PROCEDURE GUIDE

FOR STUDIES THAT REQUEST AND UTILIZE CONFIDENTIAL DATA FROM THE

Los Angeles
Cancer
Surveillance
Program (CSP)

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FOURTH EDITION
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**PREFACE**

This Procedure Guide has been prepared to facilitate research that requires access to confidential data from the Los Angeles County Cancer Surveillance Program (CSP). The registry data collected by the CSP are included as a component of the California Cancer Registry (CCR) and thus the release of Los Angeles County data are subject to the regulations pertaining to the release of CCR data.

It is the obligation of the CSP to assure that registry records are used only for appropriate purposes by qualified investigators and that all procedures are followed to protect human subjects. All investigators should review the Introduction, which provides general information about the CSP and the procedures included in this guide. Approvals must be obtained from the investigator’s institutional Human Subjects (Institutional Review Board or IRB), the California state IRB (Committee for Protection of Human Subjects, CPHS), and the CCR before access to data is granted. All investigators must sign the CSP Research Agreement and CSP Confidentiality form. The specific forms and procedures that are required for studies involving patient contact and those that do not are itemized separately (in Sections A and B) and links to blank forms are included in the Appendix. *The data will be provided once a study has met the required approvals, however, the recipient may not use the data for any other purpose than was originally specified.*

Since the CSP is not a health care provider it is exempt from the requirements of the federal Health Insurance Portability and Accountability Act (HIPAA). However, if a study requires that medical records be obtained directly from a patient’s physician or hospital then it is likely that the researcher will be required to obtain a signed HIPAA compliant medical release form from the patients. Details of these requirements and acceptable forms for USC researchers are provided on the USC IRB website (http://oprs.usc.edu/hsirb/).

Specific instructions pertinent to each study type are included as follows:

1) **Section A:** Studies that involve direct patient contact,
2) **Section B:** Studies that do not involve direct patient contact

For studies involving patient contact, investigators should be aware that, due to demands on patient’s time and energy, as well as to the integrity of individual studies, an individual patient may only be contacted for one study per year (Appendix 10). *Thus, it is important that, at the time when a study is being planned, the CSP be contacted to provide assurance that the requested cases will be available.*

Sometimes researchers want to include cases from all of California and not just from Los Angeles County. For those studies it is more efficient to request that all cases be provided directly by the California Cancer Registry (CCR). However, for patient contact studies, researchers should obtain approval first from the CSP for the Los Angeles cases. Information on how to request cancer data for research from the CCR is found at: http://www.ccrcal.org/Data_and_Statistics/Cancer_Data_for_Research.shtml
Suggestions are always welcome and should be addressed to Dr. Dennis Deapen at (323) 442-1574, ddeapen@usc.edu or to Dr. Ann Hamilton at (323) 865-0434, ahamilt@med.usc.edu or to any person listed under CSP Contacts on page 6.
INTRODUCTION

A. CSP HISTORY AND OVERVIEW
The Los Angeles County Cancer Surveillance Program (CSP) collects and analyzes cancer occurrence among residents of Los Angeles County. It is a member of the statewide population-based cancer surveillance system, the California Cancer Registry (CCR). The CSP is administered by the University of Southern California (USC) Keck School of Medicine and the USC/Norris Comprehensive Cancer Center. Since 1972, the CSP has routinely gathered information on all new cancer diagnoses made among residents of the County. With the large and diverse Los Angeles County population, the CSP has served as a resource for many epidemiological studies of cancer.

CSP data are included in the following cancer registry datasets:
State: CCR; National: SEER; and the National Program of Cancer Registries (NPCR); International: North American Association of Central Cancer Registries (NAACCR).

CCR data meets or exceeds all NAACCR, NPCR and SEER standards for quality, timeliness and completeness.

CSP: Cancer Surveillance Program
CCR: California Cancer Registry
NPCR: National Program of Cancer Registries

Background of the CSP
Organized in 1970, the CSP was initially a component of a laboratory-based viral oncology program and, as such, was part of the National Viral Cancer Program. The registry became essentially population-based by 1972 and complete incidence data for Los Angeles County are available from that year forward. As of 2014, the CSP master file contains over 1.7 million records and some 41,000 incident cancers are added annually.

Since 1981, the CSP has been the designated legal agent of Los Angeles County for collecting information on all new cancer cases occurring among County residents for the purpose of monitoring cancer incidence patterns and trends. In 1987, it became the agent of the State of California for collection of demographic and treatment information on all new cancers diagnosed or treated among Los Angeles County residents. In 1992, the CSP became the largest of the National Cancer Institute-funded Surveillance, Epidemiology, and End Results (SEER) registries; patient follow-up and SEER extent of disease coding were added at that time. This consortium of 18 population-based SEER registries provides the federal government with ongoing surveillance of cancer incidence and survival in the U.S.

Population of Los Angeles County
Los Angeles County is the most populous and probably the most ethnically diverse county in the United States (U.S.). According to the 2010 census, over 9.8 million residents, 3.2% of the total U.S. population, reside in Los Angeles County. About 9.3% of the country’s Latinos, 9.2% of...
total Asian Americans, and 10.0% of Pacific Islanders in the U.S. live in Los Angeles County. People of multi-race count for 4.5% of Los Angeles County's total population, much higher than the nationwide proportion of 2.9%.

According to the 2010 census, Latinos in Los Angeles County are not only a large but also a diverse group. Nearly 4.7 million (47.7%) of the County's residents self-reported as Hispanic or Latino in the 2010 census. Among them, 74.9% reported as Mexican, 7.7% Salvadoran, 4.6% Guatemalan, 1.0% Puerto Rican, 0.9% Cuban, 0.9% Honduran, 0.8% Nicaraguan, and 2.5% of South American countries. Latinos in Los Angeles County represent a considerable share of the U.S. total Latino population, with 21.8% of Salvadorans, 20.6% Guatemalans, 11.0% Mexicans, and 10.7% Nicaraguans. As in previous censuses, a higher proportion of Los Angeles County Latinos identified themselves as “other” race than in the U.S. as a whole (45.1% compared to 36.7%)

A high proportion of Asian Americans and U.S. Pacific Islanders also live in Los Angeles County, including 15.2% Korean, 15.0% Thai, 13.9% Cambodian, 13.9% Indonesian, 13.4% Japanese, 12.6% Filipino, 12.1% of Sri Lankan, 11.7% Chinese, and 11.1% of Samoan.

Based on the 2012 American Community Survey 1-year estimates, over 3.4 million (35.4%) of Los Angeles County residents are foreign-born; 27.3% of them entered this country since 2000. More than half (57.2%) of the total population five years of age or older in Los Angeles County speak a language other than English.

The 2.7 million (27.8%) non-Latino white population in Los Angeles County also have highly diverse origins. The population of European origin includes large numbers of persons from Britain, Germany, Ireland, Italy, Russia, French, and all other parts of Europe. In the past 30 years Los Angeles County has experienced a substantial influx of immigrants from Iran, Lebanon and the former Soviet Union. The Armenian community is estimated to number more than 200,000. Over 83,000 individuals of Arabic descent live in Los Angeles County.

Every numerically important religious group in the United States is represented with sizeable populations in Los Angeles County. There is also a wide variation in socio-economic as well as socio-cultural characteristics of the County population. Occupation and industry data reflect the diversity one would expect of a large urban metropolis. Los Angeles County is also characterized by geographic diversity, with subdivisions of mountains, valleys, deserts, and seashores.

**How Cancer Is Registered**

Under the California model of reporting, a passive cancer surveillance system has been implemented statewide in which hospitals and other facilities where cancer is diagnosed or treated bear the responsibility for identifying and reporting cancer cases to the local registry within six months after the patient’s diagnosis or treatment.
To provide complete demographic and treatment information on each new cancer occurring among the residents of Los Angeles County and to guarantee compliance with reporting requirements, the CSP combines elements of an active and a passive surveillance system. For active surveillance, each of the medical facilities in which microscopic verification of cancer occurs is monitored by a CSP field technician who systematically screens all hematology and pathology reports to identify all previously unreported cancer diagnoses. At many hospitals, this manual process has been replaced by an automated system of casefinding and transmission to the CSP.

