

# OREGON STATE HOSPITAL

PORTLAND – SALEM

## POLICIES AND PROCEDURES

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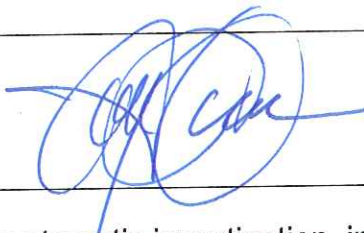
**SECTION 10: Research**

**POLICY: 10.001**

**SUBJECT: Research Committee**

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**APPROVED: ROY J. ORR**  
**SUPERINTENDENT**



**DATE: AUGUST 1, 2008**

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Definition: Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities. For the purposes of Oregon State Hospital, 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.

### I. POLICY

#### A. Purpose

The purpose of the Oregon State Hospital (OSH) Research Committee (RC) is to promote internal research, recruit external research, and guide research through the OSH system.

1. Promoting internal research might include, but is not limited to, providing research education or training to staff, developing research expertise within the staff, and helping with grant writing and preparation.
2. Recruiting external research might include, but is not limited to, communicating with area schools and universities, developing contacts and relationships with external entities, providing a research point of contact for OSH, and actively pursuing research projects and collaboration in order to create a dynamic research effort at OSH.
3. Guiding research through the OSH system might include, but is not limited to, ensuring that researchers have the materials and information they need to proceed with research at OSH, providing feedback to interested parties on protocols, consent forms, surveys,

etc., working with researchers to make the correct connections within OSH in order to carry out their research, overcoming barriers to research within OSH, facilitating a relationship between researchers and staff, administration, and hospital stakeholders (unit staff, unit directors, program directors, etc.), and recommending when a protocol is ready for Institutional Review Board (IRB) submission. Once a proposal is approved by the IRB, the RC will notify the appropriate contacts that the study will be moving forward.

**B. Authority**

The RC has the responsibility and direct authority to monitor and review all research being proposed within OSH. As a point of contact for outside institutions, the RC has authority to speak on behalf of OSH in regard to research matters. The RC has the authority to recommend or withhold recommendation for a protocol to proceed to the OSH IRB. The RC will work in cooperation with departmental research committees but will stand as the hospital governing body for research.

**C. Research**

The RC serves as the central source of information for and about research at OSH.

**D. Review**

When reviewing protocols or study proposals, the RC will consider federal, state, and hospital policy.

1. More specifically, the RC will consider the "Common Rule" 45 CFR part 46 (DHHS), DHS Policy AS-100-06, and National Bioethics Advisory Commission reports and recommendations. Final approval for research and the consideration of the protection of human subjects resides with the OSH IRB.
2. When reviewing research proposals, the RC will consider the proposed benefit to OSH and OSH patients. This consideration will not be the deciding factor when determining whether to guide a proposal through the OSH system, but must be considered in relation to other factors such as the burden on the hospital or infrastructure.
3. The patient committee member will review all proposed research surveys for content and appropriateness for OSH patients. In

addition, the committee or the patient member can convene a patient review panel to review surveys that will be directed at patients specifically.

**E. Reporting**

The RC reports directly to the Superintendent.

**II. PROCEDURES**

**A. Membership**

The RC will be made up of an interdisciplinary team of OSH staff as well as external individuals with appropriate research backgrounds.

1. The RC will have an elected Chair responsible for facilitating regular meetings, reporting to the OSH Superintendent, maintaining and creating external contacts, and providing leadership to the committee.
2. The RC Chair will be elected by a majority vote from within the membership body of the RC to a term of one year and may be reappointed.
3. The RC should strive to maintain membership from Psychology, Psychiatry, Rehabilitation Services, Nursing, Social Work, Education, and Vocational Services. Additional members may be recruited by the committee for membership to address particular research needs.
4. The RC shall be sufficiently qualified through the experience and expertise of its members, and the diversity of the members, including consideration of race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes.
5. The RC is mandated to maintain membership by a patient or if unavailable, a patient advocate.
6. Those interested in RC membership, will submit a Biographical Sketch (form will be provided) with a statement of interest. If available, a CV with statement of interest will suffice. The current RC committee will vote upon the membership candidacy, a simple majority will approve the candidate for membership. The patient or patient advocate is exempt from this provision.

7. Members will maintain their Protection of Human Subjects education certificate regardless if they are currently involved in active research at OSH.
8. The committee will maintain a membership of nine (9) with term limits of two years. The term limits should be staggered and individual members can be reappointed.
9. Conflicts of Interest
  - a. Members will not simultaneously serve on the RC as well as the IRB.
  - b. The RC Chair will not allow a member to participate in the discussion or vote of any research study in which the member has a potential or actual conflict of interest, except to provide information as requested by the RC. At the beginning of each meeting, the RC Chair will remind members to recuse themselves if they have an actual or potential conflict of interest with any submission under review.

**B. Forms**

The RC will formally review a proposal once the Research Submission Form has been submitted to the committee and will formally vote to recommend the proposal proceed to the IRB once the Feedback Form has been returned. Otherwise, the committee is available for consultation and problem-solving efforts at all times.

1. Researchers will submit a "Research Submission Form" which will provide an abstract of the proposed research protocol, investigator and hospital information, expected form of data collection, and other documents.
2. When an initial protocol is submitted or proposed to the RC, the RC will provide the researcher with copies or directions to OSH research and IRB forms and policy.
3. After reviewing the proposal, the RC will provide feedback to the investigator regarding future steps needed from the research team. This may include directions to contact OSH Research Stakeholders identified by the RC as appropriated due to the research topic. The investigator will be responsible for discussing their application with the Stakeholder. A "Stakeholder Form" will be sent directly to the

Stakeholder and will introduce the project and elicit comments/concerns regarding the project along with costing information in terms of time or FTE what costs this project will place upon their department. The form will be returned to the RC with the required signatures. The RC will be available to facilitate this forms completion.

### C. Meetings

The RC will hold monthly meetings (or as needed) in order to complete its function.

1. A simple majority of the membership listed in the most current RC roster constitutes a quorum, and is required for each vote on a protocol. If at any time during the meeting a quorum is lost the committee may not vote on submitted protocols until a quorum is reestablished. The Chair or designee will establish that the requirements for a quorum are met if a vote occurs at a meeting. Votes that have been sent to the RC Chair by electronic media or by phone will count toward the quorum requirement.
2. In order to maintain a viable and efficient process for researchers, the RC may choose to hold virtual meetings by email. The Chair will email proposals to each member for comment. A quorum vote is still required for recommendation to the IRB. Votes will be emailed to the Chair.
3. The RC will maintain meeting minutes and approve the proceeding meeting minutes at the beginning of every meeting. The results of virtual meetings will also be captured in the committee minutes.

New Policy