

Cancer Research Application Manual

Wisconsin Cancer Reporting System



Procedures and Protocols for Individual-Level Research Data Requests



WISCONSIN DEPARTMENT
of **HEALTH SERVICES**

Division of Public Health
Office of Health Informatics
Wisconsin Cancer Reporting System
P-00625 (06/2022)

Contents

I. Federal and State Regulations	1
II. Use of WCRS Data.....	2
III. Access to Data.....	3
A. Types of Individual-Level Data Requests	3
B. Confidentiality Considerations	4
C. Costs and Fees	4
D. Format and Transmission of Data	5
E. Data Storage and Security	5
IV. Publications, Reports, and Statistical Complications	6
V. Application Process	7
Step One: Application Submission.....	7
Step Two: WCRS Review	8
Step Three: Data Governance Board (DGB) Review.....	9
VI. Special Requirements and Materials for Studies Involving Patient Contact.....	10
A. DHS Sample Letter of Introduction.....	12
B. Sample Respondent Contact Letter	13

I. Federal and State Regulations

The Wisconsin Cancer Reporting System (WCRS) is a population-based registry guided by statutory mandate to collect, manage, and analyze cancer data on Wisconsin residents. WCRS was established in 1976 to collect cancer incidence data on Wisconsin residents as mandated by [Wis. Stat. § 255.04](#), Cancer Reporting. The statute specifies that all cancer cases must be reported to the state cancer registry in the manner prescribed by the Wisconsin Department of Health Services (DHS). Under the statute, DHS prescribes to all reporting facilities: (a) the form on which the cancer report shall be submitted, (b) the time schedule under which the report shall be submitted, and (c) the types of cancer and precancerous conditions to be reported. The statute also requires that data shall remain confidential.

In 1994, WCRS was enhanced by the Cancer Registries Amendment Act (Public Law 102-515), which established the National Program of Cancer Registries (NPCR). In 2002, Public Law 107-260, the Benign Brain Tumor Cancer Registries Amendment Act, was passed. This federal mandate requires cancer registries participating in the NPCR to collect data on all benign, borderline, and malignant tumors of the central nervous system in addition to the previously required data on malignant tumors. Data collection for the additional non-malignant primary and intracranial central nervous system tumors started with cases diagnosed on January 1, 2004. WCRS is an incidence-only registry.

II. Use of WCRS Data

Neither the Health Insurance Portability and Accountability Act (HIPAA) nor Wis. Stat. § 146.81, et seq. (state law regarding confidentiality of patient health care records) prohibits the reporting of information to state cancer registries. As WCRS is a public health authority, HIPAA permits reporting to WCRS for public health purposes and Wis. Stat. § 146.82 specifically names WCRS in authorizing reporting of health care information. WCRS may then re-disclose the reported information for public health purposes.

[Wis. Stat. § 255.04\(3\)](#) was amended to add a section permitting release of confidential data for the purpose of approved research.

Paragraph (c) states:

(3) Any information reported to the department under sub. (1) or (5) which could identify any individual who is the subject of the report or a physician submitting the report shall be confidential and may not be disclosed by the department except to the following:

(c) A researcher who proposes to conduct research, if all of the following conditions are met:

1. The researcher applies in writing to the department for approval of access to individually identifiable information under sub. (1) or (5) that is necessary for performance of the proposed research, and the department approves the application. An application under this subdivision shall include all of the following:
 - a. A written protocol to perform research.
 - b. The researcher's professional qualifications to perform the proposed research.
 - c. Documentation of approval of the research protocol by an institutional review board of a domestic institution that has a federal-wide assurance approved by the office for human research protections of the federal department of health and human services.
 - d. Any other information requested by the department.
2. The proposed research is for the purpose of studying cancer, cancer prevention, or cancer control.

III. Access to Data

A. Types of Individual-Level Data Requests

The information contained in this manual is applicable to requests for individual-level data. While use of aggregate data may be subject to similar requirements, this manual does not cover the processes to request and use aggregate data.

Individual-level data contain personal identifiers such as patient name, address, and date of birth, as well as diagnosis and treatment data. Due to the protected and restricted nature of these data, measures must be taken to ensure the confidentiality and integrity of the data. Because the right to privacy is of utmost importance, the confidentiality of persons diagnosed with cancer and reported to the WCRS will be the primary concern. The release of individual-level data will be approved only when the protocols and procedures described in this document have been met. Access will be subject to the limitations concerning confidentiality, security, and the prevention of potential misuse.

Individual-level data requests fall into three categories:

1. Case Ascertainment/Recruitment

Use of the WCRS database for the purpose of patient recruitment for a study (i.e., use the WCRS database to identify cancer patients who may qualify or meet the study's selection criteria for inclusion).

