

Maryland Department of Health and Mental Hygiene
Prevention and Health Promotion Administration

Maryland Cancer Registry Data Use Manual and Procedures

Larry Hogan,
Governor

Boyd Rutherford,
Lieutenant Governor

Van Mitchell,
Secretary

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**MARYLAND CANCER REGISTRY
DATA USE MANUAL AND PROCEDURES
July 2016**

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1 Introduction

This document contains Maryland Cancer Registry (MCR) procedures for the release of aggregate (non-confidential) and individual-level (confidential) cancer data.

Based within the Maryland Department of Health and Mental Hygiene's (DHMH) Center for Cancer Prevention and Control, the MCR collects, stores, and analyzes data on new cases of reportable cancers diagnosed in Maryland residents, including those diagnosed out of state. MCR data are used to track trends in cancer incidence, respond to cancer cluster concerns, and provide a data framework for cancer prevention and control activities, research, and policy decision-making.

MCR data can be used for:

- *Tracking, reporting, and evaluating* the number of cancer cases and rates of cancer across time and demographic groups.
- *Conducting Research Studies: (e.g. Cohort analyses or Case-control studies)*
- *Performing Needs Assessments and Projections:* MCR data can be used to identify populations in need of screening and/or prevention efforts, and can also be used to project future cancer case numbers (e.g. for the allocation of public health resources).
- *Conducting Patient Contact Studies:* Researchers can use confidential individual cancer patient data to perform research activities that require patient or next-of-kin contact.
- *Mapping patients by residential address at diagnosis to investigate patterns of disease by location.*

- *Performing Linkage Studies:* The MCR may link individuals in a second database with those in the MCR database.

Abbreviations:

COMAR	Code of Maryland Regulations
DHMH	Maryland Department of Health and Mental Hygiene
IRB	Institutional Review Board
MCR	Maryland Cancer Registry
NAACCR	North American Association of Central Cancer Registries
NPCR	National Program of Cancer Registries
PI	Principal Investigator
SSN	Social Security Number

Definitions:

- *Abstract record:* a file or record submitted to the MCR that contains information about one reportable cancer case.
- *Aggregate data:* a cumulative data summary of measures and cancer cases in Maryland. Aggregate data are not considered confidential and data tables provided by the MCR do not contain cells with case counts of 1-5 (i.e. suppressed data).
- *Agreement:* any formal agreement executed between the DHMH and the

party to whom data are being released to (e.g. MCR Data Use Agreement) detailing the rights and responsibilities of both parties.

- *Reportable cancer*: a tumor is reportable to the MCR under Maryland statute or regulation (see Section 2) if it is a(n):
 - invasive cancer case,
 - *in situ* cancer,
 - and other benign brain and central nervous system tumor
- *Confidential data*: data containing identifiable and/or private information such as, patient first and last name, date of birth, SSN, or personal health information. Confidential data also includes information that has the potential to identify a person by association such as:
 - street address at diagnosis,
 - latitude-longitude of address at diagnosis,
 - cancer case data that is listed with one row per tumor,
 - data on one specific type of rare cancer,
 - diagnoses in a small geographic area (zip code/census tract/block group), or
 - data cells in a table where the cell contains <6 non-zero cases (i.e., 1-5 cases) (see Section 6.2.3 for cell suppression requirements).
- *Consolidated record*: a file or record containing information on one reportable cancer case that is compiled from one or more abstract records submitted to the MCR for that cancer case.
- *Expanded data*: dataset that contains additional cancer cases from delayed reports from past or recent years that are not included in the static dataset (see definition below) for that year.
- *Requestor*: Individual or organization that submits a MCR data request form (Appendix A) requesting data from the MCR.
- *Static data*: consolidated dataset submitted to NPCR as "24-month" data, data finalized 24 months after the end of the diagnosis year. These annual static datasets are the "official" reported number of Maryland cancer cases for that year and do not include tumor reports that are submitted after the data are finalized for submission.

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2 Legal Authority

Health-General §§18-203–204 of the Annotated Code of Maryland governs cancer data reported to the MCR. A cancer report or abstract is not a “medical record” under Health-General Title 4, Subtitle 3; however, according to Health-General §18-204, the data are protected under the confidentiality requirements of Health-General §§4-101 et seq.

The MCR data shall remain in the ownership and custody of the Secretary of Health and Mental Hygiene or an agent/employee of the Secretary designated as “the custodian.” A person or governmental unit that wishes to obtain MCR data beyond MCR’s published reports shall submit a written request, the MCR Data Request Form (Attachment A), to the MCR Program Manager.

COMAR 10.14.01 provides further governance specifying which tumors are reportable, which facilities must report and how, and the circumstances under which MCR data may be released.

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3 Confidentiality

The MCR regards all abstract and consolidated records reported to the MCR as confidential and data are secured from unauthorized access or disclosure. The MCR and its data management vendor manage and disclose information in accordance with Health-General §§ 18-203 and 18-204, 4-102, and COMAR 10.14.01, Cancer Registry (see Section 6.2.1).

The MCR uses “cell suppression” or the deletion of data from cells in tables containing data on 1-5 individuals to safeguard against the unintentional identification of individuals. Guidelines are detailed in Section 6.2.3.

