Principles and Protocols for the Release of South Carolina Central Cancer Registry (SCCCR) Data

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Principles and Protocols for the Release of SCCCR Data Cancer Data Required by Section 44-35-30

I. INTRODUCTION

The South Carolina Department of Public Health (DPH), South Carolina Central Cancer Registry (SCCCR), and the Cancer Control Advisory Committee (CCAC) believe that an effective cancer control program should mobilize the scientific, educational, and medical resources that presently exist against cancer. Section 44-35-20, SC Code of Laws, 1996, established the SCCCR at DPH to record all reportable cases of cancer occurring in SC residents on or after January 1, 1996. DPH, SCCCR and the CCAC also believe in a policy of access that allows the broadest possible use of cancer data for health care facilities, physicians and other health care professionals, researchers and other governmental agencies. Effective use of this information for research to advance knowledge about cancer may require the use of confidential case identifiers. The sensitive nature of these data necessitates that measures be taken to ensure the security of the data. Two fundamental goals of the SCCCR are data confidentiality and integrity.

Confidentiality controls access to cancer data and ensures absolute confidentiality for individual patients, as well as appropriate confidentiality for health care facilities and physicians. Integrity of the databases or the accuracy, reliability and timeliness of the data means data provided must be of the highest caliber.

II. PRINCIPLES

- The right to privacy is a basic right of every South Carolinian. The confidentiality of the patient shall be of the utmost concern. The release or re-release of data, in raw or aggregate form, that can be reasonably expected to reveal the identity of an individual

patient will be made only when strict established protocols are met.

- The policy of the SCCCR shall be to make determinations on requests for information in favor of access, subject to the specific limitations concerning confidentiality, security and accuracy.
- The DPH CCAC believes that cancer registry data will guide cancer control efforts in the state by promoting prevention and early detection of cancer, extending the life of the cancer patient, identifying high-risk groups or areas with clusters of cancer cases, and improving cancer patient care. DPH and CCAC believe that these efforts will reduce morbidity and mortality from cancer in South Carolina.

III. DATA RELEASE PROTOCOL

CLASSIFICATION AND RELEASE OF DATA

To balance the principles of access and confidentiality, the SCCCR has classified the release of data collected under Section 44-35-30, SC Code of Laws, 1996. This classification scheme aims to promote the use of accurate cancer data, provide equal treatment of data requesters and data providers, expedite the release and processing, and encourage the release of the broad spectrum of data elements without compromising confidentiality. The data release classifications include two categories: unrestricted data and confidential data.

- Unrestricted data are those data elements or combinations of elements that are entirely descriptive, provided in aggregate form, excluding any patient, physician, or facility identifiers.
- Restricted/Confidential data, as hereby defined as restricted data items, are those elements that allow identification of patients, facilities, and/or physicians. There are occasions when data elements normally considered unrestricted could indirectly identify patients when reported together; e.g., race, age, and zip code

where the racial category constitutes a small minority of the zip code. Therefore, each request must be carefully scrutinized and categorized appropriately. Data cells including 1 to 4 observations will be reported as <5*. Data cells including 5 to 9 observations will be rounded to 10*.

B. UNRESTRICTED DATA RELEASE

Researchers requesting unrestricted or non-confidential data should visit the SC Tracking Cancer Dashboard or contact the SCCCR. The SC Tracking Cancer Dashboard displays recently available cancer statistics using different charts and maps and can be viewed here: https://dph.sc.gov/professionals/public-health-data/sc-tracking/sc-tracking-dashboards

If researchers require additional data, the SCCCR will release unrestricted data which are subject to the confidentiality provisions set forth in DPH Regulations. Examples of unrestricted data release include rates or percentages of cases by cancer type and/or geographic area, age, or stage distributions. Depending on the complexity of the data request, the SCCCR has the authority to require additional information. If the SCCCR has any concerns about unrestricted data requests, it will seek guidance from the Director of the Bureau of Chronic Disease and Injury Prevention, the CCAC Chair, or DPH legal staff.

