

UTAH CANCER REGISTRY
POLICY AND PROCEDURES GUIDE:
REQUESTS FOR REGISTRY DATA

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Policy & Procedures Guide:
Requests for Registry Data**

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SECTION I: GENERAL INFORMATION AND POLICIES

1. **BACKGROUND AND PURPOSE**

- A. This document describes the Utah Cancer Registry (hereto referred as “UCR” or “Registry”) policies and procedures governing the release of cancer information for research purposes.
- B. The UCR serves as the official repository for statewide cancer data per Cancer Reporting Rule, R384-100, and a Memorandum of Agreement between the Utah Department of Health and the University of Utah.
- C. This document amends previous policies and procedures as outlined in:
 - 1) Exhibit A: Section 1, Policies and Procedures for Research Use of Utah Cancer Registry Data
 - 2) Exhibit A: Section 2, Policies and Procedures for Research Use of Utah Cancer Registry Data: Exchange of Data between Research Resources.
 - 3) Utah Cancer Registry Policy & Procedures Guide (Revised December 17, 2003).
- D. Before requesting data incidence and mortality rates from the UCR, researchers are encouraged to go to the UCR website at <http://uuhsc.utah.edu/ucr/> to review the incidence and mortality data currently available online.

2. **THE HISTORY OF THE UTAH CANCER REGISTRY (UCR)**

In 1946, the Utah State Board of Health officially made cancer a reportable disease in Utah. In 1966, Dr. Charles R. Smart established the Utah Cancer Registry as a statewide, population-based cancer registry. In 1968 the State Board of Health designated the UCR as the official reporting agency to which all cancers were to be reported.

Since 1973, the UCR has operated as one of several population-based cancer registries under contract to the Surveillance, Epidemiology and End Results (SEER) Program of the National Cancer Institute (NCI). The SEER Program was established in 1973 as an outgrowth of the National Cancer Act, and has provided high quality information on time trends in cancer incidence and survival rates for the nation. UCR collects complete, timely, and accurate cancer incidence, treatment, and survival data for SEER-reportable cancer cases in Utah.

3. **DEFINITIONS**

Advisory Research Committee (ARC). The UCR ARC is responsible for overseeing the disclosure of cancer case information and approves requests for patient identifiable data from the UCR. The ARC includes representatives from community-based health care providers and health care facilities, the Utah Department of Health (UDOH), and the University of Utah, with

experts in the field of epidemiology and biostatistics. The ARC will follow guidelines approved by the HDROC and provide formal minutes of its proceedings to the HDROC via its representative on that Committee. Any request that cannot be resolved by the ARC will be referred to the HDROC. Disapproval by the ARC may be appealed to the HDROC. For a current roster of the ARC, please refer to Section III: Advisory Research Committee or visit the UCR website at <http://uuhsc.utah.edu/ucr/>.

Biomedical Research Resource (Resource). An organization within the University of Utah that provides a service to all qualifying biomedical researchers. The UCR is a resource, as is the Utah Population Database (UPDB) and the Resource for Genetic and Epidemiologic Research (RGE).

Cancer Case Information. Any information that the Utah Department of Health (UDOH) requires persons or organizations to report to the UCR pursuant to Utah Code Annotated 26-5-2 and 26-1-30.

Clinical Cancer Investigations Committee (CCIC). The CCIC works in conjunction with the University of Utah Institutional Review Board (IRB), and is responsible for reviewing cancer-related protocols for scientific merit, scientific progress, and participant accrual. It also prioritizes cancer protocols that may be competing for the same participant population. Studies involving cancer patients must receive CCIC approval before it can be approved by the IRB, though applications can be submitted to both committees simultaneously.

Confidential Data. All cancer case information at the UCR is considered confidential. The UCR is responsible for protecting the data from unauthorized access and release by maintaining strict standards of confidentiality. Data that identify patient-specific information, including biologic tissue, and information that identifies a health care provider or institution are given special consideration and requests for these data must obtain approval in accordance with UCR policies and procedures described in this document. Furthermore, information that characterizes the caseload of a provider or reporting institution is considered propriety and confidential.

Disclose or Disclosure. The communication of cancer case information to any individual or organization.

Human Database Research Oversight Committee (HDROC). The HDROC is responsible for maintaining the integrity of databases that contain confidential information, which are accessed for purposes of human subjects research. The HDROC reports to the Vice President for Research at the University of Utah.

Patient Identifiable Cancer Case Information. Any cancer case information, which either from the data disclosed or in combination with other data, identifies the subject of the cancer case information or the individual or organization who reported the cancer case information.

Research Project. A research protocol that has been approved by an appropriate Institutional Review Board (IRB), the UCR Advisory Research Committee (ARC), and/or administratively reviewed by UCR management.

Researcher. The principal investigator on a Research Project (as defined above) or the individual requesting data from the UCR.

Resource for Genetic and Epidemiologic Research (RGE). The RGE governs access to certain data and research resources provided to the University of Utah for use in biomedical research, including data from the Utah Population Database (UPDB) and the High Risk Cancer Clinics (HRCC) at the Huntsman Cancer Institute.

University. Includes all organizations, entities, and individuals under direction of the University of Utah.

Utah Population Database (UPDB). A resource for biomedical and health-related research, which links an extensive set of Utah family histories to demographic and medical information, including diagnostic records on cancer, cause of death, and medical details associated with births. These data are primarily used for genetic, epidemiological, demographic, and public health studies. The UCR contributes a limited set of cancer incidence data to the UPDB.

4. DISCLOSURE OF CANCER CASE INFORMATION

A. UCR may disclose non-identifiable cancer case information as follows:

- 1) **Aggregate Data.** Information such as age-adjusted incidence, mortality rates, frequencies, and cross tabulations may be released provided that such disclosure does not include sufficient information that would allow the requester to identify the subject of the cancer case information or the individual or organization who reported the cancer case information. This may include masking cell sizes less than 2 for tabulated data covering small geographic areas or short time intervals (i.e., county-level data for a single calendar year).
- 2) **Tumor-level Data.** The UCR may release non-identifiable tumor-level data, which may include tumor characteristics and treatment information. The tumor data will not be identified except by an identifying number with no meaning in any dataset other than the UCR. Patient demographic information will not be released.

B. **Patient Identifiable Cancer Case Information.** UCR may disclose patient identifiable cancer case information to:

- 1) Any researcher who submits a signed release from 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.
- 2) A Researcher for a Research Project when:
 - a. The identifiable cancer case information is required for the research proposed by the researcher.
 - b. The Research Project has been approved in accordance with Section I:

Number 6 (Approval of Research Projects Using Patient Identifiable Cancer Case Information) below.

c. The Researcher enters into a written agreement with UCR. The written agreement is attached to this policy as **Addendum A**.

- 3) A Researcher employed with the Utah Department of Health as specified in the Memorandum of Agreement between the University of Utah, on behalf of the Utah Cancer Registry, and the Utah Department of Health.
- 4) Institutions and physicians providing data to the Registry; however, cancer case information will be limited to information on cases reported by their own institution or practice.
- 5) UCR may provide identifiable cancer case information to a biomedical research resource if the resource meets the conditions of Exhibit A: Section 2, Exchange of Data Between Research Resources (**Addendum B**). Such access to cancer case information is governed by a written agreement between the resource and the UCR.

