

OSCaR Research Review Procedure

Before the release of any data, all research proposals requesting the use of confidential cancer registry data must be reviewed by the Oregon Health Services for compliance with the following criteria:

1. The proposed research will be used to determine the sources of cancer among the residents of Oregon or to reduce the burden of cancer in Oregon;
2. the data requested are necessary for the efficient conduct of the study;
3. adequate protections are in place to provide secure conditions to use and store the data;
4. assurances are given that the data will only be used for the purposes of the study, and assurances that confidential data will be destroyed at the conclusion of the study (see Assurances Form);
5. the researcher has adequate resources to carry out the proposed research;
6. the proposal has been reviewed and approved by the Committee for the Protection of Human Subjects or is exempt from such review;
7. any additional safeguards needed to protect the data from inadvertent disclosure due to unique or special characteristics of the proposed research have been required of the researcher; and
8. the research methodology has been reviewed for scientific excellence by a nationally recognized peer group, or if such a review has not taken place, that an ad hoc peer review subcommittee of the OSCaR Advisory Committee containing appropriately qualified scientists has performed a peer review of the research.

Additionally, all relevant research fees have been paid prior to data release.

**Oregon Health Division
Oregon State Cancer Registry
Research Proposal Review**

Please complete each section of this form and return with all attachments to: Health Services, Oregon State Cancer Registry, 800 NE Oregon Street, Suite 730, Portland, OR 97232.

Principal Investigator _____ Date _____

Organization _____

Address _____

City _____ State _____ Zip _____

Tel _____ Fax _____ Email _____

Title of Research Protocol _____

List other institutions or agencies that will collaborate in conducting the project:

Note: please attach a copy of your proposed protocol or methods section of your protocol.

1. 333-010-0010 of ORS 432.500 - 432.990 states “ *the purpose of the registry shall be to provide information to design, target, monitor, facilitate, and evaluate efforts to reduce the burden of cancer and benign brain tumors in Oregon.*” In the section below, please describe how your proposed research will be used to determine the sources of cancer among the residents of Oregon or to reduce the burden of cancer in Oregon. If additional space is needed, please attach a separate sheet.

2. Details of data necessary for conduct of the study elements.

3. Describe procedures for identifying patients (patient population).

4. All protocols including a request for confidential data require peer review for scientific merit. OSCaR accepts review by nationally recognized peer review groups. Please indicate below whether or not such a review has been done.

- No
- Yes, if your proposal has been reviewed for scientific merit, please attach a copy of that review.

If your proposal has **not** been reviewed for scientific merit by a nationally recognized peer review group, the Division shall convene an ad hoc peer review subcommittee of the Cancer Registry Advisory Committee. The data shall not be released unless and until the proposed research is judged to be scientifically meritorious by the peer group. Review for scientific merit must be completed prior to IRB review if one has not already been done.

5. All requests for confidential data must be approved by a Committee for Protection for Human Research Subjects Institutional Review Board (IRB) established in accordance with 45 C.F.R. 46. Please indicate whether or not this proposal has already been approved by an IRB.

- No Please indicate the approximate review date: _____
- Yes Date: _____

If your proposal has been approved by an IRB, please attach a copy of the approval. OHD may require approval by the OHD IRB. Please contact Mellany Bernal at (503) 731-4000 for instructions on obtaining OHD IRB approval.

6. The data must be protected against inadvertent disclosure of confidential data. In the section below, please address the following issues: (If additional space is needed, please attach a separate sheet.)

a) How you will provide secure conditions to use and store the data:

b) Assurances that the data will be used only for the purposes of the study:

c) Assurances that confidential data will be destroyed at the conclusion of the research:

The review committee may require additional safeguards if it is determined that these are necessary due to unique or special characteristics of your proposed research.

7. Prior to the release of confidential data, assurances must be given that you have adequate financial resources to carry out the proposed research. Please document adequate project funding and attach supporting documentation. If additional space is needed, please attach a separate sheet.

8. Please complete the following Researcher Assurances Form on page 5.

Attachments (please check applicable boxes):

- Research protocol attached
- IRB approval
- Project funding
- Peer review approval
- Researcher Assurances Form

Date reviewed by OHD administration: _____

Approved Denied

Comments:

Researcher Assurances Form

The undersigned agrees to (initial each statement, sign and date):

- ___ accept responsibility for the ethical conduct of the study and the protection of the rights, privacy and welfare of the individuals whose private health information is retained in the OSCaR registry;
- ___ conduct this study in compliance with the protocol as reviewed and approved by OSCaR and/or the Advisory Committee;
- ___ submit all proposed study changes, including those accepted by an IRB, to OSCaR to seek approval prior to implementing changes. This includes but is not limited to change in venue, change in PI or other investigators, change in study focus, and any change requiring IRB approval;
- ___ report upon discovery all unanticipated problems, protocol violations, and breaches of confidentiality to OSCaR;
- ___ submit copies of literature and formal presentations generated using OSCaR data;
- ___ text similar to the following shall be included in publications/presentations using OSCaR data: "These data were collected by the Oregon State Cancer Registry which participates in the National Program of Cancer Registries (NPCR) of the Centers for Disease Control and Prevention(CDC)."
- ___ pay all relevant fees prior to receiving OSCaR data (see Schedule of Research Fees); and
- ___ complete dataset received from OSCaR will be destroyed upon conclusion of the study and OSCaR will be informed.

I agree to comply with the above requirements. I attest that information in this Research Proposal Review Form and attachments are true and complete. I also attest that I have no conflicts of interests to disclose regarding this study.

Non-compliance to this agreement may result in termination of the study approval. This means approval for OSCaR study data may be revoked. If this occurs, proof is required that all data obtained from OSCaR for the purposes of this study are destroyed. If this occurs, no investigator on this study may benefit from the use of OSCaR data either monetarily, including grant funding, nor through publications, presentations, or any other means.

_____ Date _____ (P.I. signature)