce members who perform medical treatments or procedures that require informed consent.

POLICY:

Informed consent is needed prior to performing certain medical treatments or procedures for a patient. OHSU Healthcare workforce members must seek informed consent when appropriate in accordance with this policy.

Patients on OHSU research protocols are not covered by this policy. For current guidance on informed consent for research, see http://www.ohsu.edu/xd/about/services/integrity/policies/irb-policies-by-category.cfm. Research consent forms must be filed in the patient's medical record.

DEFINITIONS:

1. Decision-making capacity: The capacity to make health care decisions. To have decision-making capacity, four elements must be present:
    a. Ability to understand basic information about the treatment or procedure.
    b. Ability to understand and appreciate consequences.
    c. Ability to process information rationally.
    d. Ability to communicate choices. For how to determine decision-making capacity, please refer to the policy Determining Capacity.
2. Health care decision: A health care decision means consent, refusal of consent or withholding or withdrawal of consent to health care, and includes decisions relating to admission to or discharge from a health care facility.
3. Legally authorized health care representative: The individual designated by law or the patient (through proper and valid documentation) to give consent when the patient is not old enough or lacks decision-making capacity. Note: An instrument providing for a legally authorized health care representative that does not meet legal requirements (e.g., is expired or not properly witnessed) is not valid. Please see information on surrogate decision makers below.
    a. Parents, as the natural guardians of their children, may make health care decisions for their children under the age of 18, including providing informed consent. The informed consent of both parents is desirable, but one parent may provide effective informed consent. If the parents are not married, either parent may consent unless otherwise stipulated by a valid court document. This may be a custodial or non-custodial parent. If there are questions between the parents about who may provide consent, please request the custodial order and place it in the minor's medical record.
    b. Minors of any age who have children may make health care decisions for those children.

c. With a properly executed power of attorney (which should be made part of the patient's medical record), a parent or guardian of a minor child or incapacitated person may temporarily delegate certain powers of the parent or legal guardian regarding care, custody or property of the minor child or ward, including health care decision making authority, to the following individuals as follows:
    i. Another person for no longer than six months
    ii. For a minor child, a school administrator for no longer than 12 months.
    iii. For a minor child of a service member parent or guardian, another person (except as noted below) for a period not exceeding the term of active duty service plus 30 days when the parent or legal guardian is a member of the military (active or reserve) called to active duty. If the minor child is living with the child's other parent, delegation for the aforementioned period must be to the parent with whom the minor child lives, unless a court finds that such delegation would not be in the child's best interests. If the service member parent or guardian has joint custody of the minor child with the child's other parent or another individual, and the service member parent or guardian is married to an individual other than the child's other parent, delegation for the aforementioned period may be made to the spouse of the service member parent or guardian, unless a court finds that such delegation would not be in the child's best interest.
d. With an affidavit that meets the requirements of ORS 109.580 (which should be made part of the minor's medical record), a relative caregiver may consent to medical treatment for a minor child that the minor child cannot otherwise legally consent to if, after reasonable efforts have been made to obtain consent of the legal parent or guardian for the treatment, the consent of the legal parent or guardian cannot be obtained. The consent of the relative caregiver shall be superseded by any contravening decision of the legal parent or guardian, provided the decision does not threaten the life, health or safety of the minor child.
e. Court-appointed guardian (when patient is an adult or minor)
    i. A court may appoint a legal guardian for an adult or minor. Court appointed legal guardians will have a letter of guardianship, and a copy should be placed in the patient's medical record. This document should be reviewed for any restrictions on the guardian's ability to make health care decisions for the patient.
f. Health care representative (when patient is an adult)
    i. A health care representative is the person designated by the patient in an advance directive or health care power of attorney to make decisions if the patient becomes incapacitated. The representative may sign the informed consent form in the patient's place. The patient's medical record must include a copy of the advance directive or health care power of attorney. These documents should be reviewed for any instructions or restrictions from the patient.

