Maryland Department of Health and Mental Hygiene

Center for Cancer Surveillance and Control

Maryland Cancer Registry
Data Use Policy and Procedures

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MARYLAND CANCER REGISTY
DATA USE POLICY AND PROCEDURES
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Maryland Cancer Registry
Center for Cancer Surveillance and Control
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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) Center for Cancer Surveillance 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 a 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*: In this document "Agreement" means an MCR Data Access Agreement or a document executed between the Department and the party to whom data are released setting down the rights and responsibilities of both parties.

- *Cancer*: In this document, "cancer" refers to tumors reportable to the MCR under statute or regulation in Maryland (see 2. below) and includes invasive and in situ cancers and other benign 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, Social Security Number). Confidential data also include information that has the potential to help identify a person, such as data on one specific type of rare cancer, one date of birth, street address at diagnosis, latitude-longitude of address at diagnosis, diagnosis in a small geographic area (zip code/census tract/block group), or any data cells that contain <6 non-zero cases (i.e., 1-5 cases).

- *Consolidated record or master consolidated record:* a file or record about containing information on one reportable cancer case that is compiled from all the abstract records submitted to the MCR on that cancer case (i.e., from one or more submitted abstract records).

- *Expanded data*: data are from the master consolidated MCR records that have not yet been finalized and submitted to National Program of Cancer Registries (NPCR). Expanded data include incomplete data from the

consolidated MCR records for cases or years that have not yet been included in the Static data (see below). Expanded data contain additional cases from delayed reports from past years that were not included in the Static data set.

- *Submitted abstract data* are cancer abstract report(s) submitted by one or more reporting facilities.

- *Static data*: Static data are data from the master 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 the year, for example, January 2008 for cases diagnosed in calendar year 2005). These annual datasets are the "official" reported number of Maryland cases for that year.

2 Legal Authority

Maryland Code Annotated, Health-General ("Health-General") §§18-203 – 204 governs cancer data reported to the MCR. A cancer report is not a "medical record" under Health-General Title 4, Subtitle 3 (Health-General §18-204); however, 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 Director.

The Code of Maryland Regulations (COMAR) 10.14.01 provide further governance specifying which tumors are reportable, which facilities must report and how, and 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 6.2.1).

The MCR uses "cell suppression," or hiding cells in tables that contain 1-5 individuals, to safeguard against the unintentional identification of individuals. Guidelines are detailed in Section 6.2.1.

Note that the MCR restricts release of confidential data for research under the provisions of COMAR 10.14.01.05, and to federal, State, local or other agencies in pursuit of their legal mandates. The Secretary or the Secretary's designee must approve release of confidential cancer data, the DHMH Institutional Review Board

(DHMH-IRB) and the researcher's own IRB must approve release, and an *Agreement* with the MCR must be executed prior to release of confidential data.

4 MCR Background

The MCR is a population-based cancer incidence registry responsible for the collection of demographic, diagnostic, and treatment information on all cancer patients diagnosed and/or treated at hospitals, laboratories, radiation therapy centers, ambulatory surgical centers, and physician's offices (non-hospitalized patients) in Maryland. The MCR also collects similar information on 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 altered the reporting requirements through the years.

Effective July 1, 1991, the Maryland General Assembly enacted Maryland Code Annotated, Health-General §§18-203 and 18-204 that mandated reporting by hospitals, radiation therapy centers, and freestanding cancer diagnostic laboratories to the Secretary of all new cancers that were licensed in Maryland. 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 35 months prior to the end of the current calendar year (e.g., cancer incidence data for 2005 are available after February 2008; 2006 data will be available after February 2009). 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 restrict release of data reported to the MCR under data exchange agreement with another state or other agency if the agreement

prohibits re-release of data.

- The MCR will only 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 linkage with 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://www.fha.state.md.us/cancer/registry* 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 *www.cancersurveillance.org*, from the MCR website, *www.fha.state.md.us/cancer/registry/*, by calling the MCR office at 410-767-4055, or by submitting an MCR Data Request Form (Attachment A).

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 discuss data limitations.

