

Confidentiality Agreement for the Disclosure of California Cancer Registry De-Identified Data (Researcher)

This *Confidentiality Agreement for the Disclosure of California Cancer Registry De-Identified Data* is entered into by and between the California Department of Public Health, Chronic Disease Surveillance and Research Branch, _____, California Cancer Registry (“CCR”) and _____ (“Recipient”) effective the ____ day of _____ 20__ (“Agreement”).

As the individual signing below, I have the authority to agree to the following terms and conditions and, act on behalf of and bind Recipient, and agree to adhere to the following terms and conditions:

1. All information collected by CCR (“CCR Data”) is confidential. Recipient acknowledges that CCR Data is subject to strict confidentiality requirements imposed by state and federal law, including without limitation California Health and Safety Code section 103885.
2. Recipient acknowledges and agrees that all CCR Data disclosed to Recipient by CCR shall be and remain the sole property of CCR.
3. Recipient warrants and represents that Recipient has a valid scientific interest in CCR Data because Recipient is engaged in demographic, epidemiological, or other similar studies related to health and/or determining the sources of cancer and evaluating measures designed to eliminate, alleviate, or ameliorate their effect.
4. Recipient warrants and represents that Recipient has obtained approval of their 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 (“IRB Approval”) for the use of CCR Data, a copy of which is attached hereto as Attachment 1 and incorporated herein by reference. On that basis, Recipient has submitted an application, attached hereto as Attachment 2 and incorporated herein by reference, to CCR for use of CCR Data in accordance with the IRB Approval.
5. Recipient shall pay CCR’s costs for providing CCR Data to Recipient in accordance with the current data preparation costs schedule available on CCR’s website.
6. Upon execution of this Agreement and a Financial Acknowledgment Agreement, CCR will provide Recipient with the requested de-identified CCR Data. Any use of CCR Data authorized by this Agreement shall include only the information necessary for the stated purpose in Attachments 1 and 2 and not be further disclosed unless the original disclosure is for research that requires the Recipient to participate in data sharing with federal or federally designated data repositories and with other researchers, provided the CCR Data being disclosed does not contain individually identifiable data that could be reasonably used to identify or reidentify the CCR Data with an individual person. Any other use or release of CCR Data that is not authorized by the terms of this Agreement requires the written permission of CCR.

7. CCR Data will be formatted in a mutually agreed-upon file format. Files will be encrypted using a strong encryption (such as the Advanced Encryption Standard) and sent to Recipient per an agreed upon Secure File Transfer Protocol (SFTP).
8. Recipient warrants and represents that Recipient has established procedures and ability to maintain the confidentiality of the CCR Data. In particular, Recipient shall treat all CCR Data with at least the same degree of care as Recipient accords their own confidential information, and Recipient shall maintain CCR Data in a secured environment with appropriate administrative, technical, and physical safeguards to prevent unauthorized use of the CCR Data and to maintain appropriate control over the security of CCR Data at all times.
9. Recipient shall notify, not use, not disclose, and immediately return any CCR Data that contains personally identifiable data to CCR that may be inadvertently disclosed by CCR.
10. Recipient may only publish data in accordance with California Health and Human Services (CHHS) Data De-identification Guidelines. Refer to the link embedded here: [CHHS Data De-Identification Guidelines](#) for a PDF version of the CHHS Data De-Identification Guidelines.
11. Recipient shall maintain an accurate record of all persons who are given access to CCR Data. The record shall include: the name of the person authorizing access; name, title, address, and organizational affiliation of persons given access; dates of access; and the specific purpose for which information is to be used. The record of access shall be provided by Recipient to CCR within five (5) business days of CCR's request for the same.
12. Recipient shall notify CCR if, in the conduct of approved research or other activities involving CCR Data, there is a breach or misuse of CCR Data or disclosure of potentially identifiable information in CCR Data. Should a breach or misuse take place, Recipient shall notify CCR in writing within twenty-four (24) hours of the discovery of the breach or misuse and shall take all feasible measures to mitigate loss or damages related to such breach or misuse, including, but not limited to, bearing sole responsibility for reasonable costs, including attorneys' fees, related to mitigating the breach or misuse and providing required notices. As used herein, "breach" means the acquisition, access, use, or disclosure of CCR Data in violation of any state or federal law or in a manner not permitted under this Agreement that compromises the privacy, security, or integrity of the information, as set forth in California Civil Code section 1798.29(f) and 45 CFR §164.402. For purposes of this definition, "compromises the privacy, security or integrity of the information" means poses a significant risk of financial, reputational, or other harm to an individual or individuals." Recipient is informed and acknowledges that any unauthorized disclosure they make may be a basis for civil and/or criminal penalties.
13. In the event Recipient receives a subpoena or other compulsory legal process compelling disclosure of CCR Data, Recipient shall notify CCR within twenty-four (24) hours of receipt

of the subpoena or other compulsory legal process, and Recipient shall take legal steps to oppose the subpoena or other compulsory legal process at its sole expense.

14. To direct communications to CCR/CDPH staff, Recipient shall initiate contact as indicated below. CCR and CDPH reserve the right to make changes to the contact information below by verbal or written notice to Recipient. Said changes shall not require an amendment to this Agreement.