4. Material risk: A risk that a reasonable qualified provider knows or should know the particular patient would likely to consider important, either alone or in combination with other risks, in deciding whether to accept the proposed procedure or treatment. If a serious injury might result from the proposed procedure or treatment, the provider should inform the patient of all but extremely remote risks. Examples of serious injury include but are not limited to death, brain or other organ damage, central nervous system damage, disfigurement, sexual dysfunction, allergic reaction and irreversibility. If a potential injury is slight, the patient need only be informed of common risks.
5. Medical emergency: When the qualified provider believes the patient potentially suffers from a condition where a clinical decision must be made immediately to prevent death or serious harm.
   Please review "Special Circumstances" below for more information.
6. Qualified provider: An OHSU Healthcare workforce member acting within his or her scope of practice to perform the specific procedure or treatment for which informed consent is sought. Specifically, one of the following:
    a. An OHSU licensed independent practitioner (physician, nurse practitioner or dentist) credentialed and privileged to perform the specified procedure or treatment (Online OHSU Practitioner Clinical Privilege View; http://echoapp/echo/echonet/ProviderPortal/msldirP.htm)
    b. A physician assistant who has privileges to perform the specified procedure or treatment consistent with supervisory requirements

c. Resident physicians qualified through their training to perform the specified procedure or treatment as deemed appropriate by a supervising attending physician
d. Registered nurses qualified to place Peripherally Inserted Central Catheter (PICC) lines may obtain consent for that procedure only.

7. Relative caregiver: A competent adult who is 18 years of age or older, who is related to a minor child by blood, marriage or adoption, who is not the legal parent or guardian and who represents that the minor child lives with the adult and that the adult is responsible for the care of the minor child.
8. Required age: Individuals must reach the required age in order to provide informed consent. Ages are listed as follows (please consult the legal department with questions):
    a. Adult patients: Patients 18 years or older.
    b. Minor patients: Minor patients under 18 years old have the right to consent to care in the situations outlined below, but they do not have the right to make all health care decisions except where noted:
        i. Blood donation to a blood program: Patients age 16 and above may provide informed consent.
        ii. General medical, dental, surgical or hospital treatment provided by a physician licensed by the Board of Medical Examiners or a dentist licensed by the Board of Dentistry or an optometrist (except when the minor is obtaining contact lenses for the first time): Age 15 and above.
        Note: This includes the right to consent to prenatal care.
        iii. Health care providers may elect, but are not required, to inform a minor's parent of the medical treatment being provided to the minor (except as noted below).
        iv. Outpatient mental health or chemical dependency treatment (excluding methadone maintenance): Age 14 and above
        Note: The parent must be notified before the end of treatment unless the parent has sexually abused the minor.
        v. Birth control information and treatment for sexually transmitted diseases if the disease or condition is required by law to be reported to state or local health officers: Any age.
        vi. Emancipated minors of any age are authorized to make health care decisions about all forms of treatment.
        Note: Emancipation requires a court order to be effective. This document should be in the minor's medical record.
        vii. Married minors of any age are authorized to make health care decisions about all forms of treatment.
9. Surrogate decision maker: If the patient does not have a legally authorized health care representative, the health care team may contact one of the individuals listed below (in the order listed, with reasonable effort) and ask him or her to provide input into the plan of care or proposed treatment or procedure:
    a. Patient's spouse or registered domestic partner
    b. Adult child who can be located
    c. Parent
    d. Adult sibling of the patient
    e. Adult designated by others on this list, if no one on the list objects
    f. Other adult relative or friend

The health care team may consider input from the individuals listed above in making a final decision about the treatment or procedure. In contacting these individuals, health care team members must be sensitive to cultural diversity and familial relationships. The health care team shall provide care and treatment to the patient based on their understanding of the patient's wishes expressed before becoming incapacitated. If the patient's preferences are unknown, care and treatment will be provided in accordance with the patient's best interests. The health care team may ask an individual on the list above to sign the informed consent form, and this form shall become part of the patient's medical record. ~~See Page 3~~

Note: An instrument that would provide for a legally authorized health care representative that does not meet all the legal requirements (e.g., expired, not properly witnessed) shall constitute evidence of the patient's desires and interests.