5. **CONTACT OF SUBJECTS**

If a researcher wants to contact subjects identified through the UCR, the researcher must submit a written request directly to UCR and obtain approval in accordance with Section I: Number 6 (Approval of Research Projects Using Patient Identifiable Cancer Case Information) below. UCR will obtain patient consent for the researcher as outlined in Section I: Number 7.F. UCR has standard letters and consent forms available, which may be customized to suit the needs of the Research Project (Addendums H and I). The Researcher must obtain IRB approval for the use of these forms in conjunction with their project.

6. **APPROVAL OF RESEARCH PROJECTS USING PATIENT IDENTIFIABLE CANCER CASE INFORMATION**

To obtain approval to use patient identifiable cancer case information for a Research Project, the Researcher must complete the following steps:

- A. Discuss the approval process with the Director of the UCR or designee. Discuss the terms and conditions of the written agreement to be signed by the Researcher, including but not limited to the provisions regarding maintenance of confidentiality, patient contact, and sanctions for violating these provisions. The Director of the UCR, or designee, may provide the appropriate application forms, or the Researcher may obtain them from the UCR website (<http://uuhsc.utah.edu/ucr/>). After approval of the Research Project by the ARC, the Director of the UCR, or designee, will inform the Researcher of the approval and review applicable policies and procedures as needed.
- B. Obtain approval from an IRB and other oversight committees as needed (i.e., CCIC, RGE).

- C. The Researcher should provide the following information for the Proposed Research Project to the UCR:
- 1) Copies of the Research Project's IRB application, IRB approval, approved research forms (i.e., consent forms), and identification of the Research Project's funding agency and timetable.
 - 2) Complete list of all project personnel who will have access to identifiable cancer case information.
 - 3) Description of the proposed Research Project.
 - 4) Description of patient identifiable cancer case information required by the Research Project.
 - 5) Description of data handling procedures, for both electronic and paper records of the cancer case information as well as biologic tissue collected by the UCR for the Research Project.
 - 6) Justification of any request for patient identifiable cancer case information, including the proposed Research Project's particular need for such information, special precautions and detailed description of data handling procedures, the time period during which such information will be required, and the procedures for destroying or returning the information at the end of the specific project.
- D. Obtain approval from the UCR. All proposed Research Projects requesting patient identifiable cancer case information will be reviewed by the UCR Advisory Research Committee (ARC). The review will evaluate the adequacy of the proposed Research Project in terms of the following:
- 1) Will the proposed Research Project maintain strict confidentiality of identifiable cancer case information? How will the proposed Research Project protect against willful or accidental release of such identifiable cancer case information?
 - 2) Will the proposed Research Project make inappropriate use of information deemed proprietary by data contributors?
 - 3) Are the proposed uses of identifiable cancer case information justified by the anticipated benefits of the research? Is the anticipated benefit reasonable in light of previous research?
 - 4) Is the use of the cancer case information technically feasible?
- E. A proposed Research Project can be approved (with or without modification), rejected, or judged to be incomplete by the UCR Advisory Research Committee. Incomplete proposals require additional information from the Researcher and will receive a definitive

review following the receipt of new information by the appropriate body. If a proposed Research Project is rejected, the Researcher may reapply for approval, or he or she may appeal the decision to the Human Database Research Oversight Committee (HDROC).

- F. A quarterly report of all projects reviewed by the Utah Cancer Registry's Advisory Research Committee will be submitted to the HDROC.

7. **RESTRICTIONS ON INVESTIGATOR USE OF PATIENT IDENTIFIABLE CANCER CASE INFORMATION**

The following restrictions apply to the use of identifiable cancer case information:

- A. Maintenance and Storage of Data by Researcher. Patient identifiable data must be encrypted or kept separate from medical data stored by the researcher. This separation applies for data kept in paper format or on a computer. The medical data will not be identified except by an identifying number with no meaning in any data set other than the researcher's or UCR. The patient identifiable cancer case information will not be attributed to a source that identifies the nature of the records (e.g., the Utah Cancer Registry). Identifiable data stored on a computer network must be secured from unauthorized network access by the most effective means that are technically available.
- B. Access to Data Stored by Researcher. Access to patient identifiable data is restricted to authorized staff of the Research Project listed on the protocol that also completed HIPAA/human subjects training. Any access to identifiable cancer case information that takes place over a computer network must be secured from unauthorized network access by the most effective means that are technically available.
- C. Linkage. UCR staff will perform record-linking tasks at the UCR whenever feasibly possible. Researchers may bring identified data to the registry, and the UCR will return medical information on records that were found to link. If the Research Project has the patient's informed consent, then linkage projects will be administratively reviewed by the Director, or designee. However, ARC review and approval will be required if the Research Project does not have the patient's informed consent.
- D. Other Research Projects. The Researcher may only use the cancer case information for the specified Research Project. If the Researcher wants to use such cancer case information for another research project, he/she must first obtain the appropriate approval for the research project. The Researcher, and any individual working on the Research Project, may not disclose the cancer case information to others without the prior written consent of UCR. Moreover, the cancer case information may not be reproduced in any form except for internal use or with prior written consent from the UCR.
- E. Publication. In the event the Researcher wants to publish the results of an approved Research Project, the Researcher must:
 - 1) Provide to UCR written notice of his/her intent to publish and a draft of such publication. UCR will have thirty (30) days after receipt of the draft publication to

request in writing the removal of any portions of the publication deemed by UCR to inappropriately disclose patient identifiable cancer case information. Upon receipt of such request from UCR, the Researcher and UCR will attempt, in good faith, to agree upon the modifications or revisions to the draft publication, which are reasonably necessary to protect the privacy of the subjects of the cancer case information. In no event, however, will the Researcher publish identifiable cancer case information without the written consent of UCR.

- 2) Acknowledgement must be made that the research was supported by the UCR, which is funded by Contract #N01-PC-35141 from the NCI with additional support from the Utah State Department of Health and the University of Utah.
 - 3) Authorship may be required when UCR makes substantial contribution to the data.
- F. Contact of Subjects of Cancer Case Information. If the Researcher wants to contact subjects of cancer case information, he/she must obtain approval in accordance with Sections I and II of the UCR Policies and Procedures Guide: Requests for Registry Data. UCR will contact each subject of the cancer case information (or the legal guardian of the subject if a guardian has been appointed by a court) and request the subject's written consent to be contacted by the Researcher. In no event will the Researcher contact a subject of the cancer case information unless UCR has first obtained written consent. UCR has standard letters and consent forms available, which may be customized to suit the needs of the Research Project (Addendums H and I). The Researcher must obtain IRB approval for the use of these forms in conjunction with their project.
- G. Return of Cancer Case Information. All cancer case information will remain the property of UCR and must be destroyed or promptly returned to UCR at the end of the project, upon request of the UCR, or upon termination of the agreement between the Researcher and the UCR.
- H. Audits. As specified in the Memorandum of Agreement between the UDOH and the UNIVERSITY, UCR or UDOH may conduct on-site audits of the Researcher with or without cause. Audits will be conducted during normal business hours by a representative of the UCR, UDOH, and a member of the ARC. UCR will conduct one audit per year to observe the Research Project's practices for protecting the confidentiality of cancer case information, which may include verifying that research personnel have HIPAA/human subjects training. Prior to the audit, UCR will send the Researcher (Principal Investigator) a letter explaining the audit requirement for using UCR data, the content of the audit, and when the audit will take place (date and time). The Principal Investigator(s) and all staff with access to UCR data, including the Project Coordinator, should be present during the audit.
- I. Training. The Researcher and each member of his/her staff must provide evidence that all staff with access to UCR data have attended a HIPAA or other human subjects training course. The UCR will accept the Online Collaborative IRB Training Initiative (CITI), VA Good Clinical Practice Training, or Human Participant Protections Education

for Research Teams available via the National Cancer Institute web site. New Research Project staff members must submit evidence within 30 days of employment, and all Research staff should submit renewal certificates each year upon expiration.

