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1 Introduction

This document describes the Maryland Cancer Registry (MCR) procedures for release of cancer data and outlines the procedures to obtain both non-confidential aggregate data and confidential individual-level data.

The MCR, a division of Maryland’s Department of Health and Mental Hygiene (DHMH) Prevention and Health Promotion Administration, Cancer and Chronic Disease Bureau - Center for Cancer Prevention and Control, collects, stores, and analyzes data on all new cases of reportable cancers diagnosed in Maryland residents. MCR data are used to track trends in cancer incidence, and provide a database for cancer prevention/control activities and for research.

Uses of MCR data may include:

- **Tracking, reporting, and evaluating the number of cases of cancer, the rates of cancer overall, and demographic groupings.**

- **Analyzing trends in cases and rates over time (Incidence and Cohort analyses or Case-control Studies):** MCR staff and researchers utilize non-confidential or confidential cancer patient data to conduct activities that do not require patient contact.
• **Performing Needs Assessments and Projections:** MCR data are used to identify populations in need of screening and/or prevention efforts. Data are also used to project numbers of future cancer cases, for example, for allocation of public health resources.

• **Conducting Patient Contact Studies:** Researchers 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 the individuals in a second database with those in the MCR database to identify whether the individual has cancer or to confirm cancer diagnosis.

**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 records**: a file or record submitted to the MCR by a reporter that contains information about one reportable cancer case.

- **Aggregate data**: compiled data on cancer cases (tables, graphs, charts, etc.) that summarize cancers in Maryland. Aggregate data tables do not contain cases numbering 1-5 for that cell. Aggregate data are not considered confidential. Examples include MCR published reports and specially requested tables.

- **Agreement**: an MCR Data Access Agreement or a document executed between the DHMH and the party to whom data are released detailing the rights and responsibilities of both parties.

- **Cancer**: tumors reportable to the MCR under statute or regulation in Maryland (see Section 2), includes invasive cancer cases, in situ cancers, and other benign brain and central nervous system tumors.

- **Confidential data**: any part of the cancer report, statement, note, or other information that contains names or other personal identifiers of patients in the database (e.g., date of birth, SSN). Confidential data also include information that has the potential to help identify a person, including but not
limited to:

- information on an individual cancer case,
- date of birth,
- SSN,
- 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 on that cancer case.

- **Expanded data:** consolidated MCR records that have not yet been finalized and submitted to NPCR. Expanded data include incomplete data from the consolidated MCR records for cases or years recently reported that have not
yet been included in the static data (see definition below). Expanded data also contain additional cases from delayed reports from past years that were not included in the static dataset.

- **Submitted abstract data:** one or more cancer abstract reports submitted by one or more reporting facilities.

- **Static data:** consolidated MCR records that have been included in the most recent submission to the NPCR for “24-month” data (i.e., data finalized 24 months after the end of a year, for example, December 2012 for cases diagnosed in calendar year 2010). 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.
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.
3 Confidentiality

The MCR regards all abstract records reported to the MCR as confidential. 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 deleting data from cells in tables that contain 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 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 an Agreement with the MCR must be executed prior to such a release.
4 MCR Background

The MCR is a population-based cancer incidence registry. The MCR 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. Effective July 1, 1977, the 1977 Laws of Maryland, Chapter 454 established cancer reporting, and subsequent legislation has altered the 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

For cancer statistics, the MCR will restrict release of incidence data to static data from diagnosis year 1992 through the year approximately 26 months after the end of the incidence year (e.g., cancer incidence data for 2010 are available after February 2013). The time lag in data availability is necessary to allow: 1) reporting facilities sufficient time to record and report the case with first course of treatment information, and 2) the MCR sufficient time to validate and consolidate the 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 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 will provide researchers with static data, expanded data, or analyses from static data depending on what the researcher is requesting and what the MCR and IRB have approved.