RESPONSIBILITIES:

OHSU Healthcare workforce members are responsible to ensure that a consent form is appropriately executed in accordance with all requirements in this policy.

PROCEDURES:

1. Process for obtaining informed consent
    a. **Informed consent is required** for all procedures and treatments with viable alternatives that pose material risks, regardless of whether such procedures are carried out in operating rooms, invasive diagnostic procedure areas, at the bedside or in procedure rooms, including ambulatory care settings. The following process shall be used:
        i. Informed consent for procedures and treatments will be obtained before care or treatment and is in effect for a period determined by the following:
            1. Throughout an episode of care
            2. Throughout a course of therapy
            3. Until the risks or alternatives of the procedure or therapy have changed
            4. Until the patient rescinds the consent
            5. Until one year from the date of consent
    b. **Only qualified providers may obtain informed consent**. The process of obtaining consent cannot be delegated to a nonqualified provider. However, a qualified provider not performing the procedure or treatment may obtain consent on behalf of another qualified provider. In that instance, the qualified provider performing the procedure or treatment is expected to introduce him- or herself as the practitioner performing the procedure or treatment and to interact with the patient and family beforehand.
    c. **Requirements for obtaining consent**
        i. The individual consenting must:
            1. Have decision making capacity
            2. Have reached the required age for the treatment or procedure
    d. **Identify the appropriate individual to provide consent, in the following order**:
        i. Patient (if the patient can provide consent, go to Obtaining valid informed consent, below)
        ii. If the patient has not reached the required age to provide consent, consider first obtaining his or her permission before obtaining the legally authorized health care representative's consent.
        iii. Legally authorized health care representative
            1. Document patient's lack of decision-making capacity in patient's medical record.
            2. Confirm that valid documentation for the legally authorized health care representative is present in patient's medical record.
    e. **Legally authorized health care representatives cannot consent to**:
        i. Convulsive treatment
        ii. Psychosurgery
        iii. Sterilization
        iv. Abortion
        v. Withholding or withdrawing a life-sustaining procedure or artificially administered nutrition and hydration, except in specific circumstances.
        vi. Note: If any of the above is being considered, call Legal.
    f. **Obtaining valid informed consent**
        i. In order to obtain valid informed consent, in accordance with the CMS Conditions of Participation, Oregon law, The Joint Commission standards and OHSU policy, the qualified provider obtaining the informed consent must:
            1. Explain the procedure or treatment to be completed. The explanation should be in general terms that the patient can understand and include potential benefits and likelihood of success.

