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Utah Cancer Registry Mission Statement

The Utah Cancer Registry promotes public and population health in Utah by collecting and managing cancer incidence and mortality data for the state. The registry disseminates information to support cancer prevention and control, facilitates cancer research, and monitors cancer trends. We are committed to obtaining high quality data and to protecting the confidentiality of individuals.
1. Background: Utah Cancer Registry Authorization and Guidance for Disclosing Cancer Case Information

The Utah Cancer Registry (UCR) has functioned as a statewide, population-based cancer registry since 1966. Utah Administrative Code Rule R384-100, the Cancer Reporting Rule (1), directs the registry to collect and manage cancer incidence and mortality data. The rule directs health care providers to report information for each cancer case diagnosed or treated in Utah to UCR. The purpose statement of the rule includes “Through the routine reporting of cancer cases, trends in cancer incidence and mortality can be monitored and prevention and control measures evaluated.” The Cancer Reporting Rule states that although cancer records are collected and managed by the UCR, the Utah Department of Health (UDOH) retains ownership of the records. The Cancer Reporting Rule cites authority from the Utah Health Code, Title 26 Chapter 5 Section 3 (2), which directs the UDOH to maintain systems for detecting and monitoring chronic diseases within the state.

UCR is administered within University of Utah Health Sciences. A Memorandum of Agreement (MOA) between the University of Utah and UDOH signed July, 2016 (3) includes a section describing UCR's responsibility to protect confidential cancer information and circumstances in which the data can be disclosed. The MOA directs the UCR and its oversight committee to establish UCR policies. The present document, Utah Cancer Registry Policies and Procedures for Disclosure of Registry Data, herein also referred to as UCR Policies, presents those policies.

Disclosure of cancer registry data by UCR is thus primarily guided by the state through the Utah Cancer Reporting Rule and the MOA between the University of Utah and the UDOH, most recently updated in July, 2016. UCR has a longstanding affiliation with the U.S. National Cancer Institute’s Surveillance, Epidemiology and End Results (SEER) program (Contract No. HHSN261201300017I), and therefore UCR Policies must been in keeping with that contract and with federal guidelines on data security and human subjects' research referenced therein. Further, UCR's policies must comply with data security and confidentiality policies of the University of Utah (4). UCR data do not, however, fall within the University of Utah's Covered Entity as defined for the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA) and UCR data are not directly governed by HIPAA rules.

This UCR Policies document will be reviewed every three years, and updated as needed, according to terms specified in the MOA.

Use of italics in these UCR Policies indicates wording drawn directly from the 2016 MOA (3) between the University of Utah and UDOH.
2. Definitions

"Disclose" or "disclosure" means the communication of cancer case information to any individual or organization outside of UDOH or persons or organizations that UDOH specifically authorizes to access the data.

"Cancer case information" means any case report information that UDOH requires persons or organizations to report to UCR pursuant to Cancer Reporting Rule R384-100. Per R384-100, cases include each case of cancer or reportable benign tumor, that is diagnosed or treated in Utah.

"Identifiable cancer case information" means any cancer case information that, either from the UDOH data disclosed or in combination with other data, identifies the subject of the cancer case information or identifies the individual or organization who reported the cancer case information. For research use of cancer registry data, the following are generally not considered to be identifying: month and year of diagnosis, month and year of pathology report, month and year of birth, and county of residence. Exact date of diagnosis, exact date of birth, other exact dates of health events, and geographic units smaller than a county or UDOH-designated Small Health Area are considered to be identifying.

“Limited record-level cancer case information” means any cancer case information data set that does not contain 16 of the 18 identifiers itemized by the federal Privacy Rule for creating de-identified data. Of the 18 identifiers, it may only contain: 1) dates such as admission, discharge, service, or death; 2) city, state, five- to nine-digit ZIP Code or equivalent; and 3) ages in years, months, or days or hours.

3. Public Health Use of Utah Cancer Registry Data

3.1 Providing Utah Cancer Registry Data for Utah Department of Health Programs

Upon request, UCR shall provide cancer case information, including identifiable cancer case information, to UDOH.

Utah Cancer Registry annually provides cancer case data with geographic information to the UDOH Environmental Public Health Tracking Program. The data are made available on the UDOH Public Health Indicator Based Information System (IBIS), allowing users to view aggregated data to be queried online.

When a new UDOH program has a public health purpose to request limited, record-level, or identifiable UCR data or to link identified UCR data to other data, UCR will meet with a representative of the program to discuss the process (e.g. identifiers from UDOH sent to UCR for linkage, or the reverse), eligibility criteria for cases, and data elements requested. The two programs will then jointly write a protocol for the data request which will be signed by both data stewards. The protocol will be sent to UDOH IRB for determination of non-research data use.
3.2 Providing Utah Cancer Registry Data for County, Regional, or Local Health Agencies in Utah
When a county or regional health department or health district within the state of Utah has a public health purpose to request non-public UCR data or to link identified UCR data to other data, UCR will follow the same steps described for UDOH programs, i.e. meeting between the two parties, protocol written, and submission to UDOH IRB.