Suppression rules will be applied when necessary. Suppression rules are as follows: cells with less than 5 cases are marked as <5*; cells with 5-9 cases are rounded up to 10*. Rates with fewer than 15 cases will be suppressed because small numbers make rates unstable.

REPORTS APPROVED FOR RELEASE

Standard annual reports: Standardized annual reports will be available that include a comprehensive summary of the cancer incidence and mortality experience in SC. The report will include cancer case frequencies by primary site/histologic type category, sex, age group, and race. This report will provide population-based incidence and mortality rates, tabulated by site groupings, age, sex and county. Suppression rules will be applied when necessary.

Suppression rules are as follows: cells with less than 5 cases are marked as <5; cells with 5-9 cases are rounded up to 10. Rates with fewer than 15 cases will be suppressed because small numbers make rates unstable.

Reports to hospitals, physicians, and other reporting facilities: A summary of cases submitted from each reporting facility/physician will be provided to that facility on an annual basis. No information provided by or descriptive of one facility/physician will be provided to another.

Other government agencies: The SCCCR reports may be used by other governmental agencies in the effort to reduce morbidity and mortality due to cancer; to investigate suspected cancer clusters, to monitor high-risk health problems, and to assess cancer prevention projects.

C. RESTRICTED/CONFIDENTIAL DATA RELEASE

Confidential data refers to data items that pertain to who, where, and when, or to aggregate data resulting in cell sizes less than 10 or rates based on fewer than 16 cases. Some examples include variables associated with patient, physician, & hospital or treatment center *names, facility numbers or ids,* and *locations,* etc. Facility and/or physician names, numbers and IDs are prohibited from release. Month and year of diagnosis may be released with strong justification of need. Specific cause of death will not be released but may be categorized as cancer cause of death or non-cancer cause of death. Address or location information more specific than *county* is considered confidential. Aggregate census tract data may be released only with the proper approvals and clear justification. If these data are to be used for mapping purposes, all maps and ranges of rates to be used must be approved by the SCCCR. Counts less than 10 and rates based on counts less than 16 may not be mapped. Confidential data or data items are provided only for CCACSS approved projects that show justification that the research project cannot be completed without them (e.g., patient contact, data linkages, distance to care, etc). To assist in limiting the use of confidential data items, the SCCCR *may* be able to calculate *time to event* variables (e.g.,

survival time) in lieu of providing complete dates, or calculate distance variables in lieu of locations depending on the specific project and availability of resources, or suggest methods (recoding options) to provide data that will satisfy data needs while retaining the confidential aspects of the data.

All research data sets shall be stored on a password protected server or computer. Only those individuals specified in the Data Sharing/Use Agreement shall have access to the data.

Requests for confidential and non-confidential data items must have Institutional Review Board (IRB) approval from their affiliated organization before a request is made to the registry. Applications for the release of confidential data elements include items that allow identification of patients, and must be submitted to the SCCCR with documentation including, but not limited to the following: a list of the requested data elements, time period for the requested data elements and study protocol, intended uses of the data, policies for the protection of the confidential data elements, and a Data Sharing Agreement signed by the investigators. Data requests may include multiple years of prospective data, for the same research protocol, so that an application need not be filed for each year. It is the policy and practice of the SCCCR to provide technical assistance to applicants to assist in the application process.

The current classification of data elements will be periodically reviewed. New data elements will be reviewed and classified by the Cancer Control Advisory Committee Surveillance Subcommittee (CCACSS). Until new data elements are classified, they will be considered confidential data and will be subject to the Data Release Protocol.

1. Special Research Requests

A special research request specifies release of confidential data elements in a manner that would allow the identification of patients and/or health care facilities and/or professionals. If the

special request requires the SCCCR to aggregate the data by a confidential data element but not release the confidential data element, the request will be handled as a release of unrestricted data, so long as the confidentiality of patients and/or health care facilities and/or professionals will not be compromised. All applicants for special research requests will submit to the SCCCR the required application. Prior to submitting an application, applicants should contact the SCCCR to discuss the planned research request.

