OREGON STATE HOSPITAL

PORTLAND – SALEM

POLICIES AND PROCEDURES

SECTION 10: Research **POLICY: 10.002**

SUBJECT: **Institutional Review Board**

APPROVED: **ROY J. ORR**
SUPERINTENDENT

DATE: MARCH 31, 2010

I. POLICY

The Oregon State Hospital (OSH) Institutional Review Board (IRB) will review all research protocols to be completed at the hospital and holds authority to protect all human subjects involved in research studies. The review of research projects will comply with state and federal regulations that govern human subjects research.

II. DEFINITIONS

A. An Institutional Review Board (IRB) is a committee that has been formally designated to approve, monitor, and review research involving humans with the aim to protect the rights and welfare of the research subjects.

B. Human Subjects: Includes both patients and staff who participate in research at OSH.

C. Office for Human Research Protections (OHRP) is a federal agency that provides leadership in the protection of the rights, welfare, and wellbeing of subjects involved in research.

D. Investigators: Internal or external researchers who are qualified as defined in the OSH Research Manual to direct a research project or program.

III. PROCEDURE

A. The purpose of the OSH IRB is to protect the safety, rights, and welfare of patients and staff with special attention to vulnerable patients who are participants in research.

B. The OSH IRB is guided by the ethical principles set forth in the Belmont Report and the Declaration of Helsinki. It operates in accordance with the Code of Federal Regulations and other applicable federal and state regulation and law.

IV. THE AUTHORITY OF THE IRB

A. The OSH IRB holds authority for the review, approval, and continuing oversight of all research completed at OSH.

B. The OSH IRB has the authority to approve, require modifications, disapprove, terminate or suspend any research study based upon its considerations for the protection of human subjects.

C. The OSH IRB has the authority to require progress reports from the investigators and oversee the conduct of any research study that it has approved.

D. The OSH IRB has the authority to suspend, terminate or modify approval of any study it has originally reviewed and approved that has an unanticipated problem involving risks to the safety, rights or welfare of human subjects or serious or continuing noncompliance with any state or federal regulation or requirements of the IRB.

E. The OSH IRB has the authority to place restrictions on any study based upon its considerations for the protection of human subjects.

V. OSH RESEARCH MANUAL

A. Additional information, policies and procedures can be found in the OSH Research Manual available through the Planning, Analysis, and Research (PAR) Department. Broad policy topics are included below in order to provide an overview of the Manual content.

B. The OSH IRB shall have at least five members. Additional members may be added to assure adequate review of the submissions made to the IRB.

C. The IRB shall meet at regular intervals to discuss submitted proposals in detail and reach a decision on each submission.

D. Additional protections have been provided through the IRB process due to the vulnerable nature of the OSH patient population. These are described in the OSH Research Manual and are based on 45 Code of Federal Regulations (CFR) 46, Subpart C.

E. The OSH IRB will maintain documentation and records per federal regulation governing IRBs.

F. Investigators on IRB protocols will have sufficient authority, appropriate background, and accountability to carry out all aspects of the protocol.

G. OSH is a covered entity and subject to the regulations outlined in the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule. The Oregon State Hospital relies on the OSH IRB to act upon requests to waive or alter the Authorization requirements in relation to research.

H. Written signed informed consent is required for all research studies involving human subjects unless the study is exempt or signed written informed consent is waived or not required by the IRB or federal regulations.

I. Some research will be determined as not pertaining to human subjects and therefore not requiring IRB review and approval.

J. All publications reporting on or making use of data or information generated by the hospital, its staff, or patients is subject to IRB review.

VI. THE RELATIONSHIP OF THE IRB TO THE RESEARCH COMMUNITY

A. The Institution

1. The OSH IRB is a standing committee of OSH. The OSH Superintendent in consultation with the IRB Chair appoints its members annually. The OSH IRB falls under the administrative responsibility of the OSH Chief Medical Officer (CMO). The CMO will act as the institutional official (IO) for the IRB.

2. The IRB will report out directly to the OSH Superintendent's Cabinet, as determined by the Cabinet.

3. The IRB is administratively housed under the Planning, Analysis, and Research (PAR) Department at OSH. PAR provides administrative support, coordination, and records retention.

B. Regulatory Agencies

1. The OSH IRB interacts with the Office for Human Research Protection (OHRP) and the Food and Drug Administration (FDA). The OSH IRB maintains registration with OHRP.

VII. REFERENCES

Code of federal regulations: 45 Public Welfare, 46 Protection of Human Subjects
Comprehensive Accreditation Manual for Hospitals, The Joint Commission, 2010, Standard RI.01.03.05, pages RI10-RI11

New Oregon State Hospital Policy