

Appendix 3: Confidentiality Agreement for Disclosure of CCR Data

The California Cancer Registry is a repository of cancer incidence data collected by the California Department of Public Health and regional cancer registries throughout the state of California from cancer reporting facilities and health-care providers under the authority of California Health and Safety Code section 103885. CCR data files contain medical and other personal information about identified individuals. By law, CCR data are confidential, and cannot be disclosed except in accordance with strict safeguards.

The _____ ("Recipient Institution")
(Name of institutional recipient)

has applied to Cancer Surveillance and Research Branch/CCR ("CCR Data Custodian")
(Name of CCR Data Custodian)

for a copy of certain specified CCR data to be disclosed to

_____ (hereinafter "Principal Investigator")
(Name of Primary individual recipient)

for the following proposed use:

(Brief description or reference to application)

In consideration for the CCR Data Custodian's disclosure of CCR data to Principal Investigator, Recipient Institution and Principal Investigator represent, warrant, and agree as follows:

1. For the purposes of this Confidentiality Agreement:

"Recipient Institution" is defined as the unit of government, institution, agency, the corporation, or other entity that has requested CCR data, any other unit of government, institution, agency, corporation or other entity that owns or controls the recipient institution or of which the recipient institution is a constituent part, and the directors, officers, employees, consultants, volunteers, students, contractors, agents and associates of the recipient institution.

"Principal Investigator" is defined as the individual that the recipient institution designated in its request to receive CCR data from the CCR, and who is principally responsible for undertaking the proposed use.

"CCR data" is defined as all information relating to cases of cancer collected at any time by the California Department of Public Health, a regional cancer registry designated by the Department or any other individual or institution under the authority of California Health and Safety Code Section 103885 and predecessor statutes, whether or not such information identifies an individual or could be used to identify an individual. CCR data also means all documents, files or other records, regardless of format or medium, containing CCR data (whether alone or in combination with other data).

"Access to data " is defined as the granting of the right to examine data.

"Disclosure of data" is defined as the granting of the right to examine data and the right to create or retain a copy.

"Research" is defined as the same definition as 45 CFR Section 46.102(d).

"Aggregate data" is defined as statistical information derived from CCR data that does not include any individual item of data that represents a person, whether identified, identifiable or anonymous, and from which no information about an identifiable or anonymous person can be obtained in any manner.

"Reports and statistical information" is defined as reports, articles, special analyses, studies, and other publications and communications that contain aggregate CCR data.

"Sources of information" is defined as hospitals and other facilities or agencies providing diagnostic or treatment services to patients with cancer, and physicians, surgeons, dentists, podiatrists, and all other health care practitioners diagnosing or providing treatment for cancer patients, that have provided information contained in CCR data files.

2. California Health and Safety Code Section 103885 contains various provisions relating to use, access, disclosure, and publication of CCR data. These provisions may be different from the laws, regulations or policies applicable to other data used by Recipient Institution and Principal Investigator. Recipient Institution certifies that: (a) they have reviewed section 103885, the California Department of Public Health, Cancer Surveillance and Research Branch, "Policies and Procedures for Access to and Disclosure of Confidential Data from the California Cancer Registry" (www.ccrca.org) (hereinafter "CCR Data Access and Disclosure Policies"), and the terms and conditions of this confidentiality agreement; (b) they have had a full opportunity to discuss any questions or concerns they may have regarding the interpretation of section 103885 and their duties and obligations under the statute and the terms and conditions of this confidentiality agreement with the CCR; (c) any such questions or concerns have been resolved to their satisfaction; and (d) on the

basis of the foregoing review and discussions, they are prepared to receive and use CCR data in conformity with section 103885 and the terms and conditions of this confidentiality agreement.