Note that the MCR restricts the release of confidential data under the provisions of COMAR 10.14.01.07. The Secretary or the Secretary’s designee, the DHMH Institutional Review Board (DHMH-IRB), and the Researcher’s own IRB must all approve the release of confidential data, and a *Data Use Agreement* with the MCR must be executed prior to such a release.

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4 MCR Background

The MCR is a population-based cancer incidence registry that collects and compiles demographic, diagnostic, and treatment information on all cancer patients diagnosed and/or treated at hospitals, laboratories, radiation therapy centers, or ambulatory surgical centers. Physicians must report cancer cases that are non-hospitalized and not otherwise reported. The MCR collects the same information on *in situ* cancers and benign brain and central nervous system tumors.

In the 1970's, environmentalists became concerned about the rising cancer mortality rates in Maryland and effective July 1, 1977, the 1977 Laws of Maryland, Chapter 454 established cancer reporting, and subsequent legislation altered reporting requirements through the years.

Effective July 1, 1991, the Maryland General Assembly enacted Health-General §§18-203 and 18-204, which mandate that all licensed hospitals, radiation therapy centers, and freestanding cancer diagnostic laboratories report all new cancers to the Secretary. It further mandated the electronic submission of reports to the MCR as of July 1, 1993.

The reporting law was amended in 1996 to include reporting of non-hospitalized cancer

patients by freestanding ambulatory care facilities, and by physicians whose non-hospitalized cancer patients are not otherwise reported, beginning with cases diagnosed on or after October 1, 1996.

In 2001, the Maryland General Assembly passed a law that required the reporting of benign central nervous system tumors to the MCR effective October 1, 2001.

5 MCR Data Availability

Data requests can be fulfilled for static incidence data starting with diagnosis year 1992. The most recent diagnosis year available is typically 26 months (2 years and 2 months) before the current year (e.g. cancer incidence data for 2013 is available in 2016). This time lag in data availability permits: 1) reporting facilities sufficient time to record and report cases with first course of treatment information, and 2) the MCR sufficient time to validate and consolidate cancer abstract reports. Two years from the close of the diagnosis year is the national standard for finalizing an incidence dataset for a given diagnosis year for national central cancer registries.

The MCR will not release data reported to the MCR under an interstate data exchange agreement with another state or under a data exchange agreement with another agency if the exchange agreement prohibits Maryland from re-releasing the data.

The MCR can provide Researchers with static data, expanded data, or data analyses of static data depending on the Researcher's request and approval by the MCR and the Maryland DHMH IRB.

The MCR can perform data linkages with expanded data if requested, however please

note that MCR data may be incomplete for data with diagnosis year(s) beyond the most recent year of static data.

The MCR will provide Health Officers with limited datasets from the expanded data for their jurisdiction (See section 6.2.10).

6 Data Request Procedures

All requestors must complete the MCR Data Request Form (Attachment A), which is also available on the MCR

website http://phpa.dhmh.maryland.gov/cancer/Pages/mcr_data.aspx or by calling the MCR at 410-767-4055.

Procedures for obtaining aggregate data are detailed in Section 6.1. Procedures for obtaining confidential data are outlined in Section 6.2.

Release of MCR information to legislative representatives or the media is facilitated by the DHMH Office of Governmental Affairs at 410-767-6480 or with the DHMH Office of Public Relations at 410-767-6490. If MCR receives information requests from legislative representatives or the media, they will be directed to either of the two Offices.

6.1 Aggregate (Non-confidential) Data

6.1.1 Published MCR Reports

Published MCR documents such as the Annual Incidence and Mortality Report and the Cigarette Restitution Fund Program Cancer Report are available at http://phpa.dhmh.maryland.gov/cancer/Pages/surv_data-reports.aspx, by calling the

MCR office at 410-767-4055. Maryland cancer data are also available at the National Cancer Institute's State Cancer Profiles at <http://statecancerprofiles.cancer.gov/> and on the CDC websites <http://wonder.cdc.gov/>; https://nccd.cdc.gov/DCPC_INCA/ and <https://nccd.cdc.gov/USCS/>.

6.1.2 Requests for Data Tables

MCR is able to prepare aggregate data tables or charts per specification in the MCR Data Request Form (Attachment A). MCR staff may contact the Requestor to clarify the request and describe potential data limitations.

6.2 Release of Confidential Cancer Data

6.2.1 Code of Maryland Regulations 10.14.01 and Data Release Agreements

The MCR releases data pursuant to COMAR 10.14.01.07. Data the MCR obtains through interstate data exchange agreements, or from Veterans Administration hospitals, the National Death Index, or the DHMH Vital Statistics Administration are re-released from the MCR in accordance with the agreement between the MCR and each aforementioned entity (see Section 12 Data Considerations).

6.2.2 Release of Confidential Data

Requests for confidential data are processed according to Maryland statute and regulation, and within the constraints of interstate and agency data exchange

agreements. If requested and possible, the MCR Senior Epidemiologist will provide the number of unique cases of confidential data that MCR was restricted from releasing. Requests for confidential data fall outside of requests under the Public Information Act therefore, filling requests may be subject to MCR staff availability.

See passages below for COMAR 10.14.01.04, which defines the cancer control goals of the State, and COMAR 10.14.01.07, which defines the conditions under which confidential data may be released by the Secretary:

COMAR 10.14.01.04 Cancer Control Goals of the State.