3.3 UCR Data for National Cancer Surveillance Quality Improvement Projects
UCR actively participates in data collection for projects intended to provide insight on the current quality of cancer registry data and to develop new or improved data sources and methods for cancer surveillance. These projects are in almost all cases sponsored by the NCI SEER program or the CDC National Program of Cancer Registries. UCR's role in these projects may include collecting data items that are not currently specified as required reportable data items. The Utah Cancer Reporting Rule is quite broad in describing the potential contents of a cancer case report:

Each report of cancer or reportable benign tumor shall include information on report forms provided by the Registry. These reports shall be made in the format prescribed by the Registry and shall include items such as the name and address of the patient, medical history, environmental factors, date and method of diagnosis, primary site, stage of disease, tissue diagnosis, laboratory data, methods of treatment, recurrence and follow-up data, and physician names."

Similarly, UCR remains within its scope as defined in the rule when collecting non-reportable data items for surveillance quality improvement projects. For these National surveillance quality improvement projects, UCR will report the special non-reportable data items, along with de-identified cancer case information in the form of conventional cancer case data items, to the national organization for evaluation of data pooled across multiple registries and data dissemination.

UCR is not provided with guidance regarding contributing data to national cancer surveillance quality improvement activities under the language of the MOA between UDOH and U of Utah. Depending on the data requested, UCR may treat the activities in a similar manner to review of a research request for identifiable UCR data (section 5.3), including providing project information in a research protocol format and review by UCR’s Advisory Research Committee or by the Resource for Genetic Epidemiology (RGE) oversight committee. If the UCR director has a role in the design, conduct, and interpretation of the project that is equivalent to an investigator on a research project, the director will be named as PI for the protocol and data request. Alternatively, if UDOH IRB review may be requested for determination of non-research status of the project.

4. Disclosure of Non-Identifiable or Limited Cancer Case Information

4.1 Aggregate data
UCR may create and disclose summary reports and statistics containing non-identifiable aggregate cancer case information, such as frequencies, cross tabulations, age-adjusted incidence rates, and survival rates; provided, however, that such disclosure does not include sufficient information that would allow the requester to identify, by whatever means including linkage with other databases, the subject of the cancer case information or the individual or organization who reported the cancer case information. (3)

4.1.1 Restrictions on non-identifiable, aggregate data reports
In order to ensure that the non-identifiability conditions are met, UCR will remove any potentially identifiable information before disclosing aggregate data. Potential identifiability due to small sample sizes will be addressed by masking cell case counts fewer than five for incident cancers and fewer than 10 for cancer mortality and/or by applying standards of suppression based on relative standard error as defined by the UDOH Report of Guidelines for Data Result Suppression (6). Restrictions on disclosure of death data are based on guidance obtained from UDOH vital statistics. Aggregate data for geographic areas that are smaller than a county or a UDOH small health statistical area cannot be treated as non-identifiable.

In order to adhere to the principle that the individual or organization that reported cancer case information not be disclosed, UCR generally will not disclose aggregate data structured to disclose the number of cancer cases treated by specific providers, facilities, or health care systems. When UCR receives a request for a data summary specific to a facility or health care system, UCR will refer the request to the institution. UCR will communicate with the individual who represents that institution on the ARC committee or with a hospital administrator at that institution. UCR may refer the requestor to the institution for the data or may compile the requested summary information and work with the institution to agree on a data release that is acceptable to the institution.

Disclosure of non-identifiable, aggregate data by UCR does not require any formal review and approval process. As a best practice, when one UCR staff member generates an aggregate data report or summary, a second staff member will review the query and/or perform independent coding of the same query. The second staff member will also review the report format and labeling to assure complete and correct documentation.

4.1.2 Purpose of non-identifiable, aggregate data reports
UCR may report aggregate, non-identifiable cancer case information on its own initiative to carry out its mission to monitor trends and disseminate data. This will be done routinely in the biennial report Cancer in Utah. Other brief ad hoc reports may be produced between editions of Cancer in Utah. UCR will collaborate with UDOH cancer programs and with the Utah Cancer Action Network to report aggregate cancer data reports addressing the goals and needs of those programs.

