Oregon State Cancer Registry

Data Use Agreement

This Data Use Agreement ("Agreement") is made and entered into by and between _____("Researcher") and the Oregon Health Authority, Public Health Division, Oregon State Cancer Registry, an agency of the State of Oregon ("OHA"), hereinafter referred collectively as "the Parties".

A. Authority

This Agreement is entered into pursuant to Oregon Revised Statutes (ORS) 432.540 that permits OHA to disclose confidential data from Oregon's State Cancer Registry ("OSCaR") to third parties to conduct research for the public good.

Researcher has complied with OHA's rules that mandate certain requirements are met prior to confidential data being disclosed to a researcher. *See* OAR 333-010-0055.

Researcher has received approval from an Institutional Review Board who has determined that the research complies with 45 C.F.R. 46, as required in ORS 432.540(1).

B. Definitions

As used in this Agreement:

- "Confidential Data" means identifying information regarding individual patients, health care facilities and practitioners reported pursuant to ORS 432.520.
- "Privacy and Security Rules" mean the Standards for Privacy of Individually Identifiable Information and the Standards for Electronic Security at 45 CFR Part 160 and Part 164, as amended from time to time.
- "Research" means the project as defined by the project Protocol set forth in Appendix A.

C. Confidential Data to be Provided

Confidential Data to be disclosed by OHA to Researcher includes only the data elements set forth in Appendix B attached to this Agreement.

D. Obligations and Activities of the Researcher

1. Researcher certifies that the Confidential Data received from OHA may only be used in a manner consistent with the Protocol set forth in Appendix A attached to this Agreement and incorporated by reference herein.
2. Researcher may use and disclose Confidential Data received under this Agreement for the Research that is described in the Protocol set forth in Appendix A and as required or permitted by law.

3. Nothing in this Agreement limits Researcher's use or disclosure of data from the Confidential Data that is de-identified.
4. If applicable, Researcher will follow the patient recruitment procedure set forth in Appendix C attached to this Agreement and incorporated by reference herein. The Confidential Data includes any physician and patient lists provided to Researcher as part of a patient recruitment.
5. Access to the Confidential Data is limited to individuals directly involved in the Research and who are necessary to achieve the purposes of the Research and Researcher must limit access to the minimum amount of data necessary to achieve the purposes described in the Protocol.
6. Researcher agrees not to use or disclose the Confidential Data for any purpose other than as set forth in this Agreement. Researcher shall not use or disclose Confidential Data in any manner that would violate any laws or regulations applicable to the Researcher or the conduct of the Research, including the Privacy and Security Rules as they apply to the Researcher. Researcher will not permit others who are not authorized by the Researcher to assist with the Project or who are otherwise legally authorized to access the Confidential Data.
7. Researcher agrees to implement administrative, physical, and technical safeguards to protect the security and confidentiality, integrity and availability of the Confidential Data that Researcher receives from OHA and prevent its unauthorized use or disclosure.
8. Researcher agrees to report immediately to OHA any IRB closure of the Project due to adverse or emergency events when part or all data for the Project originated from OHA.
9. In the event that any attempt is made to obtain from Researcher any or all of the Confidential Data provided to Researcher by subpoena or other legal means, Researcher shall notify OHA immediately. Prior to responding to such demand, Researcher shall provide OHA a reasonable period of time to respond. Prior to any disclosure in response to such demand, Researcher must receive prior written authorization from OHA.
10. Researcher agrees to provide OHA with drafts of publications related to the Project for review by the OSCaR Advisory Committee and allow reasonable time to review for accuracy prior to release. Researcher will also provide OHA with copies of all published materials related to the Project.
11. Researcher agrees to include language acknowledging use of data provided by OHA in any publication of Project results similar to the following: "This research article is in part based on cancer data provided by the Oregon State Cancer Registry, one of the participating registries funded by the National Program of Cancer Registries (NPCR) under the Centers for Disease Control and Prevention (CDC)."

E. OHA Duties and Obligations

1. OHA will submit Confidential Data to the Researcher using the designated secure method.
2. OHA will provide the Confidential Data set forth in Appendix B attached to this Agreement and incorporated by reference herein. This data set comprises the minimum number of data elements necessary for conducting the Research.

F. Term and Termination

1. The provisions of this Agreement shall be effective upon execution and shall terminate upon written notice by either party to the other party. The terms of this Agreement may only be changed upon a written modification to this Agreement or the adoption of a new agreement.