- J. Annual and Final Reports. The Researcher must submit annual and final reports regarding the progress and completion of the Research Project to UCR. The reports should provide continued justification for the use of UCR data and resources, include a list of publications resulting from the Research Project, changes in the Research Project protocol or personnel, any incidents that may have resulted in the disclosure of patient identifiable cancer case information, and any other information requested by UCR, ARC, or the HDROC (see Addendum G).
- K. Renewal of the Research Project. If a Research Project continues beyond the original termination date stated in the proposal, the Researcher must notify the UCR in writing of the new termination date, submit corresponding approvals from an IRB, and obtain approval in accordance with Section I: Number 6 (Approval of Research Projects Using Patient Identifiable Cancer Case Information).
- L. Penalties for Violations. In addition to terminating the agreement for a violation of this policy, the UCR may impose sanctions on the Researcher. Individuals who have witnessed inappropriate use of UCR data or a breach in confidentiality may report violations to the UCR. Violations may also be identified via annual audits or annual reports. The UCR recognizes that violations may occur to various degrees, however, in all cases the ARC will be notified immediately and the Research Project will be suspended for a minimum of 30 days. During that time, the ARC will meet to discuss the magnitude of the violation and the steps needed to rectify the infraction(s). The ARC will also determine if the violation(s) should be reported to the proper authorities, including the IRB. The UCR may also prohibit the Researcher from using cancer case information for a certain period of time. If the Researcher is a University of Utah employee, the University may also take appropriate disciplinary action. Infractions from non-University of Utah employees may be reported to the Principal Investigator's employer.
- M. Release of Other Tumor Information. The UCR will only release tumor information applicable to the Research Project, unless the Researcher obtains consent from the patient to access information on all his/her tumors.

8. RELEASE OF AGGREGATE DATA

To obtain aggregate data as defined in Section I: Number 4.A.1, the Researcher must complete the UCR Data Request for Non-Identifiable Data (**Addendum C.1**) and contact the Director of the UCR, or designee, to describe the statistical needs and data fields necessary to fulfill the request.

SECTION II. DATA ELEMENTS, FORMS, AND PROCEDURES

1. PLANNING AND PROPOSING STUDIES

Several different types of studies can be conducted utilizing data from the UCR, including descriptive analyses, data linkage studies, medical record review, or survey studies. Requests for rates or counts of cases by cancer site or geographic area will be furnished by Registry staff without further review after the researcher completes a Data Request for Non-Identifiable Data (**Addendum C.1**). However, researchers are encouraged to visit our website at <http://uuhsc.utah.edu/ucr/> to review the incidence and mortality data currently available. Studies requiring additional data fields require completion of the Data Request for Patient Identifiable Data (**Addendum C.2**), a research proposal, signed research agreement and confidentiality statements, and other documents depending on the type of research proposed and data fields requested. Studies that involve patient contact require that initial contact with patients be performed by UCR staff, following strict procedures to assure confidentiality. As a first step in the planning phase of a study that proposes to utilize UCR data, investigators should discuss the project with the Registry Director, or designee.

2. INSTITUTIONAL REVIEW BOARD(S) (IRB) REQUIRED

All investigators who request UCR data with identifiable information or which require contact with cancer patients are required to obtain approval from an IRB. Research projects requiring patient tissue or records from individual hospitals must also obtain IRB approval from the individual hospitals. The full IRB application, including the approval letter and approved research forms, must be submitted to the UCR.

3. DATA ELEMENTS

The SEER Program has defined a list of data items that are available in its User File. For a list of these data elements, Researchers may go to <http://www.seer.cancer.gov/publicdata/documentation.html> and <http://www.seer.cancer.gov/manuals/CD2.SEERDic.pdf>. Inquiries for the SEER Public Use Tape can be made directly to the SEER Program Office at NCI (<http://www-seer.ims.nci.nih.gov>). If more current information from Utah is desired, these data can be obtained from the UCR. In such instances, the costs of producing the data tape and assistance with the interpretation of the data elements may need to be incorporated into the researcher's budget.

The UCR collects a number of data items in addition to those provided on the SEER Public Use Tape. Some of these data items are collected to assist cancer programs at local institutions meet their requirements for American College of Surgeons accreditation, to assist UCR in case-finding and report generation, and to meet Utah Department of Health or the North American Association of Central Cancer Registries requirements. A list of available data items is provided as **Addendum D**. It is the policy of UCR that certain data elements are not released under any circumstances.

4. **FORMS**

The form(s) that must be completed for each data request will vary depending on the type of research proposed, the UCR data items requested, and the required level of approval. The forms may be obtained from the Registry Director, or designee, or obtained from the UCR website (<http://uuhsc.utah.edu/ucr/>). The forms are as follows:

- A. Data Request forms:
 - 1) Researchers requesting non-identifiable cancer case information should complete the Data Request for Non-Identifiable Data (**Addendum C.1**).
 - 2) Researchers requesting identifiable cancer case information should complete the Data Request for Patient Identifiable Data (**Addendum C.2**).
- B. Research Proposal (**Addendum E**). This form must be completed when a study requires more information or additional review than those requesting general statistics. A Research Proposal must always be completed when requesting personal identifiers or patient contact. Initial patient contact must always be performed by the UCR staff. The UCR must have a signed patient consent form before releasing any name to Researchers. Note: A copy of an approved IRB research protocol may be attached and referenced where applicable. Any research project involving human subjects must be reviewed by an IRB, and, for University of Utah research involving human subjects must also be reviewed by the CCIC.
- C. Research Agreement (**Addendum A**). This agreement must be signed by all Researchers who have been approved to have identifiable cancer case information.
- D. Confidentiality Statement (**Addendum F**). Although the principle investigator is responsible for assuring that the data are kept confidential, all study staff with access to identifiable UCR data are required to sign a confidentiality pledge. These signed pledges will be kept on file at the UCR.
- E. Patient and/or Next-of-Kin Contact Letter and Permission Form (**Addendums H and I**). If a Researcher intends to contact patients identified by the UCR, the UCR must obtain consent from the patient to release his/her contact information to the Researcher. The UCR has standardized letters and permission forms available, and the Researcher may customize the letters and forms as needed for his/her Research Project. Patient and/or Next-of-Kin contact letters and permission forms must be reviewed and approved by an IRB.