UCR will produce and disclose non-identifiable aggregate cancer case information in response to requests from individuals or organizations outside UCR. Providing data for research purposes and for public health purposes is emphasized in UCR's mandate and mission. UCR's contract from the SEER program and its role at the University of Utah both emphasize facilitating cancer
research. Accordingly, requests from researchers for summary data such as case counts or incidence rates for the purpose of planning future research will be treated as high priority and will be responded to as quickly as possible. In keeping with UCR's public health surveillance mission, requests from UDOH or other public health agencies within the state for aggregate cancer data for public health and cancer control purposes are also a high priority for UCR.

UCR can also respond to requests for aggregate cancer information from others if the purpose of the request is consistent with cancer control, public health, and/or dissemination of data to the public. Examples may include requests from health care organizations, request from other cancer control stakeholders such as not-for-profit organizations with missions addressing public health and/or cancer control. Requests for cancer information from news media received by UCR will be communicated to the UDOH public relations office. UCR will work with UDOH to determine the most appropriate response to these requests.

UCR staff are able to perform queries and produce aggregate data reports in response to requests from outside organizations as described above. However, staff time that is available to devote to these activities is limited. UCR reserves the right to refer a requestor to a publicly available source of aggregate cancer information.

4.1.3 Other sources of aggregate cancer information
Utah Cancer Registry discloses cancer data to the UDOH. Individuals seeking information for public health and research purposes about cancer in Utah may query the cancer data through UDOH's Indicator-Based Information System for Public Health Data (IBIS) system to produce custom data summaries. UCR also discloses data to several research resources, including the SEER Research Data, Utah Population Database, and the Center for Disease Control and Prevention's United States Cancer Statistics. Researchers may access web-based query systems from each of these sources for aggregate cancer data. See the UCR website, "Cancer Statistics" page, for links to these data sources.

4.2 Non-Identifiable Record-level Cancer Case Information
UCR may disclose non-identifiable record-level cancer case information data files to the North American Association of Central Cancer Registries and the National Cancer Institute's Surveillance, Epidemiology, and End Results (SEER) Program to meet contractual obligations relevant to UCR’s participation in the SEER Program.

UCR has contributed data to the U.S. National Cancer Institute's SEER program since the program's inception. Information about cancers diagnosed among Utah residents since 1974 and reported to UCR are included in the SEER research data set. The contents of each case record traditionally include diagnostic information, treatment information, age at diagnosis, sex, race and ethnicity, county of residence, and vital status. In the data set, dates of birth, diagnosis, and death are represented by month and year, but not day. The SEER research data are available to researchers via a public website (see Attachment 1). Researchers must sign a data use agreement to access the SEER research data (7).
The non-identifiable data that UCR submits to SEER are also shared with other organizations that compile cancer registry data across geographic regions, including the North American Association of Central Cancer Registries and the International Agency for Research on Cancer. These organizations also incorporate the data in public-use data sets.

Beginning in 2017, UCR has been under contract to the Centers for Disease Control and Prevention (CDC) to participate in its National Program of Cancer Registries. UCR submits record-level cancer case data to CDC in fulfillment of this contract. For key events such as birth, diagnosis, and death, these data also contain month and year but not specific dates.

4.3 Limited Record-level Cancer Case Information

UCR may disclose limited record-level cancer case information to others provided that the request is for minimum necessary data for a research or public health purpose and the requestor signs an agreement that he or she will not attempt to identify, by whatever means including linkage with other databases, the subject of the cancer case information or the individual or organization who reported the cancer case information. Requests for limited cancer case information for research must have IRB approval and meet the other provisions stated below for identifiable research data disclosures. (3)

The University of Utah IRB has provided guidance that research using certain publicly available data sets, including the SEER research data, does not require IRB approval (5). UCR may disclose record-level de-identified or limited cancer case information that are equivalent to data available to researchers through the SEER research data. UCR staff will review such a request to assure that the request is for a research or public health purpose. UCR reserves the right to refer a requestor to a publicly available source of these data. See the UCR website, "Cancer Statistics" page, for links to these data sources.

Researchers may request limited or non-identifiable record-level data from UCR that include variables representing tumor characteristics and treatment information that are not available in public data. There are certain variables that are non-public because of lack of confidence in the quality of the variable's data. UCR will disclose such data if a) the request is reviewed by an IRB and approved by ARC or the RGE oversight committee and b) the limitations that may be present in the non-public data items are acceptable for the proposed research use of the data.

Record-level UCR cancer data are linked to other data sets by Utah Population Database (UPDB). This linkage uses personal identifiers including name and date of birth that are disclosed by UCR to UPDB, as described in section 5.7.2.2 of these UCR Policies. A researcher may request UCR data linked to other data through UPDB. Disclosure of UCR data linked to UPDB data, even if non-identified, is subject to RGE review in accordance with RGE policy. If non-public UCR data items linked to UPDB are requested by a researcher, those data items will be disclosed to UPDB for linkage with a record number used by UCR and UPDB. UPDB will not use the non-public data items or release them to other investigators.