3. Recipient Institution agrees to comply with the requirements of California Health and Safety Code section 103885, any and all other federal and state laws or regulations relating to confidentiality, security, use, access, and disclosure of CCR data, and the CCR Data Access and Disclosure Policies.
4. Recipient Institution certifies that the CCR data they have requested is necessary for the above-referenced proposed use. If Recipient Institution receives CCR data that are not necessary for the above-referenced proposed use, they will immediately notify CCR and destroy the unneeded CCR data.
5. Recipient Institution agrees to use the requested CCR data in strict conformity with the proposed use set forth above. Recipient Institution agrees not to use the CCR data for any other purpose, or for any purpose other than determining the sources of cancer and evaluating measures designed to eliminate, alleviate, or ameliorate their effect, and they agree not to permit the CCR data to be used for any other purpose. Recipient Institution agrees to notify the CCR Data Custodian and the Chief, Cancer Surveillance and Research Branch, California Department of Public Health if he or she becomes aware of errors or omissions in the CCR data, or of patient vital statistics or address information that is more current than the CCR data provided to them under this agreement.
6. The Principal Investigator and members of his/her research team with a need to know may have access to the CCR data. The Recipient Institution may grant access to the CCR data to other persons to carry out a specific assignment on behalf of the Recipient Institution, which is directly related to the use for which disclosure was granted. Persons seeking access must provide information sufficient to justify the request. The individual must sign an agreement to maintain the confidentiality of the data. Recipient Institution may use the CCR's Agreement for Access to CCR Data form (available at www.ccrca.org) or a comparable agreement for this purpose. Recipient Institution must maintain a list with the following information: name of the person authorizing access, name, title, address, and organizational affiliation of the persons granted access, dates of access (which may cover a prospective period not to exceed one year), and the specific purpose for which the CCR data will be used. A copy of the list must be provided annually to the CCR Data Custodian. Except as provided in this paragraph, Recipient Institution agrees not to grant access to the CCR data to any person, nor shall it permit persons to whom it has granted access to authorize others to have access to the CCR data.
7. Except as expressly authorized by paragraph 9 of this Confidentiality Agreement, Recipient Institution agrees not to disclose any part of the CCR data, whether or not it explicitly or implicitly identifies individuals, to any person or institution, not to copy or reproduce the CCR data in whole or in part (except as an institutional program of backup for disaster recovery or as a necessary condition of the research project), in

any format or medium, and not to permit others to disclose or reproduce the CCR data. If Recipient Institution has a legitimate justification for sharing CCR data with another institution, e.g. as part of a collaborative research project, the Recipient Institution must obtain approval for this re-disclosure of the CCR data from the Chief, Cancer Surveillance and Research Branch, California Department of Public Health.

8. Recipient Institution agrees to destroy all files, documents or other records containing CCR data in their custody at the earliest opportunity consistent with the conduct of the proposed use unless there is a health or research justification for retention or retention required by law. Notwithstanding the foregoing, Recipient Institution and Principal Investigator agree to destroy all files, documents or other records containing CCR data in their custody no later than three years after the date of receipt unless the CCR Data Custodian, in its sole discretion, extends the deadline for destruction by written notice to Recipient Institution and Principal Investigator. Destruction means physical destruction of files, documents or other records, and de-identification shall not be considered destruction. Immediately following the destruction of CCR data, Recipient Institution agree to provide the CCR Data Custodian with a written declaration, executed by an authorized representative of Recipient Institution, stating that the CCR data have been destroyed.
9. Recipient Institution and Principal Investigator may include aggregate data, conclusions drawn from studying CCR data, and case counts derived from CCR data such as incidence and mortality counts (provided that such case counts do not in any way identify individual cases or sources of information) in professional journals, public reports, presentations, press releases and other publications. A copy shall be provided to the CCR Data Custodian and all publications shall contain the acknowledgement and disclaimer set forth in section VI.4. of the CCR Data Access and Disclosure Policies, and a copy shall be provided to the CCR Data Custodian and the Chief, Cancer Surveillance and Research Branch, California Department of Public Health.
10. Pursuant of the California Health and Safety Code section 103885, Recipient Institution and Principal Investigator shall not grant access to, disclose, admit, produce or otherwise make available any part of the CCR data in any civil, criminal, administrative, or other tribunal or court proceeding, whether voluntarily or under compulsion. Recipient Institution and Principal Investigator shall immediately notify the CCR Data Custodian and the Chief, Cancer Surveillance and Research Branch, California Department of Public Health by telephone and fax of the receipt of any subpoena, discovery request, court order, search warrant or other form of compulsory legal process or threat of compulsory legal process in which CCR data and/or documents, data files or other materials containing CCR data are sought to be produced or examined. Recipient Institution shall immediately take all necessary legal action to oppose and resist any such compulsory legal process, e.g. file a motion to quash or written objections to a subpoena, or file written objections to a discovery request and opposition to a motion to compel.