Upon receipt of a completed application, the SCCCR will determine if the request is for research. If the research application requires confidential data, the CCACSS will review the application. If the CCACSS approves, the SCCCR will forward the documentation to the Department of Public Health Institutional Review Board (DPH IRB).

Notification of CCACSS approval will be provided after CCACSS review (at the time of DPH IRB review). If the DPH IRB approves the request, the applicants will be notified and the SCCCR will comply with the data requests in a timely manner.

If the CCACSS does not approve the request, it will supply the applicants with its rationale for disapproval. The applicant may revise the application based on the CCACSS comments and resubmit it to the SCCCR. If an application is for non-research purposes, including legal, administrative or other actions that might directly affect patients, health care facilities and/or professionals, the application will be forwarded to the Chair of the DPH IRB. The Chair will determine if the request will be handled directly by the DPH IRB. If the application requests the linking of an SCCCR database with other database(s), the linkage is subject to review by the CCACSS.

2. Student Research Requests

Students may request confidential and non-confidential data items for thesis or dissertation work. The same application procedure noted in section one applies to students

requesting data. Students are prohibited from mapping below county level, cannot contact patients, and cannot receive any distance variables. The registry reserves the right to deny any student application that would require extensive registry resources.

3. Mapping Requests

At the start of the data request process, please be clear if requesting data to be used for mapping purposes. Applications to map SCCCR data are each carefully considered and many aspects of the request determine whether it will go forward. Points that are considered include:

- Confidentiality of the data requested
- Geographic level of data requested (county level, ZIP code level, census tract level, etc.)
- How many cancer cases are available per geographic level requested
- How data will be displayed (rates, counts, proportions, low/high levels, etc.)
- Whether mapping is necessary to fulfill the researcher's aims

Protecting patients' confidentiality is a fundamental goal of the SCCCR. Confidentiality controls access to cancer data and ensures absolute confidentiality for individual patients, as well as appropriate confidentiality for health care facilities and physicians. The way maps display data must be carefully considered in order to avoid revealing confidential data. Counts less than 10 and rates based on counts less than 16 are confidential and may not be mapped. At the beginning of a mapping request, the SCCCR will run preliminary counts in order to provide the researcher with an idea of sample size (to see if the request is realistic).

Requests for data below the county level (e.g., ZIP code, census tract) are considered confidential. In nearly all cases, use of this level of individual geographic data will be limited to on-site use at the Department of Public Health (DPH). The SCCCR, in collaboration with other areas within the agency, will coordinate the creation of the requested maps. Any new or altered existing maps using these data must be reviewed and approved by the SCCCR prior to

use or publication.

When data are requested for mapping purposes, the researcher must very clearly explain in the data application what will be mapped. It is helpful to include an example of a map that is similar to what is being requested. In addition, upon all approvals, the following information needs to be provided:

- Title of maps/legend titles
- Legend ranges/values
- Color scale (which values should be the darkest color, which should be the lightest)
- Explanation of which variables will be mapped

Finally, the SCCCR must be acknowledged in any published article/manuscript that includes maps. Suggested citation is below.

South Carolina Central Cancer Registry (SCCCR), Bureau of Chronic Disease & Injury Prevention, Department of Public Health. https://dph.sc.gov/professionals/public-health-data/cancer-registry

4. Cancer Control Advisory Committee, Surveillance Subcommittee

The Cancer Control Advisory Committee Surveillance Subcommittee (CCACSS), as specified in Section 44-35-30, as amended, SC Code of Laws, 1996, will be a standing subcommittee convened to review research requests for confidential cancer data and review non-research requests upon DPH IRB or SCCCR request. The CCACSS will assist the SCCCR in such activities as periodically reviewing the appropriateness of the classification of data elements collected or maintained by the SCCCR. The subcommittee will consist of at least 7 members, drawn from the following groups with broad statewide representation:

- SCMA physician appointed by the SC Medical Association Board of Trustees
- SCHA member appointed by the SC Hospital Association Board of Trustees
- (3) Cancer researchers, at large
- Certified Tumor Registrar, appointed by SC Cancer Registrars' Association
- The Office of Revenue and Fiscal Affairs representative, appointed by the Chief of the Health and Demographics Section.