Following review and approval of a research request for limited record-level UCR data, the investigator will be asked to sign a Data Security Assurances agreement. By signing this
document, he or she will state his or her commitment to protect data confidentiality and to limit use of the data to approved project. Other individuals who will access the study data will be asked to sign a confidentiality assurance.

5. Disclosure of Identifiable Cancer Case Information

The MOA between UDOH and University of Utah defines eight types of recipients to whom UCR will disclose identifiable cancer case information, as follows.

5.1 Individuals

1) The subject of the cancer case information, upon receipt of a signed request, or to the subject's legal guardian if a guardian has been appointed, or the next of kin if the subject is deceased, as specified in UCR POLICY. (3)

UCR will ask that the requestor fill out a form available on the UCR web site and that the requestor either a) bring the form in person to our office and present state-issued identification or b) mail the form to our office with a photocopy of state-issued identification. The request from a cancer case or representative will be reviewed by the UCR Operations Manager to assure that documentation needed by UCR has been provided and to confirm that the identity of the cancer case described on the request form is a correct match to a cancer case in UCR records. UCR will retain the request form and a photocopy of the state-issued identification. UCR will print out the requested information and send it by U.S. mail or hold for pick up by the requestor.

5.2 Department of Justice

2) The U.S. Department of Justice, upon receipt of a request signed by the subject of the cancer case information, the subject's legal guardian if a guardian has been appointed, or the next of kin if the subject is deceased, for purposes specified under 42 U.S.C. 2210 (2012) Radiation Exposure Compensation Act. (3)

A request from the Department of Justice will be reviewed by the UCR Operations Manager to assure that the documentation needed by UCR has been provided and to confirm that the identity of the cancer case described on the request form is a correct match to a cancer case in UCR records. UCR will complete a form with the requested information and send it by U.S. mail to the Department of Justice.

5.3 Researchers

3) Any researcher for research and statistical purposes as defined in Utah Code Annotated § 26-3-1, provided that:

(a) the identifiable cancer case information is required for the research proposed by the researcher;
(b) the disclosure is for a specified period of time;
(c) the research project received human subjects research ethics review and approval by an Institutional Review Board;
(d) the proposed investigation is reviewed and approved by ARC or by the Resource for Genetic Epidemiology (RGE) oversight committee or by the
UDOH URC Data Use Committee, and the researcher enters into a written agreement with UCR in accordance with UCR POLICY; and (e) one of the following conditions is met:

i. The subject of the cancer case information has provided consent to release his/her information to the researcher, or

ii. The researcher requests minimum necessary identifying variables to achieve study aims that could not otherwise be accomplished, and consent was waived by the approving IRB.

For researchers wanting to contact individuals identified by UCR data, prior consent of the individual will be obtained by UCR. (3)

5.3.1 Research review
UCR will require that a researcher requesting identifiable or non-public UCR data submit an application for review and approval by the ARC or RGE committee. The application forms and review process will be integrated as much as possible with the IRB and RGE application for the same project. The application must provide adequate information about research methods, analysis plan, and sample size requirements so that the research and statistical nature of the proposed research can be evaluated. Further, the research application should address (a) through (e) above. The application must specify the cancer information requested and justify why this is the minimum necessary to accomplish the research objectives. The determination of whether the release of data is for research or statistical purposes will include review of the qualifications of the researcher. A university faculty researcher, or an individual of equivalent status as a researcher in another organization, must take responsibility for the research and for data confidentiality.

In order to assure timely review of applications, a sub-committee of a three minimum of three ARC members, including at least one member who is outside UCR (i.e. does not appear on the UCR organizational chart), may provide review and approval on behalf of ARC. Approval requires a majority of favorable votes from the members of this sub-committee.

Following review and approval of a research request for UCR data, the investigator will be asked to sign a Data Security Assurances agreement. By signing this document, he or she will state his or her commitment to protect data confidentiality and to limit use of the data to approved project. All individuals who will access the study data will be asked to sign a confidentiality assurance.