The State-mandated passive surveillance system requires each hospital or other reporting facility to complete a full report known as an abstract, including stage and treatment information, on every cancer case seen at the facility. All completed abstracts are linked by the CSP to the pathology reports obtained under active surveillance to assure that one abstract is completed for each histologically verified cancer diagnosis. In addition, any previously unrecognized cancer diagnoses among Los Angeles County residents, identified as a result of searching computerized death records, are traced back to patient records in hospitals or other facilities so that data can be abstracted, when possible, in a similar way to data found using pathology reports. All primary cancers reported to the registry for an individual over time are linked by a common patient id number.

Use of CSP Data for Research
The CSP data serve as a descriptive epidemiological resource to generate new hypotheses regarding specific cancer sites or histologic subtypes, to monitor descriptive trends and patterns of cancer incidence, and to identify demographic subgroups at high risk of cancer. A high priority is always placed on exploring demographic patterns and trends in cancer incidence among the racially and ethnically diverse population of Los Angeles County.

As a service to the community, the CSP provides community-wide or hospital-specific data on cancer occurrence specific to sub-areas of Los Angeles County. The CSP receives occasional requests from the public, community physicians and County and State health departments seeking assistance in investigating perceived cancer risks from environmental exposures.

For studies that have met rigorous standards for scientific merit and confidentiality, the CSP can identify populations of cancer patients to be invited to actively participate in research. In such studies, additional information may be gathered by personal interview, record abstraction, or by the collection and analysis of biological specimens. The results are then compared with similar information gathered from people without cancer (controls) who have been chosen to represent the general population.

B. CSP CONTACT INFORMATION

Principal Investigator and Director: Dennis Deapen, DrPH, (323) 442-1574, ddeapen@usc.edu
C. PUBLICATION/REPORTS OF STUDY RESULTS

All studies that utilize the CSP for case ascertainment must be summarized in an annual CSP report to the CCR. Please send a copy of ALL published abstracts of presentations and papers that result from the study to the Administrator of CSP Studies. The bibliography of papers from investigations that have utilized the CSP is used to track the use of the registry for epidemiologic studies.

The SEER and CCR contract numbers and acknowledgments must be cited in all publications that result from studies that utilized the CSP. The current required language can be found at: http://ccrcal.org/Data_and_Statistics/Acknowledgement&Disclaimer.shtml.
PART 1: PROCEDURES FOR STUDIES INVOLVING PATIENT CONTACT

Checklist
(These items are described in this section and must be completed or obtained before a study may commence. Forms are included in Appendix.)

1. **CSP Form A**: Description of patient records being requested, investigator contact information, and abstract of study.

2. **CSP Approval Letter**: Will be issued once it is determined that patients listed in CSP Form A are available for study.

3. **Meeting or discussion with CSP representative** to review procedures and letters to be used for patient contact. A patient letter must include specific text that describes the legal basis for reporting of cancer cases to the registry and how you obtained the patient’s name. A sample patient letter, including the required text is included as Appendix 13.. In addition, a brochure from the CCR describing how and why cancer is reported should be included with patient contact materials. A link to the brochure is included (Appendix 15). It is advisable to meet with or contact a CSP representative prior to submission of IRB application to assure that the letters being used meet the CSP requirements and that proper procedures for contacting patients and responding to their questions and concerns are being implemented.

4. **IRB approval** from your institution that includes CSP approved protocol and letters.

5. **IRB approval from the State IRB (Committee for the Protection of Human Subjects CPHS)** See Appendix 11 for requirements and contact information.

6. **Approval from the California Cancer Registry (CCR)** See Appendix 12 for the list of requirements to obtain approval from the California Cancer Registry (CCR).

7. **CSP Research Agreement** (Appendix 3).

8. **CSP Confidentiality Pledge** (Appendix 4).
A. STEPS IN PLANNING/PROPOSING STUDIES INVOLVING PATIENT CONTACT
(PRIOR TO GRANT SUBMISSION)

1) Contact CSP
Since patients may only be contacted for one study per year, it is important that you contact the CSP right away to determine if the patients you wish to include will be available. The CSP contact person for this purpose is Ann Hamilton, Ph.D. (ahamilt@med.usc.edu or 323-865-0434). Please read the policy statement regarding multiple studies that would utilize the same cancer patients (Appendix 10). We give priority to the first investigator to request cases for a study. Once we determine that your requested cases are available, we will ‘reserve’ them for your study and issue a CSP approval letter. *If this request is for a grant proposal, we ask that you notify us as soon as possible whether or not the grant was funded.*

2) Complete CSP Form A (Appendix 1)
This form collects the details of the cases that you are requesting, asks for investigator contact information, and requests that you provide an abstract of your study. Please email your completed form to Dr. Hamilton (ahamilt@med.usc.edu). It may then be important to meet with Dr. Hamilton (or another CSP representative) to discuss your project and obtain information on the CSP policies and procedures, especially regarding patient contact.

Case reports can be obtained in three ways:

(1) **Routine complete** case reports are prepared by hospitals and submitted to the CSP; 80% are reported within six months after admission. Two months after receipt, quality control checks have been done and duplicate reporting has been removed. These reports can be provided to investigators at a moderate cost. *(Current costs (subject to change) are $2500 for first file provision and $250 for each subsequent request using the same selection criteria.)*

(2) **Routine preliminary** case reports as above, but made available immediate upon receipt without quality control or duplicate consolidation; 80% are reported within six months after admission. These reports can be provided at moderate cost (similar above for routine complete case reports).

(3) **Rapid case ascertainment (RCA)** reporting requires review of all pathology reports at all hospitals in Los Angeles County to identify eligible patients and can be used as a primary source of case identification for studies. These reports are available on average within 44 days after diagnosis. This process has a per pathology report cost associated with it to cover the additional personnel time and is substantially more expensive overall than routine ascertainment *(in 2014, the cost is $11/pathology report (subject to change), and we have estimates of the average number of path reports/case based on cancer site. These cost estimates need to be made for each study based on the selection criteria).* Full quality control checks have not been completed and it is possible
to receive duplicate reports on patients who were seen at two or more hospitals for their cancer. (See Appendix 5, for detailed description of the RCA process).

You will need to include appropriate case ascertainment costs (which vary depending on whether routine or rapid case ascertainment is requested and will be estimated for you by CSP staff) in your grant application and obtain the CSP Approval letter. Your study will be assigned a CSP ID number. Please use this number when referring to your study in future correspondence with the CSP.

B. STEPS IN THE INITIATION OF NEW STUDIES ONCE FUNDING IS OBTAINED (NOTE: THIS INCLUDES STUDIES THAT WOULD INVOLVE RE-CONTACT OF CASES FROM PRIOR STUDIES AS WELL AS NEW STUDIES)

1) Notify the CSP that the study has been funded
Once the study is approved and funded, notify the CSP (Dr. Hamilton) as soon as the study commencement date is known.

2) Obtain and provide a copy of your institution’s IRB approval.

3) Obtain and provide a copy of the approval from the State IRB (Committee for the Protection of Human Subjects -CPHS) (Appendix 11).
For all studies using registry data, CPHS approval is required. Investigators are required to obtain CPHS approval by submitting the necessary documents to the state (See Appendix 11).

4) Obtain approval from the California Cancer Registry (CCR) (Appendix 12). To obtain CCR approval, the investigator (and institutional representative) must sign the most current version of the CCR Appendix 3. The CSP will facilitate obtaining CCR approval, by submitting a cover letter, copies of institutional IRB approval and CPHS approval, and the signed CCR Appendix 3 to the CCR.

4) Sign the CSP Research Agreement (Appendix 3)

5) Sign the CSP Confidentiality Pledge (Appendix 4)

6) Review the specifications on CSP Form A to assure that you will be getting the correct cases for your study.

