



University of California  
San Francisco

## Greater Bay Area Cancer Registry

### GENERAL INFORMATION ON APPLYING FOR ACCESS TO AND DISCLOSURE OF GREATER BAY AREA CANCER REGISTRY DATA

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#### GENERAL INFORMATION

**THE CANCER REGISTRY:** The University of California, San Francisco (UCSF), 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). For studies that anticipate using data from this regional registry, the following information applies.

**DEFINITION OF CONFIDENTIAL DATA:** According to California Health and Safety Code, Section 103885, all non-tabulated registry data are 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.” ([Policies and Procedures for Access to and Disclosure of Confidential Data from the California Cancer Registry](#), p. 21).
2. **SCIENTIFIC MERIT:** Each research project must be peer-reviewed to establish scientific merit. Proposals funded by the National Institutes of Health, the Department of Defense, and similar organizations with scientific peer review are considered to have sufficient scientific merit.

3. **PROTECTION OF HUMAN SUBJECTS:** Each research project must be approved by both a local Institutional Review Board (IRB) certified by the federal office for Human Research Protections, as well as the California Committee for the Protection of Human Subjects (CPHS), unless an applicable cooperative agreement exists between the local IRB and 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.

**LETTER OF SUPPORT:** An investigator applying for funding typically requests a letter of support from the cancer registry to submit with their application. The investigator will provide the Greater Bay Area Cancer Registry (GBACR) with an abstract or general description of the study that specifies: (1) how cancer registry data will be used to address a research question, (2) the general inclusion criteria (e.g., sex, age, race/ethnicity, cancer type, date of diagnosis, residence, etc.), and (3) whether the study is a patient contact study. The GBACR will then provide the investigator with a letter of support, which states that the registry can provide the cases sought for the study, once all requirements are met and if cases sought are available. Thus, this letter is not a promise or guarantee that the registry will provide the requested data. At the time that the letter of support is requested, the Data Release Coordinator will provide consultation and advice to investigators planning to contact patients, on the availability of cases meeting the study criteria and any anticipated case sharing issues.

If you require early case ascertainment (ECA), GBACR will provide a letter detailing anticipated costs to obtain the desired number of cases based on your inclusion criteria. This serves in lieu of a letter of support. Please discuss this with both the Data Release Coordinator and the ECA Coordinator.

**APPLICATION PROCESS:**

<p><b>Applying for data</b></p>	<p>You may apply for data as soon as you receive notice of funding and all necessary IRB approvals. To apply, supply the Data Release Coordinator with the following (see checklist available on the website for guidance):</p> <ol style="list-style-type: none"> <li>1. The completed GBACR Case-Listing or ECA Application available on the <a href="#">GBACR website</a>.</li> <li>2. Documentation of scientific merit. If the study is funded by the NIH or a funding agency that provided scientific peer review, submit the funding page of the grant. If the study is not funded by an agency providing scientific peer review, please discuss the request with the Data Release Coordinator.</li> <li>3. Documentation of plan for efficient and appropriate processing of cases. Please submit the methods section of the study protocol or other appropriate description of the research plan for identification and recruitment of cases. The Data Release Coordinator will use this information to determine that the study has a plan in place to process the cases in an expedient and efficient way.</li> <li>4. Documentation of adequate financial and institutional resources to complete the proposed project.</li> <li>5. Evidence of local/institutional IRB and CPHS approval, or deference under a cooperative agreement.</li> <li>6. 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.</li> <li>7. Documentation that your institution has established procedures and ability to maintain the confidentiality and security of the data. Either submit a letter discussing your procedures to maintain confidentiality of registry data, or reference the section of your approved CPHS or other equivalent IRB protocol that indicates the data security procedures you will take to maintain confidentiality of registry data.</li> <li>8. Submit your application as a single PDF file electronically to the Data Release Coordinator at <a href="mailto:gbacr@ucsf.edu">gbacr@ucsf.edu</a>.</li> <li>9. If vital statistics are required as part of the Investigator's study, a separate approval process must occur; this is an independent application process through the <a href="#">CDPH Center for Health Statistics and Informatics</a>.</li> </ol>
<p><b>Approval by GBACR</b></p>	<p>Once your application has been submitted, your documentation will be reviewed by GBACR as the regional cancer registry. At this time, for studies involving patient contact, the Data Release Coordinator will provide consultation and advice on the availability of cases meeting the study criteria and any anticipated case sharing issues.</p>
<p><b>Memorandum to Investigator</b></p>	<p>The Memorandum to the Principal Investigator must be reviewed and signed by the applicant. This document states the conditions under which confidential information will be released, the purposes for which it</p>