2. Document on the form the procedure, site or level. If there are several procedures occurring, you may mark "multiple sites, see above," and indicate the site for each procedure.
3. Document additional procedures associated with the encounter. At the bottom of the form is a list of additional processes to discuss with the patient. Mark all appropriate boxes and discuss with the patient the risks, alternatives and, if applicable, the benefits of each if the professional doing the procedure is credentialed and competent to carry out these processes. These procedures include:
    a. Transfusion. If the patient is or may be undergoing transfusion, discuss the material risks and alternatives and mark the box.
    If the patient is having only a transfusion, use the transfusion blood consent form (HIS Form #CO-1407) and the attached information sheet, "What you should know about blood transfusion."
    b. Sedation. If the patient is undergoing sedation, discuss the material risks and alternatives and mark the box.
    c. Anesthesia. For cases with planned anesthesia, mark that box and inform the patient that the anesthesiologist will discuss the material risks and alternatives with the individual providing consent.
    d. Vendor representatives and other observers. If a vendor representative or observer will be present during the procedure, inform the patient of the vendor or observer's presence or role in the procedure room and mark the box. If the vendor is only present to observe the procedure, the separate patient authorization, Authorization to Use and Disclose Protected Health Information (HIS Form #MR-1470), will be required. Indicate to the patient that the vendor representative performs no part of the procedure.
        i. Vendor representatives are prohibited from engaging in patient care or performing any part of the procedure.
    e. Photos. If photos will be taken for use in treatment, OHSU teaching or OHSU quality improvement activities, mark that box.
        i. In order to use patient photos for purposes other than patient care, obtaining reimbursement, OHSU teaching or OHSU health care operations (where operations means certain administrative, financial, legal, and quality improvement activities necessary to run and support OHSU's business and the core functions of treatment and payment), obtain additional written authorization from the patient before disclosing any individually identifiable health information about the patient. When patient photographs contain identifying information (including only a facial image), complete the form Authorization to Use and Disclose Protected Health Information (HIS Form #MR-1470). A signed release may also be required if the photo is further published. Note: This authorization must be used when patient photos or images that may identify the patient are used in publications or presentations outside of OHSU.
    f. Video and Audio Monitoring. If video or audio monitoring will be used in treatment, a special consent form, Notice of and Consent for Video/Audio Monitoring (HIS Form #CO-4779), must be completed. Please see Determination, Notification and Consent for Video and Audio Monitoring policy.
    g. Additional practitioners. Inform the patient of specific additional practitioners who will be involved in the procedure or treatment.
4. **Alternatives**. Discuss alternative procedures or methods of treatment available, including the relevant material risks, benefits and side effects. A general description of these alternatives should be provided, including the option of no treatment and possible results of non-treatment.

5. **Risks**. Explain the planned procedure or treatment, anticipated benefits, material risks and problems that might occur during recuperation as well as the likelihood of achieving goals. Include the most significant and most common risks and potential problems related to recuperation. Documentation of specific risks is not required. However, if the qualified provider wishes to document any specific risks or concerns, he or she will do so on the blank line or on an additional page or note the discussion of specific risks in the patient's medical record.
6. **Questions**. Ask the patient if a more detailed explanation is desired. If the patient requests further explanation or has questions, disclose in substantial detail the procedure, the viable alternatives and the material risks unless to do so would be materially detrimental to the patient. If the patient does not want a more detailed explanation, or if to give one would be materially detrimental to the patient, none need be given. Inform the patient of any limitations on the confidentiality of information learned from or about the patient if indicated.
7. **Documentation of informed consent**
    a. The informed consent discussion should be documented and signed by the qualified provider obtaining the informed consent and the individual consenting.
    b. The qualified provider should also document the informed consent discussion in the patient's medical record, stating either "Procedures, alternatives and risks discussed with patient. Questions answered," or "PARQ done."
    c. When a qualified provider is required by this policy to obtain informed consent, he or she must make all reasonable efforts to do so in writing using the standard OHSU Healthcare approved consent form Patient Informed Consent for Rendering of Medical Services/Surgical Services/Sedation (HIS Form# CO-1400); http://ozone.ohsu.edu/healthsystem/HIS/co1400.pdf - see links to forms in non-English languages at end of this policy).
    d. The informed consent form will then be filed in the patient's medical record.
    e. Any customized informed consent documents must use this template and be reviewed and approved in accordance with the policy Medical Record Forms Review and Approval Process before use.
    f. Telephone consent should only be accepted as a last resort when there is no reasonable way to obtain written consent. To obtain informed consent over the telephone:
        i. The qualified provider and one other person must be on the line to hear the informed consent.
        ii. The qualified provider and witness receiving the phone consent must identify themselves at the beginning of the phone conversation.
        iii. The consenting individual must be asked to identify him- or herself and describe his or her relationship to the patient, including specifying whether the consenting individual is documented as the patient's legally authorized health care representative.
        iv. The qualified provider will answer all questions before completion of the informed consent process.
        v. An appropriate statement describing the conversation and verifying discussion of the proposed procedure or treatment, risks and alternatives must be recorded in the progress notes. The qualified provider must state who served as the witness to the conversation.
        vi. The qualified provider should complete the informed consent form to document the conversation. The person who witnessed the conversation should sign, indicating that he or she witnessed the informed consent process and decision.