6.2 Release of Confidential Cancer Data

6.2.1 Code of Maryland Regulations 10.04.01 and Data Re-Release Agreements

The MCR releases data pursuant to COMAR, 10.14.01.05. Data obtained through interstate data exchange agreements, from Veterans' Administration hospitals, the National Death Index, or from DHMH Vital Statistics Administration, are re-released in accordance with the agreement between the MCR and each entity.

6.2.2 Release of Confidential Data

Requests for access to *confidential cancer data* are processed within the constraints of the 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.

Per COMAR 10.14.01.05, confidential data may be released by the Secretary to 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 Institutional Review Board (IRB) of the Department, which will further the cancer control goals of the State.

The *cancer control goals of the State* are to reduce the incidence and mortality of cancer and central nervous system (CNS) tumors and racial, ethnic, gender, age, and geographic disparities in cancer and CNS tumor incidence and mortality in Maryland, by:

(1) Advancing the understanding of cancer case and CNS tumor case demographics;
(2) Describing cancers and 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 cancer and CNS tumors.

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

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 annually;

A researcher requesting confidential cancer case data must:

- Contact the MCR Director 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 Director;
- Submit to 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 Director and, with the aid of the MCR Director, obtain approval from the Family Health Administration (Associate Director or designee) on the DHMH-IRB form; and
- Submit DHMH-IRB forms to and obtain approval from the DHMH-IRB.

The *MCR* will:

- Work with the researcher to obtain internal signatures and facilitate proposal review; and

- After final approval by the DHMH-IRB and after the formal execution of an Agreement, release requested confidential cancer case data after review and removal of any cases or fields for which release is restricted. (See 9.2, below.)

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

The MCR considers cells that contain fewer than six non-zero cases (i.e., 1-5 cases) for displaying MCR data to be confidential data and denotes in published tables cells containing 1-5 cases with "<6" rather than the actual number of cases.

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

- For confidentiality, suppress cells with counts of 1-5 cases; denote cells that contain 1-5 cases as "<6";
- Cells with no cases may show a value of "0";
- If the number 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 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 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 Principal Investigator (PI). The PI will be responsible for data confidentiality. 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's 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. To request a match between a second dataset and the MCR database, the requestor must:

- Contact the MCR Director 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 Director;
- 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 Director and, with the aid of the MCR Director, obtain approval from the Family Health Administration (Associate Director or designee) on the DHMH-IRB form;
- Submit DHMH-IRB forms to and obtain approval from the DHMH-IRB along 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 subject's consent form for participation showing consent for obtaining future diagnoses), or
    - if no prior agreement/consent, 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 an Agreement between the researcher, the research institution, and MCR/DHMH that specifies the data to be released and assures 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
- Social Security Number (SSN) (if available). (Note: Public Law 102-515 created a National Program of Cancer Registries (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 treats the investigator dataset as confidential information, maintaining such data on secure servers with access only by approved personnel, and in locked filing cabinets. The MCR will conduct the data linkage at the DHMH office. The MCR will contact the researcher if clarification is needed during the process and/or to assist in evaluating potential linkages. Upon completion, the MCR will 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 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 Director in advance of application for funding to determine whether MCR data needed for the research will be available if the research is approved;
- Decide whether the mailing to the person with cancer will ask the person:
  - to contact the researcher directly if interested 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 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 Director;
- 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 Director and, with the aid of the MCR Director, obtain approval from the Family Health Administration (Associate Director or designee) on the DHMH-IRB form;
- Submit DHMH-IRB forms to and obtain approval from the DHMH-IRB;
- Execute a 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, which fees must be paid before the request is filled;
- Conduct planned research;
- Submit information regarding enrollment and study progress to the MCR Director on a quarterly basis;
- Immediately submit information regarding adverse events (including complaints) and/or breeches in patient confidentiality to the MCR Director;
- 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 annually.

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 DHMH signatures and facilitate proposal review;

- 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,

    - 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

    - 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 to have died by a relative (coded to Follow-up Source Central = 51); 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 data are geo-coded to the Zip code, Census tract, Block group, and Latitude, Longitude on an annual basis. Interested researchers should contact the MCR to discuss the completeness and limitations of the MCR geo-coded data. The MCR will also, upon request, facilitate the geo-coding by the DHMH Information Resources Management Administration of MCR data not currently geocoded.