The Chair of the CCACSS will be appointed by the CCAC. The CCACSS will meet at least quarterly. Absence from more than two consecutive meetings constitutes a resignation. A member may not appoint someone to attend in his/her absence. A quorum for the CCACSS will be a majority of its members appointed and serving. Re-appointments shall occur annually, or as deemed appropriate by the CCAC. Due to the technical and scientific nature of the requests made to the CCACSS, there are several areas of expertise recommended for members of the CACSS. The recommended qualifications should be represented, but are not limited to:

- Use and/or development of statistical models for the analysis of cancer data
- Expertise in cancer coding and registry operations
- Expertise in research analytic methods
- Expertise in the analysis of the health data
- Expertise in medical oncology
- Expertise in Bioethics

CCACSS members need not be experts in all areas, but a familiarity with each would assist the CCACSS in making informed recommendations on the release and classification of data elements. If the CCACSS deems that a request for data could be better evaluated with assistance from additional experts, a panel of technical experts can be convened by the CCACSS. This panel will also have a vote in the CCACSS. A list of contacts of various agencies, associations and institutions will be developed and maintained by the SCCCR to

assist the CCACSS in convening these panels in a timely manner on an as needed basis.

The CCACSS will determine if the research purpose proposed by the data application can be reasonably accomplished without disclosure of confidential data elements. If confidential data elements are required, efforts will be made to ensure that the disclosure risks have been minimized and that the remaining risks are outweighed by anticipated health, economic, safety, or scientific benefits to advance knowledge about cancer in South Carolina.

5. Individual Record Requests

Per Section 44-35-40, SC Code of Laws, 1996, the individual patient or the patient's authorized representative may request their confidential data. To do so, patients must contact the SCCCR to obtain Form 4506, Individual Records Request Form. This form should be filled out with as much detail as possible and returned along with a scan or photo of the front and back of a state-issued identification card and proof of authorization (if not the individual). Once SCCCR receives all documentation, staff will search for any abstracted information for the patient. If located, all information will be extracted as a PFD and transmitted to the requestor via Web Plus, the registry's Secure File Transfer Service (SFTS).

6. Data Sharing Agreement (DSA)

Applications for the release of confidential data elements require representatives of each entity involved as well as the principal investigator to submit a signed DSA to the SCCCR. Persons with access to the data will be required to sign the DSA; the original form will be held by the SCCCR and a copy sent to the principal investigator. This DSA will include, but is not limited to, the following clauses:

- Data User may use or access the DPH Data solely for the purposes expressly authorized in this Agreement.
- Data User will not attempt to identify or reveal the identities of individual subjects in the DPH data. Unless expressly authorized in this Agreement, Data User will not attempt to

identify or contact any persons or health care facility whose information is contained in DPH Data unless expressly allowed under this Agreement. Data User will not match DPH Data to any other record level data nor allow others to do so without prior approval by DPH.

