The seal of the State of Tennessee is visible in the background, featuring a central figure holding a plow and a sheaf of wheat, surrounded by the text "SEAL OF THE STATE OF TENNESSEE" and "XVI" at the top. The words "AGRICULTURE" and "COMMERCE" are also visible.

Procedures, Protocols and Forms for the Release of Data from the Tennessee Cancer Registry



Tennessee Department of Health,
Office of Policy, Planning & Assessment,
Tennessee Cancer Registry

Revised 08/2009

Table of Contents

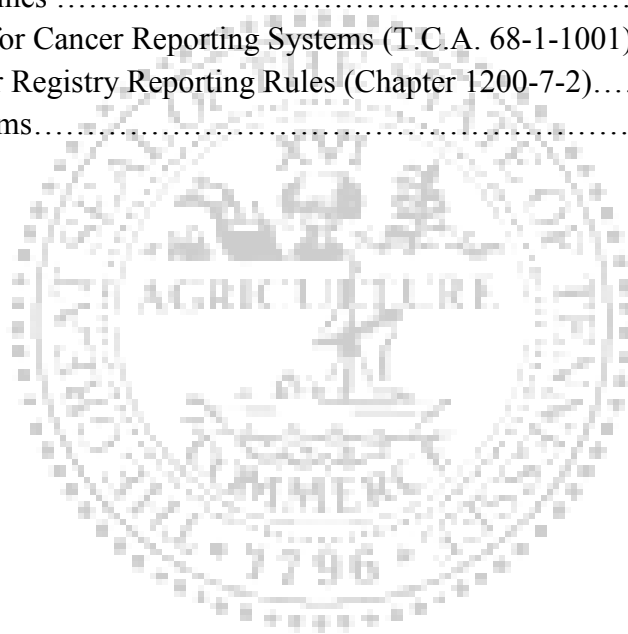
Preface.....	4
I. Procedures and Protocols for the Release of Tennessee Cancer Registry Data	
A. Introduction.....	5
B. Principles.....	5
C. Data Release Protocol.....	6
1. Data Classification.....	6
a. Aggregate Data	
<i>i.</i> Unrestricted	
<i>ii.</i> Restricted	
b. Individual-Level Data	
<i>i.</i> Potentially Identifiable Data	
<i>ii.</i> Identifiable Data	
2. Data Release Guidelines.....	7
a. External	
<i>i.</i> Research Requests	
<i>ii.</i> Data Sharing Contracts	
<i>iii.</i> Governmental and Related Agency Data Requests Policy	
b. Internal -Tennessee Department of Health Data Requests	
3. Data Security	9
a. Confidentiality Policy & Agreement	
b. Data Access Review Committee	
II. Data Request Flowchart.....	10
III. Aggregate Data	
Aggregate Data Release Policy.....	11
Aggregate Data Request Form.....	13
IV. Individual-Level Data	
Individual-Level Data Request Policy.....	16
Individual-Level Data Request Form.....	18
Confidentiality Agreement.....	25

V. Governmental and Related Agency Data Request Policy

Within the Tennessee Department of Health, Other State Agencies, Data Sharing No
Cost Contracts, other State Cancer Registries, U.S. Federal Agencies and Individual
Policy..... 27
Request for Data Form (PH-3599 Rev. 7-03)..... 28

VI. Appendix

Data Access Review Committee Member List..... 31
Data Access Review Committee Guidelines 32
Data Access Review Committee Summary Report..... 33
Request for Individual-Level Data Procedure Outline 34
Reference Guidelines 35
Tennessee Code for Cancer Reporting Systems (T.C.A. 68-1-1001)..... 36
Tennessee Cancer Registry Reporting Rules (Chapter 1200-7-2)..... 41
Dictionary of Terms..... 47



Preface

The Tennessee Cancer Registry (TCR) was established in 1983 by the Tennessee Department of Health (TDOH) in response to a state law, T.C.A. 68-1-1001 (See Appendix, page 36), that made cancer a reportable condition. This law requires hospitals, laboratories, Ambulatory Surgery Centers, and other facilities to report to the Tennessee Department of Health information on patients diagnosed and/or treated for cancer in the state. The TCR of the TDOH follows the Cancer Reporting System Rules Chapter 1200-7-2 (see page 41). These rules provide for the implementation of the Tennessee Cancer Reporting System Act of 1983 and its amendments. In May, 2000, the Tennessee Legislature amended this law broadening its scope by expanding the number of reporting sources, allowing access to medical records in the event data is not reported, and providing for the interstate exchange of data. In 1992, the 102 Congress passed Public Law 102-515 which allows states to receive federal grants to support population-based, statewide cancer registries. The TCR has received federal funding from the Centers of Disease Control and Prevention (CDC) through the National Program of Cancer Registries (NPCR) since 1999.

The TCR has endeavored to collect comprehensive, timely, and accurate information on all cancer patients diagnosed and/or treated in the state. Because this information includes demographic information, stage at diagnosis, first course of treatment, and deaths due to cancer, it is a valuable tool in the evaluation of progress towards cancer prevention and control. The mission statement of the TCR is “dedication to the collection and use of quality data for the purpose of decreasing the incidence and mortality of cancer in Tennessee”. One goal of the TCR is to make available the cancer data that has been collected for research purposes. The TCR is responsible for protecting the confidentiality of patients' data reported to the TCR.

This document describes the policies, procedures and relevant forms that the TCR uses to balance the need to protect confidential cancer data with the legislatively mandated requirement that data shall be released for valid research purposes to further the prevention, control and treatment of cancer in the state of Tennessee.