A. The cancer control goals of the State are to reduce the incidence and mortality of reportable human cancer and reportable human CNS tumors and racial, ethnic, gender, age, and geographic disparities in reportable human cancer and CNS tumor incidence and mortality in Maryland, by:

- (1) Advancing the understanding of reportable human cancer and reportable human CNS tumor demographics;
- (2) Describing reportable human cancer and reportable human CNS tumor sources, causes, risk factors, preventive measures, diagnostic tests, screening tests, treatment, and survival; and
- (3) Evaluating the cost, quality, efficacy, and appropriateness of diagnostic, therapeutic, rehabilitative, and preventive services and

programs related to reportable human cancer and reportable human CNS tumors.

B. Research that will further the cancer control goals of the State is research whose protocols have been reviewed by Department staff who have found that the research will:

(1) Advance scientific knowledge or advance knowledge of clinical practice related to cancer;

(2) Have approaches, aims, and methods that will allow the researcher to perform descriptive analyses or test hypotheses;

(3) Have one or more investigators who have training and experience with the approaches and methods; and

(4) Be conducted in a scientific environment likely to contribute to the success of the research.

.07 Confidentiality of Cancer Reports.

A. Information obtained under this chapter is not a medical record under Health-General Article, §4-301, Annotated Code of Maryland, but is subject to the confidentiality requirements of Health-General Article, §§4-101—4-103, Annotated Code of Maryland.

B. The Secretary may release confidential data to:

(1) An institution or individual researcher for medical, epidemiological, health care, or other cancer-related or CNS tumor-related research approved by the Secretary and the Department's Institutional Review

Board (IRB) in order to further the cancer control goals of the State set forth in Regulation .04 of this chapter;

(2) A reporting facility which:

(a) Routinely submits information on cases of reportable human cancer or reportable human CNS tumors to the cancer registry;

(b) Has been formally accepted as a participant in the cancer registry system; and

(c) Requests data relating to patients reported by the facility;

(3) An out-of-State cancer registry or cancer control agency which requests routine data if the:

(a) Patient is a resident of the other state, and

(b) Other state has authority to provide equivalent information on Maryland residents to this State;

(4) Each county health officer and the Baltimore City Commissioner of Health; and

(5) Another governmental agency performing its lawful duties pursuant to State or federal law.

C. The Secretary may release confidential information, subject to:

(1) A determination by the Secretary that a recipient of the information disclosed will maintain the confidentiality of the disclosed information; and

(2) An agreement signed by the Secretary and by the recipient of the confidential information that the recipient of the information will maintain the confidentiality of the disclosed information.

D. The Secretary shall release confidential data to a requestor in response to a written request only, in accordance with Health-General Article, §§4-101 and 4-102, Annotated Code of Maryland.

E. A reporting facility that in good faith submits a cancer report to the Secretary is not liable in any cause of action arising from the submission of the cancer report to the Secretary.

F. The use or publication of any statistics, information, or other material that summarizes or refers to confidential records in the aggregate, without disclosing the identity of any person who is the subject of the confidential record is not subject to the provisions of Health-General Article, §4-102, Annotated Code of Maryland.

When releasing confidential data, MCR will provide the least amount of identifiable data that will both accommodate the needs of the requestor and protect the confidentiality of the patient. Data containing unique patient identifiers (e.g. name, DOB, SSN), specific geographic divisions (e.g. county, zip code, census tract, block group) for minority patients or individuals with rare cancers, or other data that might reveal an individual's identity (e.g. address or latitude-longitude at diagnosis), will not be released without adequate justification and written assurances in an IRB application that guarantees that the Researcher will maintain the confidentiality of the data.

The MCR will release confidential data to Researchers for research that meets the Secretary's criteria, and to federal, state, local or other agencies in pursuit of their legal mandates if:

- The Secretary or his/her designee approves the release of confidential cancer data,
- The DHMH Institutional Review Board (DHMH-IRB) and the Researcher's own IRB approve the release and update the approval annually, *and*
- An Agreement (Attachment C) is executed between the MCR and the Researcher prior to release of the confidential data and updated as required by the MCR

A Researcher requesting confidential cancer case data should:

- Contact the MCR Program Manager in advance of submitting an application for research funding to determine whether requisite MCR data is/will be available if funding is granted;
- Obtain approval from the Researcher's institutional IRB;
- Visit the DHMH Institutional Review Board website (<http://dhmh.maryland.gov/oig/irb/Pages/IRB.aspx>) for information on submitting an IRB application, research protocol and other associated

documents for review. Please note that the research protocol should aim to contain:

- Purpose and method(s) of research study
 - List of MCR data elements required with information supporting the need to obtain it
 - Confirmation that prior patient consent was obtained, if available
 - Information on whether the protocol received outside peer review and/or funding
 - How the study will further the cancer control goals of the State of Maryland (see COMAR 10.14.01.04 Cancer Control Goals of the State on page 21)
 - How patient confidentiality will be safeguarded;
- After DHMH IRB approval is received, submit a completed MCR Data Request Form (Attachment A);
 - Complete the execution of the Agreement (Attachment C) that contains the provisions of the release (The MCR Senior Epidemiologist will facilitate) and;
 - Comply with all requirements of the Agreement (including no re-release and review of papers prior to publication) and with the MCR Data Use Manual and Procedures.