Procedures for obtaining 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 Director in order to obtain data. The DHMH-IRB approval is not required if the facility is only requesting data 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 the state has authority to reciprocate with Maryland for 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.

The North American Association of Central Cancer Registries (NAACCR) and the National Program of Cancer Registries (NPCR) may obtain information on Maryland resident cancer cases for the calculation of national or regional cancer incidence rates and assessing the quality of MCR data. The DHMH-IRB approval has reviewed, approved, and exempted from annual IRB approval the release of these cancer data to these two cancer agencies.

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 Director. Approvals from the FHA Associate Director (or designee) and DHMH IRB are required.

6.2.10 Maryland Local Health Officers and the Baltimore City Health Commissioner

The MCR will provide Maryland County Health Officers and the Baltimore City Health Commissioner with datasets containing 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 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 Director. 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. 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 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.

- *Audit and QA/QC Testing*: The internal (DHMH), MCR vendor, or other auditor (such as from the National Program of Cancer Registries 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. A signed Agreement and approval by the FHA Associate Director is 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 by the FHA Associate Director is required .

6.2.12 Failure to comply with Data Use Policies

The MCR and the DHMH IRB will consider disciplinary action for persons/entities who do not comply with the MCR's data use policies. This action could include exclusion from using MCR data for future studies.

7 Publication and Credit

- Data requestors shall provide 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 DHMH.

- Data requestors shall acknowledge 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.

8 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 *www.cancersurveillance.org*.

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

9 Fees

The MCR will charge a reasonable fee to cover the cost of work, as set forth at 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 filled.

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

10 Data Considerations

10.1 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 Maryland's 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.

10.2 Requests for Cancer Data Received from Interstate Notification, Veteran's Administration Hospitals, and National Death Index and for Certain Data Fields

Confidential cancer case data that the MCR has obtained from certain other sources under data sharing agreements (i.e., certain other states, DHMH Vital Statistics, 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 data set 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.

10.3 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.

10.4 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.

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

A cancer report is not a "medical record" as provided by Maryland Code Annotated, Health-General §18-204; 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, it should immediately provide a copy to the Office of the Attorney General.

ATTACHMENT A: MCR DATA REQUEST FORM

Maryland Department of Health and Mental Hygiene
Maryland Cancer Registry (MCR) Data Request Form

Date of Request_____

Office Use--
Person Receiving Request:

Person Requesting Data_____ Title: _____

From (agency, facility, general public, etc.) _____

Address: _____

City, State: _____ Zip: _____

Telephone: _____ Fax: _____

e-mail:

Purpose of Request

Diagnosis Years: _____

Site(s) of Cancer: _____

Geographical area of residence at diagnosis:

Information Requested (for example, number of cases, rates of cases, age groups, stage of cancer)

Requesting what type of data?

Are you requesting confidential information? □ Yes □ No

Do you want to contact cancer patients? □ Yes □ No

Note: Certain data may be considered confidential, e.g., name, date of birth, address, rare cancers, small numbers within a cell.

What format do you need the data in? □ Electronic □ Hard Copy □ Other: _____

Tables: (You may give shells of tables needed.)

Response requested by (month/day/year): ____/____/____

Signature of Data Requester:

Note: Requesters may be charged. Call the MCR for information.

Submit MCR Data Request Form by fax, e-mail, or mail to:	Maryland Cancer Registry Room 400 201 West Preston Street Baltimore MD 21201	fax: 410-333-5218 telephone: 410-767-4055 e-mail: To submit by e-mail, call the MCR for e-mail address.

ATTACHMENT B: DHMH INSTITUTIONAL REVIEW BOARD

See: *http://www.dhmh.state.md.us/oig/irb/*

ATTACHMENT C: MARYLAND CANCER REGISTRY AGREEMENT TEMPLATE

AGREEMENT BETWEEN

THE STATE OF MARYLAND
DEPARTMENT OF HEALTH AND MENTAL HYGIENE

AND

[_____NAME_____,
_____ UNIVERSITY
MCR#_____]

This agreement is made between the State of Maryland, Department of Health and Mental Hygiene, Maryland Cancer Registry, ("DHMH"), and, [_____,] (Principal Investigator) of [____ University], ("the Parties").

