I. PURPOSE:

This policy outlines the process for obtaining informed consent before providing medical procedures and treatments.. In an emergency, medical treatment may be rendered to treat the *emergency condition only* under the doctrine of implied consent. This policy *does not* apply to informed consent for human subject participation in research studies, which is governed by guidelines from the U.S. Office for Human Research Protections (OHRP), the Code of Federal Regulations (Title 45 CFR Part 46) and California Health and Safety Code, § 24172 and § 24173.

II. POLICY

A. SHC recognizes and respects the patient's right to be involved in the decision-making of all aspects of their care and to be informed of the risks, benefits and alternatives to proposed procedures and treatments to assure informed decision-making. Stanford Hospital and Clinics (SHC) complies with all California (CA) and federal regulations, accreditation requirements and court decisions in identifying individuals with the appropriate legal authority to consent to medical treatment

B. It is SHC's policy to obtain voluntary, informed consent from patients (or their legally designated representative, if the patient lacks capacity or is an unauthorized minor) prior to rendering medical procedures and treatments that involve material risk. Informed consent must be obtained and documented according to this policy.

C. Informed consent involves a *detailed discussion* between the patient (or their legally designated representative) and the treating physician that includes:

1. Nature of the proposed care, treatment, and services;
2. Potential benefits, risks, and side effects of the proposed care, treatment, and services;
3. Likelihood of achieving goals;
4. Potential problems that might occur during recuperation;
5. Reasonable alternatives;
6. Risks, benefits and side effects related to the alternatives, and the risks related to not receiving the proposed care, treatment and services (*informed refusal*);

7. Circumstances where information about the patient must be disclosed or reported (i.e. HIV, TB, diseases reported to Centers for Disease Control and Prevention or the California Department of Public Health);
8. Fellows or residents may be performing important tasks related to the surgery, in accordance with hospital policy, based upon skill set, level of competence and under supervision of the responsible physician;
9. Non-physician, qualified medical practitioners (i.e. CRNAs) may perform important parts of the surgery or administration of anesthesia.

III. DEFINITIONS:

A. **Legally designated representative (LDR):** Individual authorized by statute (Surrogate, Agent), judicial action (Conservator, Court appointed surrogate decision maker), or case law (closest available relative).

B. **Capacity:** Ability to understand the nature and consequences of a decision, make and communicate a decision and understand significant risks, benefits and alternatives of a proposed medical procedure or treatment.

C. **Minor:** Individuals under 18 years of age. Minors may consent to medical procedures and treatments only under the circumstances specified.

D. **Material Risk:** Significant risk that a reasonable person in the patient's position would find essential for deciding whether to accept or reject the proposed medical procedure or treatment. Includes risks with a high degree of likelihood, but a low degree of severity, as well as those with a very low degree of likelihood, but high degree of severity.

IV. PROCEDURE: The duty to obtain a patient's informed consent rests with the following individuals:

A. **Physician::** The attending physician who orders, performs or is in charge of the procedure or treatment is responsible for obtaining informed consent.

1. **Designee:** The attending physician who orders, performs and/or supervises may designate another physician of the medical team (with sufficient knowledge of the risk, benefits and alternatives of the procedure or treatment) to obtain informed consent.

a. Fellow, Resident

2. **Practitioner Authorized by the Interdisciplinary Practice Committee (IDPC):** Performance of the procedure is within the scope of the practitioner's practice and the IDPC has authorized the practice:
    a. PICC line RN
    b. Nurse Practitioner
    c. Physician Assistant

B. **Process for Obtaining Informed Consent:** Treating physician or designee initiates informed consent discussion with patient or legally designated representative (LDR)..

1. Use interpreters when language challenges are evident. present (Interpreter's must document name, date and time).
2. Provide opportunity for patient or LDR to ask questions
3. Answer questions to patient or LDR's satisfaction
4. Document discussion and decision.

C. **Who Can Provide Informed Consent**

1. **Adults with Capacity:** Persons 18 years-old or older are presumed to have decision-making capacity, unless:
    a. Primary physician determines the patient lacks capacity;
    b. Judicial determination of incapacity;
    c. Capacity determination is uncertain.– Request psychiatric consultation.

2. **Legally Designated Representative (LDR)**
    a. **Hierarchy**
        i. Surrogate decision maker as designated on Core Data Sheet
        ii. Agent appointed in Advance Health Care Directive
        iii. Conservator
        iv. Court appointed surrogate decision maker
        v. Closest available relative

b. **Telephone Consent when LDR Not Physically Present**
   i. Treating physician initiates informed consent discussion (*See* elements on page 1)
   ii. Hospital staff member must witness in real time:
      1. Informed consent discussion between the treating physician and LDR; and
      2. Verify the LDR has provided consent or refusal
   iii. Physician and witness sign, date and time the consent form and document the name and relationship of the LDR

3. **Minors Meeting Specific Criteria** - For circumstances involving minors (patients under the age of 18) please consult the "Minors Consent " policy.

D. **Documentation of Informed Consent**

1. Documentation of the discussion and patient decision should be noted in the patient's medical record.

2. **Signed Consent Form Required for**:
   a. Surgical procedures
   b. Invasive procedures listed in the Medical Staff Bylaws, Rules and Regulations
   c. Anesthesia, including sedation (*See* Moderate Sedation policy in Administrative Manual)
   d. For specific rules on hysterectomy and sterilization, *see* policy "Informed Consent for Sterilization or Hysterectomy Procedures"

3. **Signatures:** Consent form must be signed by the physician who had the informed consent discussion *and* by the patient or LDR at the time consent is obtained.