CCR Program Contact	CDPH Privacy Officer	CDPH Chief Information Security Officer
Sandy Kwong, M.P.H. Chief, Surveillance and Data Use Unit California Cancer Registry / California Behavioral Risk Factor Surveillance System Chronic Disease Surveillance and Research Branch California Dept. of Public Health Email: sandy.kwong@cdph.ca.gov Telephone: (916) 731-2532	Privacy Officer Privacy Office Office of Legal Services California Dept. of Public Health P.O. Box 997377, MS 0506 Sacramento, CA 95899-7377 Email: privacy@cdph.ca.gov Telephone: (877) 421-9634	Chief Information Security Officer Information Security Office California Dept. of Public Health P.O. Box 997377, MS6302 Sacramento, CA 95899-7413 Email: cdphiso@cdph.ca.gov Telephone: (855) 500-0016

15. All CCR Data provided to Recipient, except where explicitly stated, will be promptly returned or destroyed at the end of the term of this Agreement to CCR. If CCR Data is completely destroyed and not returned, a letter attesting to the complete destruction, which documents the destruction procedures, must be sent to CCR within thirty (30) days of destruction. In addition, all copies or derivations, including any working or archival backups of the information, of CCR Data will be physically and/or electronically destroyed or returned to CCR within five (5) calendar days immediately following the end of the term of this Agreement.
16. All persons assisting Recipient in the use of CCR Data shall be provided a copy of this Agreement and agree, in writing, to protect the confidentiality of CCR by executing the *Confidentiality Agreement* attached hereto as Attachment 3 and incorporated herein by reference. Recipient shall provide CCR with a copy of each such agreement within five (5) days of a request by CCR for the same.
17. All publications using CCR Data shall contain the current disclaimer available at www.ccrca.org/submit-data/#disclaim.

18. The term of this Agreement shall commence on the date below and remain in effect until the expiration of the IRB Approval, Attachment 1. Any use of CCR Data pursuant to an amendment or extension of the IRB approval shall be memorialized in an amendment to this Agreement.
19. This Agreement may be terminated for any reason by either party with thirty days' written notice.
20. Recipient has no right and shall not delegate, assign, or otherwise transfer or delegate any of its rights or obligations under this Agreement to any other person or entity. Any such transfer of rights shall be null and void at CCR's sole election and discretion.
21. Nothing express or implied in the terms and conditions of this Agreement is intended to confer, nor shall anything herein confer, upon any person other than CDPH, CCR, and Recipient any rights, remedies, obligations, or liabilities whatsoever.
22. The terms and conditions in this Agreement shall be interpreted as broadly as necessary to implement and comply with regulations and applicable State and Federal laws. The parties agree that any ambiguity in the terms and conditions of this Agreement shall be resolved in favor of a meaning that complies and is consistent with federal and state laws.
23. The respective rights and obligations of Recipient under Sections 3, 4, 6, 8, 10, 11, 12, 13, 15, 16 and 17 of this Agreement shall survive the termination or expiration of this Agreement.
24. The invalidity in whole or in part of any provisions of this Agreement shall not void or affect the validity of any other provisions of this Agreement.
25. This Agreement shall be governed by, construed, and enforced in accordance with the laws of the state of California without consideration of its conflict of laws provision and shall be binding upon the parties to this Agreement in the United States and worldwide.
26. This Agreement, including all attachments, constitutes the entire agreement between CCR and Recipient. Any and all modifications of this Agreement must be in writing and signed by all parties. Any oral representations or agreements between the parties shall be of no force or effect.

Signatures:

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.

(Name of Recipient Institutional Representative)

(Title)

(Signature)

(Date)

Recipient:

(Principal Investigator Name)

(Title)

(Principal Investigator Signature)

(Date)

Institution: _____

Address: _____

Telephone Number: _____

Email: _____

CCR:

By: _____ Date: _____

Mark Damesyn, M.P.H., Dr.P.H.

Chief, Chronic Disease Surveillance and Research Branch
Center for Healthy Communities
California Department of Public Health
Telephone: (530) 304-1272
Email: Mark.Damesyn@cdph.ca.gov

Attachment 1 – Institutional IRB Approval

Attachment 2 –Application for Disclosure of Confidential California Cancer Registry Data

Attachment 3 – Confidentiality Agreement

Confidentiality Agreement to be Signed by All Researchers and Their Staff Who Have Access to California Cancer Registry Data

By signing this Confidentiality Agreement, I agree to the following:

1. I have read the *Confidentiality Agreement for the Disclosure of California Cancer Registry De-Identified Data* between the California Cancer Registry (“CCR”) and the person or entity identified as the Recipient in said agreement and agree to be bound by the terms in it.
2. I will safeguard the confidentiality of all confidential information contained in data provided by CCR (“CCR Data”) to which I will be given access. I will not carelessly handle CCR Data. I will not in any way divulge, copy, release, sell, loan, review, or alter any CCR Data except as within the scope of my duties.
3. I will only access CCR Data for which I have a need to know, and I will use that information only as needed to perform my duties.
4. I will not attempt nor permit others to attempt to use CCR Data to learn the identity of any person. If I inadvertently discover the identity of a person in the CCR Data, I will make no use of this knowledge, will not permit others to use the knowledge, will not inform anyone else of this knowledge, and will inform Recipient and/or CCR of the discovery so they can take appropriate action.
5. I will access, view, transmit, print, and store all CCR Data in electronic and hard copy form in a secure and confidential manner and location at all times.
6. I will promptly report activities by any individual or entity that I suspect may compromise the availability, integrity, security, or privacy of CCR Data to the Recipient and/or CCR.
7. I understand that ownership of CCR Data is vested solely in CCR.
8. I understand that violating applicable laws and regulations governing the use and disclosure of CCR Data may result in civil and criminal penalties.

Signature: _____ **Date:** _____

Print Name: _____

Please retain a copy for your records.