Mississippi Cancer Registry

Procedure Guide

FOR STUDIES THAT UTILIZE PATIENT IDENTIFIABLE DATA FROM THE MISSISSIPPI CANCER REGISTRY

November 2008

Approval Process Summary

Federal regulations require that all research studies involving human subjects and materials of human origin be reviewed and approved by an Institutional Review Board before initiation. In compliance with this federal regulation, study investigators requesting patient identifiable data from the Mississippi Cancer Registry (MCR) must submit obtain IRB approval from an IRB with an FWA approval number. An approved IRB can be found on the following web site: http://ohrp.cit.nih.gov/search/asearch.asp#ASUR. A copy of the obtained approval or exemption must be provided to the Mississippi Cancer Registry.

In addition to obtaining IRB approval, the study investigator must complete the *Application for Research Use of the Mississippi Cancer Registry*. This application requests scientific/technical information from the researcher to assist the MCR Director and HIM Systems Analyst in fulfilling the data request needed by the study. Please submit a hardcopy of the application to:

Mississippi Cancer Registry
2500 N. State St.
Jackson, Mississippi 39216

It is the responsibility of the study investigator to provide the final recommendation (approval, rejection, pending) from an approved IRB to the Mississippi Cancer Registry Review Committee (MCRRC). The *Application for Research Use of the Mississippi Cancer Registry* cannot be processed until approval has been received from the IRB.

Approvals from an approved IRB and the MCRRC must be obtained before cancer registry data are released from the MCR.

Application for Research Use of the Mississippi Cancer Registry (MCR) Instructions

1. Please indicate the purpose of the MCR data for your research proposal. The MCR data can be requested for any of the following:

    a. *Case Ascertainment/Recruitment*: Request use of the MCR database for the purpose of patient recruitment for a study (i.e. utilize the MCR database to identify cancer patients that may qualify or meet the study's selection criteria for inclusion).
    b. *Linkage*: Request use of the MCR database for the purpose of linking the study's patient database to the MCR database to obtain follow-up data (i.e. link to the MCR database to obtain cancer outcome information). Refer to Attachment ? for data record linkage layout.
    c. *Other – Special Analysis*: Request use of non-public MCR data for a special analysis.

2. Study investigator must complete all fields of the *Application for Research Use of the Mississippi Cancer Registry*. If a field is not relevant, please indicate this is non-applicable to the study proposal. An incomplete application will delay the review process by the MCRRC.

3. Study investigator must sign a research agreement (See Attachment 1 for *Mississippi Cancer Registry RESEARCH AGREEMENT*) with the Mississippi Cancer Registry for use of the registry data for patient information and contact. The signed, original must be sent with the *Application for Research Use of the Mississippi Cancer Registry* to the Mississippi Cancer Registry

4. All study personnel who will have access to information that identifies individual cancer patients must sign and have notarized the *Confidentiality Pledge* (See attachment 2), which is retained by the Mississippi Cancer Registry.

5. All listings of cases, copies of reports, and any other materials that include confidential information must be kept in locked file drawers when not in use. Computer files must be stored on secured systems. **The original MCR data with patients' confidential information must be destroyed upon completion of the study.**

6. For studies that utilize MCR for patient recruitment and subsequently, patient contact:
Please be advised that the MCR will not extract data on those patients with whom we have a death certificate or those who were reported strictly by the VA hospitals or another state.

    A. The initial patient contact will be written correspondence summarizing your study with the lead letter from the State Health Officer (Attachment 3) to request the patient's active consent for

participation. The Investigator's patient contact letter and patient response form are sent simultaneously with the letter from the State Health Officer or his/her designee. Initial contact will initiate from the Mississippi Cancer Registry. Information will be provided to the researcher only on patients actively consenting to participate.

A *Sample Patient Contact Letter* (Attachment 4) and a *Patient Response Form* (Attachment 5) are provided for the study investigator's reference. In addition to the study investigator's description of the study, the patient contact letter must include:

- Language furnished by the MCR regarding State reporting (paragraph 2 of Attachment 4. *Sample Patient Contact Letter*)
- Assurance of voluntary nature of participation
- Assurance that participation or non-participation will not affect medical care

A patient's information will only be provided to the researcher if they return the *Patient Response Form* and indicate that they are willing to be contacted by the researcher.

