OREGON STATE HOSPITAL

POLICY ATTACHMENT

PROCEDURES A:	Research Requests	**POLICY:1.010**
POINT PERSON:	Research Committee Chair	
APPROVED:	Interim Superintendent	**DATE: MAY 15, 2024**
SELECT ONE:	○ New policy attachment	◉ Minor/technical revision of existing policy attachment
	○ Reaffirmation of existing policy attachment	○ Major revision of existing policy attachment

I. RESEARCH REQUESTS

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

B. The researcher must submit the Research Submission Form (located on the OSH Research Committee OHA website) and study protocol to the RC Chair. The RC Chair must distribute the submission to the RC committee members and convene a meeting of the committee to review and vote on the proposal.

C. The researcher may use an independent federally authorized IRB of their choosing but all research proposals must also be reviewed by the Oregon Health Authority IRB.

1. In the event that the OHA IRB determines a project is outside their scope, the RC in consultation with the OHA IRB may authorize another IRB.

2. Any IRB other than the OHA 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. Notwithstanding the above, final review and signoff must still be obtained from the OHA IRB.

D. After approval by the RC Committee, the researcher must submit the study to the OHA IRB. If submitting for review to their own independent IRB as well, the researcher may do so concurrently with application to the RC committee.

E. Any research involving the active participation of patients and/or the potential to directly impact patient subjects of the study, whether at the time of the project or

in the future, must utilize a Research Consent form that contains, at minimum, the following elements:

1. Attestation that the patient received information to help determine whether or not to participate in the research, investigation, or clinical trials;

2. Attestation that the patient was informed that refusing to participate in research, investigation, or clinical trials or discontinuing participation at any time will not jeopardize their access to care, treatment, and services unrelated to the research;

3. The name of the person who provided the information and the date the form was signed;

4. The patient's right to privacy, confidentiality, and safety.

F. Once the researcher receives approval from the OHA IRB and any other IRB, the researcher must submit the approval letter and approved study documentation to the RC Chair

G. For final authorization of the request, the RC Chair must review the OHA IRB approval and final study documentation and all project documentation and approval materials will be archived by the Research Coordinator.

H. After commencing their project, the researcher must forward all subsequent documentation and updates between themselves and any IRB to the Research Coordinator for record keeping.

I. If any adverse events occur, the researcher must notify both the RC Chair, the OHA IRB and any independent IRB, if applicable, in writing.

J. The researcher must forward a summary of study findings or all publications resulting from the approved research to the RC Chair and OHA IRB, as required.