Procedures for Data Release
North Carolina Central Cancer Registry (NC CCR)
August 2020

Purpose

The North Carolina Central Cancer Registry (NC CCR) releases data to facilitate research related to cancer etiology, prevention, control and to assist with health care assessment, monitor cancer burden and to identify populations at increased risk of cancer.

For charges associated with the release of data for studies with or without patient contact and data linkages, contact the CCR Director.

These data release procedures are based on the legislation that created and administers the CCR: North Carolina General Statutes 130A-205 through 130A-215 and Administrative Code, Chapter 26B. Additional guidance for research involving patient contact was reviewed by Legal and Regulatory Affairs, North Carolina Division of Public Health and the Advisory Committee on Cancer Coordination and Control.

All data released must include a reference to the CCR as its source. Copies of publications must be provided to the CCR on an annual basis. *Data used for another purpose, or released to another party, without explicit permission of the CCR, is strictly forbidden.*

Data submitted by the Veterans Administration (VA) Facilities *will not be released per a Data Transfer Agreement negotiated with individual VA facilities. A count of cases excluded can be provided, if requested.*

Data Release of Aggregate Statistics

In general, aggregate statistics, with no identifiable information, are freely available, pending staff resources to provide detailed reports. Cell sizes with fewer than five cases of cancer are suppressed for confidentiality. Rates for cell sizes with fewer than 16 cases of cancer are suppressed in tables as they are not stable. CCR does not produce rates by ZIP Code area as they are not well-defined geographic area. ZIP Codes can cross county boundaries, change over time, and there is no set time when these changes occur. CCR data finer than census tracts are not released and enumeration area based aggregate population with less than 5 cases are masked for confidentiality.

If the purpose of the request requires cell sizes with fewer than five cases, State Center for Health Statistics Form F-14 (SCHS F14) must be completed, and approval obtained by the Director of the State Center for Health Statistics, or his/her designee. Confidentiality agreements need to be signed by all parties with access to the data.

Data Release of Record Level Data, No Patient Contact

Data are sometimes released for research at the record level. If this is the case, the requester must complete and submit SCHS F-14 to the CCR Director, a copy of the protocol, and a copy of current Institutional Review Board (IRB) approval, from requestor's institution. Confidentiality agreements must be signed by all parties with access to the data. The CCR Director and SCHS Director must approve all requests.

Data Release of Record Level Data, Patient Contact

Requestors must submit SCHS F-14, as described above and obtain CCR Director and SCHS Director approval. The CCR will then submit the proposal for review to the advisory body for the CCR, the Advisory Committee on Cancer Coordination and Control. The following is the required order of approvals and the appropriate forms:

Step 1

Submit the following to CCR Director for the SCHS Director's approval.

- SCHS F-14
- Copy of research institution's IRB application
- Copy of research institution's IRB approval
- Protocol, to include
    - First mailing regarding the CCR: CCR brochure (attached).
    - Study informational letter to patient, which must include the voluntary nature of participation, a reminder that the data were made available via the CCR (referencing first mailing), assurance of confidentiality. See sample for requirements. The CCR brochure, published on the CCR website meets this requirement.
    - Consent forms
    - Questionnaires/instruments
    - Explicit statements regarding the frequency and number of times that patients will be contacted, adequate data security measures, assurance of confidentiality by all study personnel
    - Explicit statements indicating that the CCR will be notified immediately if the patient refuses to participate in any research study, and when the patient is no longer participating in the study. This information is needed to ensure that patients are not contacted for multiple studies, or against their will.

Step 2

Once approval is obtained by both the research institution's IRB and the SCHS Director, the proposal will be forwarded to a designated reviewer on the State's Advisory Committee on Cancer Coordination and Control. The research contact will be notified once all approvals have

been obtained (Steps 1-2) to execute the Data Use Agreement between the CCR and the Principal Investigator of the research study. All study personnel will need to submit signed confidentiality forms before data will be released.

If the study involves patient contact at least one year after diagnosis and only uses non-invasive methods such as questionnaires, the above procedures apply. Data will be provided by the CCR from regular reporting. The study need not contact the physicians for passive consent before contacting the patients. The questionnaires are mailed directly to the patients. If the patient refuses to participate or expresses concern, CCR must be notified immediately.

If the study involves more invasive methods such as biologic sampling or contact within one year of diagnosis, then **physician notification (i.e., passive physician consent) is required**. Currently, the only mechanism for physician notification is through the CCR's Rapid Case Ascertainment (RCA) system. RCA must also be used when early ascertainment of cases (within two months of diagnosis) is necessary for the research. RCA costs, as well as procedures for RCA and physician notification, should be discussed thoroughly with the RCA supervisors at UNC Lineberger and CCR Director, Chandrika Rao, before submitting proposal materials.