**State of Tennessee
Department of Health
Office of Policy, Planning & Assessment
Office of Cancer Surveillance
Tennessee Cancer Registry
Cordell Hull Building, 6th Floor North
425 Fifth Avenue North
Nashville, TN 37243**

Procedures and Protocols for the Release of Tennessee Cancer Registry Data

A. Introduction

The Tennessee Department of Health (TDOH) and the Tennessee Cancer Registry (TCR) maintain that an effective cancer control program requires a policy of information access that supports the efforts of the scientific, educational and medical communities serving the citizens of Tennessee. The Tennessee Cancer Reporting System Act of 1983 established procedures for the centralized collection of cancer incidence data, as well as a mandate for the dissemination of data. Data reported from hospitals are stored and maintained in a central registry. These data contain various personal identifiers such as patient name, address, date of birth, as well as diagnosis and treatment data. Due to the sensitive nature of these data, measures must be taken to ensure the confidentiality and integrity of the data. The following guidelines for data requests have been developed with these goals in mind.

B. Principles

Because the right to privacy is of utmost importance, the confidentiality of persons diagnosed with cancer and reported to the TCR will be the primary concern. The release of data, either individual-level or aggregate, will be approved only when the protocols and procedures described in this document have been met. A flowchart outlining the data request process is attached (see page 10)

Because the data collected are of value to public health research and medical practice, the policy of the TCR will be to make decisions regarding release of information in favor of access. However, access will be subject to the limitations concerning confidentiality, security, and the prevention of potential misuse.

The TCR believes that cancer registry data can and should inform cancer control and prevention activities by describing and analyzing demographic and disease trends, as well as by identifying geographic clusters of disease. The primary goals of these control and prevention activities are to identify specific groups at higher risk of cancer, increase survival rates, improve patient care, and to identify, quantify, and respond to cancer clusters.

C. Data Release Protocol

In the interest of balancing the principles of data access and patient confidentiality, the TCR has classified the release of data collected. These classifications are designed to promote the use of accurate cancer incidence data, expedite the data release process, and encourage the distribution of a wide array of data elements without compromising confidentiality. The two classifications of data requests described here are aggregate data (containing no personal identifiers) and individual-level data (which may or may not contain personal identifiers). Data requests fall into two categories, internal or external. Internal data request category consists of requests from within the TDOH. The external category refers to all other data requests received.

1. Data Classification

a. Aggregate Data

Standardized annual reports will be made available that include a comprehensive summary of cancer incidence in Tennessee. These reports will include frequency distributions of cancer cases by primary site, histologic type, stage/behavior, as well as gender, race and standardized age groups. The reports will provide incidence rates, as well as direct age-adjusted rates, tabulated by gender, primary site and various geographic units (state, county, health department regions, etc.). Various tables, graphs and maps will also be included. These reports will be available both in print and on the TDOH website (<http://www2.state.tn.us/health/TCR/index.htm>). Data not available in these reports will be made available based on the following guidelines:

i. Unrestricted

All requests for aggregate data must be submitted to the TCR in writing (see page 11). Aggregate data NOT provided in the TCR's Annual Report will be released after the written request has been reviewed in accordance with the following guidelines:

- No data that directly or indirectly identifies cancer patients will be provided.
- Data will be considered to have a reasonable possibility of indirectly identifying cancer patients if it includes any of the following:
 - Rates, cross-tabulations or frequencies that are based on five or fewer cases for any one site of cancer
 - Rates, cross-tabulations or frequencies over any time period that are based on five or fewer cases for any one demographic or geographic unit.

In an effort to prevent the identification of individual patients from aggregate data broken down by demographic and geographic units, counts and rates will be suppressed when fewer than ten (10) cases are recorded in any given category. This suppression guideline is based on CDC standards and policies used by other state registries. Maps created with geocoded data must adhere to the data suppression rules.

ii. Restricted

TCR staff must review and give prior approval for requests for aggregate data that include the release of frequencies and rates based on fewer than ten (10) cases. These data may be released for research purposes only and shall be presented/published in accordance with TCR guidance.

b. Individual-Level Data

All data requests for individual-level data must be submitted to the TCR in writing (see page 16). Individual-level data will be released only after the written application (see page 18) has been reviewed and the conditions described below have been satisfied. Two types of requests for individual-level data will be considered:

i. Potentially Identifiable data: Non-identifiable data, or individual-level data stripped of all personal identifiers (e.g. name, address, date of birth, data element combinations that have a reasonable possibility of indirectly identifying cancer patients).

ii. Identifiable Data: Identifiable data, or individual-level data containing personal identifiers for use in follow-up studies, or any studies that require contacting patients or clinicians to obtain additional information.

2. Data Release Guidelines:

a. External

i. Research Requests:

The TCR is prepared to provide data to outside researchers on a variety of approved cancer research projects. However, before data are released all research proposals requesting the use of individual-level data from the TCR must be in compliance with the following criteria:

- The proposed research will be used to determine the course of cancer among residents of Tennessee or to reduce the burden of cancer in Tennessee.
- The data requested are necessary for the efficient conduct of the study.
- Adequate protections are in place to insure data security, including usage, access and storage.
- Adequate assurance has been provided that data will only be used for the purposes of the study described in the proposal, and any confidential data will either be returned or destroyed following completion of the research project.
- The proposal has been reviewed and approved by an Institutional Review Board (IRB) formed in accordance with the provisions of the U.S. Department of Health and Human Services Code of Federal

Regulations Title 45, Part 46, Protection of Human Subjects (revised November 13, 2001). TDOH IRB approval is required for research involving contact with the patient or the patient's family.