2. Data Linkage

Use of the WCRS database for the purpose of linking the study's patient database to the WCRS database to obtain follow-up data or cancer information.

Please note that the main challenge with data linkage is the level of errors or omissions in the linking data in both the registry database and the researcher's data file. Providing the most data items with the most specific information possible on a person to be linked ensures the best possible outcome for a true match or no match.

Potentially linked records that still cannot be determined to be a match, after both deterministic and probabilistic matching have been conducted with manual review, will be counted as a no match and not included in the final data set returned to the researcher.

3. Other – Special Analysis

Use of non-public WCRS data for a special analysis.

Please note that if a request requires both confidential cancer incidence and mortality data, a separate request to the DHS, Office of Vital Records, will need to be completed for re-release of cancer mortality data.

B. Confidentiality Considerations

In the interest of balancing the principles of data access and patient confidentiality, WCRS has classified the release of cancer data collected. These classifications are designed to promote the use of accurate cancer incidence data, expedite the data release process, and encourage the distribution of a wide array of data elements without compromising confidentiality.

Two general types of individual-level data are considered in research requests: *Identifiable Patient Information*, and *Potentially Identifiable Patient Information*.

Identifiable Patient Information contain personal identifiers for use in follow-up studies, or any studies that require contacting patients or clinicians to obtain additional information. Identifiable confidential data elements include, but are not limited to:

- Name
- Address
- Social Security Number
- Birth Date
- Unique patient number (assigned by WCRS)
- Zip Code
- Census Tract

All items of information which relate to an attribute of an individual should be treated as potentially capable of identifying patients and hence should be appropriately protected to safeguard confidentiality. Attributes listed below are examples of **Potentially Identifiable Patient Information**, insofar as the identity of the individual in question may become ascertainable if these attributes are combined with other information.

- Race/Ethnicity
- Age
- Sex
- Year of diagnosis
- Cancer Site
- Cancer cell type
- County or other geographic areas smaller than the state designation

C. Costs and Fees

Disclosures of WCRS data require costs to obtain, compile, and transmit the information. These costs must be covered by the recipient institution. Detailed estimates are not available until all research application materials have been received and reviewed by WCRS. The following fee estimates are subject to change:

Minimum base fee for processing application: **\$800**
Hourly rate for data extraction, preparation, and/or linkage: **\$100**

D. Format and Transmission of Data

Requested data will be provided in a mutual agreed upon file format. Requested data will be transmitted through a mutually agreed upon secure file transfer system, typically Web Plus, a website with secure file transfer services administered by WCRS. WCRS will assist researchers with account creation and data transmission once application materials have been received and the request has been approved. Prior to data transmission, a fully executed **Data Use Agreement** will also be in place.

E. Data Storage and Security

All listings of cases, copies of reports, and any other materials that include confidential information must be kept in locked file drawers or secure systems when not in use.

The principal investigator will be required to read and sign a **Data Use Agreement**. This contract describes limitations on usage of data, as well as restrictions on dissemination of findings, data destruction agreement, use of personal identifiers, and contact with patients identified through data provided by WCRS.

Upon completion of the study, researchers must destroy all files, documents, and/or other records containing original WCRS data with confidential information. Immediately following the destruction of WCRS data, researchers must provide DHS a written declaration, executed by an authorized representative of research institution, which states the study name, date WCRS data have been destroyed, method used to destroy data, and confirmation that no individual level information, data, or copies were retained in the possession of the research institution.

All staff working with confidential data, or with possible exposure to confidential information from the data, are required to sign the **Confidentiality Pledge** and return to WCRS.

IV. Publications, Reports, and Statistical Complications

Before final public release of reports and other publicly available documents based on WCRS data, DHS has the right to review them for adherence to confidentiality restrictions and information regarding WCRS, the Office of Health Informatics, the Division of Public Health, and DHS. Please allow time in your schedule for this pre-release review.

Please send a courtesy copy of published abstracts of presentations and papers that result from the study to WCRS. The bibliography of papers from investigations that have used WCRS data is used to track the use of registry data for epidemiologic studies.

Copies of publications using WCRS data must be emailed to:

Hayley Tymeson, WCRS Epidemiologist
dhs-wcrsdatarequests@dhs.wisconsin.gov

V. Application Process

Step One: Application Submission

The following materials are required for application submission. Please send all materials to:

Hayley Tymeson, WCRS Epidemiologist

dhs-wcrs-datarequests@dhs.wisconsin.gov

Please indicate: "Research Application Submission" in Subject Line.

Failure to provide all necessary materials may result in delays to the application review process. Applications are reviewed on a first-come, first-served basis.

1. Application for Research Use

The **Application for Research Use** is form used to specify the data request. A completed form includes information about the study protocol, project activities, justifications for use of WCRS data, and other specifications needed for WCRS to review and determine eligibility of the request.