- Data User will ensure that access to DPH Data will only be given to Authorized Users who need access to the information to fulfill their duties, and that Authorized Users will only be given the level of access needed to perform their duties.
- Data User must maintain a list and review it no less than annually of all Authorized Users and provide the list to DPH upon request.
- Data User will ensure that any products, publications, or presentations developed from DPH Data, including but not limited to any report, poster, talk, news release, web page, or other presentation or use (print or electronic), will be consistent with the terms of this agreement, and will contain no personal identifying information. Data User also ensures that any such products, publications or presentations will:
    - Be submitted to DPH for review not less than 30 days prior to release or submission for publication; or
    - Be developed in collaboration with staff from DPH and contain an acknowledgment of DPH as the source of the data.
- Nothing contained herein shall permit DPH to control the content or prohibit the publication of an academic presentation or publication of Data User, unless such academic presentation or publication violates the terms of this Agreement, in which case DPH may take necessary steps to enforce the terms of this Agreement.
- DPH provides data on an "as is" basis and makes no claims or warranty to the accuracy or completeness of DPH Data and undertakes no responsibility to discover errors.
- Data User will work with DPH to meet any requirements necessary for data return and deletion.
- Data User will cooperate with DPH in fulfilling all legal and regulatory requests or requirements for disclosure of DPH Data associated with this Agreement and/or data including, but not limited to, court orders, subpoenas, and Freedom of Information Act and litigation discovery requests.
- Data User shall comply with all laws, regulations, and standards governing confidentiality, privacy, and data security and shall cooperate fully with and assist DPH

in complying with all such laws, regulations, and standards.

D. Studies Involving Direct Contact with Registry Patients

Approval Process Summary

Federal regulations require that all research studies involving human subjects and materials of human origin be reviewed and approved by an Institutional Review Board (IRB) before initiation. In compliance with this federal regulation, study investigators requesting patient identifiable data from the SC Central Cancer Registry (SCCCR) must submit a SCCCR data application and applicable supporting documentation (i.e. study protocol and methodology, sample patient contact forms, sample consent forms, home institution IRB, CVs/biosketches of researchers, proof of human subjects research training, etc.) to the Department of Public Health (DPH) Cancer Control Advisory Committee Surveillance Subcommittee (CCACSS) and the DPH IRB.

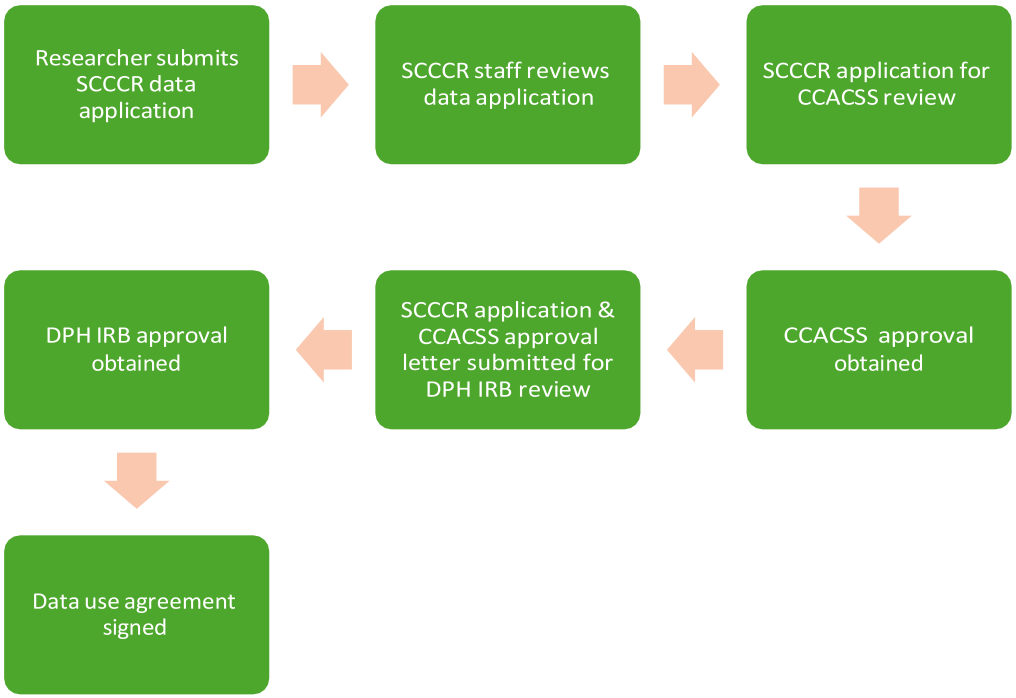
CCACSS and DPH IRB approval are not obtained concurrently (see Figure 1. SCCCR Approval Diagram). Once a SCCCR data application is submitted, it is reviewed by registry staff and prepared for CCACSS review. Once CCACSS approval is obtained, the SCCCR application, with applicable supporting documentation and CCACSS approval letter are submitted to the DPH IRB for review.