11. If the proposed use is for research, Recipient Institution certifies that it has obtained approval for the proposed use from the Recipient Institution's committee for the protection of human subjects established in accordance with part 46 (commencing with section 46.101) of title 45 of the Code of Federal Regulations, and that they will carry out the proposed use in accordance with such approval, except that the terms and conditions of this confidentiality agreement shall take precedence. Principal Investigator agrees to provide documentation of initial IRB approval and any renewals. If the proposed research involves patient contact based on information received from CCR, the Recipient Institution agrees to follow the special requirements required by CCR for patient contact studies including approval for the proposed use from the California Committee for Protection of Human Subjects (Section V. 6. c. Policies and Procedures).
12. Recipient Institution represents that it has policies and procedures in effect consistent with the California Information Practices Act (California Civil Code Section 1798.24 and California Welfare and Institutions Code Section 10850) to maintain the security of the CCR data in its custody, including preventing unauthorized access, and further represents that it will maintain and enforce such policies and procedures at all times during which Recipient Institution has custody of CCR data.
13. Recipient Institution certifies that it has policies and procedures in effect to implement and enforce its duties and obligations under this confidentiality agreement, and further certifies that it will maintain and enforce such policies and procedures at all times during which it has custody of CCR data.
14. If Recipient Institution becomes aware of or reasonably suspect that any provision of this agreement has been violated, or that any circumstances exist which would prevent it from complying with its obligations under this agreement, it agrees to immediately notify the CCR and take immediate steps to rectify the problem and prevent any recurrence.
15. This agreement creates a non-transferable limited license for Recipient Institution to use selected CCR data provided to them. Neither Recipient Institution nor Principal Investigator shall acquire any ownership, title or other interest in any CCR data or any copy of CCR data provided to them.
16. Recipient Institution agrees to indemnify, defend and hold harmless the State of California and the CCR Data Custodian and their respective agencies, officers, directors, employees and agents from and against any and all claims, losses, damages, costs, expenses or other liability, including attorney fees, arising out of Recipient Institution's receipt of CCR data.
17. The CCR Data Custodian reserves the right to terminate Recipient Institution's custody of CCR data by written notice at any time without cause. Upon receipt of such notice, Recipient Institution shall immediately and permanently destroy all copies of CCR data in its custody.

18. Recipient Institution acknowledges that if it fails to comply with any of their obligations under this confidentiality agreement, the CCR Data Custodian and the State of California may suffer immediate, irreparable harm for which monetary damages may not be adequate. Recipient Institution agrees that, in addition to any other remedies provided at law or in equity, the CCR Data Custodian and/or the State of California shall be entitled to seek injunctive relief to enforce the provisions of this agreement.
19. This is the entire agreement between the parties. It supersedes all prior oral or written agreements or understandings and it may be amended only in writing. This agreement, and the rights created hereunder, are individual and not assignable or otherwise transferable by Recipient Institution or Principal Investigator. This agreement is entered into for the benefit of the State of California, which shall have the right to enforce this agreement. This agreement and any dispute arising under this agreement shall be governed by the laws of the State of California. This agreement and the certifications contained herein shall survive the expiration or termination of Recipient Institution and/or Principal Investigator's right to custody of CCR data. Any dispute that arises under or relates to this agreement shall be resolved in the State of California, Superior Court for the county in which the CCR Data custodian is located or, at the option of the State of California, Sacramento County Superior Court. In any litigation or other proceeding by which one party seeks to enforce its rights under this agreement or seeks a declaration of any rights or obligations under this agreement, the prevailing party shall be awarded reasonable attorney fees, together with any costs and expenses, to resolve the dispute and to enforce the final judgment.
20. Notwithstanding any other provision of this agreement, the CCR Data Custodian shall have no obligation to provide CCR data to Recipient Institution unless and until this agreement is approved by the Chief, Cancer Surveillance and Research Branch, California Department of Public Health.

For Recipient Institution:

I have read the foregoing agreement. I have the authority to execute this confidentiality agreement on behalf of the Recipient Institution. By signing below I make the agreements, and certifications contained therein on behalf of the Recipient Institution. I understand that these are material representations of fact upon which reliance was placed when this transaction was entered into.

Signature

Dated

Printed Name and Title

Principal Investigator:

I have read and understood the foregoing agreement.

Signature

Dated

Printed Name and Title

APPROVAL BY CALIFORNIA DEPARTMENT OF PUBLIC HEALTH, CANCER
SURVEILLANCE AND RESEARCH BRANCH:

Signature

Dated

Printed Name and Title