The MCR will:

- Work with the Researcher to facilitate proposal review and obtain DHMH signatures;
- After final approval by the DHMH-IRB, have the Agreement (Attachment C) signed by the Secretary or designee that contains the provisions of the release;
- Review and remove any cases or fields for which release is restricted; and
- Release requested confidential cancer case data (see Sections 6.2.3 and 10).

6.2.3 Cell Suppression Requirements (Small Cell Counts) for Displaying MCR Data

For displaying MCR data, the MCR considers cells that contain fewer than six non-zero cases (i.e., 1-5 cases) to be confidential data and requires that the data be denoted in published table cells as "<6" rather than the actual number of cases.

Researchers or others who present data tables from MCR data must comply with the following requirements:

- For confidentiality, suppress cells with single or multi-year counts of 1-5 cases; denote cells that contain 1-5 cases as "<6";

- For confidentiality, suppress a cell containing a multi-year average if the total case count for all years combined is 1-5 cases in that cell;
- Cells with no cases may show a value of "0";
- If the count of cases in a cell with 1-5 cases can be "back calculated" by subtraction from a total, employ complementary suppression of data in an additional cell (denoted, for example, as "s") to prevent back calculation of the number in the cell with 1-5 cases; and
- Because rates based on small numbers have poor reliability, do not publish cancer *rates* in categories where the rate was based on 1-15 cancer cases (in the numerator). For results other than numbers and rates, discussions can be held with the MCR Program Manager.

6.2.4 Student Researchers

A student who requests confidential data for their thesis or dissertation must request the data through the student's academic advisor who will serve as the Principal Investigator (PI). The PI will be responsible for data confidentiality and for maintaining the data securely, and confidential data shall remain under the control of the PI/academic advisor and the academic institution. Procedures for data access are detailed in Section 6.2.2. Approval from both the Researcher's IRB and the DHMH-IRB is required. The student must also sign the Agreement. At no time should MCR line listed data be placed on a personal or home computer.

6.2.5 Data Linkages

The MCR data are often used to confirm or establish cancer diagnoses and provide additional information about treatment, demographic, and/or outcome status to existing cohort studies. If possible, the Researcher should strive to obtain patient consent from subjects to link their data with a registry.

To request a match between a research dataset and the MCR database, the requestor should:

1. Contact the MCR Program Manager to determine whether MCR data needed for the linkage will be available if the research is approved;
2. Obtain approval and provide documentation from the Researcher's institutional IRB that the research protocol has been reviewed and approved;
3. Submit a completed MCR Data Request Form (Attachment A) to the MCR;
4. Complete an IRB application and submit it to the MCR with a research protocol that includes the following:
 - a) Support for why the specific MCR data items are requested.
 - b) A summary of the purpose of the study, including the methods and procedures to be used.
 - c) How patient confidentiality will be safeguarded.
 - d) Indication and assurance that research subjects have previously provided consent for the release of their personal identifiers by the

Researcher to MCR in order to perform a linkage that will provide patient cancer diagnosis information (such as a subject consent form for participation indicating consent that MCR can provide future diagnoses), or

If no prior subject agreement/consent was obtained, indicate why research subjects prior consent to obtain cancer diagnosis is not possible or not required.

- e) If the study has received outside peer review (e.g. Researcher's institutional IRB) and funding, provide documentation to support this (letter stating funds awarded or approval letter).
 - f) Details on how the study will further the cancer control goals of the State of Maryland (see COMAR 10.14.01.04 Cancer Control Goals of the State on page 21).
5. Review and/or incorporate feedback received from the MCR program manager (if applicable) and submit study application for DHMH IRB review.
 6. Sign a *Data Use Agreement* (Attachment C) between the Researcher, the research institution, and MCR/DHMH which will be sent by the MCR after the DHMH-IRB approves the IRB application. This agreement contains provisions of the release, including data to be released and assurances of data confidentiality.
 7. Provide the MCR Senior Epidemiologist with the dataset that should be linked along with a data dictionary once the *Data Use Agreement* has been signed

by all respective parties. The dataset may be submitted in an electronic format as a text (.txt) file, SAS file, Microsoft Excel (.xls), Microsoft Access, or other format approved by the MCR.

a) The dataset must, at a minimum, contain the following linking variables:

- Name (first, last, middle initial [if available], maiden/birth name [if available] - each component must be a separate variable);
- Date of Birth (mm/dd/yyyy);
- Gender; and
- SSN (if available). (Note: Public Law 102-515 created a NPCR to collect information on each form of in situ and invasive cancer including demographic information about each case of cancer. SSN is a required data item by the NPCR as delineated in the Standards for Cancer Registries, Volume II, Data Standards and Data Dictionary, data item number 2320. The SSN is used with the other fields to link with high probability individuals from the two data sources).

b) The MCR, in turn, will:

- Treat the Researcher's dataset as confidential information, maintaining such data on secure servers with access only by approved personnel, and in locked filing cabinets;
- Conduct the data linkage at DHMH's secure office database
- Contact the Researcher if clarification is needed during the

process and/or if assistance is needed to evaluate potential linkages;

- Review and remove any cases or fields for which release is restricted; and
- Upon completion, provide the Researcher with a summary of the linkage results and a dataset with cancer information on matched cases, as specified in the Agreement.

If a Researcher seeks to contact patients matched in the linkage, the Researcher must follow the additional steps outlined in Section 6.2.6, Patient Contact Studies.