5. **APPROVAL PROCEDURES**

All investigators who request UCR data are required to obtain approval from the Cancer Registry. The levels of review are as follows:

A. Full Review by UCR’s Advisory Research Committee (ARC): With the exception of linkage studies, all other studies requesting data elements that may potentially identify a cancer patient, their physicians, or institutions involved in the patient’s diagnosis and/or treatment, and all Research Projects which require contact with cancer patients require full review. The review will evaluate the adequacy of the proposed Research Project in terms of the following:

- 1) Will the proposed research project maintain strict confidentiality of identifiable cancer case information? How will the proposed Research Project protect against willful or accidental release of such identifiable cancer case information?
- 2) Will the proposed Research Project make inappropriate use of information deemed proprietary by data contributors?
- 3) Are the proposed uses of identifiable cancer case information justified by the anticipated benefits of the research? Is the anticipated benefit reasonable in light of previous research?
- 4) Is the use of the cancer case information technically feasible?

A proposed Research Project can be approved, rejected, or judged to be incomplete by the ARC. Incomplete proposals require additional information from the Researcher and will receive a definitive review following the receipt of new information by the appropriate body. If a proposed Research Project is rejected, the Researcher may reapply for approval, or he or she may appeal the decision to the HDROC.

B. Administrative Review by the Director:

- 1) Studies requesting aggregate data without identifying information and where no contact is to be made with patients, their physicians, or the reporting institutions require written authorization from the UCR Director, or designee.
- 2) Studies requesting data linkage services with previously identified patients in order to obtain registry information require written authorization from the UCR Director, or designee. However, these studies should submit all the forms required for requests that involve identifiable cancer case information, including the appropriate Data Request form (**Addendum C.2**) the UCR Research Proposal (**Addendum E**), the Research Agreement (**Addendum A**) and the confidentiality statement (**Addendum F**).

6. PUBLICATION OF STUDY RESULTS

Stringent rules apply for publication of study results. The research proposal should specify procedures and the timeline for UCR personnel to review and approve any manuscripts or documents prior to submission for publication. The UCR must be acknowledged as the source of

data for such publications. For a more detailed description of UCR's publication policy, see Section I: Number 7.E.

- A. All studies that utilize UCR data will be summarized in the annual UCR report to the SEER program.
- B. Copies of all published abstracts, presentations, and papers that result from the study should be sent to the UCR Director or designee. The bibliography of papers that have utilized UCR data is used to track the use of registry data and maintain SEER support for the Registry.
- C. The SEER contract number (N01-PC-35141) must be referenced as a funding source in all publications that result from the use of UCR data.

SECTION III: THE ADVISORY RESEARCH COMMITTEE (ARC) OF THE UTAH CANCER REGISTRY (UCR)

The Memorandum of Agreement between the Utah Department of Health (UDOH) and the University of Utah, which is responsible for the UCR, requires the latter to establish the Advisory Research Committee (ARC) to oversee the disclosure of cancer case information. The Agreement mandates that the ARC include a representative of the UDOH (appointed by the UDOH) and representatives from community-based health care providers and health care facilities that contribute data to UCR. The committee membership includes experts in the fields of epidemiology and biostatistics.

The ARC will review the UCR Policies and Procedures Guide: Requests for Registry Data and establish a process for review of research proposals. The UDOH and UCR have veto power over any proposal. Criteria for approval of a proposal include at least the following: scientific merit; adequate protection of human subjects (through approval by the Institutional Review Board); protection of the confidentiality of database information; and assuring that UCR's policies and procedures are followed with respect to the use of identified patient data or contacting patients.

Minutes will be maintained by UCR and submitted to the Human Database Research Oversight Committee (HDROC), which is chaired by the Vice President for Research at the University of Utah. The HDROC also has the responsibility of reviewing and approving the Policies and Procedures of the UCR and other human databases at the University.

**UTAH CANCER REGISTRY
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**UTAH CANCER REGISTRY
ADVISORY RESEARCH COMMITTEE
MEMBER ROSTER**

St. Mark's Hospital

JP Hughes, MD
Colon & Rectal Surgery
1250 East 3900 South, Room 320
Salt Lake City, Utah 84124
Phone: (801) 266-1409
Fax: (801) 266-0685
E-Mail:
Assistant: Karen

Salt Lake Regional Hospital

John Hayes, MD
Radiation/Oncology
GammaWest Brachytherapy
1050 East South Temple
Salt Lake City, Utah 84102
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Fax: (801) 350-4021
E-Mail: jkhayes@gammawest.com
Assistant:
E-Mail: bwwhitaker_807@yahoo.com

ADDENDUM A
RESEARCH AGREEMENT

RESEARCH AGREEMENT

THIS RESEARCH AGREEMENT (the “Agreement”) is made as of this ____ day of _____, 20__ by and between the University of Utah, a body of politic and corporate of the State of Utah, on behalf of the Utah Cancer Registry (“UCR”), and [name of researcher and entity] (“Researcher”).

RECITALS

WHEREAS, UCR collects identifiable and non-identifiable cancer case information on behalf of the Utah Department of Health (“UDOH”); and

WHEREAS, Researcher desire to use such cancer case information for an IRB-approved research project (“Research Project”) in accordance with the terms and conditions of this Agreement.

NOW, THEREFORE, in consideration of the mutual covenants, promises and undertakings contained herein, the parties hereby agree as follows:

1. Definitions.

(a) “Disclose” or “disclosure” shall mean the communication of cancer case information to any individual or organization other than to Researcher or the UCR.

(b) “Cancer case information” shall mean any information that UDOH requires persons or organizations to report to the UCR pursuant to the Utah Code Annotated § 26-5-2 and § 26-1-30.

(c) “Patient identifiable cancer case information” shall mean any cancer case information which, either from the data disclosed or in combination with other data, identifies the subject of the cancer case information or the individual or organization who reported the cancer case information.

2. Use of Cancer Case Information. Researcher may use cancer case information only for the Research Project. **[Add any specific restrictions on use not covered in UCR policy]** If Researcher wants to use such cancer case information for another research project, Researcher shall first obtain the appropriate approval for the research project from the IRB, UCR, and the UCR’s Advisory Research Committee. Researcher, and any individual working on the Research Project, shall not disclose the cancer case information to others without the prior written consent of UCR. Moreover, the cancer case information shall not be reproduced in any form except for internal use or with the prior written consent of UCR.

3. Publication. In the event Researcher wants to publish the results of the Research Project, Researcher shall first provide to UCR written notice of Researcher’s intent to publish and a draft of such publication. UCR shall have thirty (30) days after receipt of the draft publication to request in writing the removal of any portions of the publication deemed by UCR to inappropriately disclose identifiable cancer case information. Upon receipt of such request from UCR, Researcher and UCR shall attempt in good faith to agree upon the modifications or revisions to the draft publication which are reasonably necessary to protect the privacy of the subjects of the cancer case information. In no event, however, shall Researcher publish identifiable cancer case information without the written consent of UCR.

4. Contact of Subjects of Cancer Case Information. If Researcher wants to contact subjects of patient identifiable cancer cases information, Researcher shall submit a written request to UCR identifying subjects Researcher wants to contact and the purpose of contacting the subjects. If UCR approves such request, UCR shall contact the subject of the cancer case information (or the legal guardian of the subject if a guardian has been appointed by a court) and the subject's physician, if appropriate, and request the subject's written consent to be contacted by Researcher. In no event shall Researcher contact a subject of the cancer case information unless UCR has first obtained such written consent.

5. Cancer Case Information. All cancer case information shall remain the property of UCR and shall be destroyed or promptly returned to UCR at the end of the project, upon request of UCR, or upon termination of this Agreement.