	will be used, and the manner in which patient confidentiality will be protected. It also details the requirements of the Principal Investigator for responding to the GBACR on a tri-annual basis and providing requested information.
<b>Agreement for disclosure of CCR data and approval by CCR</b>	Both the Principal Investigator and an Institutional Representative must sign the "Appendix 3: Confidentiality Agreement for Disclosure of CCR Data." This will, in turn, be signed by the Chief of the Chronic Disease Surveillance and Research Branch at the California Department of Public Health.
<b>Fees</b>	See <a href="#">GBACR Case Listing Fees</a> . The GBACR charges a fee for the time involved in processing your request. Fees for case listings for studies without patient contact are \$2000, and \$6000 for a study with patient contact. Subsequent case listings are \$500 (with or without patient contact). A reduced one-time fee of \$200 for listings without patient contact or \$600 for listings with patient contact is available for students (with verification of student status).  The standard fees for early case ascertainment (ECA) vary and estimates must be obtained on a per-study basis through the registry. Please discuss ECA case ascertainment details and associated fees with the ECA and Data Release Coordinators.  For all charges, GBACR needs a copy of the purchase order (P.O.) form before we can process any request and disclose registry data.
<b>Data disclosed to institution</b>	Upon CCR approval and receipt of payment, the requested data will be disclosed to the research institution. The Principal Investigator receives access automatically because he/she has signed the Agreement for Disclosure of CCR Data.
<b>Data transmission</b>	GBACR provides the case listing data in electronic files that have been encrypted and password-protected. Files will be uploaded to a secure web site and an email will be sent directly to the Principal Investigator with instructions for retrieval.

**DATA ACCESS FOR STAFF MEMBERS:** The principal investigator may grant access to registry data to other persons to carry out a specific assignment that is directly related to the use for which disclosure was granted. The individual must sign an agreement to maintain the confidentiality of the data. Institutional recipients will use [the Appendix 2: Agreement for Access to CCR Data](#). The recipient institution and the Investigator handle data access issues for staff members on their own. However, the names of all individuals granted access must be reported annually to the GBACR when requested, on the ACCESSEE LIST, which will be provided to GBACR on an annual basis (see below).

**ACCESSEE LIST:** Recipient institutions that grant access to registry data to study staff other than the principal investigator must maintain an ***accessessee list*** with the following information: (1) name of the person authorizing access, (2) name of accessee and title, (3) organizational affiliation of the persons granted access, (4) dates of access (which may cover a prospective period not to exceed one year), (5) the specific purpose for which the registry data will be used, and (6) date of annual confidentiality training for accessee. This is mandatory and is requested annually in May. A template is provided upon request.

**FREQUENCY OF LISTINGS:** Listings of cancer cases will be provided either as a one-time request or as frequently as every month.

**CASE ASCERTAINMENT:** With the advent of web-based data entry systems, the lag time for cases coming to the registry has been reduced; however, it takes one to two years for a single year's diagnoses to be considered "complete" as a result of follow up and quality control measures. Early case ascertainment (ECA) takes approximately four to six weeks from date of diagnosis

**CASE-SHARING:** 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 completed and approved application.

**PATIENT 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. These rules apply to mailings to physicians, medical records departments, etc.