PLEASE BE ADVISED…*Study investigator should avoid disclosing that the patient is being contacted for a study specific to cancer on the cover of mailings.*

B. Investigators must remember:

- Patients can always refuse to participate, even after having agreed to participate.

If, in the course of the study, the investigator finds that contact information provided by the MCR is missing or incorrect and correct information has been obtained, e.g., address, telephone number, etc., please use the *Patient Data Update Form* (Attachment 8) to notify the MCR.

7. **Please send a copy of ALL published abstracts of presentations and papers that result from the study to the MCR Director at least 60 days in advance of the presentation or release of the publication.** If 60 days is impossible, a different timeline can be requested and must be approved by the MCRRC. The bibliography of papers from investigations that have utilized the MCR is used to track the use of the registry for epidemiologic studies. The MCR research agreement number and acknowledgments must be cited in all publications that result from studies that utilized the MCR.

Copies of publications utilizing MCR data can be mailed to:

Mississippi Cancer Registry
2500 N. State St.
Jackson, Mississippi 39216

8. Please note that your request for use of patient identifiable data will be processed in a timely fashion. However, applications are processed on a first-come, first-serve basis.
Mississippi Cancer Registry Tel. 601-815-5482.

Mississippi Cancer Registry

APPLICATION FOR RESEARCH USE OF THE MISSISSIPPI CANCER REGISTRY (MCR)

Send application to:

Mississippi Cancer Registry
2500 N. State St
Jackson, MS 39216

For Office Use only
Project #_____
Date Received_____
Date Reviewed_____
Approved Yes _____ No_____

I. ORGANIZATION OR INDIVIDUAL REQUESTING USE OF MISSISSIPPI CANCER REGISTRY (MCR) DATA

A. Study (Principal) Investigator:

B. Title:

C. Organization (Include Branch, Division, Department, etc.):

D. Street Address or Post Office Box:

E. City/State/ZIP Code:

F. Telephone:

G. E-mail:

H. Primary Contact (If different from study investigator):

Please attach study investigator(s) curriculum vitae/resume.

II. SUMMARY OF STUDY PROTOCOL OR PROJECT ACTIVITIES

A. Title of Study or Project:

B. Name and address of sponsor(s) for this project (if any):

C. Specify all sources of funding for this project:

D. Please check the appropriate category. The above entitled study will utilize the Mississippi Cancer Registry (MCR) for the following:

_____Case Ascertainment/Recruitment

_____Database Linkage

_____Other: Special Analysis

Specify type of analysis:_____

E. Protection of Human Subjects: Has this project been reviewed and approved by an Institutional Review Board (IRB) for the protection of human subjects?

_____Yes. Give the name of the review board and date of approval.

NAME: _____
DATE: _____

Please attach a copy of the approval to this application.

_____No. Indicate Reason: _____
_____
_____

F. Informed Consent:

Have you developed a written informed consent for use in this study?

_____Yes. Attach sample copy of consent form to this application.

_____No. Indicate the source of the identifying information of the persons in your study.

_____
_____
_____

G. Abstract of Study Protocol or Project Activities ("Research Proposal"):

NOTE: You may append a copy of your complete study protocol (or selected sections) to this application. The abstract provided should be self-contained so that it can serve as a sufficient and accurate description of the project if separated from your appended document.

Include the following information (if applicable) in the description of your study:

- **a) Primary focus. State the specific health or medical problems addressed, or other conditions or concerns of the study.**
- **b) Objectives. State the hypotheses to be tested, if any.**
- **c) Analyses to be performed, indicating specifically how data obtained from Mississippi Cancer Registry will be used. Include a justification for each data item requested.**
- **d) Linkage, if any, with other data files, specifying the source of these files.**
- **e) Release of Results, including interim and final reports and publications to be sent to the department upon completion.**

ABSTRACT:

III. CONFIDENTIALITY OF IDENTIFIABLE DATA

A. What specific data items from the Mississippi Cancer Registry do you request for use in your study? (See attachment 9 for available data items)

B. How will you maintain the confidentiality of identifiable data obtained from the Mississippi Cancer Registry? (Identifiable data refers to any information which would permit, directly or indirectly, the identification of any individual or establishment.) Include an explanation of how such data will be stored as well as how and when you plan to dispose of the data after your study is completed.