6.2.6 Patient Contact Studies

MCR is an “Opt-in” registry for patient contact studies, which means that patients will receive an invitation from MCR to be a part of a particular research study and the subject must voluntarily *opt into* the study by contacting the Researcher directly.

Researcher responsibilities: A Researcher requesting to perform research activities that require patient contact must:

1. Contact the MCR Program Manager in advance of submitting an application for funding to determine:
 - a) If MCR data required for the research project will be available if the project is approved.
 - b) If MCR staff has time available to complete the required request.
 - c) How the letter to potential research subjects should be crafted. The

letter should describe the research project and ask the individual to contact the Researcher directly if they are interested in participating in the study.

d) How many letters will be required (will be based on case counts).

Please note that due to the small size of MCR staff, Researchers should provide MCR with stuffed, sealed and stamped envelopes with the MCR's return address affixed, and MCR staff will, in turn, affix each subject's mailing addresses.

2. Enclose the draft letter(s) and/or draft consent form(s) with the DHMH-IRB application and other required documents (see Section 6.2.5).
3. Provide MCR with stuffed, sealed and stamped envelopes with the MCR return address affixed, once DHMH-IRB approval is received. Please note that MCR staff will randomly open one percent (1%) of total sealed envelopes received from Researchers to verify that the recruitment information provided in the letter is consistent with what was approved by DHMH-IRB, so these additional envelopes should be factored into the total. (e.g. if recruitment letters need to be sent to 50 potential research subjects, Researcher should send 51 sealed envelopes).
4. Provide the MCR Program Manager with information regarding enrollment and study progress on a quarterly basis, once research study is underway.

5. Submit information regarding adverse events (including complaints) and/or breeches (see Section 7) in patient confidentiality to the MCR Program Manager as soon as it is known
6. Renew DHMH-IRB approval annually (Researcher obtains approval through the DHMH-IRB); and
7. Renew the Data Use Agreement between the DHMH and the Researcher and Researcher's institution as specified by the MCR.

MCR Responsibilities:

The MCR will:

1. Estimate and the number of envelopes needed for mailing;
2. Charge a reasonable fee to cover the cost as set forth in COMAR 10.01.08.04 for coordinating the recruitment mailings, recording the information received, and, if the MCR will receive information from individuals interested in participating, forwarding to the Researcher the contact information for those who consented to the research;
3. Submit IRB application for review to DHMH IRB;
4. Obtain necessary signatures on the Data Use Agreement (Attachment C);
5. Randomly open one percent (1%) of total sealed envelopes received from the Researcher to verify that the recruitment information provided in the

- letter is consistent with what was approved by DHMH-IRB. If MCR determines that information in a letter is not consistent with what was approved, envelopes will not be mailed to potential subjects and the Researcher will be informed and provided the opportunity to resubmit envelopes and letters to the MCR;
6. Provide the Researcher with a count of the returned envelopes and the actual numbers of persons who may have called MCR to express that they do not consent to participate in the research study;
 7. Update vital status, cause of death, and date of death in the MCR database on those patients reported as having died by a relative/next of kin; and
 8. Flag patients as “do not contact” in the MCR master database for any patient who subsequently contacts the MCR after receiving a letter for study participation and requests not to be ever contacted by Researchers.

6.2.7 Geo-coded Data

MCR data are often used for geographic analysis at the residential address - or census tract- level, and consolidated data beginning with incidence year 1992 and later are geo-coded to the latitude, longitude, zip code, census tract, and block group for the address at diagnosis. Interested Researchers should contact the MCR to discuss the

completeness and limitations of obtaining MCR geo-coded data. The MCR will also, upon request, facilitate the geo-coding of MCR data not currently geo-coded. Please note that the MCR does not have current address of cases, only address at diagnosis.

Procedures for obtaining confidential geo-coded data are detailed in Section 6.2.2, Release of Confidential Data.

6.2.8 Cancer Reporting Facilities

A cancer reporting facility may receive confidential cancer information from the MCR for patients reported from its facility if the facility:

- Routinely submits cancer patient information to the MCR in compliance with Maryland statute and regulation;
- Has been formally accepted as a participant in the MCR reporting system; and
- Requests data relating to patients of the requesting reporting facility.

The facility must submit a request in writing to the MCR Program Manager in order to obtain data. DHMH-IRB approval is not required if the facility requests data on tumors the facility previously reported to the MCR.

6.2.9 Out-of-State Cancer Registries or Other Cancer Agencies

An out-of-state cancer registry requesting confidential MCR data may have access to cancer information (static or expanded; abstract records or consolidated records) for patients with addresses at diagnosis in its jurisdiction provided that the state has authority to reciprocate the exchange of data on Maryland residents (Health-General §18-203). Other data exchange agreements from other states, Veterans Administration Hospitals, and the National Death Index may restrict the MCR from re-releasing records they reported to the MCR. The MCR shall follow the restrictions in those agreements when re-releasing those records to other requestors.

NAACCR and the NPCR may obtain information on Maryland resident cancer cases for the support of public health programs with an agreement that provides appropriate restrictions on the use and release of the shared information. Data are used for calculation of national or regional cancer incidence rates and for assessing the quality of MCR data.

Requests from these two aforementioned cancer agencies for confidential MCR data for purposes other than annual reporting must be provided as an IRB application so DHMH-IRB approval can be received.