- The request includes a comprehensive protocol containing a description of the study, the principal investigator's qualifications and affiliation(s), study background, research questions, study design, case definition and selection (where applicable), control definition and selection (where applicable), informed consent and confidentiality procedures and documentation, project resources, and data analysis plan.
- The request includes a statement identifying the benefits of the study for the residents of Tennessee.
- Completion of application and signed consent form.

Investigators should be advised that meeting the requirements listed above does not guarantee access to the data requested, only that the request will be given appropriate consideration by the TCR's Data Access Review Committee (DARC). Furthermore, the committee retains the right to impose additional conditions or reporting requirements in order to insure that the research is conducted in an appropriate manner.

ii. Data Sharing Contracts

Metropolitan Regional Health Departments within Tennessee, as well as other Tennessee state government and county agencies and universities, may establish data sharing contracts with the TDOH. These contracts allow for the timely release of requested data. Agencies contracting with TDOH must complete a data request form (aggregate or individual-level) before receiving data. If individual-level data is requested, the DARC must approve the data request before the data can be released. Information regarding the study design, methods, and dissemination of findings must be provided. A confidentiality agreement must also be signed for individual-level data requests. The requesting parties remain bound by the data release guidelines outlined above, as well as other specifications in their data sharing contracts.

iii. Other Tennessee State Agencies, other State Cancer Registries, U.S. Federal Agencies Data Requests and Individuals

All data requests from other departments within the State of Tennessee or other state agencies must be submitted using a data request form (aggregate or individual-level). If individual-level data is requested, the data request form must be reviewed and approved by the DARC before the data will be released. Requests will follow the policies outlined in the flowchart on page 10. A confidentiality agreement form must also be completed for any individual-level data request.

Occasionally faxes are received from the United States Department of Labor requesting information on a specific person. These claim forms are for the Survivor Benefits under the Energy Employees Occupational Illness Compensation Program Act. The signed survivor declaration is sufficient for release of information concerning the decedent who might be in the TCR database.

Requests from other federal agencies for TCR information will be processed on a case by case basis, but will generally follow the guidelines presented in this policy. Requests received from other State Cancer Registries will complete the Request for Data form (PH-3599 Rev. 7-03) beginning on page 28.

If an individual requests their own information, the request must be submitted in writing using the data request form PH-3599 Rev. 7-03 (see page 28). Identification of the individual must be verified by two forms of id - one of which must be a copy of their valid driver's license or other government issued id with a photo. Copies of these must accompany their data request form.

b. Internal - Tennessee Department of Health Data Requests

These requests may not require approval of the DARC. All data requests from the TDOH, including rural regional health departments, must be submitted using a data request form (aggregate or individual-level). Requests will follow the policies outlined in the flowchart on page 10. A confidentiality agreement must also be completed for any individual-level request prior to data release, signed by the person making the request and their supervisor.