C. Will your study require "follow-back" investigation to obtain additional information from the individual, next-of-kin, physicians, and/or other individuals or institutions mentioned on the cancer reports?

_____No

_____Yes Briefly describe the following:

1. Types of respondents to be contacted:

2. Information to be obtained from respondents:

3. Methods to be used in conducting such investigations:

4. Other organizations, co-investigators or consultants, if any, conducting the investigations:

D. How will you maintain the confidentiality of identifiable data obtained from the follow-back investigation? (Include an explanation of how such data will be stored as well as how and when you plan to dispose of the data after your study is completed.)

IV. OTHER DATA AND USES

A. For the purpose of this research project as you described in Section II, will any of the identifiable data obtained from this project be used by other organizations; e.g., other divisions, agencies, consultants, contractors and/or subcontractors?

_____No

_____Yes Indicate the name of the organization(s) and role(s) in, this research project. If the name is unknown at this time, indicate the type of organization (s). Describe the safeguards that exist (or will be implemented) to ensure that the data will be used solely for the purposes of this research project:

B. **Will any of the identifiable data obtained for this project be used as a basis for legal, administrative, or other actions which may affect particular individuals or establishments as a result of their specific identification in this project?**

_____No

_____Yes Indicate how the data will be used.

C. **Will the identifiable data be used either directly or indirectly for any research project other than the one described in Section II, "Summary of Study Protocol or Project Activities"?**

_____No

_____Yes

***NOTE: A separate application must be submitted for each research project which will use the identifiable data obtained through this application*.**

V. TYPES OF DATA TO BE SUBMITTED (SECTION APPLICABLE ONLY TO LINKAGE STUDIES)

A. **Each record (along with other information on a person in your study or project) which you submit can only be matched if the request contains, at a minimum, the following information:**

First and last name AND Social Security Number AND Sex
or
First and last name AND Month and Year of Birth AND Sex

B. **Multiple matches with insufficient information to uniquely identify the record of the person in your study or project will not be released. Review of possible matches may be undertaken under certain conditions, by the cancer registry. You should provide as much information about your subjects as possible in order that matches can be verified. For each item of information listed below, indicate what percent of your records contains the item.**

		% of Record
1.	**Middle Name or Initial**	_____
2.	**Date of Birth**	_____
3.	**Date of Death**	_____
4.	**Social Security Number**	_____
5.	**County of Residence**	_____
6.	**City, Town, or Village of Residence**	_____
7.	**Zip Code (9 digits)**	_____
8.	**Race**	_____
9.	**Sex**	_____
10.	**Other Items (list)**	_____

Coded information must be submitted using Mississippi Cancer Registry Codes (See Attachment 6).

C. **How many records do you expect to submit? _____**
Number

D. **Upon submission of these records, against which data year(s) will you want to conduct the search of the file? Year(s): _____**

VI. TECHNICAL INFORMATION ABOUT THE DATA TO BE SUBMITTED (SECTION APPLICABLE ONLY TO LINKAGE STUDIES)

In order to search for the records of persons in your study, they must be submitted in a manner that adheres to disk specifications, file format requirements, and coding instructions, as described in Attachment 6.

VII. PAST AND FUTURE REQUESTS FOR THIS STUDY

A. Have you requested information in the past in connection with this study?

_____No

_____Yes Indicate the project number assigned to you: Project No.:_____

B. Aside from this application, do you anticipate submitting another application in the future or the purpose of this study?

_____No

_____Yes Indicate if future "repeat" requests will be based on exactly the same names (excluding previously identified names) or will names be added to, or deleted from, your study files?

