I. **Purpose**
   This policy sets forth guidelines on obtaining legally effective Informed Consent from research subjects or from their LAR prior to research-related activities.

II. **Scope**
   This policy applies to individuals at OHS whom are engaged in human subject research including but not limited to any person paid by, under the control of or affiliated with the institution such as scientists, investigators, research coordinators, medical education, medical staff, guest researchers and collaborators.

III. **Definitions**
   A. **Assent**— A Minor’s affirmative agreement to participate in a clinical investigation.
   B. **Emancipated Minors**— The following persons under the age of 17 have the legal rights of adults due to special circumstances, including the right to consent to treatments or procedures involved in research, if they:
      a. have entered into a valid marriage whether or not it has been dissolved, or
      b. are on active duty with the armed forces, or
      c. have received a court declaration of emancipation.
   C. **Informed Consent**— A process by which a subject voluntarily confirms his or her willingness to participate in a particular trial, after having been informed of all aspects of the trial that are relevant to the subject’s decision to participate. It is documented by means of a written, signed, and dated informed consent form.
   D. **Informed Consent Document**— A form requiring a signature whereby a person can be said to have given consent based upon an appreciation and understanding of the facts and implication of an action.
   E. **Institutional Review Board (IRB)**— An independent body constituted of medical, scientific, and nonscientific members, whose responsibility it is to ensure the protection of the rights, safety, and well-being of human subjects involved in a trial by, among other things, reviewing, approving, and providing continuing review of trials, of protocols and amendments, and of the methods and material to be used in obtaining and documenting informed consent of the trial subjects.
   F. **Legal Authorized Representative (LAR)**— An individual or juridical or other body authorized under applicable law to consent on behalf of a prospective subject to the subject’s participation in the procedure(s) involved in the research.
   G. **Minors**— Persons under 18 years of age.
IV. Policy Statements
The consent process shall provide the subject or their LAR with sufficient information to make an informed decision regarding participation in a research study.

V. Procedures/Standards and Roles & Responsibilities
A. Prior to the consenting process, the research staff is responsible for the following:
   1. No study related activities are performed prior to obtaining the consent.
   2. Ensure the most recent IRB approved version of the consent is used during the consent process.
   3. Only individuals who have completed research training requirements may obtain research consent.
B. There are special circumstances in obtaining consent from Minors and employees.
   1. Minors.
      a. For legal Minors, only a parent or legal guardian may grant permission for their child’s participation in research.
      b. Emancipated Minors may consent to research without parental permission.
      c. Assent is to be sought from the Minor, only after permission has been obtained from the parent.
   2. Employees.
      a. If an employee agrees to participate in a research study, the employee shall also sign an “Employee Non-Coercion Statement.”
      b. In addition, a witness with no direct connection to the research study shall be present during the consent process and must sign the consent form.
C. Research staff shall assist potential research subjects when language constraints are present.
   1. For non-English speaking subjects, the International Health Services department shall be contacted to provide an interpreter.
   2. In the case of a shift in the subject population, it may be necessary to have a consent translated into a second language.
   3. The use of a short form is acceptable for subjects who do not speak English. For further information, refer to the IRB Short Form Guidance.
D. If a subject is unable to read, the consent shall be read to the subject by the person obtaining the consent.
1. An impartial witness must observe the process and sign the consent form as a witness.

E. Research staff shall ensure no undue influence or coercion is used in the consent process.

F. Ample time shall be provided for the subject to review the consent.
   1. The investigator will be available to answer any questions.

G. Once the consent form has been signed the following shall happen:
   1. Provide a copy of the signed consent to the subject.
   2. The original consent is maintained with the subject’s study files.
   3. A copy of the consent is submitted to medical records for scanning into the electronic medical record.
      a. For hospitalized subjects, a copy of the consent is maintained in the hospital chart and scanned into the medical record.
   4. The consent process is documented in the electronic medical record.

H. During the research trial, the consent process continues by:
   1. An ongoing exchange of information between the research team and the subject throughout the course of the research study.
   2. Revised IRB-approved consents requiring subjects to be re-consented should be presented in a timely manner.
      a. This process documents the subject’s decision to continue participation in the trial.

I. Any concern of improper consenting shall be investigated either by the HRPP Office, the Executive Vice President and Chief Academic Officer or the Compliance and Privacy Department.

J. The IRB Chair or designee determines if a waiver of Informed Consent can be obtained.

VI. **Enforcement and Exceptions**
   Failure to comply with this policy may result in progressive discipline up to and including termination of employment for employees or termination of contract or service for third-party personnel, students or volunteers.

VII. **Internal References**
    IRB Written Procedures
Ochweb/Research/IRB Tab/Policies
Louisiana Law regarding Legally Authorized Representative
Ochweb/Research/IRB Tab/Guidance Documents

VIII. External References
45 CFR 46.116
21 CFR 50.20, 50.23-24, 50.3

IX. Policy History
8042-19 Informed Consent in Clinical Research

X. Approved
Warner Thomas, President and Chief Executive Officer
William Pinsky MD, Executive Vice President & Chief Academic Officer

Reviewers
System Policy Review Committee, 2/3/2016

Joe Breault, MD, ScD, MPH, MS, CIP
Executive Chair, Ochsner Institutional Review Boards

Stephanie Gaudreau, CIP
IRB Administrator, HRPP Manager

Paul Colomb
Compliance & Privacy Director and Privacy Officer