3. Data Security

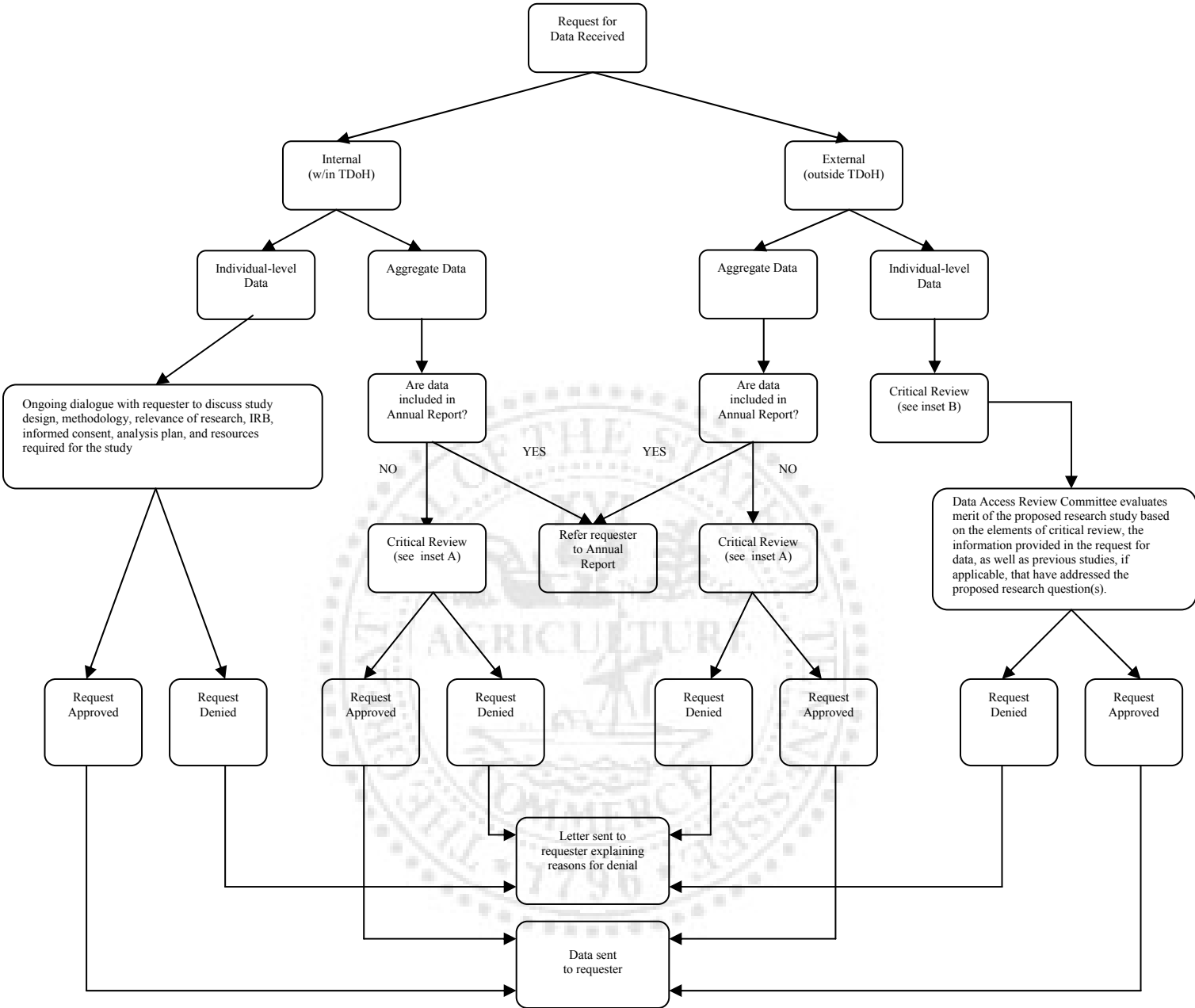
a. Confidentiality Agreement

Investigators should also be advised that the committee may require further assurances regarding the release of information to subcontractors, security of data storage, and informed consent procedures. The principal investigator will be required to read and sign a Confidentiality Agreement (see page 25). This contract describes limitations on usage of data, as well as restrictions on dissemination of findings, use of personal identifiers, and contact with patients and medical providers identified through data provided by TCR. No individual-level data will be released before this document is signed and returned to TCR.

b. Data Access Review Committee (DARC)

The DARC is a formal subcommittee of the TDOH Data Policy Committee. The committee's charge is to review all applications for individual-level data. (See page 31 for current member list.) The committee will review all external applications to determine if: 1) the research is in compliance with the Tennessee Cancer Reporting Law; 2) the research is an appropriate use of TCR data; 3) the study design and methods are appropriate, and 4) provisions have been made to protect confidentiality of the data. The DARC Guidelines are listed on page 32. A step-by-step procedure for individual-level data is outlined on page 34. The committee may approve the request, suggest changes, or disapprove the request. Each DARC member must complete and return the DARC Summary Report as listed on page 33.

TCR Data Request Flowchart



- Inset A:**
- 1) Are data readily available?
 - 2) Are data elements and analysis in compliance with HIPAA regulations for summary data?
 - 3) Are project goals consistent with the principles and protocols of TCR?
 - 4) Has adequate information been received to evaluate request?
 - 5) Has requester agreed to acknowledge TCR in all presentations/publications based on the data provided?

- Inset B:**
- | | |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <ol style="list-style-type: none"> 1) Are data readily available? 2) Is research of public health importance? 3) Is the study design methodologically sound? 4) Does the study provide benefit for residents of Tennessee? 5) If case-control study, have cases and controls been adequately defined? 6) Are patient identifiers required? 7) IRB approval: Requestor and/or TDOH IRB (both required for subject contact). | <ol style="list-style-type: none"> 8) Have data security issues been addressed? 9) Is informed consent required? 10) Are research goals consistent with the principles and protocols of TCR? 11) Has adequate information been received to evaluate the request? 12) Has requester agreed to acknowledge TCR in all presentations/publications based on the data provided? |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|



STATE OF TENNESSEE
Department of Health
Office of Policy, Planning & Assessment
Office of Cancer Surveillance
Tennessee Cancer Registry
Cordell Hull Building, 6th Floor
425 Fifth Avenue North
Nashville, TN 37243

Aggregate Data Release Policy

SYSTEM NAME: Tennessee Cancer Reporting System

DESCRIPTION: This policy applies to the release of aggregate data from the Tennessee Cancer Registry (TCR). Computerized information for each case of cancer occurring in Tennessee is captured from medical records of patients who have cancer. By law (T.C.A. 68-1-1001, page 36), all cancer cases diagnosed or treated in Tennessee must be reported to the TCR. Included in this database are identifying information (e.g., name, address, and social security number), demographic information (e.g., age, race, and sex) and general information about the case of cancer (e.g., primary site, histology and stage).

It is important to note that not all Tennesseans with cancer are diagnosed or treated in Tennessee and not all individuals diagnosed or treated with cancer in Tennessee are Tennesseans. This database contains all cases of cancer diagnosed or treated in Tennessee regardless of residence. While non-resident cases are included in the TCR database, they are not included in any analyses, studies, reports, etc., conducted by the TCR. Non-resident cases are reported to the state of residence. Cancer cases of Tennessee residents that were diagnosed in other states are also obtained for inclusion to the TCR database.

GENERAL ACCESSIBILITY: Release of aggregate data will not include access to identifying information (e.g., name and address). All identifying data captured from the medical record is considered confidential and release of aggregate data will be formatted to ensure the confidentiality of all reported cancer cases.

Any person may request these data by completing a Request for Aggregate Data stating: (1) the uses for which the information is desired, (2) preferred breakdown of cases (e.g. primary site, sex, race, etc.), and (3) assurances that the data will be released, published or otherwise disseminated in accordance with the data release policies outlined by the TCR.

ACCESS TO PROVISIONAL DATA: The term “provisional data” is used to describe a data file that is not considered to be finalized. Aggregate data will not be released until the data file has been finalized.