_____1. The same list of names.

_____2. The same list of names, plus _____ additional names.

_____3. The same list of names, excluding _____ names.

_____4. An entirely different list of names, such as:_____

_____5. How many "repeat" requests for this study do you expect to make?

_____
Signature
_____
Name
_____
Organization
_____
Date

Attachment 1.

Mississippi Cancer Registry
RESEARCH AGREEMENT

This agreement ("Agreement") is entered into by the Mississippi Cancer Registry ("MCR"), and _____, hereinafter referred to as the Investigator.

RECITALS

I. Investigator has submitted the Research Proposal to the MCR specifying the personal data desired ("Research Proposal").
II. Investigator has received approval for the Research Proposal, including the use of the above-referenced personal data, from a federally mandated Institutional Review Board.
III. Investigator has the authority to bind Investigator's Institution as to relevant terms of this Agreement

NOW THEREFORE, for good and valuable consideration, the parties hereto agree:

A. COMPOSITION OF AGREEMENT

1. This Agreement,
2. Investigator's Research Proposal ("Research Proposal"), and
3. Mississippi Cancer Registry Procedure Guide, June 2007 ("Procedure Guide").

B. AGREEMENT PERIOD

This Agreement begins upon the date it is fully executed and ends upon completion of performance by the parties or termination consistent herewith.

C. TERMS

1. The above recitals are true and correct and incorporated as if fully stated herein;
2. Investigator shall comply with all terms of this Agreement and the Procedure Guide;
3. MCR shall create a data file in ASCII format of the personal data from the cancer registry as specified in the Research Proposal (the "Data File");
4. The costs of assembling the Data File shall be set, and shall be paid to MCR prior to transfer of The Data File to Investigator;
5. Investigator shall arrange for transfer of the Data File in person, via messenger or by traceable delivery service, subject to MCR prior approval;
6. Investigator shall not use the Data File for any other purpose than that specified in the Research Proposal;
7. Upon completion of the work outlined in the Research Proposal, Investigator shall destroy the Data File and any and all copies thereof;

8. Upon completion of the work outlined in the Research Proposal, Investigator must provide 60 days prior to publication, a courtesy copy of the articles and/or reports accepted for publication to MCR.
9. The Investigator and Investigator's Institution, except where prohibited by applicable Mississippi Law, agree to hold harmless, indemnify, and defend MCR from all liabilities, demands, damages, expenses, or losses arising out of performance under this Agreement, except to the extent where such liabilities, demands, damages, expenses or losses are the result of MCR negligence or willful misconduct; and
10. The law governing this Agreement shall be Mississippi Law and the venue for disputes over this Agreement shall be a State Court of Competent Jurisdiction in Hinds County, Mississippi.

IN WITNESS WHEREOF, the parties hereto executed this two-page Agreement, with attachments, on the dates stated below.

THE INVESTIGATOR

Signature: _____

Printed Name: _____

Title: _____

Organization: _____

Date: _____

MCR

Signature: _____

Title:

Date: _____

Attachment 2.

CONFIDENTIALITY PLEDGE

I recognize the importance of maintaining the confidentiality of all data collected by the Mississippi Cancer Registry (MCR) and of assuring the right to privacy of persons whose records I receive.

I understand that confidential information or data is defined as any information where the individual, hospital(s), or physician(s) is named or otherwise identifiable.

I therefore agree to protect the confidentiality of the data in accordance with the following requirements:

I will avoid any action that will provide confidential information to any unauthorized individual or agency.

I will not make copies of any confidential records or data except as specifically authorized.

I will not remove confidential identifying information from my place of employment except as authorized in the performance of my duties.

I will not discuss in any manner, with any unauthorized person, information that would lead to identification of individuals described in confidential files or data.

I will use confidential files and data only for purposes for which I am specifically authorized.

I will not provide any computer password or file access codes which protect these data to any unauthorized person.

If I observe unauthorized access or divulgence of confidential data or records to other persons, I will report it immediately to the MCR. I understand that failure to report violations of confidentiality by others is just as serious as my own violation, and may result in civil or criminal penalties and termination of current and future access to confidential data.

I therefore pledge that I will not divulge to any unauthorized person confidential information or data obtained from the MCR files.