6.2.10 Maryland County Health Officers and the Baltimore City Health Commissioner

The MCR will provide Maryland county health officers and the Baltimore City Health Commissioner with aggregate datasets for their jurisdictions on an annual basis.

Maryland county health officers and the Baltimore City Health Commissioner will be asked to sign a Data Use Agreement prior to release.

Maryland county health officers and the Baltimore City Health Commissioner may request additional confidential data for patients with address at diagnosis in their jurisdictions pursuant to the following activities:

- *Program Activities:* Maryland county health officers and the Baltimore City Health Commissioner may request confidential cancer data to carry out program activities that do not require patient contact by submitting a written request to the MCR Program Manager and completing a MCR Data Request Form (Attachment A).
 - Data will be provided for patients whose address at diagnosis is in the Requestor's jurisdiction (static or expanded data).
 - DHMH-IRB approval is required if patient contact will be made or if name, SSN, and date of birth are released. Once approval is received, Maryland county health officers and the Baltimore City Health Commissioner will

sign a joint Data Use Agreement prior to release, which will include the requirement of maintaining the confidentiality of the released data.

- *Cancer Cluster or Small Area Variation Studies:* Maryland county health officers and the Baltimore City Health Commissioner may request confidential or non-confidential data to investigate reports of cancer clusters or small area variation.
 - A requestor must complete the MCR Data Request Form (Attachment A).
 - A requestor will be provided with data for patients whose address at diagnosis is in the requestor's county or jurisdiction (final data, incomplete data, or submitted abstract data). DHMH-IRB approval may be required. Maryland county health officers and the Baltimore City Health Commissioner will sign an Agreement prior to release, which will include the requirement of maintaining the confidentiality of the released data.

6.2.11 A Government Agency Pursuant to Federal or State Law

Federal and state government agencies performing their lawful duties may request confidential data pursuant to the following activities:

- *Annual data submission to the National Program of Cancer Registries of the Centers for Disease Control and Prevention (see Section 6.2.9), Audit and QA/QC Testing:* The internal (DHMH), MCR vendor, or other auditor (such as from the NPCR Audit Program) shall have access to confidential cancer data for evaluation

of the quality of the MCR data. A signed Agreement is required.

- *Cancer Cluster or Small Area Variation Studies:* A state agency, regardless of need to contact a patient, may request and have access to confidential cancer data (static or expanded). Requestors must complete the MCR Data Request Form (Attachment A) and DHMH-IRB approval may be required.
- *Program Activities:* A state agency requesting confidential or aggregate cancer data to carry out program activities that does not require patient contact must submit a MCR Data Request Form (Attachment A). The agency shall have access to static data and DHMH-IRB approval is not required. A signed Data Use Agreement will be required.

7 Data Breaches and Unintentional Disclosures

If the MCR has provided confidential data, the Researcher must take every measure to ensure data is secure and only used for purposes approved by the DHMH-IRB. MCR data should never be stored on a personal computer.

The Researcher must implement administrative, physical, and technical safeguards that reasonably and appropriately protect the confidentiality, integrity, and availability of the electronic confidential data that they receive, create, maintain, or transmit.

If a data breach does occur, the Researcher must notify the MCR Program Manager within 24 hours of the discovery of the breach.

The Researcher must take appropriate and immediately data security measures to prohibit further breach of MCR data, collect evidence supporting the existence of the breach and secure information technology systems to allow for an investigation of the breach.

The Researcher must submit a draft letter to MCR for approval which notifies research subjects that that their confidential data has been, or is reasonably believed to have been, the subject of a breach that includes, to the extent possible:

1. A brief description of what happened, including the date of the breach and the date of the discovery of the breach, if known;
2. A description of the types of confidential data that were involved in the breach (such as full name, SSN, date of birth, home address, or other types of information that were involved);
3. Any steps the individuals should take to protect themselves from potential harm resulting from the breach;
4. A brief description of what the Researcher and/or research institution is doing to investigate the breach, to mitigate losses, and to protect against any further breaches; and
5. Contact information that research subject can utilize to ask questions or voice further concern, which shall include a toll-free telephone number, an e-mail address, website, or postal address.

8 Failure to Comply with Data Use Manual and Procedures

The MCR and the DHMH-IRB will consider disciplinary action for persons/entities who do not comply with the MCR's Data Use Manual and Procedures. This action could include exclusion from using MCR data for future studies or signoff on IRB renewal request.

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9 Publication and Credit

Data requestors shall provide the MCR with a copy of any final reports, analysis, data, presentations, publications submitted, or other information resulting from the use of MCR data a minimum of 10 business days before distribution, for review and comment by DHMH.

Data Requestors and Researchers shall acknowledge DHMH as the source for data disclosed under the Data Use Agreement in any publication, presentation, or report utilizing the disclosed data by including in the publication, presentation or report a statement, as specified (see Attachment C).

Data Requestors found to have not provided the MCR with copies prior to presentation/ publication, or do not include acknowledgement of the data source should refer to Section 8 for failure to comply with Data Use Manual and Procedures.

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10 Data Release Formats

The MCR will release aggregate data in hard copy documents, faxes, e-mails, or in electronic files. Current published reports are available on the MCR website at http://phpa.dhmh.maryland.gov/cancer/Pages/surv_data-reports.aspx.

The MCR will release confidential data in hard copy documents, electronic files on an encrypted password protected CD, or electronic files on document servers that facilitate encrypted secure data exchange via the internet.