INACCESSIBLE RECORDS: Aggregate data are suppressed when fewer than ten (10) cases are reported for any given subgroup over any given time period. Rates are suppressed when calculated based on fewer than ten (10) cases too. These suppression rules apply regardless of time frame or for any time period. Suppression is necessary to prevent the potential identification of individuals diagnosed with cancer.

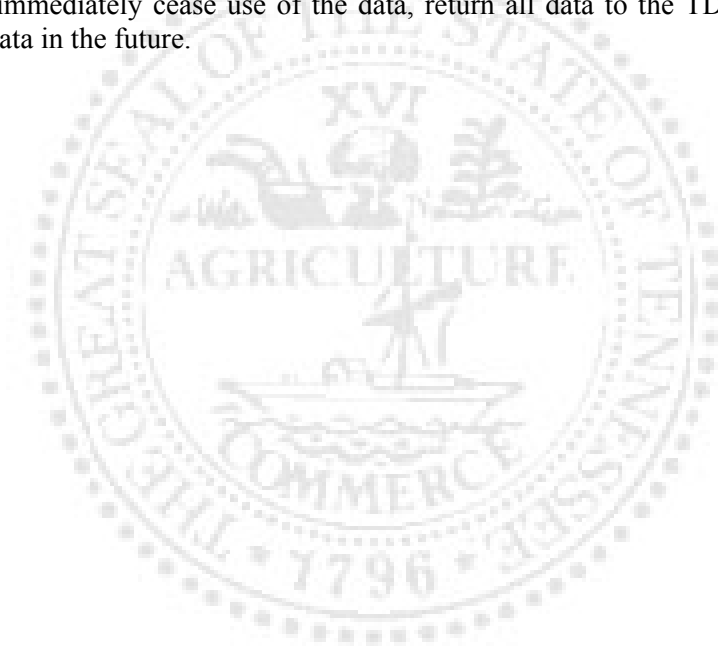
CHARGE POLICY: Access to aggregate data may be provided at no charge.

PROVISION OF DATA: All data will be supplied in tabular format.

The data will contain all records accessible for the period of time specified by the request.

All reports or manuscripts utilizing TCR data must be approved by the Office of Cancer Surveillance (OCS) prior to any distribution or publication.

BREACHES OF CONFIDENTIALITY: The Tennessee Department of Health (TDOH) may choose to take legal action if confidentiality is breached. Breaches of confidentiality will require the requester to immediately cease use of the data, return all data to the TDOH, and forfeit all rights to access data in the future.





STATE OF TENNESSEE
 Department of Health
 Office of Policy, Planning & Assessment
 Office of Cancer Surveillance
 Tennessee Cancer Registry
 Cordell Hull Building, 6th Floor North
 425 Fifth Avenue North
 Nashville, TN 37243

Aggregate Data Request

Name of Person Making Request	Title			
Organization				
Street Address				
City	State	Zip	Phone Number	Fax Number
			() -	() -
Email Address				
Purpose for which data is requested (please be specific, and use additional sheets if needed):				
Is there a deadline for receipt of data? YES NO If YES, please provide date and reason: DATE _____				
Preferred form of output: PAPER DISK CD				

Description of data required:

1. Anatomical site(s):				
2. Counts?	YES	NO		
3. Rates:	Incidence	Mortality		
4. Age-adjusted rates?	YES	NO		
5. Time frame:	_____ thru _____			
6. Sex of cases:	Females	Males	Both	
7. Race:	White	Black	Other	All Races
8. Breakdown by standard age groups?	YES	NO		
If YES, which groups?	5-year	10-year	Other	
9. Geographic Region:				
10. Geographic breakdown:	State	County	Health Department Region	
Census Tract				
Other, please explain:				

Requestor should be advised that rates based on 16 or fewer cases and frequencies based on five or fewer cases will be suppressed, regardless of time frame.

Declaration:

The Tennessee Department of Health and the Tennessee Cancer Registry will be acknowledged using the suggested references in any publications and/or presentations based on the data provided.

**Source: Tennessee Department of Health
Office of Cancer Surveillance**

**Reference: Tennessee Department of Health
Office of Cancer Surveillance
Tennessee Cancer Registry, Year(s). Nashville, Tennessee**

1. I will not allow others to, nor will I myself, match this data set to other patient-level data sets, health care facility and/or professional level characteristics or use these data to identify any health care facility, health care professional or patient without prior Tennessee Cancer Registry approval.
2. The Tennessee Department of Health, Office of Policy, Planning & Assessment, Tennessee Cancer Registry does not warrant the accuracy of any information in the records that will be provided and shall not be held liable for any inaccuracies in such records or any damages from the use thereof.
3. I understand that a copy of any further analysis or research findings generated using these data MUST be provided to the Tennessee Cancer Registry.
4. I understand that the Tennessee Department of Health may choose to take legal action if confidentiality is breached. Breaches of confidentiality will require that you immediately cease use of the data; return all data to the Tennessee Cancer Registry; and forfeit all rights to access data in the future.