Name: _____
Print

Signature: _____

Date: _____

Address: _____

Notarized by: _____ NOTARY

Attachment 3.

Letter from State Health Officer or His/Her Designee

Dear Mississippian:

We are asking for your help. The Mississippi Cancer Registry (MCR for short) is a record of every person in Mississippi that had to fight cancer just like you did. Out state leaders asked the Mississippi Legislature to start this record. They passed a law allowing every person in the state with cancer to have their information recorded by the MCR. We hope that by following the medical records of all of these people, we can help find some of the causes of cancer which may even lead to cures. We got your name from the MCR because we are studying people with cancer. We can only share your records with research people that have gotten special approval from a Committee for the Protection of Human Subjects. These federal committees were created to protect you and we are not allowed to share your information with anyone else.

In this package are papers from the researcher that explain this study. You will also find a cord to send to the MCR to let them know if you have or have not agreed to help. You do not have to help if you do not want to. Only the people that work for the MCR will ever read this card.

If you have any questions at any time, please feel free to call Deirdre Rogers, the Director of the Mississippi Cancer Registry, at (601) 815-5479.

Sincerely,

State Health Officer or His/Her Designee

Enclosures

Attachment 4.

LETTER FROM RESEARCHER

Dear Mr./Mrs./Ms._____,

We need your help. We are writing to ask you to help us learn more about cancer. _____ is in charge of this project. With your help, we hope to learn more about what may cause _____cancer in _____.

We got your name from the Mississippi Cancer Registry (MCR for short) because you have had to fight cancer like a lot of people in Mississippi. The MCR is a record of every person in Mississippi that has had to fight cancer just like you did. Our state leaders asked the Mississippi Legislature to start this record. They passed a law allowing every person in the state with cancer to have their information recorded by the MCR. We hope that by following the medical records of all of these people, we can help find some of the causes of cancer which may even lead to cures. The MCR can not share your medical history with anyone unless you say they can. If you say it is alright, they can only share your information with research people that have gotten special permission from a Committee for the Protection of Human Subjects. The MCR is sending you this letter to ask for your help and to make sure you will allow MCR to share your medical records with us. If you can help us, the only thing that you will need to do is answer a couple of questions over the phone or by mail. A phone call would only take about ___ minutes.

If you would please check off one of the answers on the next page in this packet, the MCR will then know if you wish to help. You do not have to help us. We have given you an envelope that already has a stamp and the MCR address on it. All you have to do is put the paper with your answer in that envelope and mail it to us. If you have answered "YES", we will call or write to you and talk more about the research study. Please know that you are not alone. We are hoping to have (hundreds?) of people just like you answering these same questions.

If you have any questions at any time, please feel free to call the Mississippi Cancer Registry, at (601) 815-5482.

Sincerely,

Investigator
Title
Institution

Attachment 5.

SAMPLE PATIENT RESPONSE FORM

Please check one response and mail this form in the enclosed postage-paid envelope. If you have any questions, please call Deirdre Rogers with the Mississippi Cancer Registry at 601-815-5482. Thank you.

ٱ YES, I am interested in participating in the study.

ٱ I would like more information.

ٱ NO, I do not want to participate in the study.

ٱ I do not want to participate in the study and I do not wish to be contacted for any future studies.

Name: _____

Address: _____
_____

Telephone: Day: (___) _____- _____

Evening: (___) _____- _____

Best time to call: ٱ _____ a.m. ٱ _____ p.m.

Attachment 6

FILE SPECIFICATIONS FOR LINKAGES

Files submitted for linkage with MCR data must be tab delimited and the columns must appear in the order listed below. Also, the data must be cleaned and coded to the specifications in the table. If you are unable to clean and code your data according to these specifications, there will be an additional charge for MCR staff to do this. The MCR has a secure FTP site for exchange of data. Once the study is approved and the linkage file is prepared, contact Ramona Sandlin at 601-815-5480 or rsandlin@dis.umsmed.edu to submit your file.