5.3.2 Exclusions
For disclosure of identifiable data UCR will exclude the following cases:
- HIV associated cancers. This exclusion is based on UDOH restrictions
- Cases for whom the sole source of information was a cancer registry in another state, due to restrictions in the Interstate Data Exchange agreement among State cancer registries.
- Cases for whom the sole source of information was a Veterans Health Administration facility. This exclusion is in accordance with terms of UCR's agreement with the Veterans Health Administration.
- Individuals who have contacted the UCR and requested that they not be contacted for research and/or that their information be withheld.
5.3.3 Out of state cancer cases receiving treatment in Utah
Under state rule, the UCR receives reports of cancer cases diagnosed or treated in Utah regardless of the state of residence of the case. UCR recommends that researchers limit UCR data requests to cases who are Utah residents. UCR data are complete only for Utah residents. Including residents of other states receiving treatment in Utah in a research data set would create a non-population-based and non-representative sample. Data for non-Utah-resident cases reported to the UCR have not been subject to UCR’s coding and editing procedures. Residents of other states are likely to have received diagnostic procedures and/or care outside of Utah which would not be reported to UCR. However, if an investigator describes a research question for which cancer case data from non-Utah residents would still be relevant, after taking into account these limitations, the ARC or RGE committee will consider the request.

5.3.4 Alternatives to disclosing identifiers without consent
In keeping with the spirit of disclosing the minimum necessary information to perform research, for projects that will not obtain consent from participants UCR will propose alternatives to the release of identifying data.
Examples of alternatives to releasing identifying data:
- For research projects requesting exact dates such as date of birth, date of cancer diagnosis, and date of death, UCR will propose to a) calculate the number of days between two events of interest and release number of days as a variable or b) perturb dates. (In the case of perturbed dates, the amount of perturbation will not be revealed to the investigator but may be as little as two days.) UCR's preference will be to release the data items representing days between events or perturbed dates but not exact dates.
- For research projects requesting provider identifiers, UCR will work with the researcher to identify the characteristic of the provider that is of interest, e.g. specialty or distance between patient address and provider office, and will propose to link provider identifiers to the data items representing the characteristic. UCR's preference will be to release the data items representing provider characteristics but not provider identifiers.
- For research projects requesting geographic areas such as zip code or census tract, UCR will work with the researcher to identify the characteristics of the geographic unit that are of interest, e.g. socioeconomic variables or distance between patient address and facility, and will propose to link case identifiers to the data items representing characteristics. UCR's preference will be to release the data items representing characteristics of the geographic unit but not zip code or census tract.

5.3.5 Linkage of other Identifiable Data to UCR Cases for Research Purposes
For a research project that requests UCR identifiers for the purpose of linking to a research data set or list of consented participants, UCR's preference will be that UCR staff or UPDB will perform the linkage. Researchers may securely transmit identified data to the registry, and the UCR will return information on records that were found to link. Researchers transmitting data to UCR for linkage should be aware that UCR is outside the University of Utah's Covered Entity and that therefore consent or an IRB waiver should be obtained for this disclosure of data to UCR.
For a research project requesting that UCR disclose identifiable data to an Honest Broker or Trusted Third Party for data linkage, UCR will request documentation of the Third Party's procedures to protect data confidentiality and its legal obligation (e.g. contract with a federal agency) to do so. Such a request will be evaluated in the RGE review process on a case-by-case basis.

5.3.6 Reporting Delay for Disclosure for Research
Cancer case reports are often received by UCR six months after the diagnosis of the case, and sometimes reports are further delayed. UCR's processes of consolidating, editing, and quality assurance for cancer cases require additional time to complete. UCR observes SEER program deadlines for compiling complete cancer case report data for each calendar year. Data verified by UCR as meeting our completeness and quality standards are submitted to SEER for a November deadline, 23 months after the end of the diagnosis year. Therefore best quality data for research requests for record-level cancer data and/or data linkage are available at that time. UCR submits a more limited data set including cancer case diagnosis date, site, and histology to SEER in February, 14 months after the end of the diagnosis year; these data may be made available to researchers if justified by research need and if the data quality issues will not compromise the research.

5.3.7 Contacting cancer cases for research recruitment
For researchers wanting to contact individuals identified by UCR data, prior consent of the individual will be obtained by UCR. (3)

5.3.7.1 Rapid case ascertainment
For research requests to contact cancer patients, it will often be desirable to contact a case soon after diagnosis rather than wait until the cancer case eligibility data is considered final for cancer registry reporting purposes. There are several reasons for contacting cases closer to the time of diagnosis: individuals with certain cancers may have short survival; the case may relocate, so that the contact information that UCR received with the case report becomes out of date; individuals may be more motivated to participate in research closer to their diagnosis date; the research may involve collecting information that can better be obtained closer to the time of diagnosis. For approved studies, UCR will conduct rapid case ascertainment of potentially eligible cases. UCR staff will review potentially eligible cases close to the time that an initial report is received by the registry. If the case is confirmed by a certified tumor registrar to be a likely eligible case, UCR research staff will proceed to contact the case for the study. However, UCR will avoid contacting individuals within a few weeks after cancer diagnosis, a time when the individual and his or her family are likely to be experiencing unusual stress.

