

**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.