vii. If the consenting individual is available later, he or she should be asked to co-sign the informed consent form. If possible, obtain a confirming email, fax or other printed confirmation from the responsible party.

g. Consent in special circumstances
   i. **Medical emergency**
      1. Emergency care may be provided under the concept of implied consent, unless there is clear and convincing evidence that the patient would refuse such treatment or procedure (e.g., the patient has a do not resuscitate order). The ability to provide care under the doctrine of implied consent lasts only as long as the emergency. Once the emergency is over, follow the process for obtaining informed consent outlined above. If providing care with implied consent:
         a. Document the emergent nature of the patient's situation
         b. Document efforts to obtain informed consent (if any) in the patient's progress record.
   ii. **Guardian refuses consent for a minor where the refusal could cause death, disability or serious harm or injury**
      1. If a minor's guardian (parents or legal guardian) refuses to give informed consent:
         a. Document the refusal and the guardian's understanding that staff physicians may be obligated to provide lifesaving treatment or blood products to prevent serious irreversible harm, permanent injury or disability to the minor patient.
         b. Staff physician should consult with the OHSU administrator on duty, available through the OHSU operator, and then work with a social worker to notify the Department of Human Services (DHS).
         c. DHS should be provided with the natural guardian's name, patient's name and date of birth, address and phone number if known, the essential medical information and the problem with consent from the guardian.
         d. DHS has the authority to provide consent if it intercedes.
         e. Overriding a guardian's refusal is not taken lightly. If the treatment or procedure is elective, persuasion or referral of the case to another member of the medical staff may resolve the guardian's concerns. If transfusion for a minor patient is the issue, contact the OHSU Transfusion Service Director for further information and assistance (503-494-8276 or page through the OHSU operator).

h. Withdrawal of life-sustaining procedure for adult patient lacking capacity
   i. Refer to the policies Do Not Resuscitate, Advance Directives, Physician Orders for Life-Sustaining Treatment (POLST) and End-Of-Life Decision-Making Process.

i. Not withdrawing life-sustaining procedure, adult patient lacking capacity (no legally authorized health care representative)
   i. Document patient's lack of decision-making capacity in medical record.
   ii. Document attempts to identify a legally authorized health care representative and the fact that none was found.
   iii. Identify potential surrogate decision makers, working with the OHSU Patient Advocate office or social workers as needed to help locate and identify them.
   iv. If no one can be identified as an appropriate surrogate decision maker (acting in the patient's best interest), or willing to consent for the patient, continue to next situation below.
   v. If an appropriate surrogate decision maker is identified, proceed with the process for obtaining informed consent.
   vi. Obtain information on providing care and treatment based on the surrogate decision maker's understanding of any wishes the patient expressed before becoming incapacitated or, if the patient's wishes are unknown, in accordance with the patient's best interest.
   vii. Complete Section B on the informed consent form and obtain the surrogate decision maker's signature.
   viii. One attending physician's signature is required.
   ix. Note: Surrogate decision makers cannot consent to:

1. Convulsive treatment
2. Psychosurgery
3. Sterilization
4. Abortion
5. Withholding or withdrawing a life-sustaining procedure or artificially administered nutrition and hydration, except in specific circumstances.