The following policies apply to all research involving patient contact: Rerelease of patient identifiers without patient and CCR consent is prohibited.

Re-contact of patients for any purpose not described in the protocol requires new approval. If the proposal includes a question to obtain consent for contact for future studies, then no new approval by the CCR is necessary. Note: If a study consents the patient for future contact by the investigator, and that consent process was included in the original CCR data request, then the patient's choice (consent or not) determines future contact. **Investigators from different studies may also collaborate to submit a joint application to the CCR, including patient consent on more than one study at the same time; these studies will be considered on a case by case basis.**

A spreadsheet on participants' status must be submitted to the CCR every six months **(June 15 and December 15)** to ensure no overlap of contact by multiple studies. A template spreadsheet is available.

If a study obtained participant demographic information from CCR regular reporting (not RCA) and learns of corrected participant information, then the study must send the Data Correction Form to the CCR. If a participant indicates that he/she does not wish to be contacted for any future research studies, ***the study must notify the CCR Director immediately***.

Please note that all potentially eligible patients may not be released for research if the date of last contact for a prior study is less than one year. Although this occurrence should be rare, it could affect the study in terms of recruiting the required number of patients and generalizing the study results.

Step 2 for Rapid Case Ascertainment (RCA) studies:
The RCA Coordinator will cross check submitted confidentiality forms and maintain a copy within RCA. In addition, the RCA Coordinator will ensure any new researchers added to the study team, after the study started, will submit a signed confidentiality form to the CCR. "New researchers" are defined as a new Project Manager, Study Coordinator, and anyone who performs a secure download or upload of PHI from/to RCA.

The RCA study must notify the CCR Director and the RCA Coordinator immediately if:

- the patient reported that he/she learned of his/her cancer diagnosis from the RCA study researcher, before being told by his/her medical provider.
- the patient denied having cancer upon initial contact from the study.
- the patient was identified by the study as being a "Do Not Contact" patient.

The studies will submit the Participants' Status Report **quarterly** to the RCA Coordinator (April 15, July 15, October 15, and January 15). The RCA Coordinator will compile the reports from all the studies and submit to the CCR Director and CCR Statistical Supervisor quarterly.

This report will include:

- A comprehensive list of all patients submitted from RCA to the study
- Patients' enrollment status
- Patient's refusal to participate in the current study
- Patient's refusal to participate in any research study

If a study uses RCA and discovers a participant's contact information (address, phone number or email) is no longer current, then the study may upload the Data Exchange Form to the study's secure MS Team requesting information updates. Updated patient contact information can aid study enrollment. RCA will reach out to its hospital contact via phone or encrypted Zix Corp email. No PHI will be spoken in any voicemail and no patient's SSN will be entered into any encrypted email.

Data linkages between all active study databases that enroll patients will occur prior to any upload of new patient data from RCA to the study. The database linkage will also include the RCA database titled "Do Not Contact". The "Do Not Contact" database includes all RCA study patients, that were identified by any prior or current RCA study as someone who should never be contacted ever again for any future study. And finally, the database linkage will include all RCA study databases that enrolled patients and have an official, signed "study stop letter" dated within the past 1 year. If the patient matches among any of these database linkages, the patient will be excluded from any upload to the subsequent (second) study.

Data Charges
Typically, for routine aggregated data requests, requiring less than a few hours of a statistician's time, there is no cost for data analysis and release. The NC CCR reserves the right to charge for

complicated data requests, data linkages or record level data as it requires additional staff time. It is best to discuss data charges with the CCR Director prior to submitting a proposal for funding.

Similarly, there are costs associated with data release for research with patient contact. The appropriate staff should be contacted to discuss an appropriate budget prior to submitting a proposal for funding: the RCA Director if RCA is used; otherwise, the CCR Director.

Contacts

Chandrika Rao, CCR Director, (919) 792-5946: Chandrika.Rao@dhhs.nc.gov
ClarLynda Williams-DeVane, SCHS Director, (919) 792-5741: ClarLynda.Williams-DeVane@dhhs.nc.gov
Heather Tipaldos, Project Manager, RCA, Lineberger, (919) 966-9438: Heather_Tipaldos@unc.edu

Attachments*

Sample Contact Letter from Research Institution
Confidentiality Form
Questions and Answers for Patients
CCR Brochure
Data Update Form
RCA Participant Status Spreadsheet with Data Exchange Form

** For attachments, data processing charges and other information, please contact CCR Director, Chandrika Rao, at (919) 792-5946*

Reference:
Grubesic, T.H., Matisziw, T.C. On the use of ZIP codes and ZIP code tabulation areas (ZCTAs) for the spatial analysis of epidemiological data. *Int J Health Geogr* **5,** 58 (2006). https://doi.org/10.1186/1476-072X-5-58
https://ij-healthgeographics.biomedcentral.com/articles/10.1186/1476-072X-5-58

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