The MCR will perform a data linkage to expanded data if requested, but the MCR will notify the requestor that the MCR data may be incomplete for data with diagnosis
year(s) beyond the last year of the static data.

The MCR will provide Health Officers with datasets from the expanded data.
6 Data Request Procedures

All requestors must complete the MCR Data Request Form (Attachment A). The form is also available on the MCR website http://fha.dhmh.maryland.gov/cancer/SitePages/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.

The MCR will coordinate release of information to legislators or to the media with the DHMH Office of Governmental Affairs at 410-767-6480 or with the DHMH Office of Public Relations at 410-767-6490.

6.1 Aggregate (Non-confidential) Data

6.1.1 Published MCR Reports

Published MCR documents such as the Annual Incidence Report and the Cancer Report of the Cigarette Restitution Fund Program are available at http://fha.dhmh.maryland.gov/cancer/SitePages/surv_data-reports.aspx, by calling the MCR office at 410-767-4055, or by submitting an MCR Data Request Form (Attachment...
A). Maryland cancer data are also available at the National Cancer Institute’s State Cancer Profiles at http://statecancerprofiles.cancer.gov/.

6.1.2 Requests for Data Tables

Requesters may request that the MCR prepare aggregate data tables or charts by submitting an MCR Data Request Form (Attachment A). MCR staff may discuss the request with the requestor to clarify the request and to describe 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, from Veterans Administration hospitals, from the National Death Index, or from the DHMH Vital Statistics Administration are re-released from the MCR in accordance with the agreement between the MCR and each entity (see Section 10 Data Considerations).

6.2.2 Release of Confidential Data

Requests for access to confidential data are processed within the constraints of Maryland statute and regulation, and interstate and agency data exchange agreements. Requests for confidential data fall outside of requests under the Public Information Act; therefore, filling requests is subject to MCR staff availability.
COMAR 10.14.01.04 defines the cancer control goals of the State, and COMAR 10.14.01.07 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.

The MCR will release confidential data giving out as little specific information as possible to accommodate the legitimate needs of the requestor and to protect the confidentiality of the patient. Data without the name or other identifiers of the patient from a specific civil division (county, zip code, census tract, block group) or other data that might reveal an individual’s identity (address at diagnosis, latitude-longitude at diagnosis), will not be released without adequate justification and without written assurances guaranteeing that the researcher will maintain the confidentiality of the data.

The MCR may 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 approve 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;
- 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 must:

- Contact the MCR Program Manager in advance of his/her application for research funding to determine whether MCR data needed for the research will be available if the research is approved and funded;

- Obtain approval from the researcher’s institution’s IRB and provide documentation that the research protocol has been reviewed and approved by the researcher’s institution’s IRB;

- Submit a completed MCR Data Request Form (Attachment A) to the MCR Program Manager;

- Submit to the DHMH a research protocol that supports the data items requested and summarizes the purpose of the study, including the methods and procedures to be used, specifies whether the protocol has received outside peer review and/or funding, specifies how the study will further the cancer control goals of the State of Maryland, and specifies how confidentiality will be safeguarded;

- Obtain approval from the MCR Program Manager and, with the aid of the MCR Program Manager, obtain necessary DHMH approvals on the DHMH-IRB form; and

- Submit the DHMH-IRB forms to and obtain approval from the DHMH-IRB.
• Execute the Agreement (Attachment C) that contains the provisions of the release; and

• Comply with all requirements of the Agreement 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).

### 6.2.4 Student Researchers

A student who requests confidential data for his/her thesis or dissertation must request the data through the student’s academic advisor who will serve as the PI. The PI will be responsible for data confidentiality and for maintaining the data securely. 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.

6.2.5 Data Linkages

The MCR data are often used to confirm or establish cancer diagnoses and to provide additional information about treatment, demographic, and/or outcome status to existing cohort studies.