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11 Fees

The MCR may charge a reasonable fee to cover the cost of work, as set forth in COMAR 10.01.08.04. Except for the first two hours which are free, the standard charge for responding to requests for public information is \$25 per hour of employee time.

Employee time to respond to a request may include time spent searching and copying and any other similar tasks. When copies are reproduced using a computer printer or copier machine, the charge for each copy is 50 cents per page. The charge for mailing or delivery is the actual cost to the DHMH. No work will begin until these charges have been accepted in writing by the requestor. All applicable fees shall be paid before the request is fulfilled.

All fees are waived for data requests from governmental institutions, other cancer registry systems, and reporting facilities carrying out official registry duties.

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12 Data Considerations

12.1 Access to Cancer Mortality Data

Cancer mortality data remains under the jurisdiction of the Maryland Vital Statistics Administration (<http://dhmh.maryland.gov/vsa/Pages/home.aspx>) and cannot be released by the MCR without specific permission from the DHMH Vital Statistics Administration (410-767-5950) to obtain cancer mortality data. Once an IRB application is submitted, the MCR Program Manager will facilitate permission from DHMH Vital Statistics Administration on behalf of the Researcher. If permission is granted and IRB approval received (if relevant), then the MCR data released may contain information on vital status, cause of death, and date of death, and may contain cases reported to the MCR only through death certificates.

12.2 Access to Data from Other Sources

Confidential cancer case data obtained by MCR from other sources under data sharing agreements (i.e., other states, the DHMH Vital Statistics Administration, National Death Index, Veterans Administration hospitals) will be removed from a dataset before release to a Requestor. Similarly, certain data items contained within a requested record that comes from other sources (e.g., vital status, date of death, cause of death) will also be removed from a dataset before release to a Requestor. The data Requestor must approach the source of the removed data to obtain data directly or request and obtain

approval for release by MCR.

12.3 Medical Provider or Facility-Specific Information

The MCR will not release information about a physician associated with a cancer case or about individual reporting facilities. The MCR will direct persons requesting facility-specific information (e.g., provider name, facility name, or number of cases submitted by particular facilities) to the reporting facility of interest.

12.4 Requests for Confidential Data by the Patient

The MCR will not release confidential data held by MCR to an individual requesting their own cancer data. In such cases, the MCR will refer the individual to the reporting facility and/or their medical provider for this information.

12.5 Requests for Confidential Data for a Family Member

The MCR will not release confidential data held by MCR to an individual requesting information on behalf of or about a family member's cancer data. The MCR will refer the individual to the reporting facility and/or their medical provider for this information.

12.6 Requests for Confidential Information by a Treating Physician

The MCR will provide patient information to a treating physician if the patient has signed a consent form and the physician's office has been vetted through the Physician's State Licensing Board.

12.7 Requests for Confidential Data from the Press or Agents of the Courts

Since a cancer report is not considered a “medical record” as provided by Health-General §18-204 Annotated Code of Maryland; it is protected under the confidentiality requirements of Health-General §§4-101, et seq. The press, lawyers, law enforcement agencies, and agents of the courts do not have access to confidential cancer registry data upon request.

If the MCR is served a subpoena, the MCR shall immediately provide a copy to the DHMH Office of the Attorney General.

ATTACHMENT A: MCR DATA REQUEST FORM

See

http://phpa.dhmh.maryland.gov/cancer/Documents/mcr_DataRequestForm_DHMH4663.pdf

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ATTACHMENT B: DHMH INSTITUTIONAL REVIEW BOARD

See: <http://dhmh.maryland.gov/oig/irb/Pages/IRB.aspx>

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ATTACHMENT C: MARYLAND CANCER REGISTRY AGREEMENT TEMPLATE

AGREEMENT BETWEEN

THE STATE OF MARYLAND
DEPARTMENT OF HEALTH AND MENTAL HYGIENE

AND

RESEARCHER, INSTITUTION
MCR#XX-XX

This agreement is made between: (1) the State of Maryland, Department of Health and Mental Hygiene, Maryland Cancer Registry, (“DHMH”), and (2) Institution and the Principal Investigator (“PI), (“the Parties”).

WHEREAS, DHMH is required under Md. Code Ann., Health-General, (“Health-General”), §18-204, to establish and maintain the Maryland Cancer Registry (“MCR”), a statewide cancer registry containing cancer information about Maryland's residents, which is subject to the confidentiality requirements of Health-General §§4-101-4-103; and

WHEREAS, the Secretary of Health and Mental Hygiene, in accordance with Health-General §§4-101--4-103 and Code of Maryland Regulations (“COMAR”) 10.14.01.07, may release the confidential cancer data to an individual researcher for medical, epidemiological, health care, or other cancer-related research approved by the Secretary; and

WHEREAS, Principal Investigator on behalf of the Institution has submitted to DHMH a written request for information in the MCR to carry out a research project entitled:_____ (see Attachment 1, Maryland Cancer Registry Data Request) in accordance with COMAR 10.14.01.07; and

WHEREAS, the MCR on behalf of the Secretary of Health and Mental Hygiene has determined that the project would further the cancer control goals of the State in accordance with COMAR 10.14.01.04.

