# MONTANA CENTRAL TUMOR REGISTRY CONFIDENTIAL DATA RELEASE POLICY

## PURPOSE

This policy defines the conditions in which confidential data from Montana Central Tumor Registry (MCTR) may be released to external entities for public health and epidemiologic research while protecting the integrity and confidentiality of the MCTR data and complying with applicable state and federal laws.

## POLICY

It is the policy of MCTR to adhere to the provisions of Montana Code Annotated (MCA) 50-15-704 which states:

> **Confidentiality**. Information received by the department pursuant to this part may not be released unless:

1. it is in statistical, non-identifiable form;
2. the provisions of Title 50, chapter 16, part 6, are satisfied;
3. the release or transfer is to a person or organization that is qualified to perform data processing or data analysis and that has safeguards against unauthorized disclosure of that information;
4. the release or transfer is to a central tumor registry of another state and is of information concerning a person who is residing in that state; or
5. the release is to a health care practitioner or health care facility that is providing or has provided medical services to a person who has or has had a reportable tumor.

Consistent with the MCA, it is the policy of MCTR to release or transfer Registry data to a cancer researcher only if the researcher is qualified to perform data analysis; has safe guards against unauthorized disclosures; and is using data for the purpose of cancer prevention and control. The following paragraphs describe the parameters of the implementation of this policy.

It is the policy that confidential data will be released in as non-specific form as possible to accommodate the legitimate needs of the researcher requesting cancer registry information, while safeguarding the confidentiality of the patients, healthcare professionals, and reporting facilities. Therefore, it is the policy of the MCTR that data which may directly or indirectly identify a patient, healthcare professional, or reporting facility will not be released without adequate justification and assurances of data confidentiality and security.

It is also recognized that complex data elements, such as those involving cancer treatment and diagnostic procedures, require an expert level of technical sophistication to interpret. Thus, it is the policy that sensitive and confidential data will be released only after assurances are obtained that the data shall be analyzed in an epidemiologically competent manner. Epidemiological competence includes, but is not limited to, the researchers' awareness and understanding of the effects of bias that are subject to occur during the processes of data collection, classification and coding, and statistical analysis. Further, it is the policy of MCTR that any publication of findings conforms to rigorous epidemiologic standards and may be subject to review by MCTR prior to submission for publication. It is the policy of MCTR that no information that might identify a patient, healthcare professional or reporting facility shall be presented in the results of analyses or other reports or in releases of information concerning such reports.

It is the policy of the MCTR that all applicants requesting a data set for research purposes must have a final Institutional Review Board (IRB) or Human Subjects Protection Committee approval from an entity recognized by the Office for Human Research Protections of the US Department of Health and Human Services.

Confidential cancer case data that the MCTR has obtained from certain other sources under data sharing agreements (e.g., certain other states, National Death Index, Veterans Administration hospitals) will be removed from the data set before release.

It is the policy of the MCTR that confidential data will never be made available for uses such as: businesses that are marketing a product to cancer patients, health care institutions recruiting new patients, insurance companies that are trying to determine the medical status of a patient, or any other political, legal, or commercial purpose.

It is the policy of the MCTR that the Principal Investigator must have made sufficient assurances, in writing, to keep the data sets physically secure.

It is the policy of the MCTR that data sets may be used only for the purposes for which the initial approval is granted. No additional data analyses may be undertaken without the prior written authorization of the MCTR. Further, data sets must be destroyed after completion of project or end of Data Use Agreement, whichever date comes first.

It is the policy of the MCTR that no data set will be released until the Principal Investigator and all other researchers who will have access to the data set have made sufficient assurances, in writing, of data confidentiality and security through the Data Use Agreement.

A Data Use Agreement will ordinarily be for one year (with potential for renewal), but may not exceed the effective dates of the corresponding IRB approval. If necessary, the applicant must obtain an IRB extension before a Data Use Agreement will be renewed.

## SCOPE

This policy applies to the release of all data sets from the Montana Central Tumor Registry to external entities containing confidential information.

## RESPONSIBILITY

A. The MCTR Data Use Review Committee will make a determination to whether participation with the proposed request advances a compelling governmental interest.

B. Each Principal Investigator (PI) is required to be knowledgeable regarding the policy and procedure statements herein, and to ensure that they are strictly followed by every person accessing the data.

## DEFINITIONS

*Confidentiality*: Data or information is protected from unauthorized persons or processes. Any information that specifically identifies a patient, health care professional, or reporting facility is considered confidential. Information that characterizes the caseload of a specific institution or health care professional may also be considered proprietary and confidential.

*Confidential information:* Information with identifiers about a patient, health care professional, or reporting facility, when those entities have not given consent to make that information public.

*Individual identifiers:* Those elements of the confidential record that state the name, address, social security number, or other information that exactly identify the subject of the record.

*Confidential data elements:* Data elements which by themselves or in conjunction with other elements in the record could easily lead to the identification of the subject. In addition to individual identifiers, these elements may include date of birth, municipality, name of physician, name of hospital, and others; whether these data elements are considered confidential depends on the data set.

*Informed consent:* Informed consent must (i) be provided individually by each participant for whom data are requested, and (ii) be in writing, and (iii) specify the investigator or institution to whom the data are to be released, and (iv) specify the data elements to be released, and (v) be signed and witnessed according to Institutional Review Board specifications.

*MCTR Data Use Review Committee*: The MCTR Data Use Review Committee is comprised the Montana Cancer Control Programs Section Manager, a MCTR staff member who is a Certified Tumor Registrar, and the State Medical Officer.

## RELATED DOCUMENTATION

1 The "Tumor Registry Act", Montana Code Annotated Title 50 Chapter 15 Part 7

2 The "Cancer Registries Amendment Act", Public Law 102-515