2. Study Protocol or Project Activities

The **Study Protocol or Project Activities** is a document provided by the researcher which includes a description of the study, the principal investigator's qualifications and affiliation(s), study background, research questions, study design, case definition and selection (where applicable), control definition and selection (where applicable), confidentiality procedures and documentation, project resources, and data analysis plan.

3. Principal Investigator's Curriculum Vitae/Résumé

The Principal Investigator's Curriculum Vitae/Résumé should include a career summary, qualifications, academic background, publications, presentations, and achievements.

4. Institutional Review Board (IRB) Approval Letter

An IRB Approval Letter is a letter that shows that the research study has been reviewed and approved by the researcher's IRB), in accordance with the provisions of the U.S. Department of Health Services and Human Services Code of Federal Regulations Title 45, Part 46, Protection of Human Subjects. It should include name of review board, approval date, and approval expiration date.

5. Data Request Specifications

The **Data Request Specifications** is an Excel workbook to be completed by the researcher. It includes spreadsheets for **Variable Request**, **Selection Criteria**, and **Site-specific Factors**.

- **Variable Request:** Must be completed by the researcher. Includes a list of all data items

which can be requested. Includes notes on data items and links to data definitions.

Additional details on data items can be found in the Data Dictionary in the [WCRS Coding Manual](#).

- Selection Criteria: Must be completed by the researcher. Includes list of data items which can be specified to determine the selection of data.
- **Site-specific Factors:** Table which lists site-specific factors, applicable schemas, and availability by year of diagnosis. Researcher should reference this table if requesting site-specific factor variables to ensure only valid and applicable variables are requested for the schemas and diagnosis years being analyzed.

6. Linkage Request Specifications (required only for linkage requests)

The **Linkage Request Specifications** is an Excel spreadsheet which includes a list of required and recommended data items for data linkage files sent to WCRS. These linkage files are to be provided by the researcher once the application has been reviewed and approved. It includes allowable values, formats, and links to data definitions. Additional details on data items can be found in the Data Dictionary in the [WCRS Coding Manual](#). Please note that researchers must also complete the **Data Request Specifications** to indicate the variables they would like to receive from WCRS for linked records.

7. Data Use Agreement

The **Data Use Agreement** is a form to be signed by the Principal Investigator. It indicates understanding and assurance that data will only be used for the purposes of the study described in the submitted application, and that any confidential data will be destroyed following completion of the research project.

8. Confidentiality Pledge

The **Confidentiality Pledge** is a form to be signed by **all staff working with confidential data**, or with possible exposure to confidential information from the data. It indicates understanding and assurance that adequate protections are in place to ensure data security during usage, access, and storage.

Step Two: WCRS Review

Once all application materials have been received by WCRS, an initial review is conducted.

1. WCRS receives completed application materials.
2. WCRS verifies that all materials are complete and verified. If materials are incomplete or unverified, WCRS conducts follow-up with researcher.
3. Once all materials are verified, WCRS forwards application for Data Governance Board Review

Step Three: Data Governance Board (DGB) Review

The third and final step of the application process is DGB review. The DGB is a formal review board comprised of senior Division of Public Health managers, chief medical officers, and program staff. DGB review may take several months from the time of application submission to WCRS.

The DGB reviews all applications to determine if:

- ✓ The research is in compliance with state and federal statutes, including § 255.04(3)(c).
- ✓ The research is an appropriate use of WCRS data.
- ✓ The study design and methods are appropriate.
- ✓ Provisions have been made to protect confidentiality of the data.

In addition to the above considerations, the DGB follows these guidelines during review:

- Is research of public health importance and provide a benefit for residents of Wisconsin?
- Is the study methodologically sound and science based?
- Are IRB supporting application and approval included?
- Is patient contact required, and if so, are there appropriate voluntary consent procedures?
- Are patient identifiers required to meet objectives of study?
- Have all data security requirements been addressed to maintain confidentiality of data before, during and after the study?
- Does the study have an end date? WCRS will not release data to supply large research entities with a pool of data from which they can conduct future studies.
- Has the requester agreed to acknowledge WCRS in all presentations/publications which use the provided data?

The DGB will review and either approve, suggest modifications, or disapprove the request. If modifications are suggested, revisions and subsequent DGB review are conducted.

VI. Special Requirements and Materials for Studies Involving Patient Contact

In addition to all requirements and materials mentioned elsewhere, the following applies to studies involving patient contact:

- Investigators must remember that the patient may be experiencing difficult emotional and physical circumstances, although many, if not most, patients welcome the opportunity to participate in research.
- Any patient who states they do not wish to be contacted again for future studies must be promptly reported to WCRS. The researcher must document the refusal in writing, and send the documentation to WCRS via mutually agreed upon secure file transfer systems. Upon receipt, WCRS will record the fact in the WCRS database by marking the patient record with a Do Not Contact Flag.
- The researcher must notify WCRS if he or she becomes aware of errors or omissions in WCRS data and any more current information on a patient's vital statistics, current address, or telephone number. This information must be sent to WCRS via mutually agreed upon secure file transfer systems.
- Researchers must avoid disclosing on the cover of mailings that the patient is being contacted for a study specific to cancer.