To request a match between a second dataset and the MCR database, the requestor must:

- Contact the MCR Program Manager to determine whether MCR data needed for the linkage will be available if the research is approved;
- Obtain approval from the researcher’s institution’s IRB and provide documentation that the research protocol has been reviewed and approved by the researcher’s institution’s IRB;
- Submit a completed MCR Data Request Form (Attachment A) to the MCR Program Manager;
- Submit to the MCR a research protocol that supports the data items requested, summarizes the purpose of the study including the methods and procedures to be used, states whether the protocol has received outside peer review and funding by showing funds awarded or an approval letter, specifies
how the study will further the cancer control goals of the State of Maryland, and states how confidentiality will be safeguarded;

- Obtain approval from the MCR Program Manager and, with the aid of the MCR Program Manager, obtain necessary DHMH approvals on the DHMH-IRB form; and

- Submit DHMH-IRB forms with:
  - Indication and assurance that the subjects have already agreed to have the researcher release their identifiers to the MCR to perform linkage in order to obtain their cancer diagnosis information (such as the research study’s subject consent form for participation showing consent for obtaining future diagnoses), or
  - If no prior subject agreement/consent was obtained, indication why the subjects consent to obtain cancer diagnosis is not possible or not needed before the MCR will release matched names with cancer information to the researcher;

- Upon approval by the DHMH-IRB, execute the Agreement (Attachment C) between the researcher, the research institution, and MCR/DHMH that contains the provisions of the release including the data to be released and assurances of data confidentiality; and

- Provide the MCR with the dataset to be linked. The dataset may be
submitted in an electronic format including text (.txt), Microsoft Excel or Microsoft Access, or other format approved by the MCR. A data dictionary must accompany the file. 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).

The MCR will:

- Have the Agreement (Attachment C) that contains the provisions of the release signed by the Secretary or designee;
• 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 the DHMH office;

• 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 wants to contact the patients who match in the linkage, the researcher must additionally follow the steps outlined in Section 6.2.6, Patient Contact Studies.

6.2.6 Patient Contact Studies

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

• Contact the MCR Program Manager in advance of application for funding to determine the following:

  o Whether MCR data needed for the research will be available if the research is approved; and
Whether MCR staff have the time to complete the required request;

- Decide whether the mailing to the person with cancer will ask the person:
  - To contact the researcher directly if interested in participating in the study, or
  - To contact the MCR to indicate willingness to have the MCR disclose his/her name to the researcher.

- Send with the DHMH-IRB application the draft letter(s) and/or draft consent form(s) that the researcher wants the DHMH to send to the patient to request consent for research participation;

- Obtain approval from the researcher’s institution’s IRB and provide documentation that the research protocol has been reviewed and approved by the researcher’s IRB;

- Submit a completed MCR Data Request Form (Attachment A) to the MCR Program Manager;

- Submit to the MCR a research protocol that summarizes the source of study funding and the purpose of the study including the methods and procedures to be used, and specifies how the study will further the cancer control goals of the State of Maryland and how confidentiality will be maintained;

- Obtain approval from the MCR Program Manager and, with the aid of the MCR Program Manager, obtain necessary DHMH approvals on the DHMH-IRB
form;

- Submit DHMH-IRB forms to and obtain approval from the DHMH-IRB;

- Upon approval by the DHMH-IRB, execute the signed Agreement between the DHMH and the researcher and the researcher’s institution;

- Pay for MCR mailings (see Section 6.2.6, MCR Responsibilities, below, second bullet regarding mailing) to potential study participants, those fees which must be paid before the request is filled;

- Conduct planned research;

- Submit information regarding enrollment and study progress to the MCR Program Manager on a quarterly basis;

- Immediately submit information regarding adverse events (including complaints) and/or breeches (see Section 7) in patient confidentiality to the MCR Program Manager;

- Renew DHMH-IRB approval annually (researcher obtains approval through the DHMH-IRB); and

- Renew the Agreement between the DHMH and the researcher and researcher’s institution as specified by the MCR.

