University of California
San Francisco

Greater Bay Area Cancer Registry

APPLICATION FOR DISCLOSURE OF CONFIDENTIAL REGISTRY DATA FOR RESEARCH PURPOSES: CASE-LISTINGS

PART I. BASIC INFORMATION

Application Date: _____
Principal Investigator: _____
Institution: _____
Address: _____
Phone Number: _____
Fax: _____
E-Mail: _____

Contact person (if other than Principal Investigator):
Name: _____
Address: _____
Phone Number: _____
Fax : _____
E-Mail : _____
Project Title: _____

1. HUMAN SUBJECTS REVIEW:

a) Institutional Review Board (IRB)

Institution providing human subjects review: _____
Date of most recent human subjects review: _____
Most recent review was: ☐ concept approval ☐ final approval
Notice of final approval is: ☐ attached ☐ pending
Approval expiration date: _____

b) Committee for the Protection of Human Subjects (CPHS) review:

Date of most recent CPHS review: _____
Most recent CPHS review was: ☐ concept approval ☐ final approval
Notice of CPHS approval is: ☐ attached ☐ pending
Approval expiration date: _____

2. PROJECT FUNDING (please specify whether “total costs”, or “direct costs only”):

Source of funding: _____

Amount of funding: _____

Notice of funding is: ☐ attached ☐ pending

Date funding begins: _____ Date funding ends: _____

Grant number: _____

3. ESTIMATED PROJECT COMPLETION (mm/yyyy): _____

4. CASE SHARING: Please list the Titles and Principal Investigators of all other ongoing research projects of which you are aware that include contact with patients with the same tumors and inclusion criteria of interest as your study (i.e., what studies have case overlap with your study?) Please indicate the extent of overlap and describe any case-sharing arrangements that have been made.

_____

_____

5. Will you be applying for access to Veterans Affairs hospital data (requires that your study have a VA co-investigator and VA IRB approval)?

☐ no

☐ yes, _____

6. STORAGE AND DESTRUCTION OF DATA: Please describe by what method cancer registry data will be securely destroyed at the end of the project. Refer to the California Cancer Registry’s “Confidential Data Handling Essentials” document for further information.

_____

7. EXPECTED AND REQUIRED NUMBERS OF CASES: What is the total number of cases you expect to identify over the entire study period? For patient contact studies, how many cases do you want to enroll? Given your anticipated participation rate, how many cases do you need to identify through the registry to attain this enrollment?

_____

Is your study population-based? ☐ no ☐ yes

8. PATIENT CONTACT: Does your study involve contacting the cancer patients identified through the registry?

☐ no ☐ yes —> Please review the CCR guidelines for patient contact studies.

PART II. DESCRIPTION OF CASES FOR INCLUSION AND FILE PREPARATION INSTRUCTIONS

Sites (ICD-O-2 or ICD-O-3): _____
Site Codes: _____

Histologies: _____
Histology Codes: _____
☐ ICD-O-2 or ☐ ICD-O-3

Or provide the SEER site recodes: _____

☐ All DIAGNOSTIC YEARS
☐ Only dates _____

☐ All SEXES
- ☐ Males and Females only
- ☐ Females only
- ☐ Males only

☐ All RACES/ETHNIC groups
- ☐ Non-Hispanic Blacks
- ☐ Hispanics/Latinos
- ☐ Non-Hispanic Whites
- ☐ Asians/Pacific Islanders
- ☐ Chinese
- ☐ Filipinos
- ☐ Japanese
- ☐ Other, _____

☐ All DIAGNOSIS AGES
- ☐ Only ages _____ to _____ inclusive

☐ All STAGES
- ☐ Carcinoma in situ only
- ☐ Invasive cancers only
- ☐ Other, please specify _____

☐ All VITAL STATUS
- ☐ Alive only

☐ RESIDENCE in all 5 counties (California Cancer Registry Region 8)
- ☐ Alameda
- ☐ Contra Costa
- ☐ Marin
- ☐ San Francisco
- ☐ San Mateo

☐ RESIDENCE in all 4 counties (California Cancer Registry Region 1)
(Note: earliest data is 1988)
- ☐ Monterey
- ☐ San Benito
- ☐ Santa Clara
- ☐ Santa Cruz

☐ Any SEQUENCE
- ☐ First primary

☐ First and only primary
☐ Other, please specify _____

OTHER RESTRICTIONS, please specify _____

Date you wish to receive the initial case listing: _____

How often do you need updated listings?

☐ monthly
☐ one-time only

Date you wish to receive the final listing: _____

Please list the CCR variables you would like to appear in the data file. The listing should be organized by topic, with written justification for each topic. Please refer to the Greater Bay Area Cancer Registry General Information document for a listing of the standard data items. For further information on non-standard data items, please consult the Data Release Coordinator. If applicable, you may reference the section from your approved CPHS or other IRB protocol where these variables are listed with accompanying justifications for their inclusion in the research project.

In what FORM would you like this information returned?

☐ CSV (comma delimited) FILE
☐ SAS DATA FILE
☐ EXCEL FILE

Please list any other instructions, comments, clarifications, etc.

_____

PART III. SUPPORTING DOCUMENTATION

Additionally, please provide the following supporting documentation:

1. 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 (excluding Appendices). This should be from the approved protocol the researcher submitted to his/her institutional IRB or to the Committee for the Protection of Human Subjects (CPHS).

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, you will need to obtain documentation of scientific merit from your institution.

3. Documentation of adequate financial and institutional resources to complete the proposed project. The funding page of the grant provides sufficient documentation.

4. Evidence of both local and State Institutional Review Board approval (if required). CPHS approval is required for patient contact studies.

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 submit a completed Procedures to Maintain Confidentiality of CCR Data (Appendix 5) signed by the principal investigator, 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.

7. A Confidentiality Agreement for Disclosure of CCR Data (Appendix 3) signed by the principle investigator.

QUESTIONS

Direct all questions and return all items to:

Data Release Coordinator
Greater Bay Area Cancer Registry
University of California, San Francisco
E-mail: gbacr@ucsf.edu

APPROVAL CERTIFICATIONS
THIS SECTION FOR USE BY UCSF

REGISTRY PROGRAM	APPROVED	☐
PURPOSE/QUALIFIED INSTITUTION	APPROVED	☐
HUMAN SUBJECTS	APPROVED	☐
SCIENTIFIC MERIT	APPROVED	☐
ADEQUATE RESOURCES	APPROVED	☐

Signature _____ Date _____

Reasons for disapproval:

_____

_____

_____