6. Annual Reports. On or before the **[insert date]**, Researcher shall submit to UCR an annual report regarding the progress of the Research Project, all publications resulting from the Research Project, changes in the Research Project protocol or personnel, any incidents that may have resulted in the disclosure of identifiable cancer case information, and any other information requested by UCR or the Advisory Research Committee.

7. Audits. UCR or UDOH may conduct on-site audits of Researcher during normal business hours to observe practices for protecting the confidentiality of cancer case information. Researcher shall reimburse UCR or UDOH for the reasonable costs of such audits.

8. Representations and Warranties of Researcher. Researcher represents and warrants to UCR, upon execution of this Agreement and throughout the term of this Agreement, that:

(a) Researcher has obtained appropriate approval for the Research Project from (i) an IRB, (ii) the UCR, and (iii) the Advisory Research Committee.

(b) Researcher, and any individual working on the Research Project, shall comply with the terms of this Agreement and the Utah Cancer Registry's Policies and Procedures Guide: Requests for Registry Data.

(c) Researcher, and any individual working on the Research Project, shall conduct the Research Project in accordance with all applicable federal, state, and local laws, rules, and regulations.

9. Indemnification. Researcher shall indemnify, defend and hold harmless UCR against any claims, liabilities, damages, and expenses, including, without limitation, reasonable attorneys' fees incurred by UCR arising out of or related to the acts or omissions of Researcher in connection with this Agreement. **[Remove this Paragraph for University Researchers]**

10. Term. The term of this Agreement shall commence on the date hereof and shall end on **[insert date]** or on the date the Research Project ends, whichever occurs first, unless sooner terminated as provided herein. This Agreement may be renewed or extended for additional terms by mutual written agreement of the parties.

11. Termination.

(a) For Cause. UCR may terminate this Agreement upon breach by Researcher of any material provision of this Agreement, provided such breach continues for ten (10) working days after receipt by Researcher of written notice of such breach from UCR.

(b) Without Cause. Either party may terminate this Agreement without cause by giving the other party at least thirty (30) days' advance written notice thereof.

(c) Effect of Termination. In the event of such termination, the Researcher shall promptly return all cancer case information to UCR, in any and all formats. The following provisions shall survive the termination of this Agreement: Paragraphs 3, 4, 5, and 9.

12. General Provisions.

(a) Assignment; Subcontracting. No assignment or subcontract of this Agreement or any right or interest herein by Researcher shall be effective unless UCR shall first give its written consent to such assignment. This Agreement shall be binding upon and inure to the benefit of any successors or assigns of either party.

(b) No Waiver. No waiver of any breach of any term or condition of this Agreement by any party shall be construed to waive any subsequent breach of the same or any other term or condition of this Agreement.

(c) Notices. Notices to the parties hereunder shall be deemed given if in writing when delivered in person or by courier, prepaid overnight express services, U.S. Mail or certified mail, return receipt requested, and shall be considered given on the next business day, if sent overnight or Express Mail, and on the third (3rd) business day after mailing if sent certified mail. Notices shall be addressed as follows:

To Researcher: _____

To University: Utah Cancer Registry
650 Komas Drive, Suite 106B
Salt Lake City, Utah 84108
Attn: Antoinette Stroup, PhD

With a copy to: Office of General Counsel
University of Utah
309 Park Building,
Salt Lake City, Utah 84112

or to such other persons or places as either party may from time to time designate by written notice to the other party.

(d) Governing Law. This Agreement shall be governed by and constructed in accordance with laws of the State of Utah, without application of choice of laws rules.

(e) Entire Agreement. This Agreement contains the entire understanding of parties with respect to the subject matter hereof and supersedes all prior agreements, written or oral, and all other communications between the parties relating to such subject matter. All Exhibits to this Agreement are incorporated herein by this reference. This Agreement may not be amended or modified except by mutual written agreement.

(f) Execution by Counterpart. This Agreement may be executed separately or independently in any number of counterparts, each and all of which together shall be deemed to have been executed simultaneously and for all purposes to be one Agreement.

IN WITNESS WHEREOF, the parties have caused this Agreement to be signed and entered into by their authorized representatives as of the date first set forth above.

“University”

“Researcher”

Antoinette M. Stroup, Ph.D.
Co-Principal Investigator & Deputy Director
Utah Cancer Registry

[FILL NAME]
[FILL TITLE]
[FILL DEPARTMENT]

Rosemary Dibble
Director of Operations
Utah Cancer Registry

ADDENDUM B

EXIHIBIT A: SECTION 2

Policies and Procedures for Research Use of Utah Cancer Registry Data:

Exchange of Data between Research Resources

Exhibit A: Section 2
Policies and Procedures for Research Use of Utah Cancer Registry Data:
Exchange of Data between Research Resources

1. Purpose

The purpose of this policy is to define the relationship between the Utah Cancer Registry (hereto referred as “UCR” or “Registry”) and other Biomedical Research Resources (hereto referred as “Resource”). All use of cancer case information through the Resource will be in accordance with this policy and the UCR Policies and Procedures Guide: Requests for Registry Data.

2. Definitions

Human Database Research Oversight Committee (HDROC). The HDROC is responsible for maintaining the integrity of databases that contain confidential information, which are accessed for purposes of human subjects research. The HDROC reports to the Vice President for Research at the University of Utah.

Biomedical Research Resource (Resource). An organization within the University of Utah that provides a service to all qualifying biomedical researchers. The UCR is a resource, as is the Utah Population Database (UPDB) and the Resource for Genetic and Epidemiologic Research (RGE).

Cancer Case Information. Any information that the Utah Department of Health (UDOH) requires persons or organizations to report to the UCR pursuant to Utah Code Annotated 26-5-2 and 26-1-30.

Patient Identifiable Cancer Case Information. Any cancer case information, which either from the data disclosed or in combination with other data, identifies the subject of the cancer case information or the individual or organization who reported the cancer case information.

Researcher. The principal investigator on a Research Project (as defined above) or the individual requesting data from the UCR.

Research Project. A research protocol that has been approved by an appropriate Institutional Review Board (IRB), the UCR Advisory Research Committee (ARC), and/or administratively reviewed by UCR management.

3. General

UCR May Share or Exchange Cancer Case Information With Resources. The UCR may provide identifiable cancer case information to a biomedical research resource. Such access to cancer case information will be governed by a written agreement between the Resource and the UCR.

Contact of Subjects. If a Researcher or Resource wants to contact subjects identified through cancer case information obtained from a Resource, the Researcher must submit a written request to UCR and must obtain approval for the Research Project in accordance with Sections I and II of the UCR Policies and Procedures Guide: Requests for Registry Data.

Research Only Using UCR Data. The Policies and Procedures Guide: Requests for Registry Data take precedence when UCR data is used solely and no other Resource data is required to complete the research project.

4. Exchange of data between Biomedical Research Resources

- A. A University of Utah Biomedical Research Resource that follows the same review procedures and has the same enforcement mechanisms as UCR may receive information regarding identifiable cancer cases from UCR. Such biomedical research resources must fall under the oversight purview of the HDROC. Ownership of the data remains as indicated in the policies of the contributing resource. The HDROC will:
 - 1) Review all proposed agreements with Resources.
 - 2) Be responsible for oversight and auditing of the use of data that are within its purview.
- B. The nature and extent of any exchange will be specified in an agreement between UCR and the Resource. The agreement should include the following terms and conditions:
 - 1) Identification of the cancer case information to be shared.
 - 2) Justification for the use of identifying cancer case information (e.g., for record linking) and a description of the precautions for handling such information.
 - 3) Procedures for maintaining physical and/or computer security of all cancer case information, with particular reference to any patient identifiable cancer case information.
 - 4) The review procedures for proposed Research Projects applying for access to cancer case information held by the Resource. The representatives of the UDOH and the UCR will have veto power over such Research Projects.