7) Meet or contact Dr. Hamilton about the generation of new patient listings and/or the CSP Rapid Case Ascertainment Coordinator (see page 6) to initiate rapid case ascertainment.

C. INVESTIGATOR’S RESPONSIBILITY FOR MAINTAINING CONFIDENTIALITY OF PATIENT RECORDS
1) Have all of the study personnel who will have access to information that identifies individual cancer patients sign the CSP Confidentiality Pledge, and provide originals to the CSP.

2) Have all of the study personnel who will have access to information that identifies individual cancer patients sign the CCR Appendix 2 (which is to be kept on file by the investigator).

3) All listings of cases, copies of reports and any other materials that include confidential information must be kept in locked file drawers when not in use. Computer files must be stored on secured systems.

**D. PATIENT CONTACT PROCEDURES**

State regulations mandate that no patient may be contacted less than six weeks after diagnosis. A letter should be used that includes specific language on how the investigator has obtained the patient’s name and the rights of the patient for this study and provides reference to an enclosed CCR brochure that describes the development and purpose of the California Cancer Registry (investigators are responsible for having these brochures printed for their study).

The research version of the CCR brochure can be found at: [http://www.ccrcal.org/pdf/Reports/research.pdf](http://www.ccrcal.org/pdf/Reports/research.pdf) (Appendix 15).

These letters are reviewed by the registry to assure that proper language is included. We have provided a Sample Patient Contact Letter(Appendix 14) that includes the required language.

Some patients will ask how the investigator obtained their names and details of diagnosis; study staff must provide clear and accurate responses (see How Did You Get My name? Questions and Answers, Appendix 14). In addition to the investigator’s description of the study, the patient contact letter must include:

- language furnished by California Cancer Registry regarding cancer reporting including reference to enclosed CCR brochure (paragraph 2 of Sample Patient Contact Letter)
- assurance of voluntary nature of participation
- assurance that participation or non-participation will not affect medical care

Investigators should remember the difficult emotional and physical circumstances that the patient may be experiencing. Many, if not most, patients welcome the opportunity to participate in research. It is important to remember the following:

- Patients can always refuse to participate, even after having agreed to participate.
- Patients may be surprised to be contacted by an investigator or institution other than the physician(s) and institution(s) with whom they are familiar.

During the patient recruitment phase of the study, the CSP should be notified if any problems arise with contacting patients. Any patient who states that he/she does not wish to be contacted
again by future research studies must be reported promptly (within 24 hours) to the Administrator of CSP Studies or Director; this fact will be recorded in the CCR database. Please report these events on the form provided (Appendix 9).

E. INVESTIGATOR REPORTING REQUIREMENTS AND OBTAINING UPDATES

1) **Patient data changes:** The investigator must notify the CSP if he or she becomes aware of errors or omissions in the CCR data and any more current information on a patient's vital statistics and current address. Please use the Patient Data Change form in Appendix 7 for this purpose.

2) **Return data on non-participants:** The investigator must return the names and contact information of all patients who were not included as subjects for the study to the CSP within six months of receipt. The reason for non-inclusion, e.g. decline to participate, unable to locate, physician advised no contact, not eligible, etc. should be specified for each patient. Please use the format specified in Appendix 8 for this purpose.

3) **Provide dates of participation:** The investigator must inform the CSP of the date of participation of all patients who do participate in their study. This will allow determination of when these patients would be eligible for future studies. However, if the investigator plans to re-contact their patients for follow-up interviews, **then the CSP should be informed of this plan**, so that the patients would not be provided to future studies. **If the investigator does not notify the CSP that they plan to re-contact patients, it will be assumed that they do not plan to do so and the patients can be released to other studies after a year.** Please use the format specified in Appendix 8 for this purpose.

4) **Notification of end of RCA selection:** If the patients are being selected through RCA, please notify the Administrator of CSP Studies one month before case ascertainment activity is scheduled to end.

5) **No contact form:** *If a patient expresses extreme distress when contacted about participation in any study, this should be reported immediately (within 24 hours) to the Administrator of CSP Studies or Director (see page 6). If a patient does not wish to participate in ANY study, submit the Patient No Contact Form (Appendix 9).*

6) **Obtaining updates from the CSP:** During the course of the study you may wish to obtain updates (e.g., vital status) on your cases. Refer to Appendix 8, for the procedures to follow.

7) **Provision of IRB and CPHS updates:** Please provide the CSP with copies of updated IRB approvals from both the institution and the CPHS.
PART 2: PROCEDURES FOR STUDIES THAT DO NOT INVOLVE PATIENT CONTACT

Checklist
(These items are described in this section and must be completed or obtained before a study may commence.)

1. **CSP Form B (Appendix 2):** Description of records being requested, investigator contact information, and abstract of study.

2. **CSP Approval Letter:** Will be issued if requested for grant application and will provide CSP commitment to provide data for the study and cost associated with it.

3. **Obtain and provide a copy of your institution’s IRB approval.**

4. **Obtain and provide a copy of the approval from the State IRB (Committee for the Protection of Human Subjects -CPHS) (Appendix 11).**
   For all studies using registry data, CPHS approval is required. Investigators are required to obtain CPHS approval by submitting the necessary documents to the state (See Appendix 11).

5. Obtain approval from the California Cancer Registry (CCR) (Appendix 12),. To obtain CCR approval, the investigator (and institutional representative) must sign the most current version of the CCR Appendix 3. **The CSP will facilitate obtaining CCR approval, by submitting a cover letter, copies of institutional IRB approval and CPHS approval, and the signed CCR Appendix 3 to the CCR.**

6. **Sign the CSP Research Agreement (Appendix 3)**

7. **Sign the CSP Confidentiality Pledge (Appendix 4)**

8. **Meeting or discussion with CSP staff** to finalize data request.
A. STEPS IN PLANNING/PROPOSING STUDIES THAT DO NOT INVOLVE PATIENT CONTACT

1) Contact CSP.
It is important to contact the CSP to discuss your proposed study. We can provide you with descriptions of variables and assist with planning your data request. Also there are costs involved that you should be aware of (for file provision) and IRB (both institution and CPHS) and CCR approvals are required for these studies as well as those that involve patient contact. The current (2014) cost of a file provision is $2,500 and the cost of a linkage of another file with the CSP database that involves use of probability matching software is $5,000 (costs subject to change).

2) Complete CSP Form B (Appendix 2).
This form specifies the type of study (file provision or record linkage) and asks for the details of the file that you are requesting, the for investigator contact information, and requests that you provide an abstract of your study and specify variables that you wish to obtain (Appendix 6). Please email (preferred) or mail your completed form to Dr. Hamilton (ahamilt@med.usc.edu). Your study will be assigned a CSP ID number. Please use this number when referring to your study in future correspondence with the CSP.

B. STEPS IN THE INITIATION OF NEW STUDIES ONCE FUNDING IS OBTAINED

1) Notify the CSP that the study has been funded.
Once the study is approved and funded, notify the CSP (Dr. Hamilton) as soon as the study commencement date is known.

2. Obtain and provide a copy of your institution’s IRB approval.

3. Obtain and provide a copy of the approval from the State IRB (Committee for the Protection of Human Subjects -CPHS) (Appendix 11).
For all studies using registry data, CPHS approval is required. Investigators are required to obtain CPHS approval by submitting the necessary documents to the state (See Appendix 11).

4. Obtain approval from the California Cancer Registry (CCR) (Appendix 12), To obtain CCR approval, the investigator (and institutional representative) must sign the most current version of the CCR Appendix 3. The CSP will facilitate obtaining CCR approval, by submitting a cover letter, copies of institutional IRB approval and CPHS approval, and the signed CCR Appendix 3 to the CCR.

5. Sign the CSP Research Agreement (Appendix 3)

6. Sign the CSP Confidentiality Pledge (Appendix 4)
7) Review the specifications on CSP Form B to assure that you will be getting the correct file for your study.

