

**The Northern California Cancer Center
Greater Bay Area Cancer Registry**

**DISCLOSURE OF CONFIDENTIAL REGISTRY DATA FOR RESEARCH
PURPOSES: BEFORE YOU APPLY FOR A GRANT**

GENERAL INFORMATION

THE CANCER REGISTRY: The Northern California Cancer Center (NCCC), a nonprofit corporation, holds contracts with the State of California to operate the cancer registries covering Region 1 (Monterey, San Benito, Santa Clara, and Santa Cruz Counties from 1988 to date) and Region 8 (Alameda, Contra Costa, Marin, San Francisco, and San Mateo Counties from 1973 to date) of the California Cancer Registry (CCR).

DEFINITION OF CONFIDENTIAL DATA: According to California Health and Safety Code, Section 103885, all non-tabulated registry data are considered to be confidential. Thus, any file containing individual patient records is considered confidential, whether or not personal identifying information is included. Only data in summarized or tabulated form is considered non-confidential.

ACCESS TO DATA: Access is a term meaning the right to examine the data. It does not include the right to copy or retain the data.

DISCLOSURE OF DATA: Disclosure of data means the granting of the right to examine the data and to create or retain a copy for the use of the institution.

Access to and disclosure of confidential information on cancer patients from the regional registries for the purposes of research is restricted by California state law (see California Health and Safety Code 103885).

REQUIREMENTS FOR DISCLOSURE: In order for confidential information to be disclosed, the research must undergo reviews in the following areas:

1. **PURPOSE:** The research must be for the purposes of “determining the sources of cancer and evaluating measures designed to eliminate, alleviate, or ameliorate their effect.”
2. **SCIENTIFIC MERIT:** Each research project must be peer-reviewed to establish scientific merit. Proposals funded by the National Institutes of Health, the National Office of the American Cancer Society, and some similar organizations are considered to have undergone sufficient peer review. Other proposals will be reviewed by the NCCC's Scientific Review Committee.

3. **PROTECTION OF HUMAN SUBJECTS:** Each research project must be approved by both a local Office for Human Research Protections (OHRP) certified Institutional Review Board, as well as the California Committee for the Protection of Human Subjects (<http://www.oshpd.state.ca.us/CPHS/>).
4. **ADEQUATE RESOURCES:** Each project must be reviewed to establish adequate financial and institutional resources to complete the proposed project.
5. **SECURITY AND CONFIDENTIALITY:** The institution to which the data are being disclosed must document adequate procedures and ability to maintain the confidentiality and security of the data. Please see the California Cancer Registry's Information Security Policy (<http://www.ccrca.org/pdf/CCR-Information-Security-Policy-v1.47-03-26-07.pdf>), and their Confidential Data Handling Essentials.

LETTER OF SUPPORT: An investigator applying for funding may request a Letter of Support from the cancer registry. This letter will indicate that the registry will provide the cancer cases sought for the study. However, the letter of support is not a promise or guarantee that the registry will provide the requested data. The Investigator must meet the requirements for data release and the registry will only release a given cancer case to one study at a time for patient contact purposes.

If you require early case ascertainment (ECA), then you must request that NCCC prepare a proposed budget for the project. This serves in lieu of a letter of support. Please discuss this with both the Data Release Coordinator and the ECA Coordinator.

APPLYING FOR DATA: You may apply for data as soon as you receive notice of funding and IRB approval. To apply, supply the Data Release Coordinator with the following:

1. The GBACR Case-Listing or ECA Application provided by the Data Release Coordinator.
2. Documentation of scientific merit. If the study is funded by the NIH, the National Office of the ACS, the DOD, the CDC, or the California Cancer Research Program, submit the funding page of the grant. This is generally a one-page notification of funding indicating the source, amount, and period of funding. If the study is not funded by one of these agencies, please discuss the request with the Data Release Coordinator. The study will need to be reviewed and approved by the NCCC Scientific Review Committee in a separate application process.
3. Documentation of adequate financial and institutional resources to complete the proposed project. Documentation is the same as that described for scientific merit.
4. Evidence of local and State Institutional Review Board approval.