- 5) The mechanisms for transferring cancer case information from the UCR to the Resource or vice versa.
 - 6) The obligations of the Resource to report use of cancer case information by Researchers for Research Projects (e.g., in an annual or quarterly report).
 - 7) Procedures for publication review and inclusion of acknowledgements to funding resources and grants.
 - 8) Provisions for extending, renewing, and canceling the agreement.
- C. In addition to any specific guarantees made in the agreement, all Resource staff who will have access to cancer case information will sign confidentiality pledges to be held on file at the UCR, and will be trained in handling cancer case information in the same manner as the staff for other Research Projects.

5. Restrictions on Cancer Case Information Released by UCR

- A. Because cancer case information received by community health care facilities require extensive editing and records often require consolidation, the UCR will only release cancer case information that has passed the National Cancer Institute's Surveillance, Epidemiology, and End Results (SEER) Program edits process.
- B. The UCR will limit data fields to information that has undergone extensive quality control and fields agreed upon by the UCR and the Resource.
- C. The UCR will exclude individuals with cancer case information who have contacted the UCR and requested that their information be withheld.
- D. The UCR will exclude cancer case information with cancer diagnoses that have not been confirmed (ambiguous terminology).
- E. The UCR will exclude cancer case information from HIV associated cancers.
- F. The UCR will exclude cancer case information if the sole source of such information was a cancer registry in another state and in accordance with contractual terms set forth in UCR's Agreement for Exchange of Cancer Data with other state agencies.
- G. The Resource agrees to provide UCR with a copy of data disclosed to the Resource including any improvements to the quality or completeness of those data while the data were in custody of the Resource.
- H. The Resource and its appropriately designated agents or researchers agree to provide proper safeguards to maintain the security and confidentiality of all individually-identifiable information provided by UCR.

6. Release of Cancer Case Information by Resource

- A. The Resource may release to Researchers only the cancer case information specifically permitted to be released under the terms of the agreement between UCR and the Resource.
- B. No individually identifiable information from UCR will be released by the Resource to the public, to any governmental agency, to any private organization, or to any individuals without the prior consent of UCR.
- C. All proposed Research Projects seeking cancer case information through the Resource must be approved by an IRB and the UCR Director, or designee. The appropriate means for obtaining the UCR approval is described in the agreement between the UCR and the Resource and the UCR Policies and Procedures Guide: Requests for Registry Data.

7. Policy Review

- A. This policy will be reviewed every two years in conjunction with the review of the UCR Policies and Procedures Guide: Requests for Registry Data.
- B. In the event the data are inappropriately released, all data access will be immediately suspended until the circumstances of the release have been resolved. In addition, no further data will be transferred from UCR to the Resource until such resolution has been made.
- C. If any portion of this agreement is interpreted at any time to be inconsistent with UCR's contractual agreements with the National Cancer Institute or other contractors, this policy will be immediately suspended and/or amended.

ADDENDUM C

C.1

DATA REQUEST FOR NON-IDENTIFIABLE DATA

C.2

DATA REQUEST FOR PATIENT IDENTIFIABLE DATA



**Utah Cancer Registry
Data Request for Non-Identifiable Data**

- Tabulated Data
- Incidence/Mortality/Survival (Rates)
- Tumor-Level Data (De-Identified)

Date: _____
 Data Request#: _____
 Done By (name): _____
 Date Completed: _____
 Time to Complete: _____

SECTION I: PRINCIPAL INVESTIGATOR & PROJECT TITLE

Requestor/Principal Investigator:	
Department:	
Address:	
Phone Number:	Fax Number:
Email:	
Reason for Request:	
Date Needed:	Date Promised:

SECTION II: CANCER SITE AND PATIENT INFORMATION

<u>Cancer Information</u>	<u>Patient Information</u>
Site:	Sex: <input type="checkbox"/> Male <input type="checkbox"/> Female <input type="checkbox"/> Both
Histology:	Age: <input type="checkbox"/> All Ages
Behavior: <input type="checkbox"/> Benign (Brain Only) <input type="checkbox"/> In Situ <input type="checkbox"/> Borderline (Ovarian Only) <input type="checkbox"/> Invasive	Race/Ethnicity: <input type="checkbox"/> All Race/Ethnicities <input type="checkbox"/> Non-Hispanic White <input type="checkbox"/> Non-Hispanic Black <input type="checkbox"/> Hispanic <input type="checkbox"/> Asian/Pacific Islander <input type="checkbox"/> Native American/Alaskan Native <input type="checkbox"/> Other:
Diagnosis Years:	Vital Status: <input type="checkbox"/> Alive <input type="checkbox"/> Deceased <input type="checkbox"/> Both
Tumor Sequence: <input type="checkbox"/> All <input type="checkbox"/> First Primary	
Diagnosis County: <input type="checkbox"/> All <input type="checkbox"/> Other: _____	Other Site/Patient Criteria:

SECTION III: COMMITTEE REVIEW & APPROVALS (Tumor-Level Data Only)

Review Boards	Initial Review		Renewal	
	Date Approved	Expiration Date	Date Approved	Expiration Date
Home Institution IRB (if not U of U): # _____				
University IRB: # _____				
RGE				
CCIC				
ARC: # _____				
HDROC				
IHC: # _____				
Hospital IRB:				

SECTION IV: OUTPUT DESCRIPTION

Referred to UCR Website

Tables:

Incidence/Mortality/Survival (Rates):

- Age-Adjusted
- Age-Specific

Tumor-Level Data (De-Identified):

<p><i>Output Format:</i></p> <ul style="list-style-type: none"><input type="checkbox"/> MS Word <input type="checkbox"/> MS Excel<input type="checkbox"/> ASCII<ul style="list-style-type: none"><input type="checkbox"/> Fixed Column <input type="checkbox"/> Delimited: _____<input type="checkbox"/> SAS dataset<input type="checkbox"/> Other: _____	<p><i>Send Data:</i></p> <ul style="list-style-type: none"><input type="checkbox"/> Email (zipped, password, encrypted)<input type="checkbox"/> 3 1/2" Floppy<ul style="list-style-type: none"><input type="checkbox"/> Mail <input type="checkbox"/> Pick-Up<input type="checkbox"/> CD-ROM<ul style="list-style-type: none"><input type="checkbox"/> Mail <input type="checkbox"/> Pick-Up<input type="checkbox"/> Other: _____
---	---



**Utah Cancer Registry
Data Request for Patient Identifiable Data**

<input type="checkbox"/> Patient Contact Study	Date: _____
<input type="checkbox"/> Tumor Block Study	UCR Study ID#: _____
<input type="checkbox"/> Data Linkage Study: Data Request #: _____	
Done By (Name): _____	
Date Completed: _____	
Time to Complete: _____	

SECTION I: PRINCIPAL INVESTIGATOR & PROJECT TITLE

Principal Investigator:		Study Coordinator:	
Department:		Department:	
Address:		Address:	
Phone:	Fax:	Phone:	Fax:
Email:		Email:	
Project Title:			
Contact/Tumor Collection Start Date:		Contact/Tumor Collection End Date:	