5.3.7.2 Contact protocols
UCR staff will contact research participants using evidence-based strategies to achieve good response rates. Contact protocols will include multiple contacts and usually will include multiple modes. UCR staff will work with researchers to tailor study-specific contact protocols which may include collection of consent forms and/or questionnaires. For all reportable cancers, UCR obtains data for address at diagnosis as part of its surveillance efforts. If UCR research staff are unable to contact the case at the address in cancer registry records, or if several years have passed since the address information was received, UCR
research staff will make reasonable attempts to obtain new contact information. This may include using forwarding address information provided by the post office or by an individual responding the study mailing who is not the intended participant. UCR staff may search secure online proprietary databases for new contact information. As part of our best practices, before attempting to contact a potential research participant, UCR research staff may make reasonable efforts to discover whether the cancer case may have died. This will usually be done if the case's current age is elderly and/or if the case was diagnosed with a type or stage of cancer that indicates poor prognosis. The purpose of these efforts is to avoid causing distress to other household members by sending mail addressed to a person who is deceased. UCR staff will use death information obtained from the UDOH and further, may contact the hospital registry that reported the case for new follow-up information or may conduct online search of newspaper obituaries.

5.3.7.3 Contacting next-of-kin or proxies
For a study protocol that includes UCR contacting cancer cases, UCR will determine in advance how study staff should proceed if it is determined that the cancer case eligible to be contacted for the study is deceased. For some protocols it may be appropriate for UCR staff to make contact with a family member or other proxy. UCR may contact a proxy if the purpose is to obtain information about the case from the proxy, and if the information from the proxy is important to the research question. If it is determined that the case is deceased before any attempt to contact that case is initiated, UCR staff will wait until three months after the date of death of the cancer case to attempt to contact a proxy. If a UCR staff member learns that the case is deceased only when contacting a household by telephone, the staff member will use his or her judgment to decide whether to initiate a conversation about proxy participation. If the researcher wishes to contact family members of a deceased cancer case for the purpose of recruiting the family members into a study because UPDB data indicates that those family members are part of a high-risk cancer family, the initial contact with the family will be made through RGE.

5.3.7.4 Multiple studies contacting the same individual through UCR
Situations arise in which a group of cancer cases has been contacted by UCR for participation in a research study, and then a second researcher wishes to contact cancer cases with overlapping eligibility criteria. In this case UCR will contact both researchers to make them aware of this overlap. The researchers will be encouraged to arrive at a plan, for example time delay between contact for the two different studies, to support good recruitment rates and thus the research integrity of both studies.

UCR, when contacting an individual for a second study, will acknowledge this in the wording of the cover letter, for example "We know that you were recently contacted regarding a research study. We are now contacting you regarding a different study which may be eligible."

5.3.7.4 Data on non-participants
For research protocols in which UCR contacts potential participants, UCR will provide information to the researcher on eligible individuals whom UCR was unable to contact or who declined to have contact information released to the researchers. This will be in the form of de-identified record-level information on case characteristics such as year of diagnosis, age, gender, and stage. This data is for the purposes of complete study reporting and the need to describe non-participating eligible cases when describing study results.
UCR will ask that researchers return to UCR or destroy identifying data for cancer cases who were contacted by UCR and agreed to have identifiers released to the researcher but who did not ultimately consent to the study protocol. This will typically be within six months of the researcher receiving the identifiable cancer case information. Further, UCR will request that the researcher report to UCR the reason for each case's non-participation, e.g. declined to participate, unable to locate, not eligible. This information is for UCR's purposes of understanding factors related to study participation and ongoing quality improvement of recruitment processes.

5.3.8 Disposition of Cancer Case Information
All record-level cancer case information disclosed by UCR must be destroyed or returned to UCR at the end of the research project, upon request of the UCR, or upon termination of the agreement between the researcher and the UCR. The standard period for approval of a research project using identifiable or record-level non-public UCR data will be five years. Near the end of that period, UCR will contact the investigator to determine whether the investigator will request to renew the project. If the project is not renewed, UCR will request that the investigator confirm that the data have been destroyed.

A protocol that includes re-sharing of Utah Cancer Registry reportable, coded data items may be approved if a) the re-sharing is included in the investigator's approved NIH Data Sharing Plan and b) the Data Sharing Plan is reasonably sufficient to prevent re-identification of individuals.

5.3.9 Publications
Researchers who obtain UCR data from UCR or from UPDB will be requested to submit abstracts and publications resulting from the research project to UCR. UCR will review the publication to assure that UCR has been appropriately acknowledged and that no cancer case information is reported in a manner that is potentially identifiable. Potential identifiability due to small sample sizes should be addressed as described above (section 4.1.1), by masking cell case counts fewer than five for incident cancers and fewer than 10 for cancer mortality and/or by applying standards of suppression based on relative standard error as defined by the UDOH Report of Guidelines for Data Result Suppression (6). UCR will also compile bibliographies of published work resulting from UCR data disclosed by UCR or through UPDB for reporting to its funding and oversight organizations.