2. OHA has the right to terminate this Agreement if it determines that Researcher has violated a material term of this Agreement. If OHA determines that such a violation has occurred, OHA shall either (a) provide Researcher with an opportunity to cure the violation within a specified period of time or (b) if cure is not possible, terminate this Agreement immediately.
3. Either party may terminate this Agreement upon 30 days notice to the other party.
4. In the event of termination of this Agreement, Researcher on behalf of itself and its contractors and agents shall destroy the Confidential Data received from OHA under this Agreement in compliance with state record retention requirements in ORS 192.105.
5. In addition to the termination rights set forth above, OHA may immediately revoke Researcher's access to Confidential Data under this Agreement for Researcher's failure to comply with the requirements of this Agreement

G. Miscellaneous

1. The obligations of Researcher under Section D of this Agreement shall survive termination or expiration of this Agreement.
2. This Agreement may be amended or modified only upon the mutual written consent of the parties.
3. Any notices to be given under this Agreement shall be given in writing either by (a) personal delivery or (b) certified mail return receipt requested and postage pre-paid to the address each party shall specify in writing upon the execution of this Agreement. All notices so addressed and delivered shall be deeded received and effective five (5) days after the date of mailing, unless given by personal mail in which case notice will be effective when actually delivered to the recipient.
4. No provision of this Agreement may be waived except by an agreement in writing signed by the waiving party. A waiver of any term or provision shall not be construed as a waiver of any other term or provision.
5. The persons signing below have the right and authority to execute this Agreement and no further approvals are necessary to create a binding agreement. Each copy of this Agreement and amendments so executed shall constitute an original.
6. This Agreement shall be construed in accordance with and governed by the laws of the State of Oregon.

IN WITNESS WHEREOF, the parties have executed this Agreement in duplicate original effective as of the date of the last party to sign below.

Researcher	OHA
Signed: _____	Signed: _____
Name: _____	Name: _____
Title: _____	Title: _____
Date: _____	Date: _____

APPENDIX A: Project Protocol

[Approved Protocol submitted by Researcher]

APPENDIX B: Required Data Elements

[To be determined by agreement between OHA and Researcher]

APPENDIX C: Patient Recruitment Procedure

1. OHA will provide Researcher a list of patient names and the physician names and most recent mailing addresses for the physicians of record for those patients that match the criteria listed in the Protocol.
2. Prior to contact with any patient, Researcher will make a good faith effort to contact a patient's current treating physician to inform them of the study. If Researcher is notified that the physician of record is no longer the patient's physician and an alternative physician for the patient is provided on a Physician Response Form, Researcher will attempt to contact the alternative physician for the patient.
3. Researcher will inform a patient's physician of the Project and the identity of the eligible patient. Researcher will ask the physician if direct contact by the Researcher would be appropriate or if the patient has a medical, psychological, or social situation that would make contact regarding the Project inappropriate. A physician is under no obligation to disclose the specifics of the medical, psychological, or social situation.
4. Researcher will allow one month for a physician to respond to any patient inquiries sent. Once the appropriate amount of time to respond has been allowed, Researcher will send OHA confirmation that all physicians for the patients provided have been contacted and provide OHA with a list of patients whose physicians determined that contact regarding the Project would be inappropriate.
5. Once Researcher confirms that all physicians have been contacted and provides a list of patients who should not be contacted, OHA will provide Researcher a list of patients, the patients' most recent mailing addresses and telephone numbers available in the OSCaR database, and other data elements specified in the Confidential Data set. The data set provided will exclude information for any patients whose physician determined that contact regarding research would be inappropriate.
6. Unless otherwise approved by the Institutional Review Board of authority, Researcher will make initial contact of patients by mail using the approved cover letter and consent for contact forms. Researcher will include no information on the envelopes used for a patient mailing that states or implies a recipient's diagnosis (e.g., "Cancer Survivorship Study" cannot appear on the envelope). If a patient is contacted via telephone regarding participation in the Project, Researcher may only inquire if the potential participant has received the mailing and whether or not the patient intends to participate in the study. The number of patient contact attempts will be limited as agreed upon by OHA and Researcher.
7. If Researcher is informed by a potential participant that the patient does not intend to participate in the Project, no further contact is permitted. Researcher will inform OHA of any patients who do not wish to participate in the Project or do not wish to be contacted again regarding any future OSCaR-related research project by method as agreed upon by OHA and Researcher.
8. During and after completion of the patient recruitment, Researcher will provide OHA with the following information:
    a. A list of patients for whom a current physician has advised against contacting;
    b. A list of address corrections for patients' physicians;
    c. A list of updated patients' current treating physicians;
    d. A list of patient address corrections;

e. A list of patients who declined to participate in the Project; and
f. A list if patients who requested not to be contacted regarding any future OSCaR-related research project.

9. Researcher will deliver the information described in Section 8 to OHA as agreed upon by OHA and Researcher. Researcher will use a secure, traceable method for mail delivery of any material related to the Project (e.g., FedEx).