5. An NIH-style abstract describing the research rationale, objectives, and methods. Please submit the abstract electronically in the body of an email or attached as a Word document. This abstract will be submitted to the California Cancer Registry for publication in Research Utilizing the California Cancer Registry.
6. Documentation that your institution has established procedures and ability to maintain the confidentiality and security of the data. Please review California Cancer Registry documents entitled “Information Security Policy” (<http://www.ccrca.org/pdf/CCR-Information-Security-Policy-v1.47-03-26-07.pdf>) and “Confidential Data Handling Essentials” and submit a letter discussing your procedures to maintain confidentiality of registry data. Address the following topics:
 - a. Where will the CCR data be physically located? (E.g. on a server that can be accessed by how many computers? On one or more non-portable single user personal computers? On one or more portable computers?)
 - b. How are these computers physically secured when not in use (password protected computer lock after some amount of inactivity; or locked door, or...)?
 - c. Who will have access to the CCR data? Have these persons been advised of the restrictions upon use and access to the CCR data? Have they given assurance that they will abide by these restrictions?
 - d. How will access to the CCR data be limited to these authorized persons (include both electronic and physical controls if applicable)?
 - e. Is there an Institutional Security Plan or other documents that would govern treatment of the CCR data?
 - f. Is there an institutional Disaster Recovery Plan that would govern treatment of CCR data?
 - g. How will the media containing the CCR data that were sent by the CCR be stored?
 - h. How will printouts of patient-specific data be stored when not in use?

APPROVAL BY NCCC: Once your application is complete, your project must be approved by the NCCC.

THE LETTER OF AGREEMENT: Next, a Letter of Agreement between the Principal Investigator and the NCCC, acting as the designated agent of the California Department of Health Services, must be signed. The Letter states the conditions under which confidential information will be released, the purposes for which it will be used, and the manner in which patient confidentiality will be protected. The Investigator must provide assurances that adequate procedures are in place to protect the confidentiality of patient information and that information on individuals will not be disclosed further. NCCC will draw up the Letter of Agreement and forward it to the Principal Investigator for her/his signature or the appropriate institutional signature prior to releasing any confidential information. Please ask for a current copy of the Letter of Agreement to familiarize yourself with the requirements.

AGREEMENT FOR DISCLOSURE OF CCR DATA: In addition, both the Principal Investigator and an Institutional Representative must sign the “Agreement for Disclosure of CCR Data.” Please ask for a current copy to familiarize yourself with the requirements. Also request the accompanying document, “Policies and Procedures for Access to and Disclosure of Confidential Data from the California Cancer Registry.”

APPROVAL BY THE CALIFORNIA CANCER REGISTRY: Finally, your project must be approved by the California Cancer Registry.

DATA ARE DISCLOSED TO THE INSTITUTION: Data are disclosed to the research institution. The Principal Investigator receives access automatically because he/she has signed the Agreement for Disclosure of CCR Data.

DATA ACCESS FOR STAFF MEMBERS: The Investigator’s staff members do not automatically receive access to the data. Recipient institutions may grant access to registry data to other persons to carry out a specific assignment on behalf of the institutional recipient, which is directly related to the use for which disclosure was granted to the recipient. Persons seeking access must provide information sufficient to justify the request. The individual must sign an agreement to maintain the confidentiality of the data. Institutional recipients may use the Agreement for Access to CCR Data (from “Policies and Procedures for Access to and Disclosure of Confidential Data from the California Cancer Registry” Appendix 2) or a comparable agreement for this purpose. The recipient institution and the Investigator handle data access issues for staff members on their own.

ACCESSEE LIST: Recipient institutions that grant access to registry data to persons other than their principal investigator must maintain an accesssee 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 registry data will be used. A copy of the list must be provided annually to NCCC.

PROCESSING TIME: The process of getting the project approved, drawing up the Letter of Agreement and the Agreement for Disclosure of CCR Data, obtaining signatures on the documents, and releasing the data takes approximately one month from the time that the application for data is complete. This process can take longer if the request is complicated by data-sharing or other issues.

FREQUENCY OF LISTINGS: Listings of cancer cases will be provided either as a one-time request or on a monthly basis.

FEES: We do charge fees for the time involved in processing your request. Fees for cancer case listings include \$1000 for initial listings without patient contact, \$3000 for initial listings with patient contact, \$100 for subsequent listings without patient contact, \$250 for subsequent listings with patient contact, and \$150-\$600 for investigator-requested programming changes. A reduced one-time fee of \$100 for listings without patient contact and \$300 for listings with patient contact is available for students (with verification of student status). Fees for early case ascertainment (ECA) fluctuate with

the volume of research and will be negotiated on an individual basis. Please discuss this with the ECA Coordinator. For all charges, we need a purchase order (P.O.) number before we can release cases. Any investigator may request, in writing, that all or a portion of the fees be waived. Please include the circumstances and justification for such a request.