8) Contact CSP to obtain file or provide data for linkage.
C. INVESTIGATOR’S RESPONSIBILITY FOR MAINTAINING CONFIDENTIALITY OF PATIENT RECORDS

1) Have all of your study personnel who will have access to information that identifies individual cancer patients sign the CSP Confidentiality Pledge (Appendix 4), and provide originals to the CSP.

2) Have all of the study personnel who will have access to information that identifies individual cancer patients sign the CCR Appendix 2 (which is to be kept on file by the investigator).

3) All listings of cases, copies of reports and any other materials that include confidential information must be kept in locked file drawers when not in use. Computer files must be stored on secured systems.

D. INVESTIGATOR REPORTING REQUIREMENTS AND OBTAINING UPDATES

1) **Data changes:** The investigator must notify the CSP if he or she becomes aware of errors or omissions in the CCR data and any more current information on a patient's vital statistics and current address. Please use the Patient Data Change form in Appendix 7 for this purpose.

2) **Obtaining updates from the CSP.** During the course of the study you may wish to obtain updates (e.g., vital status) on your cases. Refer to Appendix 8, for the procedures to follow.

3) ) **Provision of IRB and CPHS updates :**Please provide the CSP with copies of updated institutional IRB and CPHS approvals
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Appendix 1
CSP FORM A: Studies Involving Patient Contact (3 pages)
This form is to be used to initially request, and/or change a previous request for casefinding. Please complete the following and send to Ann Hamilton, Ph.D, Keck School of Medicine of USC, via the CSP Secure Cancer Researcher Portal.(or to ahamilt@med.usc.edu).

Study Title: _______________________________________________________________________

Investigator: ___________________________________________ Today’s date: _____________

Primary site and/or histology: _______________________________________________________

Please check parameters of the cases being requested:

Disease extent:
- Invasive? ○ Yes ○ No
- In Situ? ○ Yes ○ No

Sex: ○ Male ○ Female ○ Male and Female

Race: ○ White ○ Hispanic ○ Black ○ Asian ○ Other (specify) _______________ ○ All

Age range: From ________________ To ________________

Vital Status: ○ Alive ○ Alive or Dead

Other (specify): ___________________________________________________________________

Combinations of above variables (if applicable): _______________________________________

_______________________________________________________________________________

Ascertainment Time Period: Please state in terms of the diagnosis date the beginning month and year, and ending month and year of the desired ascertainment period.

From ________________ To ________________

Estimated sample size: _______________________

Reporting mechanism: ○ Routine ○ Rapid Case Ascertainment (RCA) (additional cost)

Type of Patient Contact:
Do you wish to contact patients for: Release of medical records: ○ Yes ○ No
- Collection of biological specimens: ○ Yes ○ No
- Interview: ○ Yes ○ No

Estimated date cases will be needed: _______________________

Type of file requested: _ ○ ASCII ○ Excel
Investigator contact information

Principal Investigator Name ______________________________ Degree __________
Title __________________________________________________________________________
Email address ______________________________________________________________________
Institution ____________________________ Phone # __________________
Address __________________________________________________________________________

Co-Investigator Name ______________________________ Degree __________
Title __________________________________________________________________________
Email address ______________________________________________________________________
Institution ____________________________ Phone # __________________
Address __________________________________________________________________________

Primary Contact Person Name ______________________________ Degree __________
Title __________________________________________________________________________
Email address ______________________________________________________________________
Institution ____________________________ Phone # __________________
Address __________________________________________________________________________
CSP Form A: Page 3 of 3

Additional Study Information

**Grant Status:**  ○ Planning stage; ○ Submitted to Agency; ○ Funded; ○ Not grant supported

Grant start date: ________________________  Grant end date: ________________________

**Funding Agency:** _____________________________________________________________

**Total Cost of Project:** $ ________________________

**Institutional IRB Approval #**: ________________________  Date of Approval: ________________  Date of Expiration: ________________

**CPHS Approval #**: ________________________  Date of Approval: ________________  Date of Expiration: ________________

**CCR Approval:** Date received: __________________________________________

**Is this study a continuation of, or linked with, any other CSP Study:**  ○ Yes  ○ No

If Yes: Specify: __________________________________________________________________

**Study Abstract:** (can be sent as separate page from grant proposal, send via the CSP Secure Cancer Researcher Portal)

*Send copy of Institutional IRB Approval, CPHS approval, and signed CCR Appendix 3 via the CSP Secure Cancer Researcher Portal (or to ahamilt@med.usc.edu).*
Appendix 2
CSP FORM B: Studies NOT Involving Patient Contact (3 pages)
This form is to be used to initially request, and/or change a previous request for casefinding. Please complete the following and send to Ann Hamilton, Ph.D, Keck School of Medicine of USC, via the CSP Secure Cancer Researcher Portal (or to ahamilt@med.usc.edu).

Study Title: __________________________________________________________

Investigator: ___________________________________________ Today’s date: __________

Type of Project:
1)  ○ Request for file with individual records to be analyzed by investigator (see below)

2)  ○ Request to link another file to CSP records by using matching variables and receive back a file with the matched cases and other variables (go to next page)

If Type 1 (request for file with individual records): Please check parameters of the cases being requested:

Primary site and/or histology: __________________________________________

Disease extent:
Invasive?  ○ Yes  ○ No
In Situ?  ○ Yes  ○ No

Sex:  ○ Male  ○ Female  ○ Male and Female

Race:  ○ White  ○ Hispanic  ○ Black  ○ Asian  ○ Other (specify) ________________  ○ All

Age range: From ________________ To ________________

Vital Status:  ○ Alive  ○ Alive or Dead

Other (specify):

Combinations of above variables (if applicable):

________________________________________________________________________

Diagnosis Dates: From ________________ To ________________
Month/ Year  Month/ Year

Additional Variables requested: Send CSP variable listing (Appendix 6) with variables checked that are being requested, via the CSP Secure Cancer Researcher Portal.

Estimated sample size: _______________________

Estimated date file will be needed: _______________________

Keck School of Medicine of USC
2001 N. Soto Street, SSB305
Los Angeles, CA 90089-9238*

Tel. (323) 442-2300 Fax (323) 442-2301
*for courier, use zip code 90032
If Type 2 (Linkage Study):

Describe file to be linked to CSP data:
Source of file ________________________________________________________________
Number of records ____________________________________________________________
Dates of records: From: ___________________ To: ________________________________
Number of linkages expected (if estimate is available): _________________________

Specific Cancer Sites Being Studied: Specify: ___________________ All sites: ______

Variables available for linkage: First name:_____ ; Middle name or initial:___ ; Last
Name:________
Birth date:_____; SSN:_____; Diagnosis date:_____ ; Address:_________; Zip
Code:_______;
RCA number:_______ ; Region number:_____ ; Other?
Specify:______________________________________________________________

Type of matching requested: Probability:_______ ; Record Merge:_______ Manual:_______

Method to resolve uncertain matches: CSP to resolve:_______ , Investigator to resolve:_____

Variables to be provided to investigator with matches (Send CSP variable listing (Appendix 6)
with variables checked that are being requested, via CSP Secure Cancer Reporting Portal).

Estimated date file will be needed: ____________________________

Type of file requested: _ O ASCII O Excel

For All Studies:
Investigator contact information

Principal Investigator Name ______________________________________________________
Degree ____________________
Co-Investigator Name

Title

Email address

Institution

Phone #

Address

Primary Contact Person Name

Title

Email address

Institution

Phone #

Address

Additional Study Information

Grant Status:  ○ Planning stage;  ○ Submitted to Agency;  ○ Funded;  ○ Not grant supported

Grant start date: ___________________________  Grant end date: ___________________________

Funding Agency:

Total Cost of Project:  $ ___________________________
Institutional IRB Approval #: _______________ Date of Approval: _______________

Date of Expiration: _______________

CPHS Approval #: _______________ Date of Approval: _______________

Date of Expiration: _______________

CCR Approval: Date received: ________________________________

: _______________

Is this study a continuation of, or linked with, any other CSP Study:  ○ Yes  ○ No

If Yes: Specify: ________________________________

Study Abstract: (can be inserted from grant proposal)

Please send separately via the CSP Secure Cancer Researcher Portal.