Signature: _____ Date: _____

Please return completed form to:

Attn: Epidemiologist
STATE OF TENNESSEE
Department of Health
Office of Policy, Planning & Assessment
Office of Cancer Surveillance
Tennessee Cancer Registry
Cordell Hull Building, 6th Floor
425 Fifth Avenue North
Nashville, TN 37243
Tele: 1-800-547-3558
Fax: (615) 532-7904



STATE OF TENNESSEE
Department of Health
Office of Policy, Planning & Assessment
Office of Cancer Surveillance
Tennessee Cancer Registry
Cordell Hull Building, 6th Floor
425 Fifth Avenue North
Nashville, TN 37243

Individual-Level Data Request Policy

SYSTEM NAME: Tennessee Cancer Reporting System

DESCRIPTION: This policy applies to the release of individual-level records from the Tennessee Cancer Registry (TCR). Computerized information for each case of cancer occurring in Tennessee is captured from medical records of patients who have cancer. By law (T.C.A. 68-1-1001, page 40), all cancer cases diagnosed or treated in Tennessee must be reported to the Tennessee Cancer Registry. Included in this database are identifying information (e.g., name, address, and social security number), demographic information (e.g., age, race, and sex) and general information about the case of cancer (e.g., primary site, histology and stage).

It is important to note that not all Tennesseans with cancer are diagnosed or treated in Tennessee and not all individuals diagnosed or treated with cancer in Tennessee are Tennesseans. This database contains all cases of cancer diagnosed or treated in Tennessee regardless of residence. While non-resident cases are included in the TCR database, they are not included in any analyses, studies, reports, etc., by the TCR. Non-resident cases are reported to the state of residence. Cancer cases of Tennessee residents that were diagnosed in other states are also obtained for inclusion to the TCR database.

GENERAL ACCESSIBILITY: Release of individual cancer case records may include access to identifying information (e.g., name and address). All identifying data captured from the medical record is considered confidential and access will be limited to approved research.

Access to identifying and confidential cancer information is limited to research-related requests by law consistent with T.C.A. 68-1-1001, page 40. Any person may request these data by completing an Application for Individual-Level Data stating: (1) the uses for which the information is desired, (2) reasons confidential data elements are necessary, (3) assurances that the data will be treated with the same level of confidentiality as that maintained by the TCR, and (4) that upon completion of the research project, all data provided by the TCR and all copies of these data will be destroyed or returned. Upon recommendation by the TCR Data Access Review Committee, the TCR may approve or deny the request.

ACCESS TO PROVISIONAL DATA: The term “provisional data” is used to describe a data file that is not considered to be finalized. Provisional cancer data are only released for research purposes when required by an approved study.

INACCESSIBLE RECORDS: Confidential information with personal identifiers is accessible only to approved research projects. Data for cancer cases occurring in non-resident while in Tennessee may not be accessible. Also, data for cancer cases occurring in Tennessee residents while outside of Tennessee may not be accessible, depending on the data sharing agreement with that state or area.

CHARGE POLICY: Access to individual-level cancer data may be provided to qualified, approved researchers at no charge.

PROVISION OF DATA: All data will be supplied in the format requested by the researcher on CD or floppy disk.

The data will contain all records accessible for the period of time specified by the research request. Requesters will be provided with documentation (e.g., code sheets and file layouts) to correctly interpret the data.

Data cannot be released to any other organization or individual by the person or entity to whom the State of Tennessee provides the data.

BREACHES OF CONFIDENTIALITY: The Tennessee Department of Health (TDOH) may choose to take legal action if confidentiality is breached. Breaches of confidentiality will require the requester to immediately cease use of the data, return all data to the TDOH, and forfeit all rights to access data in the future.

All researchers requesting access to TCR data must complete the confidentiality agreement specific to the use of individual-level cancer incidence data.



STATE OF TENNESSEE
Department of Health
Office of Policy, Planning & Assessment
Office of Cancer Surveillance
Tennessee Cancer Registry
Cordell Hull Building, 6th Floor
425 Fifth Avenue North
Nashville, TN 37243

Individual-Level Data Request

TO: Potential Research Requestor:

You have inquired about obtaining access to the Tennessee Cancer Registry (TCR) database. Because you are requesting individual-level data, it is necessary to complete the enclosed application materials. The TCR Data Access Review Committee (DARC) will consider your request upon receipt of your completed application. *Any areas of this application left blank without explanation will delay the review process, so please review your completed application carefully.*

If the DARC determines that part or all of your request can be accomplished through internal analyses, a public-use dataset, or the creation of proxy variables, we will contact you to advise you of this option. This may allow the review process to be expedited, and give the TCR the opportunity to meet your data needs in a more timely manner.

Maintaining confidentiality of the individuals in our database is paramount to the mission of the TCR. For this reason, it is important that the need for confidential data containing unique identifiers be specified throughout the application. Although this process may seem arduous and repetitive, it is a small burden compared to the privilege of working with this very sensitive information, and provides assurances to the TCR that procedures are in place to safeguard TCR data.

As you complete the application, you will find guidance regarding unique identifiers and proxy variables. Please feel free to contact TCR for technical assistance in decision making regarding proxy or “dummy” variables. Please select the minimum amount of variables needed for your research. This will limit the amount of data management required and minimize issues regarding patient confidentiality. TCR will make every effort to provide you with the data requested, and we ask for your help by asking only for those data elements necessary for your research project.

Please send your completed application materials to the following address:

Epidemiologist
STATE OF TENNESSEE, Department of Health
Office of Policy, Planning & Assessment
Office of Cancer Surveillance, Tennessee Cancer Registry
Cordell Hull Building, 6th Floor
425 Fifth Avenue North
Nashville, TN 37243

If you have any questions, please contact the TCR at (615) 253-5937 or (800) 547-3558 or e-mail at TNCancer.Registry@tn.gov.