- **Respondent Contact Letter**

The Respondent Contact Letter is written correspondence to be sent to subjects/respondents providing a summary and description of the study. A sample letter must be provided to WCRS at the time of application submission. In addition to a summary and description of the study, it must include:

- ✓ Language furnished by WCRS regarding state reporting
- ✓ Assurance of the voluntary nature of participation.
- ✓ Assurance that participation or non-participation will not affect medical care.
- ✓ Assurance that identifiable information will be kept confidential.

The [Sample Respondent Contact Letter](#) provides an example of written correspondence.

- **Phone Script (When Applicable)**

If telephone contact is part of the study, a sample copy of the phone script that will be used to introduce the study to the patient should be provided to WCRS at the time of application submission.

Patients may commonly ask questions about how and why a researcher got their information. WCRS will provide a sample script of common questions and answers to assist the researcher if application is approved.

- **Written Informed Consent (When Applicable)**

If Written Informed Consent is necessary for subjects/respondents in the study, a sample copy must be

provided to WCRS at the time of application submission.

- **DHS Letter of Introduction (When Authorized)**

The DHS Letter of Introduction is written correspondence provided to the researcher by WCRS after the study has been approved by the DGB. It is to be sent to subjects/respondents only when authorized by DPH. Not all approved studies will receive authorization to use the DHS Letter of Introduction. The [DHS Sample Letter of Introduction](#) provides an example of the letter.

A. DHS Sample Letter of Introduction

Dear Wisconsin Resident:

You are being contacted by a research scientist regarding participation in a cancer research project, and this letter explains how your name was obtained for this purpose. Every cancer diagnosed in Wisconsin is required by law to be reported to the Wisconsin Department of Health Services, which oversees the Wisconsin Cancer Reporting System (WCRS). The WCRS was created by the Wisconsin Legislature in response to public concern that not enough was being done to find the causes and cures of cancer. Information on individuals with cancer can be released from the WCRS for research purposes, and only to qualified researchers who have obtained approval for the study from a federally approved Committee for the Protection of Human Subjects and have agreed to maintain the confidentiality of the information.

By law, the Wisconsin Department of Health Services can provide cancer registry data for medical research. However, the department does not endorse, recommend, or favor any proposed research project. Enclosed with this letter are materials from the researcher explaining further details of this specific study and giving you the option of whether or not you wish to participate. You are under no obligation to participate, nor will you incur any penalties or disadvantages if you decide not to do so. On the other hand, if you give your consent on the basis that the research will serve a useful purpose and that you would be comfortable as a participant, be assured that your confidentiality and dignity will be protected. The researchers have agreed to strict safeguards for the protection of all confidential information. While the research has met all DHS requirements for access to data, and will potentially benefit the health and well-being of Wisconsin residents, the research is conducted by an independent contractor and not part of DHS.

Should you have any questions, either before making your decision or at any time in the course of this project, please feel free to call _____.

Sincerely,

Name

Title

Division and Department

B. Sample Respondent Contact Letter

Dear _____:

We are writing to ask you for your help in a very important study being conducted by _____. The purpose of this study is to learn more about factors that may be related to the development of _____ cancer in _____.

Your name was obtained from the Wisconsin central cancer registry, which was created by the Wisconsin Legislature in response to public concern that not enough was being done to find the causes and best treatment for cancer. Every cancer diagnosed in Wisconsin is required by law to be reported to the Wisconsin Department of Health Services, which is responsible for the state cancer registry. Information on individuals with cancer can only be released for research purposes to qualified researchers who have obtained approval for the study from a federally approved Committee for the Protection of Human Subjects, and have agreed to maintain the confidentiality of the information they collect.

Methods of contact: The study would involve answering some questions over the telephone (or in person or via mailed questionnaire) regarding your lifetime exposures to environmental factors, past illnesses, and habits. The interview should take about [number of minutes]. Your participation is voluntary. Your decision whether or not to participate in this study will have no impact on your medical care. All information will be kept strictly confidential and is protected by law.

Manner of participation: Please complete the enclosed response form and mail it back in the enclosed postage-paid envelope. An interviewer will call you to provide more information about the study and to answer any questions you may have. Your assistance in this effort is very much appreciated as the validity of this type of study depends on being able to interview as many patients as possible. If you have questions at this time, please call the study office at _____.

Sincerely,

Investigator

Title

Institution