*Send copies of Institutional IRB Approval, CPHS Approval, and signed Appendix 3 via CSP Secure Cancer Researcher Portal (or to ahamilt@med.usc.edu).
APPENDIX 3: CSP RESEARCH AGREEMENT

This agreement is entered into this____ day of ______, 20____ , by and between the University of Southern California (USC) Cancer Surveillance Program, hereinafter referred to as the CSP, and __________________, hereinafter referred to as the Investigator.

The purpose of this collaboration is to engage in research into the causes, control or prevention of cancer.

This agreement is entered under the authority of Assembly Bill 136 and California Health and Safety Code sections 103875-103885. Both parties understand that data access authorized by this agreement is to occur in accordance with all applicable sections of the Health and Safety Code including penalties and with the following provisions:

1. The CSP agrees to provide the Investigator confidential information on selected cancer patients in Los Angeles County.

2. The confidential information will be transferred by secure electronic or traceable delivery service.

3. The Investigator will comply with all policies described in the Procedure Guide for Studies that Request and Utilize Confidential Data from the Cancer Surveillance Program (CSP).

4. The Investigator agrees to not disclose or release the confidential data obtained from the CSP to any other party or for any other use than that specified in the research protocol provided to the CSP.

5. The CSP agrees to hold harmless, indemnify and defend the Investigator from all liabilities, demands, expenses or losses arising out of performance of this agreement, except to the extent where such liabilities, demands, damages, expenses or losses are the result of the Investigator's negligence or willful misconduct.

The Investigator agrees to hold harmless, indemnify and defend the CSP from all liabilities, demands, expenses or losses arising out of performance of this agreement, except to the extent where such liabilities, demands, damages, expenses or losses are the result of the CSP's negligence or willful misconduct.

6. Either party may terminate this agreement upon written notification of the other party.

This agreement is hereby executed by the following parties:

The Investigator:

_______________________         ______________
Name               Date   ________________________

University of Southern California
Cancer Surveillance Program:

_______________________
_______________________
Name               Date   ________________________

Keck School of Medicine of USC
2001 N. Soto Street, SSB305
Los Angeles, CA 90089-9238*

Tel. (323) 442-2300 Fax (323) 442-2301
*for courier, use zip code 90032

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Appendix 4

CSP CONFIDENTIALITY PLEDGE

I recognize the importance of maintaining the confidentiality of all data collected by the USC Cancer Surveillance Program (CSP) and of assuring the right to privacy of persons whose records I receive.

I understand that, under California law, all individual level data are considered confidential regardless of whether the individual, hospital(s) or physician(s) is named or otherwise identifiable.

I therefore agree to protect the confidentiality of the data in accordance with the following requirements:

I will avoid any action that will provide confidential information to any unauthorized individual or agency.

I will not make copies of any confidential records or data except as specifically authorized.

I will not remove confidential identifying information from my place of employment except as authorized in the performance of my duties.

I will not discuss in any manner, with any unauthorized person, information that would lead to identification of individuals described in confidential files or data.

I will use confidential files and data only for purposes for which I am specifically authorized.

I will not provide any computer password or file access codes which protect these data to any unauthorized person.

If I observe unauthorized access or divulgence of confidential data or records to other persons, I will report it immediately to the CSP. I understand that failure to report violations of confidentiality by others is just as serious as my own violation and may result in civil or criminal penalties and termination of current and future access to confidential data.

I therefore pledge that I will not divulge to any unauthorized person confidential information or data obtained from the Cancer Surveillance Program files.

Name: ___________________________  Print: ___________________________

Signature: ________________________

Date: ____________________________

Keck School of Medicine of USC
2001 N. Soto Street, SSB305
Los Angeles, CA 90089-9238*

Tel. (323) 442-2300 Fax (323) 442-2301
*for courier, use zip code 90032
Appendix 5
THE RAPID CASE ASCERTAINMENT (RCA) PROCESS

The CSP has an experienced staff of Field Technicians who are assigned to each hospital in Los Angeles County. They screen pathology at their assigned hospitals on a regular basis (at least monthly) and review all pathology reports that have been produced since their previous visit to identify new cancer cases. When requested to do so for a specific study, they will select pathology reports that meet a study’s selection criteria.

The pathology report contains little demographic information, usually limited to:
- name, first and last
- patient MRN number
- requesting physician’s name

This information is usually insufficient to determine whether the patient meets study eligibility requirements or to make contact with the patient. Upon identification of potential RCA cases, demographic information is obtained by the CSP Field Technician for each patient from the hospital’s admission record.

The pertinent demographic information obtained includes:
- patient address
- phone number
- sex
- race/ethnicity
- birthdate
- birthplace (if available)
- social security number (if available)
- vital status (if available)
- religion (if available)

These items are captured along with the scanned pathology report by the CSP field technician. (Collection of additional data items incurs additional cost and must be determined before the study is funded.) With the implementation of e-path (collection of pathology reports electronically), the demographic data listed above is printed directly on the pathology report. The pathology reports, with the demographics, are available to investigators on average within 44 days after diagnosis. Photocopies of the reports are delivered to study investigators.

For each selected pathology report, the CSP master file is searched to identify those patients with a previous cancer diagnosis of that cancer or any other. Since a patient may be seen at multiple hospitals for their diagnosis and treatment of their cancer it is possible (and likely) that more than one pathology report per patient will be obtained by the CSP Field Technicians. We estimate
that on average, 1.7 path reports/patient are obtained for each tumor, although this figure varies by cancer site. The investigator should develop their own procedures to identify multiple reports for the same patient. **A bar code label with the Rapid Case identification number is attached to the pathology report.**

All cases identified are entered into the CSP’s RCA database. The rapid case ascertainment database tracking system includes:

- patient name
- birthdate
- SSN
- reporting hospital
- pathology report date
- specimen number
- RCA study number
- date of ascertainment by CSP
- date pathology report was sent to study investigator

The investigator should be aware that the **RCA process identifies pathologically-confirmed tumors of patients seen at hospitals.** Thus, RCA does not identify:

- non-pathologically-confirmed tumors
- hospitals outside of Los Angeles County
- Veteran’s administration hospitals.

This proportion varies by disease; contact the RCA Coordinator for more details. If the investigator wishes to determine the number and characteristics of cases not identified by the RCA process, they may do so by reviewing monthly case listings. As complete hospital reports are added to the CSP Master File (averaging 9 months after diagnosis) all eligible patients are listed on monthly case listings. **Investigators can review these listings for any cases which have not been previously obtained by RCA. Investigators should promptly discuss any possible missed RCA case with the RCA Coordinator to ensure complete ascertainment.**

In addition to an eligible patient listing, a computer file of the most frequently requested data items (Appendix 8: CSP Data Interchange Format) may be requested by the investigator.
Appendix 6: CSP Variable Listing