STATE OF TENNESSEE
Department of Health
Office of Policy, Planning & Assessment
Office of Cancer Surveillance
Tennessee Cancer Registry
Cordell Hull Building, 6th Floor
425 Fifth Avenue North
Nashville, TN 37243

Individual-Level Data Request

Part A: General Information

Title of project: _____

Date of submission to TCR (mm/dd/yyyy): _____

Principal Investigator: _____ Title: _____

Address: _____

Organization: _____ Tele #: () _____

E-Mail: _____ Fax #: _____

Names of Co-investigators: _____

Sponsoring/funding organization (if applicable): _____

Grant period: From: _____ to _____

Part B: Summary of Research Study Protocol:

Please submit a copy of your research/study/project protocol.
Use as much space as needed to answer the questions below.
Attach a separate document if necessary.

1. Title of study or project:

2. Need for study or project: How will this study benefit residents of Tennessee and/or public health? The answer should include the number or proportion of residents who may be affected by the results of the study.

3. Requestor’s qualifications and affiliation(s): (describe or attach resume/cv)

4. Personnel: List all research staff who will have access to the confidential data (include personnel, subcontractors, and affiliated agencies).

5. Source of funding: Describe the source(s) of all funding for the study (including in kind contributions).

6. Study background and design: If available, attach research protocol and skip to Question 7. If this request is not part of a scientific research study, please provide an abstract describing the background and design of the project and the reason for requesting individual-level data. Please address the following:

- What are the specific aims of your project? Specifically state the goal(s) of the research.
- Based on the study goal(s), provide an outline of the study, start and completion dates, and sampling or data collection methodology.
- Describe the study’s case definition (demographics, clinical criteria, geographic location, and any other appropriate descriptors).
- Describe the data analysis methods, including sub-group analyses, multi-variate models, and any software packages you anticipate utilizing in the analysis.

**For TCR Review
Only Included?**

YES

NO

For TCR Review Only Included?

YES NO

7. Data management: Please describe, in detail, the methods used to store the data (include how data are accessed, use of passwords, network servers, etc.).

8. Results: Describe the format of your results (e.g., publication, grant application poster presentation, agency brochure, internet web page, etc.). What will be the lowest geographical level of analysis that will be released for publication or presentation (e.g., state, county, census tract)?

9. Contact with subjects: Will the study or project activities involve contact with persons identified in the requested dataset? If so, please explain the need for, and the exact nature of, any such contact. **IRB approval must also be obtained from the Tennessee Dept. of Health. Please contact Dr. Bridget McCabe or Donna Hurst for more information at bridget.mccabe@tn.gov or donna.hurst@tn.gov or (615) 741-5225.**

10. Confidentiality Agreement: Please read and sign the TCR Confidentiality agreement.

Part C: Data Elements Requested

×	Potentially Confidential Elements	Provide Justification for Need, Filters, Groups
	Cancer Registry Patient ID Number	Need:
	Patient Tumor Record Number	Need:
	Address of residence at diagnosis	Need:
	City of residence at diagnosis	Need:
	County of residence at diagnosis	Need:
	Zip code of residence at diagnosis	Need:
	Race	Need:
	Age at diagnosis	Need:
	Date of birth	Need:
	Date of diagnosis	Need:
	Date of initial RX	Need:

	Accession number – Hosp	Need:
	Sequence number – Hosp	Need:
	Year of diagnosis	Need:
	State at diagnosis	Need:
	Marital status at diagnosis	Need:
	Sex	Need:
	Primary Site	Need:
	Laterality	Need:
	Morphology (Type and Behavior)	Need:
	Grade	Need:
	Reporting hospital	Need:
	Summary stage	Need:

**For a complete list of data elements available, please contact TCR.

Part D: Data Request Specifications

- 1) A. Years of analysis: Please indicate analysis time frame (in years). Data are available from 1991 through current.

From: _____ through _____

B. Expected date of data return/destruction _____

- 2) Gender of subjects:

____ Males and Females

____ Males only

____ Females only

- 3) Age of subjects:

____ Adults only (20+)

____ Children only (under age 20)

____ All ages

____ Age range from _____ through _____

____ Standard age groups (5-year age groups; 0-4, 5-9,, 74-79, 80-84, 85+)

____ User-defined age groups

Specify age groups: _____

4) Cancer sites/histologies:

Primary Sites (ICD9/ICD10/ICDO Codes)

Histologies (ICDO-M Codes)

5) Geographic Areas

____ Tennessee (entire state)

____ Middle Tennessee

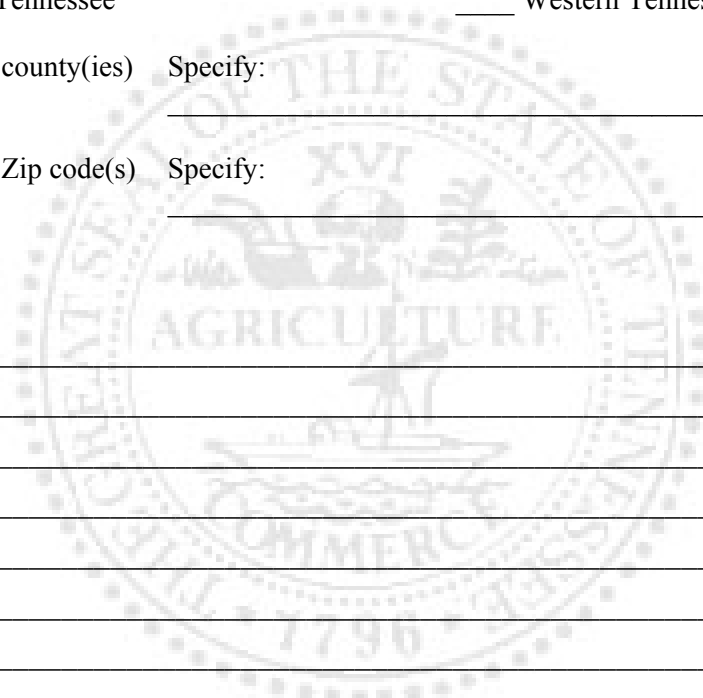
____ Eastern Tennessee

____ Western Tennessee

____ Specific county(ies) Specify:

____ Specific Zip code(s) Specify:

6) Comments:



Part E: Statement by Researcher Seeking Access

I, _____, hereby state that all of the information provided in this application for release of data is true, complete, and correct to the best of my knowledge.