SECTION II: CANCER SITE AND PATIENT INFORMATION

Cancer Information	Patient Information
Site:	Sex: <input type="checkbox"/> Male <input type="checkbox"/> Female <input type="checkbox"/> Both
Histology:	Age: <input type="checkbox"/> All Ages
Behavior: <input type="checkbox"/> Benign (Brain Only) <input type="checkbox"/> In Situ <input type="checkbox"/> Borderline (Ovarian Only) <input type="checkbox"/> Invasive	Race/Ethnicity: <input type="checkbox"/> All Race/Ethnicities <input type="checkbox"/> Non-Hispanic White <input type="checkbox"/> Non-Hispanic Black <input type="checkbox"/> Hispanic <input type="checkbox"/> Asian/Pacific Islander <input type="checkbox"/> Native American/Alaskan Native <input type="checkbox"/> Other:
Diagnosis Years:	
Tumor Sequence: <input type="checkbox"/> All <input type="checkbox"/> First Primary	
UT Residents Only <input type="checkbox"/>	Vital Status: <input type="checkbox"/> Alive <input type="checkbox"/> Deceased <input type="checkbox"/> All
Diagnosis County: <input type="checkbox"/> All <input type="checkbox"/> Other: _____	Other Site/Patient Criteria:

SECTION III: COMMITTEE REVIEW & APPROVALS

Review Boards	Initial Review		Renewal	
	Date Approved	Expiration Date	Date Approved	Expiration Date
Home Institution IRB (if not U of U): # _____				
University IRB: # _____				
RGE				
CCIC				
ARC: # _____				
HDROC				
IHC: # _____				
Hospital IRB:				

ADDENDUM D
REGISTRY DATA ITEMS



Utah Cancer Registry Data Items

1. CTR Number and Sequence Number
2. Reporting Source
3. Last Name
4. First Name
5. Middle Name
6. Maiden Name
7. Alias
8. Name Prefix
9. Name Suffix
10. If Dx Elsewhere, Give Place
11. Social Security Number
12. Street Address (Current)
13. City, State (Current)
14. Zip Code (Current)
15. Street Address (At Diagnosis)
16. City at Diagnosis
17. State at Diagnosis
18. Zip Code at Diagnosis
19. County Code at Diagnosis
20. Patients Phone Number and Type
21. Census Track
22. Census Type
23. Race
24. Sex
25. Ethnic Type
26. Age at Diagnosis
27. Date of Birth
28. Place of Birth
29. Marital Status at Dx
30. Name of Spouse
31. Date of initial Diagnosis
32. Primary Site
33. Laterality
34. Other Primary Tumors
35. Diagnostic Confirmation
36. Description of Diagnosis
37. Histology, Behavior, Grade
38. Tumor Marker 1 and 2
39. Summary Stage
40. Size of Tumor in Mm
41. Number of Positive Regional Nodes

Utah Cancer Registry Data Items (continued)

42. Number of Regional Nodes Examined
43. Expanded EOD
44. Diagnosis Information
45. Sites of Distant Metastases
46. Date First Course Therapy Began
47. Surgery
48. Surgery Code, Attr, Course and Date
49. Surgery Approach
50. Reason for No Surgery
51. Radiation
52. Radiation Code, Attr, Course and Date
53. Chemotherapy
54. Chemo Code, Attr, Course and Date
55. Radiation Sequence with Surgery
56. More Treatment
57. More RX, Type, Code and Type
58. Residual Tumor
59. Date of Last Follow-up or Death
60. Status of Patient
61. Describe Place of Death
62. Place of Death
63. Cause of Death
64. Autopsy
65. Surgeon
66. Sequence Number

ADDENDUM E
RESEARCH PROPOSAL

Utah Cancer Registry Research Proposal

1. PRINCIPAL INVESTIGATOR: _____
Name PI Signature

Department / Agency Telephone

2. TITLE OF RESEARCH PROJECT:

3. IRB #: _____ DATE APPROVED: _____
EXPIRATION DATE: _____

4. TIMETABLE:

5. FUNDING AGENCY:

6. BACKGROUND AND SIGNIFICANCE:

7. SPECIFIC AIMS:

8. RESEARCH METHODS AND PROCEDURES, INCLUDING SPECIFIC DATA ITEMS REQUESTED:

Utah Cancer Registry Research Proposal (continued)

9. JUSTIFICATION OF PARTICULAR NEED FOR PATIENT IDENTIFIERS:

10. PROCEDURE TO MAINTAIN CONFIDENTIALITY OF DATA AND DETAILED DESCRIPTION OF DATA HANDLING PROCEDURES:

11. PROCEDURES FOR UCR REVIEW AND APPROVAL OF DRAFT MANUSCRIPTS PRIOR TO SUBMISSION FOR PUBLICATION:

12. COMPLETE LIST OF PERSONNEL WHO WILL ACCESS TO IDENTIFIABLE CANCER CASE INFORMATION:

13. DRAFT BUDGET TO COVER UCR COSTS:

Utah Cancer Registry Research Proposal (continued)

Your project has been:

Administratively reviewed Date: _____

Fully reviewed by the Utah Cancer Registry's Advisory Research Committee

 Date of Review: _____

Outcome:

Approved.

 Date Expires: _____

Conditional Approval pending the following:

 Description:

Rejected

Signature(s):

UCR Director/Deputy Director

Date

ADDENDUM F
CONFIDENTIALITY PLEDGE

UTAH CANCER REGISTRY CONFIDENTIALITY PLEDGE

In consideration of my employment with the University of Utah, or in consideration of my access to medical records, abstracts, and computer printouts located at the Utah Cancer Registry (collectively “UCR Records”), I have read any applicable Research Policy and Procedures between UCR and investigators, and I agree:

1. To maintain strict confidentiality in all matters related to the knowledge or use of UCR Records provided; I may publish or otherwise disclose information obtained from such records and documents in a manner that does not permit identification of the patients or their families whose records were used, or the patient’s physician or hospital, in connection with the Study listed below but for no other purpose:

Name of Study _____

IRB No. _____

2. Not to disclose my UCR user number and password and not to provide access to UCR Records to any unauthorized persons.
3. To indemnify, defend and hold UCR harmless from any causes of action or liability arising or alleged to arise from my failure to comply with any provisions of this UCR Confidentiality Pledge.
4. Not to remove any document containing information from UCR records which would identify patients, physicians or hospitals from the UCR office unless I have obtained the prior written consent of the UCR Director.
5. To destroy all individual identifiers associated with UCR Records or information in UCR Records which identify a patient, physician, or hospital which is in my possession by virtue of my access to UCR Records as soon as the purposes of the research for which I have been given access to UCR information have been accomplished and to notify UCR to this effect in writing.
6. To comply with the provisions of Utah Laws regarding confidentiality of individually identifiable medical records.

It is my understanding that a violation of any disclosure restrictions is a gross misdemeanor and may result in a civil penalty.