DATA TRANSMISSION: We will provide the data in electronic files that have been encrypted and password-protected using WinZip 9.0, AES encryption. The files will be placed on CD-ROM and sent directly to the Principal Investigator by tracked courier service (e.g., FedEx).

CASE ASCERTAINMENT: Be aware that cases take time to come onto the database. For example, cases diagnosed in 2004 will not start to come onto the database until February of 2005; they will not be complete until February of 2006 or later; and they will not be completely followed until November of 2006. Therefore, the last cancer case listing will be conducted in November of the year for which the last diagnosis year specified is considered complete. Please determine which cases to use for your study accordingly.

For early case ascertainment (ECA), case ascertainment takes approximately 4-6 weeks from the date of diagnosis.

CASE-SHARING: If your study involves patient contact, you should contact the Data Release Coordinator to discuss potential case-sharing issues. Cases for patient contact are released to only one study at a time and the Data Release Coordinator will know of any other studies already accessing cases with the same criteria as your study. Cases are released on a first-come-first-served basis to investigators who are funded and who have a complete application.

PHYSICIAN CONTACT: If your study involves patient contact, you must first contact each patient's physician by mail to inquire about contraindications to contacting the patient. Your mailing must include the brochure, "Cancer Research in California" which can be obtained from the CCR website: www.ccrca.org. If a doctor responds that a patient should not be contacted, you may not contact the patient. If a doctor does not respond within two weeks, you are free to contact the patient. Be sure to budget for the time and mailing costs associated with this requirement. We will provide information about each patient's follow-up and attending physicians as available. We suggest contacting the follow-up physician first. If you are unable to make contact, you can then contact the attending physician.

MAILINGS: You must enclose patient identifying information in a separate envelope marked "confidential" anytime you send a mailing to someone other than the patient or patient's next-of-kin. You must also include a copy of Appendix A of the Letter of Agreement. Please ask the Data Release Coordinator for a copy. These rules apply to mailings to physicians, medical records departments, etc.

PATIENT CONTACT: No patient contact is allowed during the first six weeks after diagnosis. First contact with a patient must be in writing. Specifically, the investigator

must send a contact letter to the patient that explains how the patient's name was obtained and why the CCR was created. Your mailing must include the brochure, "Cancer Research in California" which can be obtained from the CCR website: www.crcal.org. Be prepared to answer questions about how you received the patient's name and contact information. In addition, if a patient indicates that he/she does not want to be contacted again by any research study, then please inform the Data Release Coordinator immediately. The registry will mark the patient's cancer record so that it will not be released again.

IRB APPROVAL: Please note again the requirements for the physician, patient, and other mailings just described above and construct your letters and IRB applications accordingly. Please note additional confidentiality requirements outlined in the "Letter of Agreement" and the "Policies and Procedures for Access to and Disclosure of Confidential Data from the California Cancer Registry". You will need to abide by the rules of these documents and the State and local IRBs, and if they should conflict, the strictest requirement holds.

EXCLUDED CASES: The Veterans Affairs Medical Center of San Francisco has instituted a policy whereby we cannot release cases diagnosed at their facility to a research study for patient contact purposes unless the study is first approved by one of their committees and by their IRB. Please ask the Data Release Coordinator for more details. Cases diagnosed at certain institutions may not be available through early case ascertainment (ECA). Please discuss this with the ECA Coordinator.

ANNUAL PROGRESS REPORTS: Annual progress reports, as outlined in the Letter of Agreement, will be requested in the Spring of each year and should be submitted to the Data Release Coordinator. The reports should include 1) a description of study progress, 2) updated vital status and contact information for patients, 3) publications resulting from the use of registry data, 4) the accessee list described above and 5) any complaints made by physicians or other health professionals, study subjects, or other members of the public.

Documentation of continued approval by both State and local Institutional Review Boards should also be provided annually.

Additionally, cases not included as study subjects or for whom interviewing and other data collection are complete must be returned to the registry triannually at the request of the registry staff.

PUBLICATIONS, REPORTS, STATISTICAL COMPILATIONS: Individual cases or individual sources of information shall not be identified in any way. For example, for a geographic area with a small population (less than 10,000) the minimum number of incident cases reported for a specific anatomic site of cancer by five-year age group and race shall be five. Rates shall not be released if calculated with counts less than fifteen due to the instability of rates with small counts. All publications must include the acknowledgment and disclaimer statement provided in the Letter of Agreement.

