

OREGON STATE HOSPITAL

POLICY

SECTION 1: Administration **POLICY:1.010**

SUBJECT: Research at Oregon State Hospital

POINT PERSON: Research Committee Chair

APPROVED: Sara Walker, MD  **DATE: MAY 15, 2024**
Interim Superintendent

SELECT ONE: ☐ New policy ☒ Minor/technical revision of existing policy
☐ Reaffirmation of existing policy ☐ Major revision of existing policy

PURPOSE AND APPLICABILITY

- A. This policy establishes and defines the function of the Research Committee (RC) at Oregon State Hospital (OSH). The purpose of the RC is to review and promote internal research, recruit external research, ensure patient and staff privacy, protect patient rights, and guide research through the OSH system.
- B. This policy applies to all staff including employees, volunteers, trainees, interns, contractors, vendors, and other state employees assigned to work at OSH.

I. POLICY

- A. All research conducted at Oregon State Hospital (OSH) must be reviewed by the OSH Research Committee (RC) and the Oregon Health Authority (OHA) Institutional Review Board (IRB). Both the RC and OHA IRB approval must be secured before commencing the research study at OSH.
- B. The RC is responsible for determining whether a particular research study is appropriate and feasible for OSH.
- C. Any IRB authorized by the RC to review a project must have a current Federal-wide Assurance, federal registration through the Department of Health and Human Services, and a signed authorization agreement with OSH.
- D. OSH follows all applicable regulations, including federal and state statutes and rules; Oregon Department of Administrative Services, Shared Services, and Oregon Health Authority policies; and relevant accreditation standards. Such regulations supersede the provisions of this policy unless this policy is more restrictive.
- E. Staff who fail to comply with this policy or related procedures may be subject to disciplinary action, up to and including dismissal.

II. DEFINITIONS

- A. “Research,” for the purpose of this policy, means a systematic investigation including research development, testing and evaluation designed to develop or contribute to generalizable knowledge based on data collected from OSH staff or patients. For the purposes of OSH, research does not include activities such as program evaluation or quality improvement data collection and analysis, unless the expressed purpose of that activity is to contribute to the generalizable knowledge through publication or other means.
- B. “Institutional Review Board” means 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.
- C. “Human subjects” for the purpose of this policy includes patients and health care personnel (HCP) who participate in research at OSH.
- D. “Staff” includes employees, volunteers, trainees, interns, contractors, vendors, and other state employees assigned to work at Oregon State Hospital (OSH).

PROCEDURES

Procedures A Research Requests

RELATED OSH POLICIES AND PROTOCOLS

OSH Policy 1.014 Data Governance

OSH Policy 2.008 Privacy and Security of Patient Information

REFERENCES

Oregon Administrative Rule § 943-014-0000 — 943-014-0465.

Centers for Disease Control and Prevention. (2021, June 29). *Additional requirement – 31*. Centers for Disease Control and Prevention.