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

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I. INTRODUCTION

The South Carolina Department of Health and Environmental Control (DHEC), 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 DHEC to record all reportable cases of cancer occurring in SC residents on or after January 1, 1996. DHEC, 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 confidentiality and integrity of the data. Confidentiality is the control over access to cancer data and assurance of absolute confidentiality for individual patients, and 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 DHEC 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. DHEC and CCAC believe that these efforts will reduce morbidity and mortality of cancer in South Carolina.

III. DATA RELEASE PROTOCOL

A. CLASSIFICATION AND RELEASE OF DATA

In order 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 process, 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 combination 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 first visit SCAN. The SCAN data query system allows users to generate tables and maps of South Carolina cancer incidence and mortality data. If the desired non-confidential data is not available on SCAN, researchers should contact the SCCCR.

The SCCCR will release unrestricted data upon request and is subject to the confidentiality provisions set forth in DHEC 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. Should the SCCCR have any hesitation about unrestricted data requests, guidance will be sought from the Director of the Office of Public Health Statistics and Information Systems, the CCAC Chair, or DHEC legal staff.

Suppression rules will be applied when necessary. Suppression rules are as follows: cells with less than 5 cases marked as <5*, cells with 5-9 cases are rounded up to 10*. Rates with fewer than 15 cases will be suppressed due to the instability of small numbers when calculating rates.

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 frequencies of cancer cases by primary site/histologic type categories by 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 marked as <5, cells with 5-9 cases are rounded up to 10. Rates with fewer than 15 cases will be suppressed due to the instability of small numbers when calculating rates.

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 the 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. For example, variables associated with patient, physician, & hospital or treatment center *names, facility numbers or ids,* and *locations,* etc; and dates more specific than *year*. Address or location information more specific than *county* are considered confidential. 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.

Requests for confidential data items must have Institutional Review Board (IRB) approval from their affiliated organization before a request is made to the registry. Application for the release of confidential data elements include items that allow identification of patients, facilities, and/or physicians, 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 Use 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. Upon the receipt of completed application, the SCCCR will determine if the research request is for research. If the research application requires confidential data, the CCACSS will review the applications. If the CCACSS approves, the SCCCR will forward the documentation to the Department of Health and Environmental Control Institutional Review Board (DHEC IRB). Notification of CCACSS approval will be provided after CCACSS review (at the time of DHEC IRB review). If the DHEC 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 rational 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 DHEC IRB. The Chair will determine if the request will be handled directly by the DHEC IRB. Health care facilities and/or professional identifiable data elements approved for the applicant's use by the DHEC IRB may not be released in any product, publication or communication without the written approval of the DHEC IRB and review and comment by the affected health care facilities and/or professionals. If the application requests the linking of an SCCCR database with other database(s), the linkage is subject to review by the CCACSS.

2. 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 request upon DHEC IRB 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 representations:

- 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 Research and Statistical Services 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 recommend 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 the vote to 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.

3. Data Use Agreement (DUA)

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

- I will not allow others nor will I myself use the data elements for purposes other than the study protocol and the purposes specified in the SCCCR's Research Data Request application and any limitations described in my CCACSS Approval Letter. Use of confidential data elements for a research project other than the one described in the

SCCCR application will not be undertaken until a separate application form for that project has been submitted and approved under the procedures established in the DHEC SCCCR Data Release Protocol.

- I will not allow others to nor will I myself release, furnish, disclose, publish or otherwise disseminate these data in any manner other than those approved and specified in this application.
- I will not allow others to nor will I myself use these data to attempt to learn the identity of any person whose data is contained in the file, nor release the identity or any information which may disclose the identity of any patient without prior legal authority.
- I will not allow others to nor will I myself use these data to identify any health care facility and/or professional without prior SCCCR approval.
- I will not allow others to nor will I myself publish, disseminate, communicate or otherwise re-release health care facility and/or professional identifiable data without prior approval by the SCCCR and review and comment by the affected facilities.
- I will not allow others nor will I myself match these data set(s) to other patient level data sets by use of patient, health care facility and/or professional level characteristics without prior approval by the SCCCR.
- I will not allow others nor will I myself release data in a report or disseminate data with a cell size of less than 5 without prior approval by the SCCCR.
- I will remain as the sole holder of the data and ensure access to the data is limited to persons under my supervision and whose names are in the SCCCR's Research Data Request application. A new application will be submitted in the event of a proposed change of the lead entity for the project.
- I will submit a final report of the data to the SCCCR.
- All data released for this project by the SCCCR will either be returned to the SCCCR or destroyed upon completion of the project.

  Also Note:

- The SCCCR will be held harmless from damages resulting from the use/misuse of the data.
- The data are the property of the State of South Carolina and must be surrendered

upon direction of DHEC.

- Approval by DHEC for the release of data is not equivalent with endorsement of the project. Failure to comply with the DUA may result in legal action as specified in Section 44-35-30 SC Code of Laws.

D. STUDIES INVOLVING DIRECT CONTACT WITH REGISTRY PATIENTS

Patient contact for follow-back studies having met the procedures for accessing confidential/restricted data items must be conducted through the collaboration with the health care facility and/or professionals and requires the informed consent of the patient or the patient's representative. Researchers will provide the registry with staff or support to assist in the consent process of the healthcare facility and/or professional. The research staff (or support) will conduct the consent process of the eligible participants for the study according to the registry's SCCCR Case Ascertainment & Recruitment Protocol. After consent from the participants is received, the registry will provide the researchers with the prepared dataset.

The purpose of the studies shall not be disclosed to anyone, when trying to locate patients, other than the entity originally providing the SCCCR with the data, the patient or the patient's representative. No undue burden shall be placed upon health care facilities and/or professionals to comply with follow-back studies. Studies that require information to be collected directly from patients identified by the SCCCR must involve the steps outlined in the SCCCR Case Ascertainment & Recruitment Protocol. Briefly, these steps include:

Step1: Physician of record will be contacted by DHEC describing the study and asking permission to contact the study subject. If, after 2 weeks, no response is received from the physician, then passive consent is assumed.

Step 2: For all patients who are identified through Step 1, a letter is sent from DHEC to the patient indicating that he or she is eligible for the study, and will be contacted unless he or she does not wish to be contacted, in which case they should call a toll free number at DHEC or contact the researcher directly. After one week, the SCCCR contacts patients via phone to obtain permission to be contacted by research staff.

Step 3: If physician passive consent (Step 1) and patient active consent (Step 2) is obtained, the researcher may contact the patient directly (e.g., by letter or phone, per approved protocol).

E. 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 Office of Research and Statistics (ORS) 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 ORS's surveillance activities and epidemiological investigations. Memorandums of Agreement (MOA) between the SCCCR and ORS for collaborative projects will be developed as necessary.

IV. MANAGEMENT OF POLICIES FOR DHEC AND SCCCR

A. PROCEDURES FOR MAINTAINING CONFIDENTIALITY OF OTHER DATA

Employees, contractors and agents of the SCCCR and DHEC, 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 to require its employees, contractors and agents, and members of its committees, task forces and advisory groups to maintain the confidential nature of the confidentiality contract. The SCCCR in compliance with DHEC 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.

B. PROCEDURE FOR DATA VERIFICATION AND REVIEW

Section 44-35-40, SC Code of Laws, provides for DHEC to promulgate regulations concerning 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 has a very detailed editing and "de-duplication" process that it follows in 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 DHEC or SCCCR to limit access to cancer data through the adoption of unreasonable fees. The SCCCR follows the policy of the DHEC 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.