NOW, THEREFORE, the Parties hereby agree to the following terms in the carrying out of the project:

- 1) DHMH agrees that it will:

- a) Identify information to be released in the MCR; and
 - b) Release to the PI the following data: list data to be released.
- 2) The Institution and the Principal Investigator agree that they will:
- a) Keep confidential, in accordance with applicable laws, regulations, and ethics requirements including Health-General §4-102, any information that identifies a person that is disclosed to the Institution and the Principal Investigator under this Agreement;
 - b) Ensure that every individual involved in the study who will have access to the disclosed information signs a “Confidentiality Agreement” before being given access to any of the information, (see Attachment 2, Confidentiality Agreement);
 - c) Maintain the confidentiality of the information disclosed under this Agreement notwithstanding termination of this Agreement;
 - d) Reveal abstracts and any individual identifying information only to persons who need to know the information for analysis or completion of the study;
 - e) Use this information only as approved by DHMH and **follow the restrictions on data release below:**
 - 1. For confidentiality, suppress a cell with single or multi-year *count* of 1-5 cases; denote a cell that contains 1-5 cases as “<6”;
 - 2. For confidentiality, suppress a cell containing a multi-year *average* if the total case *count* for all years combined is 1-5 cases in that cell;
 - 3. A cell with no cases may show a value of “0”;
 - 4. For confidentiality, employ complementary suppression of data in an additional cell to prevent back calculation of the count of cases in the cell with 1-5 cases if the count of cases can be “back calculated” by subtraction from a total; and
 - 5. For reliability, do not publish cancer rates that are based on 1-15 cancer cases in the numerator;
 - f) Acknowledge DHMH as the source for data disclosed under this Agreement and the sources of MCR finding in any publication,

presentation, or report utilizing the disclosed data by including in the publication, presentation or report the following statement(s) or equivalent text:

“Cancer incidence data were provided by the Maryland Cancer Registry, Center for Cancer Prevention and Control, Department of Health and Mental Hygiene, 201 W. Preston Street, Room 400, Baltimore, MD 21201, http://phpa.dhmf.maryland.gov/cancer/Pages/mcr_home.aspx, 410-767-4055.

We acknowledge the State of Maryland, the Maryland Cigarette Restitution Fund, and the National Program of Cancer Registries of the Centers for Disease Control and Prevention for the funds that support the collection and availability of the cancer registry data.

The findings and conclusions of this report are those of the authors and do not necessarily represent the views of the Department of Health and Mental Hygiene”;

- g) Provide DHMH with written annual updates on the status of the project and on the use or publication of the information disclosed under this agreement;
- h) Provide DHMH with a copy of any final reports, analyses, data, presentations, or publications submitted resulting from the evaluation of and the use of the information disclosed under this agreement a minimum of 10 business days before distribution, for review and comment by DHMH; and
- i) Return to DHMH or destroy upon completion of the project or termination of this Agreement all copies of files that contain patients' age, gender, race, address, coordinates of the address, census tract, and any other information provided to the PI and Institution by DHMH and submit to DHMH an affidavit, (Attachment 3, Data Disposal Affidavit), attesting to the fact that all data/copies obtained from DHMH have either been returned to DHMH or destroyed, unless prior written approval for data retention has been obtained from DHMH.

3) The Parties agree that:

- a) This Agreement will commence upon the last date of the signing of it by the representatives of the Parties;
- b) If the PI or his/her staff does not comply with the provisions of this Agreement, the Agreement may be terminated by the MCR and/or the MCR may reject future requests for MCR data from the investigator;
- c) This Agreement may be terminated by the DHMH or the Parties upon thirty (30) days written notice to the other Party;
- d) This Agreement will remain in effect until, or termination by either Party;
- e) This Agreement may be amended as the DHMH and the Parties mutually agree in writing;
- f) Any legal enforcement or disputes concerning this agreement will be brought in the Circuit Court of Maryland for Baltimore City; and
- g) The following documents are attached hereto and incorporated into this Agreement:
 - i) Attachment 1, Maryland Cancer Registry Data Request;
 - ii) Attachment 2, Confidentiality Agreement(s); and
 - iii) Attachment 3, Data Disposal Affidavit.

IN WITNESS WHEREOF, the following authorized representatives of the Parties hereby set forth their signatures showing their consent to abide by the terms of this Agreement:

**STATE OF MARYLAND
DEPARTMENT OF HEALTH AND MENTAL HYGIENE**

by: _____
Howard Haft
Deputy Secretary for Public Health
Date: _____

by: _____
Kimberly Stern, Program Manager
Maryland Cancer Registry
Date: _____

INSTITUTION: _____

by: _____
NAME (printed) _____
Title: _____
Date: _____

by: _____
PI NAME (printed) _____
Title: _____
Date: _____

The services and facilities of the Maryland Department of Health and Mental Hygiene (DHMH) are operated on a non-discriminatory basis. This policy prohibits discrimination on the basis of race, color, sex, or national origin and applies to the provisions of employment and granting of advantages, privileges, and accommodations.

The Department, in compliance with the Americans with Disabilities Act, ensures that qualified individuals with disabilities are given an opportunity to participate in and benefit from DHMH services, programs, benefits, and employment opportunities.

Maryland Cancer Registry

Center for Cancer Prevention and Control
Maryland Department of Health and Mental Hygiene
201 West Preston Street, Room 400
Baltimore, MD 21201

410-767-4055
Fax--410-333-5218

<http://phpa.dhmh.maryland.gov/cancer/pages/Home.aspx>