Tumor data items

AGE    Age at Diagnosis
AGE_GRP Age Group
AJCSTAG_DER Derived AJCC Stage Group (DX 2004 or Later)
AMBIG_TERM_DX Ambiguous Terminology Diagnosis (DX>2006)
BEH3 Behavior Code (ICD-O, 3rd Edition)
BLK_GRP Census Tract Block Group
BLK_GRP00 2000 Census Block Group
CASEFIND Casefinding Source
CENSUS00 2000 Census Tract
CENSUS80 1980 Census Tract
CENSUS90 1990 Census Tract
CENS_CITY 2000 Census City Code
CHEMOSUM Chemotherapy Summary
COUNTY County of Residence at Dx
CS_LNSUM_EVAL CS Lymph Nodes Evaluation-Path/Clinical (DX 2004 or Later)
CS_METS_EVAL CS Metastasis At Diagnosis Evaluation-Path/Clinical (DX 2004 or Later)
CS_TUSIZE_EVAL CS Tumor Size/Extent Evaluation-Path/Clinical (DX 2004 or Later)
CTBAS00 2000 Census Certainty
CT_BASIS Basis for Census Tract
DATEDX Date of Diagnosis
DATE_SURG_PRIM_FIRST Date of First Primary Surgery (DX>2006)
DIFFERN2 Grade/Differentiation (ICD-O, 2nd Edition)
DIREXT Extent of Disease - Extension
DIREXT_CS CS Extent of Disease - Extension (DX 2004 or Later)
DXADDR Address of Diagnosis - Street
DXCITY Address of Diagnosis - City
DXCONF Diagnostic Confirmation
DXSTATE Address of Diagnosis - State
DXZIP Address of Diagnosis - Zip Code
EXNODES Number of Regional Lymph Nodes Examined-Surgery Summary
FIND Father's Industry (CSP)
FOCC Father's Occupation (CSP)
HISTO3ED Histology (ICD-O, 3rd Edition)
HORMSUM Hormone Therapy Summary
HOSP_DEF_SURG Hospital Definitive Surgery (DX>2006)
HOSP_FIRST_SURG Hospital First Surgery (DX>2006)
IMMUSUM Immunotherapy Summary
IND70 1970 Industry Code (CSP)
IND80 1980 Industry Code
LASTFUTU Follow Up Last Type (Tumor)
LATERAL Laterality
LATITUDE Latitude
LNSUM Extent of Disease-Lymph Node Involvement
LNSUM_CS CS Ext of Disease-Lymph Node Involvement (DX 2004 or Later)
LONGITUDE Longitude
MARKER1 Tumor Marker 1 (ERA) (DX < 2004)
MARKER2 Tumor Marker 2 (PRA) (DX < 2004)
MARKER3 Tumor Marker 3 (DX < 2004)
MARKER_CA1 Tumor Marker 1 (Breast Only)
MARSTAT Marital Status
METS_DX_CS CS Metastasis At Diagnosis (DX 2004 or Later)
MIND Mother's Industry (CSP)
MOCC Mother's Occupation (CSP)
M_CODE_DER Derived AJCC M Code (DX 2004 or Later)
Patient Data Items

BIRTHPL  Birthplace
CADDRESS  Contact Street Address
CADDRESS_CCR  CCR Contact Street Address
CCITY  Contact City
CCR_RACE  CCR Race Code (California)
CDEATH  Cause of Death (ICD-0, 7th Edition)
CNAME  Contact Name
COMPETHN  Computer Derived Ethnicity
CSTATE  Contact State
CTYDEATH  County of Death (CSP)
CZIP  Contact Zip Code
DCFILE#  DC State File Number
DCNUM  DC Local Number
DC_BIRTHPL  DC Birthplace
DC_RACE  DC Race
DC_SPANISH  DC Spanish Origin
DC_SSNO  DC Social Security Number
DOB  Birth Date
ETHNSRC  Computed Ethnicity Source
FNAME  First Name
FUCADDRESS_CCR  CCR Follow Up Contact Address
FUCN_ADDR  Follow Up Contact Street Address - Other
FUCN_CITY  Follow Up Contact City - Other
FUCN_NAME  Follow Up Contact Name - Other
FUCN_STATE  Follow Up Contact State - Other
FUCN_ZIP  Follow Up Contact Zip Code - Other
FUDATE  Date of Last Patient Contact or Death
LASTFU  Follow Up Last Type (Patient)
LNAME  Last Name
LSTFUHSP  Follow Up Hospital
MIDLNAME  Middle Name
MOM_FNAME  Mother's First Name
NAME_SUF  Name Suffix
NHIA  NAACCR Hispanic Identification Algorithm
NPI_PHY_FOLLOW  NPI Physician Follow-up (DX>2006)
PHONE  Telephone
PHONEOWN  Telephone Own
PLDEATH  Place of Death
RACE  Race
RACE2   Multiracial Race #2 (DX >= 2000)
RACE3   Multiracial Race #3 (DX >= 2000)
RACE4   Multiracial Race #4 (DX >= 2000)
RACE5   Multiracial Race #5 (DX >= 2000)
REGIONNO  Region Patient Number
RRACE   Recoded Race (CSP)
RRACE2  Recoded Race2 (CSP)
SEX   Sex
SPANISH  Spanish/Hispanic Origin
SPSUR  Spanish Surname
SSNO   Social Security Number
SSNSUF  Social Security Number Suffix
VITSTA   Vital Status

**Admission Data Items (multiple/patient)**

AKA   Alias Last Name
AKAFN  Alias First Name
CHEMHOSP Chemotherapy at This Hospital
CLASS  Class of Case Indicates Place of DX or RX
CLUSTERNO Hospital Patient Number
DATEAD  Date of First Admission
DOCID   Document ID
DRCODE1  Physician (Attending)
DRCODE2  Physician (Referring)
DRCODE3  Physician (Surgeon)
DRCODE4  Physician (Other)
DRCODE5  Physician (Other)
DRCODE6  Physician (Radiation Oncologist)
DRCODE7  Physician (Medical Oncologist)
FUMD   Physician (Following)
HORMHOSP  Hormone Therapy at This Hospital
HOSPFROM Hospital Referred From
HOSPNO  Hospital Number (Reporting)
HOSPTO  Hospital Referred To
IMMUHOSP  Immunotherapy at This Hospital
MAIDNAME  Maiden Name
MEDRECNO  Medical Record Number (Hospital)
OTHOSP  Other Therapy at This Hospital
PATHNO_BX  Path Number Biopsy
PATHNO_SURG Path Number Surgery
PAYER1  Payor Source (Primary)
PAY_TEXT  Payor Source Text (Primary)
PEDSTAGE  Pediatric Stage
Pedsyst  Pediatric Stage System
PLACEDX  Place of Diagnosis
PROTOCOL_PART  Protocol Participation
RADHOSP Radiation at This Hospital
REGIONNO  Region Patient Number
REGTUMNO Region Tumor Number
SULNEX_PRC1 Surgery of Node-Procedure 1
SULNEX_PRC2 Surgery of Node-Procedure 2
SULNEX_PRC3 Surgery of Node-Procedure 3
SUMARG_PRC1 Surgical Margin-Procedure 1
<table>
<thead>
<tr>
<th>Variable</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>SUMARG_PRC2</td>
<td>Surgical Margin-Procedure 2</td>
</tr>
<tr>
<td>SUMARG_PRC3</td>
<td>Surgical Margin-Procedure 3</td>
</tr>
<tr>
<td>SUOTH_PRC1</td>
<td>Surgery of Other Regional Site-Procedure 1</td>
</tr>
<tr>
<td>SUOTH_PRC2</td>
<td>Surgery of Other Regional Site-Procedure 2</td>
</tr>
<tr>
<td>SUOTH_PRC3</td>
<td>Surgery of Other Regional Site-Procedure 3</td>
</tr>
<tr>
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</tr>
<tr>
<td>SURGDT_PRC2</td>
<td>Date of Surgery-Procedure 2</td>
</tr>
<tr>
<td>SURGDT_PRC3</td>
<td>Date of Surgery-Procedure 3</td>
</tr>
<tr>
<td>SURGHNCD</td>
<td>Surgery at This Hospital - Non-Cancer Directed</td>
</tr>
<tr>
<td>SURGHREC</td>
<td>Surgery at This Hospital - Reconstructive</td>
</tr>
<tr>
<td>SURGHS_PRC1</td>
<td>Surgical Hospital Where Procedure 1 is Done</td>
</tr>
<tr>
<td>SURGHS_PRC2</td>
<td>Surgical Hospital Where Procedure 2 is Done</td>
</tr>
<tr>
<td>SURGHS_PRC3</td>
<td>Surgical Hospital Where Procedure 3 is Done</td>
</tr>
<tr>
<td>SURGNCD</td>
<td>Surgery Summary - Non-Cancer Directed</td>
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<td>SURGPS_HOS</td>
<td>Surgery at This Hospital</td>
</tr>
<tr>
<td>SURGPS_PRC1</td>
<td>Surgery of Primary Site-Procedure 1</td>
</tr>
<tr>
<td>SURGPS_PRC2</td>
<td>Surgery of Primary Site-Procedure 2</td>
</tr>
<tr>
<td>SURGPS_PRC3</td>
<td>Surgery of Primary Site-Procedure 3</td>
</tr>
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<td>Scope of Regional Lymph Node Surgery-Procedure 1</td>
</tr>
<tr>
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<td>Scope of Regional Lymph Node Surgery-Procedure 2</td>
</tr>
<tr>
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<td>Scope of Regional Lymph Node Surgery-Procedure 3</td>
</tr>
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<td>Site Text</td>
</tr>
<tr>
<td>TUMRECNO</td>
<td>Hospital Tumor Record Number</td>
</tr>
<tr>
<td>TYPEADM</td>
<td>Type of Admission</td>
</tr>
<tr>
<td>T_EHOSP</td>
<td>RX Hospital-Transplant/Endocrine Procedures</td>
</tr>
</tbody>
</table>