**PATIENT CONTACT:** Patient contact is not 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. 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 you are required to inform the GBACR Data Release Coordinator immediately*, so GBACR can note this in their record and the patient will not be released to another study.

**EXCLUDED CASES:** Under an agreement with the Veterans Administration (VA), we cannot release cases ever seen at a VA facility to a research study for patient contact purposes unless the study has a VA co-investigator and has been approved by the Veterans Affairs Institutional Review Board. However, the number of VA cases excluded can be made available upon request to the Data Release Coordinator. 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.

**TRI-ANNUAL PROGRESS REPORTS (TRI-ANNUAL MAILINGS):** Tri-annual progress reports to the GBACR will requested via email in January, May and September of each year and must be submitted to the Data Release Coordinator promptly. The required documents vary by study phase but generally include: (1) study phase, (2) updated vital status and contact information for patients (any follow up data), (3) publications resulting from the use of registry data, (4) the accessee list described above, (5) any complaints made by physicians or other health professionals, study subjects, or other members of the public, and (6) documentation of continued approval by both State and local Institutional Review Boards. Patients who refuse participation or for whom interviewing and other data collection are complete must be returned to the registry during the next reporting period. Failure to respond to any request by the Data Release Coordinator during the reporting periods will result in non-compliance of your study with the GBACR and CCR Policies and Procedures.

**PUBLICATIONS, REPORTS, STATISTICAL COMPILATIONS:** Individual cases or individual sources of information shall not be identified in any way. *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 Memorandum to Investigators*

**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 the GBACR for approval from both GBACR 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.

**DESTRUCTION OF DATA:** All copies of data must be destroyed as soon as possible consistent with the proposed use unless there is justification for data retention. Each year, the investigator will be asked to provide the Data Release Coordinator either with written justification for why the data must be retained or he/she must document via an email or letter that all GBACR data have been destroyed. De-identification does not satisfy the destruction requirement.

**ADDITIONAL REQUIREMENTS:** Additional requirements for confidentiality, security, use, access, disclosure and publication of the registry data are specified in the Agreement for Disclosure of California Cancer Registry Data (Appendix 3). 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 GBACR, 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 CASE FILES:** For ECA listings, medical record number and pathology number are also included (patients assumed to be alive). If data are requested electronically, the following standard 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
- Summary of treatment (e.g. chemo, hormones, immunology, radiation, and/or surgery)\*\*
- Date of diagnosis
- Date of initiation of treatment\*\*
- Age at diagnosis
- Vital status at date of last contact\*\*\*
- Date of last contact
- 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
- SEER site recode\*

\* Availability may be limited for ECA; discuss with ECA coordinator.

\*\* Data is based on first course of treatment, and is not a complete set of treatment information. Please consult Data Release Coordinator for further details if you are interested in receiving these data items.

\*\*\*Patient assumed to be alive for ECA.

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. For further information regarding non-standard data items, please consult the Data Release Coordinator.

**DATA DICTIONARY:** You should be familiar with registry data and its use. Some data items are problematic. Please consult with other investigators who have used registry data. See [CCR Data Dictionary](#).

## CONTACT PERSONS:

Questions regarding data release should be directed to:

Meg McKinley, Data Release Coordinator  
Greater Bay Area Cancer Registry  
University of California, San Francisco  
E-mail: [gbacr@ucsf.edu](mailto:gbacr@ucsf.edu)  
E-mail: [meg.mckinley@ucsf.edu](mailto:meg.mckinley@ucsf.edu)

Questions specific to ECA should be directed to:

Kathleen Davidson-Allen, Directory of Registry Operations  
Greater Bay Area Cancer Registry  
University of California, San Francisco  
E-mail: [Kathleen.davidson-allen@ucsf.edu](mailto:Kathleen.davidson-allen@ucsf.edu)