**MCR Responsibilities:**

The MCR will:

- Estimate a cost for the subject recruitment and mailing;
• Charge a reasonable fee to cover the cost as set forth at 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;

• Work with the researcher to obtain required DHMH signatures and facilitate proposal review;

• Have the Agreement (Attachment C) that contains the provisions of the release signed by the Secretary or designee;

• Mail the recruitment information that was approved by the IRBs to the cancer patients who meet the researcher’s inclusion criteria and who are in the MCR’s finalized dataset;

• If the MCR will receive information from the patients with cancer interested in participating:
  
  o Release confidential patient data including names and addresses to the researcher on only those patients who have consented to be a part of the study; and

  o Provide the researcher with actual numbers and the age, race, ethnicity, sex, and jurisdiction of residence of persons who do not consent to participate in the research;
• Maintain records of letters mailed, numbers returned, and names submitted to the researcher if the MCR will handle the recruitment;

• 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

• Flag patients as “do not contact” in the MCR master database for any patient who subsequently contacts the MCR and requests not to be contacted ever by researchers.

6.2.7 Geo-coded Data

The MCR data are often used for geographic analysis at the house level or census tract level. The MCR consolidated data with incidence year of 1992 or later are geo-coded to the latitude, longitude, zip code, census tract, and block group. Interested researchers should contact the MCR to discuss the completeness and limitations of obtaining the MCR geo-coded data. The MCR will also, upon request, facilitate the geo-coding of MCR data not currently geo-coded.

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 have access to confidential cancer information for patients reported from its facility if the facility:

- Routinely submits cancer patient information to the cancer registry 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. The DHMH-IRB approval is not required if the facility is only requesting data on tumors that 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 with Maryland to exchange 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 report 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 cancer agencies to use confidential MCR data for purposes other than annual reporting must be submitted in writing to the MCR Program Manager. Approvals from the Secretary (or designee) and the DHMH-IRB are required.
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 datasets or access to data contained in expanded or static data on persons diagnosed with cancer who are residents of their jurisdictions on an annual basis. Maryland county health officers and the Baltimore City Health Commissioner will sign an 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. Requestors must complete the MCR Data Request Form (Attachment A). They shall have access to data for patients whose address at diagnosis is in the Requestor’s jurisdiction (static or expanded data). The DHMH-IRB approval is required if patient contact will be made or if name, SSN, and date of birth are released. 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.

- **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. Often these studies will be in conjunction with the DHMH Environmental Health Bureau. A requestor must complete the MCR Data Request Form (Attachment A). A requestor shall have access to data for patients whose address at diagnosis is in the requestor’s county or jurisdiction (final data, incomplete data, or submitted abstract data). The 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. Requestors must complete the MCR Data Request Form (Attachment A). A signed Agreement is required.

- **Cancer Cluster or Small Area Variation Studies:** A state agency, whether or not desiring 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). The DHMH-IRB approval may be required.

- **Program Activities:** A state agency requesting confidential or aggregate cancer data to carry out program activities that do not require patient contact must submit a MCR Data Request Form (Attachment A). The agency shall have access to static data. The DHMH-IRB approval is not required. A signed agreement and approval is required.
7 Data Breaches and Unintentional Disclosures

If the MCR has provided the researcher with confidential data, the researcher will take every measure to make sure this data is secure and only used for the requested and DHMH-IRB approved purpose.

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

If a data breach occurs, the researcher will notify the MCR Program Manager within 24 hours of the discovery of the breach.

The researcher will secure breach evidence and secure information technology systems to allow for an investigation of the breach. The researcher will also secure any additional data to prevent further hacking or theft.