5.4 Providers

4) A "health care provider" as defined in Utah Code Annotated § 78B-3-403 who needs access to the identifiable cancer case information in order to provide medically-related or cancer-related services to the subject of the identifiable cancer case information or who needs access to identifiable cancer information for a case treated by that provider for the purpose of quality improvement and quality assurance of cancer care. (3)

For a provider who has reported a cancer case to UCR, UCR may return information about the case that UCR obtained from other sources. This information may include diagnostic, treatment, and follow-up variables. In practice, UCR will most often disclose these data to hospital tumor registries that report cases to UCR on behalf of the providers at their institutions. With the approval of a hospital or other health care institution, UCR may disclose cancer case data for
cases reported by the institution to an organization contracted by the facility to manage cancer data. UCR often receives treatment information six months after the diagnosis of the case, and sometimes reports are further delayed. Therefore providers and tumor registrars should not rely on UCR as a primary or real-time source of treatment information. For case follow-up data, UCR will provide vital status and date of last follow-up obtained from a variety of sources including UDOH vital records. UCR will observe restrictions from the data source, such as Utah Department of Health or National Death Index (NDI), on release of vital status, date of death, and cause of death. Release of information received from the Utah Department of Health Office of Vital Records and Statistics for non-research purposes must be approved by the Office of Vital Records and Statistics data steward (8).

5.5 Cancer Registries in Other States

5) A cancer registry that has entered into a signed agreement with UCR to exchange identifiable cancer case information regarding:
(a) individuals who are residents of the collaborating registry’s area of coverage and may have been diagnosed or treated for cancer in Utah; or
(b) individuals who are residents of Utah and may have been diagnosed or treated for cancer in the collaborating registry’s areas of coverage. (3)

The North American Association of Central Cancer Registries (NAACCR) has developed a National Interstate Data Exchange Agreement. Participating central (state) registries exchange data for cancers reported to a registry in one state but determined to reside in another state. The NAACCR Interstate Data Exchange Agreement states that records received through data exchange shall not be re-released for research. UCR participates in the NAACCR Interstate Data Exchange Agreement, with the stipulation that cancer records for Utah residents received from other registries may be disclosed to UPDB, although not re-released by UPDB. Two states that border Utah, Nevada and Arizona, do not participate in the NAACCR data exchange. UCR has bilateral data exchange agreements with these two states. These data exchanges have similar restrictions.

5.6 Linkages for Surveillance

6) An organization that assists UCR with linkage of identifiable cancer case information to other information for UCR’s surveillance activities. Organizations include, but without limitation, U.S. Social Security Administration, Centers for Disease Control and Prevention’s National Death Index, Center for Medicare and Medicaid Services, Bureau of the Census, and Indian Health Service. UCR shall enter into a written agreement subject to UDOH review with such organizations regarding the release and confidentiality of identifiable cancer case information. The organization shall agree to delete UCR cancer case information following completion of the linkage. (3)

Linkages with Social Security Administration and National Death Index are important sources of follow-up data, i.e. vital status and last contact date, for UCR cancer cases. UCR observes restrictions on re-releasing data based on agreements with these organizations. UCR will not release cause of death information received from National Death Index due to restrictions on those data.
5.7 Research Resources

7) Research resources for the purpose of linking UCR cancer case information to other data to increase the research value of the cancer data. Research resources may receive identifiable cancer case information provided the resource has policies for disclosure of data to researchers that are acceptable to the UDOH and ARC. The University of Utah Resource for Genetic Epidemiology is such a resource and is addressed below. Another example of a research resource is the SEER-Medicare Linked Database. When a research resource is not under the University of Utah’s authority, a separate data sharing agreement between the UCR and the research resource is needed. (3)

5.7.1 National Research Resources

Research resources administered by the SEER program, i.e. SEER-Medicare and SEER-Medicaid, have an established data request process including research application, documentation of IRB approval at the researcher's institution, and data use agreement. The data released by SEER-Medicare to researchers does not contain identifiers from UCR data. With special request and justification, investigators may receive one or more of the following potentially identifying variables from the Medicare data: patient zip code, patient census tract, hospital zip code, hospital census tract, and provider identifier number. Protocols that request these potential identifiers are reviewed by the UCR Director. UCR disclosure of identifiable data for the purpose of linkage to create research resources not under the University of Utah's authority is subject to review and approval by the UDOH IRB.