RE-DISCLOSURE: Data are disclosed to a particular institution for a particular purpose. Re-disclosure of confidential registry data is prohibited under State law. If the recipient institution wants to re-disclose the data to another institution (e.g. as part of a collaborative project), that collaborative institution must also submit an application to NCCC for approval from both NCCC and the California Cancer Registry.

Re-disclosure of confidential registry data can also include releasing names and other identifying information on cancer patients outside of authorized study staff, such as mentioning names of other patients to other people or sending patient information to other researchers not part of the authorized study team. In addition, the Investigator is not permitted to submit patient information to search companies or other search sites on the internet in electronic or hard-copy batch files as this is also considered re-disclosure of registry data. However, Investigators may use an NCCC computer to conduct internet searches with selected companies that have established confidentiality agreements with the Greater Bay Area Cancer Registry. Investigators may only conduct such searches through NCCC, a designated agent of the California Cancer Registry. Please contact the Data Release Coordinator for more information about this process.

DESTRUCTION OF DATA: All copies of data must be destroyed as soon as possible consistent with the proposed use unless there is justification for retention. The data must be destroyed within three years of receipt unless approval is obtained from NCCC to keep it longer. Each year, the investigator will be asked to provide NCCC either with evidence of continuing IRB approval or a written statement verifying complete destruction of the data. De-identification is not considered destruction.

ADDITIONAL REQUIREMENTS: Additional requirements for confidentiality, security, use, access, disclosure and publication of the registry data are specified in the Letter of Agreement and the Agreement for Disclosure of California Cancer Registry (CCR) Data. Any person or institution with access to or possession of registry data is required to be in compliance with all of the following:

- Ca. Health and Safety Code § 103885, including without limitation the provisions relating to confidentiality, security, use, access, disclosure and publication of CCR data.
- Cal. Code Regs., tit. 17, §2593.
- Ca. Information Practices Act (State Bill 13).
- All other federal and state laws or regulations applicable to confidentiality, security, use, access, disclosure and publication of CCR data.
- The Common Rule on protection of human subjects (45 CFR part 46, subpart A) and the terms and conditions of approval by an institutional review board of any human subjects research using CCR data.

- The terms and conditions of any agreement entered into with DHS, the NCCC, the Public Health Institute (PHI), or a recipient of CCR data that relates to the confidentiality, security, use, access, disclosure or publication of CCR data.

If these authorities conflict, the most restrictive requirement shall govern.

DATA ITEMS FOR STANDARD CASE FILES: If data are requested as printed abstracts, a copy of the registry abstract, which provides detail on the patient's cancer, will be supplied to the investigator for each eligible case identified. If data are requested electronically, the following data items will be included:

Registry ID number*
 Cancer sequence number*
 Patient's name (last, first, and middle names)
 Date of birth
 Sex
 Race/ethnicity*
 Spanish origin*
 Primary site (if multiple sites are being studied)
 Histology – type
 Histology – behavior
 Histology – grade*
 Laterality
 Date of diagnosis
 Age at diagnosis
 Vital status at date of last contact**
 Date of last contact (date of death if patient is deceased)**
 Follow-up and attending physicians as available
 Hospital of diagnosis
 Last known address and phone number (if available)
 Address at diagnosis
 County of residence at diagnosis
 Stage of disease at diagnosis*
 Method of diagnostic confirmation*
 Report source
 Cause of death*
 SEER site recode*

*Not available for ECA

**Patient assumed to be alive for ECA

Medical record number and pathology number are also included for ECA.

Much of the above information is encoded. Documentation for interpreting these codes will be provided.

Social security number is not released as a routine data item for case-listings. Researchers requiring social security number to conduct research should provide a written justification to the registry to be reviewed by the registry staff.

DATA DICTIONARY: You should be familiar with registry data and its use. Some data items can be problematic. Consult with other investigators who have used registry data. The California Cancer Registry provides additional information on their website: <http://www.ccrca.org/registrar.html>
See California Cancer Reporting System Standards, Volumes I and III.

CONTACT PERSON: Questions regarding data release should be directed to:

Kari Fish, MPH
Epidemiologist / Data Release Coordinator
Northern California Cancer Center
2201 Walnut Avenue, Suite 300
Fremont, CA 94538
Telephone: 510-608-5036
Fax: 510-608-5095
E-mail: kari.fish@nccc.org

Questions specific to ECA should be directed to:

Karen Hussain, RHIA, CTR
Manager, Data Collections
Northern California Cancer Center
2201 Walnut Avenue, Suite 300
Fremont, CA 94538
Telephone: 510-608-5117
Fax: 510-608-5100
E-mail: KHussain@nccc.org