WHEREAS, DHMH is required under Maryland Code Annotated, Health-General, ("Health-General"), §18-204, to establish and maintain the Maryland Cancer Registry, 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 the Code of Maryland Regulations, ("COMAR"), 10.14.01, the Cancer Registry, 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 [_____ University] has submitted to DHMH a written request for the release of [LIST here or attach list--topography (site), age at diagnosis, gender, race/ethnicity, summary stage, and first course treatment…] of all persons who were registered in the Maryland Cancer Registry during the years 1998 through 2002 and reside in [the counties of _____ and _____ counties], (see Attachment 1, Maryland Cancer Registry Data Request), and

WHEREAS, the Maryland Cancer Registry on behalf of the Secretary of Health and Mental Hygiene determined that the project would further the cancer control goals of the State.

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 persons who were registered in the Maryland Cancer Registry during the years [1998 through 2003 with XX characteristics]; and

b) Release to [____ University] only the topography (site), age at diagnosis, gender, race/ethnicity, SEER summary stage, and first course treatment of all [____] persons who were registered in the Maryland Cancer Registry during the years [1998 through 2003].

2) [_____ University] agrees that it will:

a) Keep confidential, in accordance with Health-General §4-102, any information that identifies a person that is disclosed to [_____ University] 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) Use this information only as approved by DHMH and **not** release
   1. **frequencies** for subcategories with fewer than 6 non-zero cases (i.e., 1-5 cases), and
   2. **rates** for areas or time intervals of fewer than 16 non-zero cases (i.e., 1-15 cases) (in the numerator);

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) Maintain the confidentiality of the information disclosed under this Agreement notwithstanding termination of this Agreement;

f) Provide DHMH with written annual updates of the status of the evaluation and use of the information disclosed under this agreement;

g) Provide DHMH with a copy of any final reports, analysis, data, presentations or publications submitted, or other information 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;

h) Acknowledge 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 the following statement:

> **"Cancer incidence data have been provided by the Maryland Cancer Registry, Center for Cancer Surveillance and Control, Department of Health and Mental Hygiene, 201 W. Preston Street, Room 400, Baltimore, MD 21201, *www.fha.state.md.us/cancer/registry/*, 410-767-4055.**
>
> **We acknowledge the State of Maryland, the Maryland Cigarette Restitution Fund, and the National Program of Cancer Registries (NPCR) of the Centers for Disease Control and Prevention (CDC) for the funds that helped support the availability of the cancer registry data.";**

i) Return to DHMH or destroy upon completion of this 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 [_____ University] by DHMH and submit to DHMH an affidavit, (see 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;

j) Pay DHMH all fees incurred pursuant to COMAR 10.01.08.04 in regard to the production of information under this agreement; and

k) Operate so that no employee or applicant for employment is discriminated against because of sex, race, age, color, religion, creed, marital status, ancestry, national origin, or physical or mental handicap; so that a clause similar to this nondiscrimination clause is included in all subcontracts, except in subcontracts for standard commercial supplies or raw materials; and so that it posts and requires each subcontractor to post conspicuously in a place that is available to employees and applicants for employment, a notice that sets forth the provisions of this non-discrimination clause.

3) The Parties agree that:

a) This Agreement will commence upon the signing of it by the representatives of the Parties;

b) This Agreement may be terminated by either Party upon thirty (30) days written notice to the other Party;

c) This Agreement will remain in effect until [, 200X], or termination by either Party;

d) This Agreement may be amended as the Parties mutually agree in writing; and

e) 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 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

[_____ UNIVERSITY]

by:_____
John M. Colmers
Secretary

by:_____
[Name]
[Dean for _____]

Date: _____

Date:_____

by:_____
Kimberly Stern, Director
Maryland Cancer Registry

by:_____
[NAME]
[Title] Principal Investigator

Date: _____

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 Surveillance 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

www.fha.state.md.us/cancer/registry/