Coding information for these variables can be found in the CSPedia (cspedia.usc.edu) and in the CCR data dictionary (http://dd.ccr.ca.gov/)
Appendix 7: CSP PATIENT DATA CHANGE FORM

We ascertained that the following information provided by the CSP was missing or incorrect.

Investigator's Name: ____________________________________________________

Study Name: ___________________________________________ CSP Study ID: ____________

Name of person completing this form: _______________________________ Date: ____________

Patient Name: _______________________________________________

Eureka Patient Number (Patient ID___________________ Patient RCA number:__________

(Only fill in the information for the missing or incorrect variables)

**Variable with incorrect or Corrected information**

**missing information**

First Name

Last Name

Vital Status

Date of Death

Date of Birth

Address-Street

Address-City

Address-State

Address-Zip

Telephone Number

Other: ________________

Other: ________________

Other: ________________

Source of correct information (e.g., patient interview, spouse interview, tracing etc.)

______________________________

Please mail or email to:

Donna Morrell, CTR, Cancer Surveillance Program; 2001 N. Soto Street, SSB305;

Los Angeles, CA 90089-9238

Email: dmorrell@usc.edu

Keck School of Medicine of USC

2001 N. Soto Street, SSB305

Los Angeles, CA 90089-9238*
Appendix 8: CSP Data Interchange Format

FOR REPORTING PATIENT CONTACT RESULTS TO CSP OR REQUESTING UPDATES FROM THE CSP ON CASES.

A. For reporting participation and non-participation of patients selected for studies.

Please provide a file (can be in ASCII, excel, or other convenient format) that includes:

1) Patient ID (if applicable)
2) Sequence number (if applicable)
3) RCA number (if applicable)
4) Patient first name
5) Patient last name
6) Date of participation or determination of non-participation
7) Final status code (see codes below)

Codes for final status:
1. Participated in study, no further follow-up planned
2. Participated in study, further follow-up planned
3. Physician refused contact
4. Unable to locate/Lost to follow-up
5. Patient deceased
6. Contacted patient, but too ill or incompetent to participate
7. Contacted or located patient, but ineligible for your study (e.g. did not speak English, too old, lived out of country, in prison, etc.).
8. Patient said they didn’t have cancer
9. Patient refused

B. For requesting an update of vital status or other information on your patients:

Please provide a file (can be in ASCII, excel, or convenient format) that includes:

1) Patient ID (if applicable)
2) Sequence number (if applicable)
3) RCA number (if applicable)
4) Patient first name
5) Patient last name

and specify variables that you need (see Appendix 6).

Please submit all files with password protection to Dr. Ann Hamilton, (ahamilt@med.usc.edu) Cancer Surveillance Program; 2001 N. Soto Street, SSB318E, MC9239, Los Angeles, CA 90089-9239)
Appendix 9:
PATIENT NO CONTACT INFORMATION FORM

All investigators contacting patients whose names have been provided by the Cancer Surveillance Program must notify the CSP immediately if a patient indicates that they do not want to be contacted again for any study. Please fill out all the information listed below and return the form to:

Dennis Deapen, DrPH
Director, Los Angeles Cancer Surveillance Program
University of Southern California
Cancer Surveillance Program;
2001 N. Soto Street, SSB305
Los Angeles, CA 90089-9238

Date ______________________

Patient IDo. ____________________ or RCA Number:__________________

Patient last name ____________________________________________________

Patient first name ____________________________________________________

Name of investigator _________________________________________________

Name of study ______________________________________________________

CSP Study ID number ____________________

Source of information
(patient, spouse, parent) _______________________________________________

Reason given for not wanting to be contacted:

_____________________________________________________________________

_____________________________________________________________________

_____________________________________________________________________

Keck School of Medicine of USC
2001 N. Soto Street, SSB305
Los Angeles, CA 90089-9238*
GUIDELINES FOR PRIORITIZING RESEARCH PROJECTS INVOLVING PATIENTS IDENTIFIED BY THE CCR OR ITS REGIONAL REGISTRIES:

(1) With all projects involving use of confidential data from the CCR, evidence must be presented that approval has been obtained from a federally-designated Institutional Review Board. Depending on the specific procedures of the eight Regional Registries comprising the CCR, investigators might also require approval from one or several Regional Registry External Advisory Committees, depending on whether or not the proposed patient contacts are confined to patients identified by a single Regional Registry.

(2) If patient contacts for a proposed research project overlap with the patient contacts for an existing ongoing project which has met criterion (1) above,

(a) the new project may be folded into the existing project (i.e., necessary information for both projects may be obtained during a single patient contact),

(b) the new project may contact the patient at a later date than the existing project (under these circumstances the investigator of the new project should acknowledge to the patient that this constitutes a second separate study with different goals),

(c) any other mutually agreed upon alternative may be implemented. If no agreement has been reached, a review committee will be established by CARCR comprised of Regional and non-Regional representatives,

(d) the new project may be disapproved entirely.

(3) If multiple institutions are responding to a government RFA or RFP which could result in simultaneous funding to test the same hypothesis using the same patients during the same time frame.

(a) If the Regional Registry itself or its associated investigators (same university department or equivalent) apply and are funded, they will get first priority for patient contact. If the Regional Registry is contacted by outside investigators who also intend to respond to the
RFA or RFP, the Regional Registry must disclose to these other investigators its intent to respond.

(b) If multiple other centers (i.e., other than the Regional Registry) respond to an RFA or RFP and both are funded simultaneously, the first institution which contacts the Regional Registry gets priority. (Providing that criterion (1) has been met).

(4) If multiple institutions are funded simultaneously to study the same patients testing different hypotheses,

(a) The Regional Registry or Associated Investigators get first priority and criterion (2) above is then applied.

(b) If multiple centers other than the Regional Registry are simultaneously funded, the first investigator to have contacted the Regional Registry gets priority and criterion (2) above is applied.

(5) In all cases, the Regional Registry has an obligation to disclose to investigators proposing to study patients identified by the CCR that these guidelines will be imposed and of the priority status of the project being proposed.