5.7.2 Utah Population Database

5.7.2.1 Release of Cancer Case Information from UCR to RGE

A. UCR may release cancer case information to the University of Utah Resource for Genetic and Epidemiologic Research (RGE), the oversight body of the Utah Population Database, in accordance with RGE's Memorandum of Agreement with UDOH and in accordance with UCR POLICY. UCR may provide annual updates of selected cancer case information to RGE at an agreed upon schedule and as mutually agreed upon by the UCR and RGE, and approved by UDOH. (3)

UCR will annually release to UPDB an updated data set with final edited cancer case information. UCR data released to UPDB will include identifiers such as social security number, name, and address for the purposes of linkage. Data that will become available for research use include diagnostic and treatment variables comparable to what is available through SEER research data. The same exclusions to the release of cancer case information that apply to researchers, described above in Section 5.3.2, apply to the data shared with UPDB.

All transmission of identifiable data between UCR and UPDB shall be conducted via Secure File Transfer Protocol (SFTP).

B. RGE shall make UCR data available to qualified and approved research projects in accordance with the RGE Policies and Procedures and UCR POLICY.
C. UDOH, through its appointed agent, will sit on the RGE Review Committee. Identifiable cancer case information provided by UCR to RGE will only be made available through RGE for projects approved by that UDOH representative. (3)

Researchers wishing to use UCR data available through UPDB will submit a research protocol for RGE review through the ERICA system. A UPDB data navigator will encourage researchers to meet with UCR research staff about their research projects and how UCR data fit in before submitting the proposal for RGE review. RGE must review and approve data requests prior to investigators receiving access to UPDB data.

UPDB may perform approved linkages between UCR data held by UPDB and identifiable data provided by researchers.

RGE/UPDB shall routinely provide a report of all research projects approved by RGE that access UCR data via the UPDB.

D. The RGE Review Committee shall have a voting UCR representative. UCR, as a data contributor, may veto proposals and publications involving UCR data as described in the RGE Policies and Procedures. The RGE shall not release any identifiable cancer case information obtained from UCR to the public, any governmental agency, any private organization, or any person, except as provided in this agreement or with the prior consent of UDOH and UCR, as described in the RGE Policies and Procedures and UCR POLICY.

E. In accordance with RGE Policies and Procedures, RGE shall require that any researcher who has access to cancer case information held by RGE does not contact any individual identified in the data without prior consent of the individual obtained by UCR. (3)

5.7.2.2 Release of Data from UPDB to UCR
In addition to UCR’s routine transmission of edited cancer information to UPDB in November of each year, identifiable cancer cases known to UCR will be shared with UPDB at an earlier time each year, around February, for the purposes of linkage to UDOH All-Payers Claims Data (APCD). UPDB will perform linkage of UCR data with APCD. For cases who link, UPDB will return claims to UCR for surveillance purposes. UCR will use these claims to fill in missing cancer treatment data and other surveillance variables as appropriate. UCR and UPDB will submit a written protocol for RGE review and approval before initiating this linkage process. UCR will not share or disclose the claims information except in the form of coded cancer registry variables, the content of which will not be distinguished as coming from APCD versus other cancer registry data sources.

Investigators wishing to use APCD data linked to UCR data must obtain these data through UPDB. The research data request must be submitted for RGE review and approval.

Upon request, UPDB shall provide UCR with any available updated address information for UCR cancer cases.
5.8 Data Management Contractors

8) Organizations providing data management services to UCR. These organizations must enter into a signed agreement with UCR subject to approval by UDOH. These organizations must provide assurance that University of Utah and UDOH data privacy and security requirements are met and that identifiable UCR cancer case information is not further disclosed by such organizations. (3)

UCR receives cancer case reports in electronic format and then performs a series of processes that result in its final quality assured cancer registry data set. These processes include linking records representing the same case, consolidating, coding, editing, and quality assurance. Cancer registry data management software greatly facilitates these processes. Currently UCR uses the SEER Data Management Software (SEER*DMS) product from Information Management Services (IMS) Inc., Rockville, MD to facilitate UCR's work with the data. UCR data are hosted within IMS Inc.'s secure server environment. UCR has a data security and hosting agreement with IMS Inc.

IMS employees who have signed a non-disclosure agreement may access UCR data to support the UCR, including the following:

- Investigate technical support issues submitted by registry staff,
- Test algorithms developed by IMS staff for the benefit of the registry,
- Test algorithms developed by external organizations for the benefit of the registry, and
- On the Registry’s behalf and after notifying the Registry, create summary reports and statistics containing non-identifiable aggregate cancer case information, such as frequencies and cross tabulations, and disclose such reports to NCI SEER staff. This would apply if the purpose of the request for aggregate data is consistent with cancer control, public health, or cancer registry process evaluation or improvement. The aggregate information must be de-identified as described in section 4.1 above.

References cited