Last Name	
First Name	
Middle Name	
Suffix	
Social Security Number	9 digit SSN with no dashes
Race 1	01-White, 02-Black, 03-American Indian, 98-Other, 99-Unknown
Race 2	01-White, 02-Black, 03-American Indian, 98-Other, 99-Unknown
Race 3	01-White, 02-Black, 03-American Indian, 98-Other, 99-Unknown
Race 4	01-White, 02-Black, 03-American Indian, 98-Other, 99-Unknown
Race 5	01-White, 02-Black, 03-American Indian, 98-Other, 99-Unknown
Sex	1-Male, 2-Female, 3-Other(Hermaphrodite), 4-Transexual, 9-Unknown
Birthdate	MMDDYYYY
Street Address	
City	
State	2 letter State abbreviation
Zip Code	5 digit Zip Code
County	3 digit FIPS County Code

Attachment 7.

HOW DID YOU GET MY NAME? QUESTIONS AND ANSWERS

Q: How did you get my (or my relative's) name?

A: Like many other diseases, cancer is a reportable disease in Mississippi. This means that, by state law, a report of all cancer diagnoses must be prepared by the hospital or physician . The law requires cancer reports to be collected by the Mississippi Cancer Registry. The Mississippi Cancer Registry has approved this study and is contacting you to determine if you are willing to be contacted by (Investigator) or his/her staff.

Q: Why is cancer reportable?

A: The Mississippi Legislature, the Mississippi Department of Health and many Mississippians place a high priority on seeking the causes of and methods for prevention of cancer. A statewide system of cancer registration provides a complete and timely mechanism for conducting research into cancer patterns and trends.

Q: Can I remove my name from the statewide cancer registry, the Mississippi Cancer Registry?

A: While the law includes no provision for removing a report from the registry, individuals may request that they not be contacted for future research studies.

Attachment 8.

PATIENT DATA UPDATE FORM

In contacting the following patient, we ascertained that the following information provided by the MCR was missing or incorrect.

Patient Name: _____, SSN _____

Incorrect or missing information: _____

Correct information: _____

Source of correct information (e.g., patient interview, telephone conversation with spouse.)
_____

Investigator's Name: _____

Study Title: _____

Name of person completing this form: _____

Date: _____

Please return to:
Deirdre Rogers, Director

Mississippi Cancer Registry
2500 North State Street
Jackson, Mississippi 39216-4505

Telephone: 601-815-5479

Thank you.

Attachment 9.

DATA ITEMS AVAILABLE FROM THE MISSISSIPPI CANCER REGISTRY

The following data items may be requested for research. However, the requested items must be justified in the research proposal. For definitions and coding information on these fields, refer to the *NAACCR Standards for Cancer Registries, Volume II, Data Standards and Data Dictionary* (http://www.naaccr.org/filesystem/pdf/Vol_II_draft_board%20-%20Fix%20Pg%2098.pdf).

Address at Diagnosis - City	
Address at Diagnosis - State	
Address at Diagnosis - County	
Address at Diagnosis - Postal Code	
Race 1	
Race 2	
Race 3	
Race 4	
Race 5	
NHIA Derived Hispanic Origin	
Sex	
Age at Diagnosis	
Birth Date	
Sequence Number - Central	
Date of Diagnosis	
Primary Site	
Laterality	
Grade	
Diagnostic Confirmation	
Histology ICD-O-3	
Behavior ICD-O-3	
SEER Summary Stage 2000	
RX Summ - Surgery Primary Site	
Date of Last Contact	
Vital Status	
Name - Last	Only for Studies Involving Patient Linkage/Contact
Name - First	Only for Studies Involving Patient Linkage/Contact
Name - Middle	Only for Studies Involving Patient Linkage
Name - Maiden	Only for Studies Involving Patient Linkage
Name - Suffix	Only for Studies Involving Patient Linkage
Social Security Number	Only for Studies Involving Patient Linkage
Derived Summary Stage 2000	
Address Current - No. & Street	Only for Studies Involving Patient Contact
Address Current - Supplemental	Only for Studies Involving Patient Contact
Address Current - City	Only for Studies Involving Patient Contact
Address Current - State	Only for Studies Involving Patient Contact
Address Current - Postal Code	Only for Studies Involving Patient Contact

Geocoded Data Items