4. **Patient Edits:** If patient strikes a line or paragraph on a consent form, the treating physician must address the patient's concerns with the patient directly. Consent forms should not be altered.

5. **Multiple procedures by Different Practitioners in Single Operation**: Each physician must obtain a separate informed consent for his/her procedure and ensure appropriate documentation is in the medical record.

6. **Practitioner Performing Procedure is Different than Practitioner Documented:** Prior to procedure, practitioner performing procedure must:
    a. Introduce self to patient;
    b. Explain he/she will be doing the procedure;
    c. Confirm that patient has no further questions; and obtain the patient's agreement to proceed.

E. **Duration of Informed Consent:** Valid until
1. Patient revokes consent ; or
2. Circumstances change so as to materially affect the nature of, risks of the procedure and/or alternatives to the procedure which the patient consented

F. **Emergency Treatment Exception:** Informed consent is not required for treatment of a medical emergency where:
1. Immediate services are required to alleviate severe pain; or
2. Immediate diagnosis and treatment of unforeseeable medical conditions are required, if such conditions would lead to serious disability or death if not immediately diagnosed and treated.
    a) Important notes
        i. The exception applies only to treatment of the medical emergency.
        ii. Treatment that exceeds the necessary response to treat the medical emergency requires consent as with nonemergent treatment.
        iii. If the medical emergency is the result of a condition or treatment that is not *specifically related* to the condition or injury for which a patient previously refused treatment, treatment under the emergency treatment exception should proceed unless and until clear revocation of consent is provided.
            a. Consult Ethics and Risk Management as needed

b. Any existing documents containing previous wishes must be obtained for review, i.e. ADHD, POLST

G. **Documentation of Emergency Treatment Exception**: Physician must document in a progress note:
1. The emergency condition and immediate need for treatment;
2. Physician does not sign consent form on behalf of patient

H. **Managing Refusal of Treatment:** Adults with capacity or their LDRs have the right to refuse medical treatment and physicians have the duty to disclose anticipated risks of refusal to comply with medical recommendations.
1. **Physician discussion when patient refuses care:** The treating physician or their designee should:
   a. Disclose any foreseeable risks or consequences to the patient's health that could be expected to result from refusal, as well as reasonable therapeutic alternatives.

   Document in the progress notes the reason for the patient's refusal and information provided to the patient or LDR

I. **Procedures Requiring Informed Consent**
1. Surgical procedures in the operating room (excludes simple laceration repair) or other clinical setting
2. Invasive procedures involving skin incision or puncture associated with serious risks and the potential to cause harm or adverse reactions (excludes venipuncture, IV therapy)
3. Blood transfusions or use of other blood products
4. Planned use of moderate sedation
5. Anesthesia
6. Electroconvulsive therapy
7. Non-invasive treatments of a diagnostic or therapeutic nature associated with substantial risk of harm
8. Consents required by law (i.e. genetic testing, HIV, tubal ligation).

V. COMPLIANCE

A. All workforce members including employees, contracted staff, students, volunteers, credentialed medical staff, and individuals representing or engaging in the practice at SHC are responsible for ensuring that individuals comply with this policy;

B. Violations of this policy will be reported to the Department Manager and any other appropriate Department as determined by the Department Manager or in accordance with hospital policy. Violations will be investigated to determine the nature, extent, and potential risk to the hospital. Workforce members who violate this policy will be subject to the appropriate disciplinary action up to and including termination.

VI. RELATED DOCUMENTS:

Administrative Manual Policies

Advance Directives of Adult Patients
Blood Transfusion Consent and Gann Act
Health Care Decisions for Adult Patients Who Lack Capacity
Health Care Decisions for Patients Who Lack Capacity and Lack Surrogates
Informed Consent for Sterilization or Hysterectomy Procedures
Interpreter and Translation Services
Patient Rights and Responsibilities
Medical Staff Rules and Regulations March 2010

VII. DOCUMENT INFORMATION:

A. Legal Authority/References

1. The Joint Commission, 2009 Comprehensive Accreditation Manual, "Rights and Responsibilities of the Individual"; RI.01.03.01

2. 42 C.F.R. §482.24 (c)(2)(v), 42 C.F.R. §482.51 (b)(2), 42 C.F.R. §482.13(b)(2)

3. 42 Code of Federal Regulations §50.202-210

4. California Code of Regulations (CCR) Title 22, §70707.1 through §70701.7

5. Family Code 7120 and 7122

B. Author/Original Date: D. Orquiza/June 2011

C. Gatekeeper of Original Document
1. _____

D. Distribution and Training Requirements
1. This policy resides in the Administrative Manual of Stanford Hospital and Clinics
2. New documents or any revised documents will be distributed to Administrative Manual holders. The department/unit/clinic manager will be responsible for communicating this information to the applicable workforce members.

E. Review and Renewal Requirements
1. This policy will be reviewed and/or revised every three years or as required by change of law or practice.

F. Review and Revision History
1. _____
2. _____

G. Approvals
1. October 2011, SHC Board Credentials, Policies & Procedures Committee_____
2. _____