j. Adult patient lacking capacity (Not withdrawing life-sustaining procedure, no legally authorized health care representative or appropriate surrogate decision maker)
   i. Document patient's lack of decision-making capacity in medical record.
   ii. Document attempts to identify legally authorized healthcare representative or surrogate decision-makers.
   iii. Consider obtaining a temporary or permanent guardianship for the patient.
   iv. If the patient is developmentally disabled and living in a facility or home licensed as a 24-hour residential service, the patient may be entitled to an individual support plan team who can help appoint a health care representative (see OAR 411-365-0200).
   v. **If the patient's condition requires treatment within approximately 72 hours**
      1. Two attending physicians shall complete Section C of the informed consent form before performing the procedure or treatment.
   vi. **If the patient's condition does not require treatment within approximately 72 hours**
      1. Continue attempts to identify and locate a legally authorized health care representative or surrogate decision makers.
      2. Refer case to the Clinical Ethics consult service for review and recommendations. The Clinical Ethics consult service will review all information related to the case and advise the primary care provider.
      3. After the Clinical Ethics consult service has provided a recommendation, the health care team will decide how to proceed.
         a. If the health care team decides to proceed with treatment, complete Section C on the informed consent form.
         b. Two attending physicians shall sign Section C before performing the procedure or treatment.
   vii. **If the patient wants to leave hospital without treatment**
      1. Determine whether there is a hold on the patient (i.e., mental health hold or physician hold). If so, patient may continue to be treated while the hold is in place. See Physician Hold for Non-Mental Health Patients and Hospital Hold for Treatment of Mental Illness policies.
      2. If the patient is not on a hold, the patient does not require emergent treatment and a legally authorized health care representative or surrogate decision maker has not been identified, contact the Administrator on Duty for guidance. Except in unusual circumstances, voluntary patients have the right to refuse treatment and leave the hospital.

RELEVANT REFERENCES:

- Oregon Revised Statutes 109.056, 109.570- 109.580, 109.610, 109.640, 109.670, 109.675, 127.505 – 127.660
- 42 CFR 482.24(c)(4)(v)
- The Joint Commission Hospital Accreditation Standards

RELATED DOCUMENTS/EXTERNAL LINKS:

- Decision-Making Capacity Assessment
- Initiation Continuation or Withdrawal of Life-Sustaining Treatments with Conflicts Among Health Care Professionals Patients Surrogates
- Recording or Filming of Patients by Family or Friends

- Correct Site Universal Protocol
- Research Documentation in the Integrated Health Record
- Determination, Notification and Consent for Video and Audio Monitoring
- Notice of and Consent for Video/Audio Monitoring (CO-4779)
- Medical Record Forms Review and Approval Process
- Authorization to Use and Disclose Protected Health Information
- Transfusion Manual
- Health Information Services Medical Record Forms search
- Transfusion Blood Consent Form (HIS Form# CO-1407)
- Authorization to Use and Disclose Protected Health Information (HIS Form# MR-1470)
- Do Not Resuscitate, Advance Directives, Physician Orders for Life-Sustaining Treatment (POLST) and End-Of-Life Decision-Making Process
- Patient Informed Consent for Rendering of Medical Services/Surgical Services/Sedation (HIS Form# CO-1400)
- Research – Institutional Review Board
- "Patient Informed Consent for Rendering of Medical Services / Surgical Services / Sedation" forms:
    a. English: CO-1400
    b. Spanish: CO-1401
    c. Russian: CO-1402
    d. Vietnamese: CO-1403
- "Transfusion Blood Consent" forms (prints with an information sheet "What you should know about blood transfusion"):
    a. English: CO-1407
    b. Spanish: CO-4609
    c. Russian: CO-4610
    d. Vietnamese: CO-4608
- "Transfusion Blood Refusal" forms (prints with an information sheet "What you should know about blood transfusion"):
    a. English: MR-1418
    b. Spanish: MR-4612
    c. Russian: MR-4613
    d. Vietnamese: MR-4611

TITLE, POLICY OWNER:

OHSU Director, Patient Relations

APPROVING COMMITTEE(S):

- Health Information Committee
- OHSU Institutional Ethics Committee
- Legal Department

FINAL APPROVAL:

OHSU Healthcare Administrative Committee

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