In addition to obtaining approval from CCACSS and DPH IRB, a data use agreement must be signed by study investigator(s) and all study personnel who will have access to information that identifies individual cancer patients.

Approvals from the CCACSS and DPH IRB must be obtained and a data use agreement signed before cancer registry data are prepared and released. Please note that each request for use of patient identifiable data will be processed in a timely fashion. However, applications are placed in a queue for review. If additional work needs to be done to prepare the initial application for presentation to the

CCACSS, this could affect the timeliness of review.

Figure 1. SCCCR Summary Approval Diagram.



SCCCR PATIENT CONTACT PROCESS FOR STUDIES REQUIRING CASE ASCERTAINMENT/RECRUITMENT

Case Ascertainment/Recruitment requests are defined as requests for the use of the SCCCR database for the purpose of patient recruitment for a study (i.e., utilize the SCCCR database to identify cancer patients that may qualify or meet the study's selection criteria for inclusion).

SCCCR's policy is to contact the eligible patient's physician, notifying them via letter of the study and their patient's eligibility. If no contraindication is received after two weeks, a mailing will be sent to eligible patients informing them of the study and how to contact the study team if they wish to learn more. No further contact from the SCCCR will be made.

I. PATIENT CONTACT PROCESS

For studies that utilize SCCCR for patient recruitment (see Attachment) and, subsequently, patient contact: *Please be advised that the SCCCR will not contact those patients who are deceased nor those who were reported strictly by Veteran's Affairs hospitals.*

A. **PULL ELIGIBLE CASES TO CREATE STUDY RECRUITMENT FILE:** SCCCR staff pulls desired data items for study sample (e.g., African American women with primary invasive breast cancer and no other primary diagnosis of cancer, ages 25-75) from SCCCR database to create Study Recruitment File.
B. **MATCH DATA TO PHYSICIAN FILE:** SCCCR staff matches Study Recruitment File to physician file to obtain physician name and contact information. NPI number and medical license numbers recorded for each patient are utilized for the match.
C. **SEND PHYSICIAN LETTER:** SCCCR staff/graduate assistant sends Study-approved Physician Letter to physician of record for each patient to inform him/her that he/she has a patient who is eligible for the study and requests a response if he/she knows of any contraindications as to why the patient should not be contacted. Physician Letters are sent out on a weekly basis in batches (usually 20 patients per week).

   C1. PHYSICIAN LETTER RETURNED: Updated physician information is requested from the data source (where the case report originated) for more accurate physician contact information.

   C2. PHYSICIAN DOES NOT WANT PATIENT CONTACTED: If the physician contacts the SCCCR stating he/she does not want the patient contacted, the patient contact process ends. The patient is given a code indicating the physician does not want patient contacted (including any contraindications indicated) and these codes are recorded in the tracking database.

   C3. PHYSICIAN STATES PATIENT IS DECEASED: If the physician contacts the SCCCR stating the patient is deceased, the patient contact process ends. Patient is recorded as deceased.

D. SEND PATIENT LETTERS: Two weeks from the date that the Physician Letter was mailed, a Patient Letter is mailed for patients who are living and for those whose physician provided no contraindication for contacting. This assumes passive consent from the physician.

D1. PATIENT LETTER RETURNED: Updated patient contact information is requested from data source where information originated. If a current address cannot be found or a Patient Letter is returned a second time, patient is coded as "unable to obtain accurate contact information".

D2. PATIENT CONTACTS RESEARCH TEAM: Patient contacts the study team directly to enroll in the study or opt out of participation. The SCCCR is not involved in this process.