Adopted: May 27, 1993
Appendix 11: Steps to obtaining CPHS approval
Investigators must comply with the requirements of the state IRB (Committee for the Protection of Human Subjects or CPHS). The CPHS holds meetings every two months (6 times/year) and materials must generally be submitted about 6 weeks before the meeting. The meeting schedule can be found at:
http://oshpd.ca.gov/General_Info/Public_Meetings.html#CPHS

Investigators must register for an account and submit their studies to CPHS online at:
https://cphs.keyusa.net/

Instructions
For information on how to submit your online protocol on CalPROTECTS, click on the following links:

- Instructions for Researchers:
  http://oshpd.ca.gov/Boards/CPHS/InstructionsforResearchers.pdf#Untitled
- CalPROTECTS User Guide:
- Frequently Asked Questions (FAQs): http://oshpd.ca.gov/Boards/CPHS/faqs.html
Appendix 12: REQUIREMENTS TO OBTAIN CCR APPROVAL

CCR (California Cancer Registry) approval is required for all studies using individual patient information (both patient contact and non-contact studies). The CSP (Dr. Hamilton) will facilitate obtaining CCR approval, which will be requested after approvals from the institutional IRB and the CPHS have been obtained. In addition to these approvals, the investigator and a responsible official from the investigator’s institution must sign the most recent version of the CCR’s Appendix 3.
CCR Appendix 3: Confidentiality Agreement for Disclosure of CCR Data

Access the most current version of the CCR Appendix 3 at:


click on: Appendix 3-electronic

Appendix 2: Confidentiality Agreement for Access to CCR Data

(This form is to be signed by the P.I. to assure that all persons working with the data will maintain confidentiality)

Name of applicant: _____________________________________________________
Title: ________________________________________________________________
Organizational affiliation: _________________________________________________
Street address: ________________________________________________________
City/state/zip code: _______________________________________________________

Instructions
Access to California Cancer Registry (CCR) data (i.e., the right to examine CCR data) is strictly limited under California law. Persons seeking access to CCR data in the custody of the California Department of Public Health, Cancer Surveillance and Research Branch, the Public Health Institute, or a regional registry (hereinafter the “CCR Data Custodian”) must complete this application, sign and submit it to the custodian of the data. Attach additional pages as necessary. Approval will be mailed to Applicant at the address shown above.

1. Applicant requires access to CCR data to engage in the following demographic, epidemiological or other similar studies related to health:
   ____________________________________________________________________
   ____________________________________________________________________
   ____________________________________________________________________

2. The specific purpose for which Applicant will use CCR data and the data files to be accessed (e.g. type(s) of cancer, patient characteristics, diagnosis years, geographical areas) and other relevant information are:
   ____________________________________________________________________
   ____________________________________________________________________
   ____________________________________________________________________

3. Applicant’s qualifications to engage in these activities are as follows:
   ____________________________________________________________________
4. In consideration for CCR Data Custodian's approval of this application, Applicant represents, warrants, and agrees as follows:

a. For purposes of this confidentiality agreement, "CCR data" means 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).

b. 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 Applicant. Applicant represents and warrants that: (a) Applicant has 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.ccrcal.org) (hereinafter "CCR Data Access and Disclosure Policies"), and the terms and conditions of this confidentiality agreement; (b) Applicant has had a full opportunity to discuss any questions or concerns Applicant may have regarding the interpretation of section 103885, Applicant's duties and obligations under the statute and the terms and conditions of this confidentiality agreement with Custodian; (c) any such questions or concerns have been resolved to Applicant's satisfaction; and (d) on the basis of the foregoing review and discussions, Applicant is prepared to access and use CCR data in conformity with section 103885 and the terms and conditions of this confidentiality agreement.

c. Applicant 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.

d. Applicant agrees to access and use the requested CCR data in strict conformity with the specific purposes set forth in his or her application. Applicant agrees not to use the CCR data for any other purpose. Applicant agrees not to copy or reproduce the CCR data in whole or in part, in any manner or format, or permit others to do so.

e. Applicant may describe the results of Applicant's use of CCR data in professional journals, public reports, presentations, press releases and other publications, provided that a copy is provided to the institution from which Applicant receives access and that all publications contain the acknowledgment and disclaimer set forth in section VI.4. of the CCR Data Access and Disclosure Policies.

f. If Applicant becomes aware that any person or institution not authorized to access CCR data has attempted to gain access or gained access to the CCR data, Applicant agrees to immediately notify CCR Data Custodian. If Applicant inadvertently gains access to CCR data for which he or she has not been approved, Applicant agrees not to make use of the data, not disclose the data to any other person or institution, to notify the CCR data custodian, and take immediate steps to prevent any recurrence.
g. CCR Data Custodian reserves the right to withdraw Applicant's right to access and use CCR data at any
time without cause. Upon receipt of notice thereof, Applicant agrees to immediately terminate its
access to and use of CCR data.

h. Applicant acknowledges that if he or she fails to comply with any of Applicant's obligations under this
confidentiality agreement, CCR Data Custodian and the State of California will suffer immediate,
irreparable harm for which monetary damages will not be adequate. Applicant agrees that, in addition to
any other remedies provided at law or in equity, CCR Data Custodian and the State of California shall be
entitled to injunctive relief to enforce the provisions of this agreement.

i. Notwithstanding any other provision of this confidentiality agreement, CCR Data Custodian shall have
no obligation to grant Applicant access to CCR data unless and until his or her application is approved.

By my signature I declare as follows:

I have read the foregoing agreement. By signing below I make the agreements and representations contained
therein. I understand that these are material representations of fact upon which reliance was placed when this
transaction was entered into.

__________________________________
Signature

__________________________________ ___________________
Printed Name and Title Dated

APPROVAL BY CCR DATA CUSTODIAN:

__________________________________
Signature Dated

__________________________________
Printed Name and Title
Appendix 14

SAMPLE PATIENT CONTACT LETTER
(SurveyDesign)

Dear Mr./Mrs. _________________:

We are writing to ask you for your help in a very important study being conducted by ________. The purpose of this study is to learn more about factors that may be related to the development of ____ cancer in ______________.

Required language:
Your name was obtained from the Los Angeles Cancer Surveillance Program, a member of the California Cancer Registry, which was created by the California Legislature in response to public concern that not enough was being done to find the causes and cures of cancer (See enclosed CCR brochure). Every cancer diagnosed in California is required by law to be reported to the California Department of Health Services, which is responsible for the registry. Information on individuals with cancer can only be released for research purposes to qualified researchers who have obtained approval for the study from a federally approved Committee for the Protection of Human Subjects, and have agreed to maintain the confidentiality of the information they collect. We did not obtain your name from your health care provider.

The study would involve answering some questions regarding your lifetime exposures to environmental factors, past illnesses, and habits. The survey should take about ___ minutes and your participation is entirely voluntary. Your decision whether or not to participate in this study will have no impact on your medical care. All information will be kept strictly confidential and is protected by law.

Your assistance in this effort is very much appreciated as the validity of this type of study depends on being able to interview as many patients as possible. If you have questions at this time, please call the study office at ___________.

Sincerely,

Investigator
Title
Institution
Appendix 16

HOW DID YOU GET MY NAME? QUESTIONS AND ANSWERS

Q: How did you get my name?
A: Like many other diseases, cancer is a reportable disease in California. This means that, by state law, a report of all cancer diagnoses must be prepared by the hospital or physician for use by the State health department. The law requires cancer reports to be collected by a regional cancer registry. For Los Angeles County, the regional registry is the Cancer Surveillance Program at USC. After the investigator’s institution’s IRB, the California State IRB (Committee for the Protection of Human Subjects), and the California Cancer Registry approved this study, your name was provided to Dr. (Investigator) to invite your participation.

Q: Why is cancer reportable?
A: The California Legislature, the State health department and many Californians place a high priority on seeking the causes of and methods for prevention of cancer. A statewide system of cancer registration provides a complete and timely mechanism for conducting research into cancer patterns and trends.

Q: Can I remove my name from the State cancer registry?
A: While the law includes no provision for removing a report from the registry, individuals may request that they not be contacted for research studies.

Q: Why didn't the hospital tell me about cancer registration?
A: Hospitals are required to provide notification of the reportability of cancer in California. Some hospitals post notices on a wall; others include this notification on admitting forms.

Q: Why are you contacting me? I don’t have cancer
A: We apologize as sometimes we may have incorrect contact information and have contacted you by mistake. If you have any further questions, please check with your doctor.
Appendix 17: CCR Brochure