OREGON STATE HOSPITAL

POLICIES AND PROCEDURES

SECTION 1:	**ADMINISTRATION**	**POLICY: 1.010**
SUBJECT:	**RESEARCH AT OREGON STATE HOSPITAL**	
POINT PERSON:	**RESEARCH COMMITTEE CHAIR**	
APPROVED:	**DOLORES MATTEUCCI** **SUPERINTENDENT**	**DATE: MARCH 25, 2020**

I. POLICY

A. All research conducted at Oregon State Hospital (OSH) must be reviewed by the OSH Research Committee (RC) and an authorized Institutional Review Board (IRB). Both RC and IRB must approve the research study before it commences.

B. The purpose of the RC is to promote internal research, recruit external research, and guide research through the OSH system. The RC is responsible for determining whether a particular research study is appropriate and feasible for OSH.

C. All authorized IRB 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. This policy applies to all staff including employees, volunteers, trainees, interns, contractors, vendors, and other state employees assigned to work at OSH.

E. 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.

F. Staff who fails to comply with this policy or related procedures may be subject to disciplinary action, up to and including dismissal.

II. DEFINITION

"Research" means a systematic investigation, including research development and testing and evaluation, designed to develop or contribute to generalizable knowledge. 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.

"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.

"Human subjects" for the purpose of this policy includes patients and health care personnel (HCP) who participate in research at OSH.

III. PROCEDURE

A. Before submitting a request, the researcher must consult the appropriate OSH stakeholders relevant to the project and show evidence in the request that input was sought, barriers and risks have been addressed, and that the stakeholder acknowledged the capacity to support or accommodate the study.

B. The researcher must submit the Research Submission Form and study protocol to the RC Chair.

   1. The RC Chair must distribute the submission to the RC for review and indicate the IRB to be authorized for the project.

   2. Alternatively, the researcher may ask for assistance from the RC to connect with an IRB.

C. The researcher must submit the study to the authorized IRB.

D. Once the researcher receives approval from the authorized IRB, the researcher must submit the approval letter and approved study documentation to the RC Chair.

E. For final authorization of the request, the RC Chair must review the IRB approval and final study documentation.

F. After approval has been received from the RC Chair, the researcher must forward all documentation between themselves and the IRB to the RC.

G. If any adverse events occur, the researcher must notify both the RC Chair and the IRB in writing.

H. The researcher must forward a summary of study findings or all publications resulting from the approved research to the RC Chair.

IV. REFERENCES

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

Oregon State Hospital Policy and Procedure Manual. *Data governance*, 1.014. Author.

Oregon State Hospital Policy and Procedure Manual. *Privacy and security of patient information*, 2.008. Author.