If a patient is found to be deceased at any time throughout the contact process, the patient is coded "Deceased" in the tracking database

E. CONSENT FOR RELEASE OF CANCER REGISTRY DATA: For studies that request identifiable cancer registry data for patients enrolled in a study, consent for the release of cancer registry data must be obtained prior to release of data to the study team. To minimize enrolled participant burden, the preferred method is for the study team to integrate the consent form to release cancer registry data in their informed consent process and subsequently send the executed documentation to the cancer registry team. The consent form should include a statement indicating records from the state cancer registry will be requested. An example of this language is: ""We may request updated medical records or other data, including information from your state cancer registry, using your identifying information to study treatment and health over time. Information will be protected as required by law". Alternatively, the cancer registry team can send a registry consent form for release cancer registry data to enrolled participants. Only data for those who return the consent form will be released to the study team.

II. CONTACT LETTERS

A *Sample Physician Letter* (Attachment 1) and *Patient Contact Letter* (Attachment 2) are provided for the study investigator's reference. In addition to the study investigator's description of the study, the physician and patient contact letter must include:

- Language furnished by the SCCCR regarding State cancer reporting
- Assurance of voluntary nature of participation
- Assurance that participation or non-participation will not affect medical care

III. Investigators must remember:

- Patients can always refuse to participate, even after having agreed to participate.
- Study investigator should avoid disclosing that the patient is being contacted for a study specific to cancer on the cover of mailings.
- Efforts to recruit a patient should stop immediately when the patient clearly indicates he or she does not wish to participate.
- **Any patient who states that he/she does not wish to be contacted again must be reported promptly to the SCCCR**; this fact will be recorded in the SCCCR databases. That person will not be re-contacted for any study.

F. Release of Data to Entities as Required by Law

If an entity obtains statutory authority for the release of confidential data elements, that entity must submit to the SCCCR:

- Written statutory evidence indicating entitlement of access to the data, and;
- A copy of or citation of the status(s) and/or regulation(s) that requires the entity to maintain the confidentiality and security of the data; or
- If statutory and/or regulatory requirements of the maintenance of the confidentiality and security of the data do not exist or do not satisfy the intent of Section 44-35-30, as amended, SC Code of Laws, and in all persons (including staff, subcontractors and committees) with access to the data will be required to sign a confidentiality contract supplied by the SCCCR. These contracts shall be available upon request by the SCCCR.

Release of confidential data elements for follow-back investigations must be mandated by statutory law. The SCCCR encourages entities performing follow-back investigations with confidential data to adopt the SCCCR policies for follow-back investigations.

The SCCCR recognizes that South Carolina Revenue and Fiscal Affairs Office (RFA) has responsibility for the collection of health data in South Carolina based on legal authority. Therefore, the SCCCR will collaborate to the greatest extent possible with RFA's surveillance activities and epidemiological investigations. Memorandums of Agreement (MOA) between the SCCCR and RFA for collaborative projects will be developed as necessary.

IV. MANAGEMENT OF POLICIES FOR DPH AND SCCCR

A. PROCEDURES FOR MAINTAINING CONFIDENTIALITY OF OTHER DATA

Employees, contractors and agents of the SCCCR and DPH, as well as members of their committees, task forces and advisory groups, will have occasion to work with confidential data elements on a regular basis. This responsibility will be treated with the highest degree of respect and integrity. The SCCCR has established a policy requiring its employees, contractors, agents, and members of its committees, task forces, and advisory groups to maintain the confidentiality of the confidentiality contract. The SCCCR in compliance with DPH policies and state and federal law will develop internal security policies for all cancer data. These internal security policies will be reviewed by the CCAC. Access to confidential and data elements will be strictly controlled following extensive security measures. All employees, contractors and agents of the SCCCR sign data confidentiality agreements prior to accessing any confidential data.

B. PROCEDURE FOR DATA VERIFICATION AND REVIEW

Section 44-35-40, SC Code of Laws, authorizes DPH to promulgate regulations governing the submission of cancer data. These regulations require the SCCCR to ensure that the data meet specific timeliness, accuracy and completeness criteria. Additionally, the SCCCR follows a detailed editing and "de-duplication" process when preparing data files. Data supplied to the SCCCR will not be released until the data supplier has an opportunity to verify the accuracy of the data and submit revisions and supporting documentation if the data are found to not be accurate.