The researcher will also provide to the MCR for approval a draft letter for the researcher to utilize to notify the individuals that their confidential data has been, or is reasonably believed to have been, the subject of a breach that includes, to the extent possible:
a) A brief description of what happened, including the date of the breach and the date of the discovery of the breach, if known;

b) 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);

c) Any steps the individuals should take to protect themselves from potential harm resulting from the breach;

d) A brief description of what the researcher is doing to investigate the breach, to mitigate losses, and to protect against any further breaches; and

e) Contact procedures for individuals to ask questions or learn additional information, 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.
9 Publication and Credit

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

Data requestors shall acknowledge the DHMH as the source for data disclosed under this Agreement in any publication, presentation, or report utilizing the disclosed data by including in the publication, presentation or report a statement, as specified in the Agreement (see Attachment C).
10 Data Release Formats

The MCR will release aggregate data in formats such as hard copy, fax, e-mail, or electronically. Current published reports are available on the MCR website or at http://fha.dhmh.maryland.gov/cancer/SitePages/surv_data-reports.aspx.

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

The MCR will 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 searching for records, preparing records to be copied, copying records, 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.
12 Data Considerations

12.1 Access to Cancer Mortality Data

Cancer mortality data remain under the jurisdiction of the Maryland Vital Statistics Administration and cannot be released by the MCR without specific permission to obtain cancer mortality data from the DHMH Vital Statistics Administration (410-767-5950). If permission is granted and IRB approval received (if needed), 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 that the MCR has obtained from certain other sources under data sharing agreements (i.e., certain other states, the DHMH Vital Statistics Administration, National Death Index, Veterans Administration hospitals), or certain data items contained within the record requested (e.g., vital status, date of death, cause of death) will be removed from the dataset before release. The data requestor will need to approach the source of the data to request and obtain approval for release, and then re-contact the MCR or obtain the data that the MCR received from the other registry.
12.3 Facility-specific Information

The MCR will not release information about the physician caring for the 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 or facilities of interest.

12.4 Requests for Confidential Data for Self-knowledge

The MCR will not release confidential data to an individual who requests information for self-knowledge of his/her own data held by the MCR. The MCR will refer the individual to the reporting facility and/or his/her medical provider for the requested information.

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

A cancer report is not a “medical record” as provided by Health-General §18-204 Annotated Code of Maryland; however, 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 merely upon request.

If the MCR is served a subpoena, the MCR shall immediately provide a copy to the Office of the Attorney General.
ATTACHMENT A: MCR DATA REQUEST FORM

See

ATTACHMENT B: DHMH INSTITUTIONAL REVIEW BOARD

See: http://dhmh.maryland.gov/oig/irb/SitePages/Home.aspx
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://fha.dhmh.maryland.gov/cancer/SitePages/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: ________________________________
Frances B. Phillips, RN, BSN, MHA
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: ________________________________
ATTACHMENT D: DATA DISPOSAL AFFIDAVIT

STATE OF MARYLAND
MARYLAND DEPARTMENT OF HEALTH AND MENTAL HYGIENE
MARYLAND CANCER REGISTRY
AFFIDAVIT OF DATA DISPOSAL

MCR Number:

I, _______________________________________(Name-typed or print clearly) hereby make oath or affirm under the penalties of perjury and upon personal knowledge that the copies of files and all confidential data released to me from the Maryland Cancer Registry (MCR) in regard to the study or project named below, were handled as follows: (check all that apply)

___ Data deleted from all computers
___ Data disk returned to MCR
___ Data disk destruction
___ Paper copies shredded
___ NA (Never had hard copy or disks)

Signature of Principal Investigator _______________________________________

Name of Principal Investigator: _______________________________________

Study or Project Name: _______________________________________

Organization or Institution: _______________________________________

Date _______________________________________

I hereby certify that on ______________________________(Date) before me a notary public of the State of Maryland, personally appeared ________________________(Investigator’s name) known to me or satisfactorily proven to be the individual whose name is subscribed to the within instrument and who acknowledges that he/she executed the same for the purposes therein contained. Witness my hand and notarial seal.

Signature of Notary Public______________________________________

Printed/Typed Name of Notary Public _______________________________________

My Commission Expires  ______________________________________

(SEAL)

4/2008
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://fha.dhmh.maryland.gov/SitePages/Home.aspx