Name (Print)

Date

Signature

Phone number

Position

Fax number

ADDENDUM G
UCR ANNUAL/FINAL REPORT

ADDENDUM H
UCR PATIENT CONTACT LETTER
AND PERMISSION FORM

UCR Patient Contact Letter

Date

Patient's Name
Patient's Address

Dear Patient's name:

Researchers at the ***FILL IN INSTITUTION*** are conducting a study of ***FILL IN SITE*** cancers. This investigation is sponsored by ***FILL IN FUNDING SOURCES***. Results from this investigation ***FILL IN POTENTIAL BENEFITS OF STUDY***. <<***RESEARCHERS HAVE THE OPTION OF INCLUDING THEIR NAME TO THIS PARAGRAPH***>>

The Utah Cancer Registry is required by state law to collect information on all cancers that are diagnosed in Utah. According to the Registry, you may be eligible to participate in this study. In our experience, most people who have been diagnosed with cancer are pleased to participate in such scientific investigations, and many find it to be a rewarding experience. Nonetheless, it is the policy of the Utah Cancer Registry to ask for your permission to allow these researchers to contact you about their investigation.

Participants in this research project may be asked to ***FILL IN INFORMATION ABOUT WHAT THE STUDY INVOLVES***.

This study has been approved by the University of Utah's Institutional Review Board, which reviews all University research that involves people. All information obtained through this study will be kept strictly confidential.

If you agree to be contacted by a member of the research group to discuss this project and have your questions answered, please check box 1 on the attached form. Choosing this option does not mean that you agree to participate in the study; it only means that you have given permission for a member of the research team to contact you to discuss the project and answer your questions. If you would like more information about this study before releasing your name to study investigators, please check option 2, and we will call you with further information. Please check options 3 or 4 if those are applicable. If you do not wish to be contacted by a member of the research team, please check option 5.

Please complete the enclosed participation form and return it to our office in the postage-paid envelope provided. One of our staff members will contact you by telephone if we do not hear from you within two weeks.

Thank you for your serious consideration of this request. Cancer research will be enhanced by the investment of time from individuals whose lives have been affected by this disease. You may wish to discuss this with your personal physician. If you, or your physician have questions or need further information, please call Susan VanRoosanDaal, Study Coordinator for the Utah Cancer Registry, at 585-9300, or toll-free at 1-800-444-8638, extension 5-9300. Your help will be greatly appreciated.

Sincerely,

Antoinette M. Stroup, PhD
Deputy Director

Enclosures

UCR Patient Permission Form

Research Project – *FILL IN PRINCIPAL INVESTIGATOR AND STUDY TITLE*

NAME: <field32> <field34> <field33>

CTR: <field8>

DATE OF BIRTH: <field7>

DATE OF DIAGNOSIS: <field9>

Please Mark any that apply:

1. **Yes, I give consent to release my name, contact information, and Utah Cancer Registry data to investigators for this study.**
Choosing this option does not mean that you are agreeing to participate in the research study; it only means that you have given permission for a member of the research team to contact you to discuss the project and answer your questions.
2. **Yes, I would like the Utah Cancer Registry to call me with more information about the study before I decide to release my name.**
3. **Yes, I would like more information, but cannot participate at this time.**
4. **Yes, the person to whom this letter is addressed is unavailable, but I would be willing to discuss the study with study investigators.**
5. **No, I do not give consent to release my name to investigators for this study.**

If you checked options 1-4, please provide the following:

Full Name: _____

Address: _____

City, State: _____

Zip Code: _____

Home Phone: _____

Work Phone: _____

If checked #4, please indicate relationship to patient: _____

Can you be contacted at your place of work? _____ Yes _____ No

Signature: _____ Date: _____

Thank you for taking the time to complete this form.

Please Return To: Utah Cancer Registry
 Attention: Susan VanRoosanDaal
 University of Utah
 650 Komas Drive, Suite 106B
 Salt Lake City, UT 84108

ADDENDUM I
UCR NEXT-OF-KIN CONTACT LETTER
AND PERMISSION FORM

UCR Next-of-Kin Contact Letter

DATE

Next-of-Kin Name

Next-of-Kin Address

Dear **Next-of-Kin Name**:

Researchers at the *FILL IN INSTITUTION* are conducting a study of *FILL IN SITE* cancers. This investigation is sponsored by *FILL IN FUNDING SOURCES*. Results from this investigation *FILL IN POTENTIAL BENEFITS OF STUDY*. **<<RESEARCHERS HAVE THE OPTION OF INCLUDING THEIR NAME TO THIS PARAGRAPH>>**

The Utah Cancer Registry is required by state law to collect information on all cancers that are diagnosed in Utah. That information can be used to help studies identify persons who are eligible for participation in research. Your relative, **<PATIENT'S NAME>**, was identified by the Registry as being eligible for inclusion in this study of *FILL IN SITE* cancer. For the purposes of this investigation and with your consent, researchers would like to *FILL IN INFORMATION ABOUT WHAT THE STUDY INVOLVES*.

This study has been approved by the University of Utah's Institutional Review Board, which reviews all University research that involves people. All information obtained through the study will be kept strictly confidential.

As **<PATIENT'S NAME>'s, next of kin, we are writing to ask if you will allow researchers to contact you regarding this study.** If you agree to be contacted by a member of the research team to discuss this project, please check box 1 on the attached form. Choosing this option does not mean that you are agreeing to participate in the study; it only means that you have given permission for a member of the research group to contact you to discuss the project and answer your questions. If you would like more information about this study before releasing your name to study investigators, please check option 2, and we will call you with further information. Please check options 3 or 4 if those are applicable. If you do not wish to be contacted by a member of the research team, please check option 5.

Please complete the enclosed participation form and return it to our office in the postage-paid envelope provided. One of our staff members will contact you by telephone if we do not hear from you within two weeks.

Thank you for your serious consideration of this request. Cancer research will be enhanced by the investment of time from individuals whose lives have been affected by this disease. If you have questions or need further information, please call Susan VanRoosanDaal, Study Coordinator for the Utah Cancer Registry, at 585-9300, or toll-free at 1(800) 444-8638, extension 5-9300. Your help will be greatly appreciated.

Sincerely,

Antoinette M. Stroup, PhD
Deputy Director

Enclosures

UCR Next-of-Kin Consent Form

Research Project – *FILL IN PRINCIPAL INVESTIGATOR AND STUDY TITLE*

PATIENT NAME: «patientname»

CTR: «ctr»

PATIENT DATE OF BIRTH: «dob»

NEXT-OF-KIN NAME: «FirstName»

Please Mark any that apply:

1. Yes, I give consent to release my relative's name, contact information, and Utah Cancer Registry data to investigators for this study.
Choosing this option does not mean that you are agreeing to participate in the research study; it only means that you have given permission for a member of the research team to contact you to discuss the project and answer your questions.
2. Yes, I would like the Utah Cancer Registry to call me with more information about the study before I decide to release my relative's name.
3. Yes, I would like more information, but cannot participate at this time.
4. Yes, the person to whom this letter is addressed is unavailable, but I would be willing to discuss the study with study investigators.
5. No, I do not give consent to release my relative's name to investigators for this study.

If you checked options 1-4, please provide the following:

Full Name: _____

Relationship to Patient: _____

Address: _____

City, State: _____

Zip Code: _____

Home Phone: _____

Work Phone: _____

Can you be contacted at your place of work? _____ Yes _____ No

Signature: _____ Date: _____

Thank you for taking the time to complete this form.

Please Return To:

Utah Cancer Registry
Attention: Susan VanRoosanDaal
University of Utah
650 Komasa Drive, Suite 106B
Salt Lake City, UT 84108