C. FEES

It is not the intention of the DPH or SCCCR to limit access to cancer data through the adoption of unreasonable fees. The SCCCR follows the policy of DPH to charge for the release of reports and other data based on a cost recovery basis.

Cost-recovery fees will be applied to work that is over and above normal registry activities required for the research study. Fees will be reasonable based on the scope of the project. In general, fees for data and statistical support for students are typically waived. If only unrestricted data items are requested, students may also be eligible for an expedited approval process.

ATTACHMENT 1. SAMPLE PHYSICIAN LETTER

Dr. <first name> <last name>
< address line 1>
< address line 2>

Dear Dr: <last name> <Current date>

I am contacting you regarding the study entitled [Study Title], which is currently funded by the [Funding Institute]. The study has been approved by the SC DPH Institutional Review Board (IRB), the DPH Cancer Control Advisory Committee Surveillance Subcommittee (the oversight committee for release of SC Central Cancer Registry (SCCCR) data used for research), and the [Home Institution IRB].
The purpose of this study is [Brief description]. For patients, the primary outcomes are [Outcomes].
All participant information will be kept strictly confidential. Your patient, _____, is eligible for this study. If you know of any reason why this patient should not be contacted, please contact Bezawit Kase, the cancer registry Data Use Manager and Epidemiologist, within two weeks. You may contact her by phone at 803-898-0700, or by e-mail, cancer.registry@dph.sc.gov. Otherwise, one of my staff will proceed by sending the patient a letter that will explain that s/he is eligible for this study, what s/he can expect by participating in the study, and that s/he will be contacted by the SCCCR. No reference to the patient's former or current physician will be made in the letter. If the patient is interested, s/he will contact the study team directly. The registry will have no further contact with the patient after the initial mailing. I have included a pamphlet about the study with more information [If applicable. If available, include study website]. If the patient does not give permission, we will not make further contact.
Due to a large number of eligible cases, you may be contacted multiple times through staggered mailings. Thank you very much for your assistance.

Sincerely,

Stephanie Chiodini, MSPH
Program Director, SC Central Cancer Registry
Bureau of Chronic Disease & Injury Prevention
South Carolina Department of Public Health

ATTACHMENT 2. SAMPLE PATIENT LETTER

Mr./Ms. <first name> <last name>
<patient address line 1>
<patient address line 2>

Dear Mr./Ms. <last name> <Current date>

I am writing to let you know you may be eligible to take part in an important study called the [Study Title]. It is being conducted by [PI], a researcher at [Institute].

The purpose of the study is [brief description of purpose]. Hopefully, the information learned from this study can be used to help others in the future.

You were identified through the South Carolina Central Cancer Registry (SCCCR) at the Department of Public Health (DPH) in Columbia, SC. This registry tracks where and how often cancers occur in South Carolina. It also supports cancer prevention and control efforts by helping researchers understand the causes of cancer.

I have included a pamphlet about the study with more information [If applicable. Can add a study website if available as well]. You may contact the study team directly with any questions at [Phone number].

If you agree to participate, you will be asked to [Brief overview of tasks/requirements of participants]. This information will be used for research only. It will not affect the clinical care that you receive or your privacy.

Deciding to take part is up to you. Whether you participate or not will have no effect on your medical care. Taking part offers you an exciting chance to help discover new information. This information could lead to improvements in [information].

You may contact the SCCCR at any time if you have questions. You can do this by calling Bezawit Kase at 803-898-0700 or e-mailing cancer.registry@dph.sc.gov. Thank you for your consideration.

Sincerely,

Stephanie Chiodini, MSPH
Program Director, SC Central Cancer Registry
Bureau of Chronic Disease & Injury Prevention
South Carolina Department of Public Health