Name of responsible party

Title

Organization/Institution

Telephone Number

Signature

Date

Note: IRB approval must be obtained from an IRB formed in accordance with the provisions of the U. S. Department of Health and Human Services Code of Federal Regulations Title 45, Part 46, Protection of Human Subjects (revised November 13, 2001). A copy of the IRB must accompany the Individual-Level Data Request Application. Please contact Dr. Bridget McCabe or Donna Hurst regarding IRB approval from the TN Dept. of Health at bridget.mccabe@tn.gov or donna.hurst@tn.gov or (615) 741-5225.

Please send completed form to: ATTN: Epidemiologist
STATE OF TENNESSEE
Department of Health
Office of Policy, Planning & Assessment
Office of Cancer Surveillance
Tennessee Cancer Registry
Cordell Hull Building, 6th Floor
425 Fifth Avenue North
Nashville, TN 37243



STATE OF TENNESSEE
Department of Health
Office of Policy, Planning & Assessment
Office of Cancer Surveillance
Tennessee Cancer Registry
Cordell Hull Building, 6th Floor
425 Fifth Avenue North
Nashville, TN 37243

Confidentiality Agreement for Individual-Level Data

All persons requesting individual-level data from the Tennessee Department of Health, Tennessee Cancer Registry must agree to and sign this agreement of confidentiality. The confidentiality of cancer information reported to the TCR is of primary importance. The TCR has developed data use policies in accordance with the Health Insurance Portability and Accountability Act of 1996 (HIPAA), and expects researchers using TCR data to adhere to these policies. Breaches of confidentiality may result in legal action, and the researcher may forfeit all rights to access data in the future.

- 1) I agree that all information provided in the Individual-Level Data Request Application form is correct.**
- 2) I will not allow others to, nor will I myself, use data provided by the TDOH TCR for purposes other than the study proposal and the purposes specified in this application.**
- 3) I will not allow others to, nor will I myself, release, furnish, disclose, publish, or otherwise disseminate these data in any manner without the approval of the TCR.**
- 4) I will not allow others to, nor will I myself, use these data to identify any health care facility and/or health care professional without prior TCR approval.**
- 5) I will not allow others to, nor will I myself, publish, disseminate, communicate or otherwise re-release health care facility and/or professional identifiable data without prior approval from the TCR and review and comment by the affected facilities.**

- 6) I will not allow others to, nor will I myself, match these data set(s) to other patient-level data sets, health care facility and/or professional level characteristics without prior approval from the TCR.
- 7) I will not allow others to, nor will I myself, release data in a report or for dissemination with a cell size of less than ten (10) or rates of less than 10 without prior approval (regardless of the time frame, or for any time period), in accordance with the data release policies of the TCR. Maps generated using geocoded data must adhere to the data suppression rules.
- 8) The TCR does not warrant the accuracy of any information in the records that will be provided and shall not be held liable for any inaccuracies in such records or any damages from the use thereof. Provisional data is incomplete and may contain inaccuracies.
- 9) I understand that these data are the property of the State of Tennessee TCR and must be surrendered or destroyed upon completion of the approved research project.
- 10) I understand that a copy of any results generated using these data MUST be provided to the TCR.
- 11) I understand that the TDOH TCR may choose to take legal action if confidentiality is breached. Breaches of confidentiality will require that you immediately cease use of the data; return all data to the TCR; and forfeit all rights to access data in the future.

Principal Investigator Name: _____

Principal Investigator Signature: _____

Date: _____

Co-Investigator Name: _____

(If applicable)

Co-Investigator Signature: _____

(If applicable)

Date: _____

Supervisor Signature: _____

(If applicable - *Required for TDOH internal data requests*)

Date: _____



State of Tennessee
Department of Health
Office of Policy, Planning & Assessment
Office of Cancer Surveillance
Tennessee Cancer Registry
Cordell Hull Building, 6th Floor
425 Fifth Avenue North
Nashville, TN 37243

Governmental & Related Agency Data Request Policy

All data requests from the **Tennessee Department of Health (TDOH)** and other Tennessee State agencies must follow the procedures previously outlined for Aggregate and Individual-Level data requests. See Flowchart on page 10.

The following agencies currently have **Data Sharing No Cost Contracts** with the Tennessee Cancer Registry (TCR): Metro-Nashville Health Dept., Memphis/Shelby County Health Dept., Jackson-Madison County Health Dept., Sullivan County Regional Health Dept., East TN State University, Meharry Medical College, Middle TN State University, Tennessee State University, University of Memphis, UT Memphis, Vanderbilt University Medical Center (Dept. of Preventive Medicine) and National Opinion Research. These agencies must follow the procedures previously outlined for Aggregate and Individual-Level data requests, unless specific revisions of their respective contracts allow for limited exceptions.

State Cancer Registries that are contiguous with the State of Tennessee have data sharing contracts for the purpose of exchanging cancer data for Tennessee residents diagnosed and/or treated in their state. In the absence of a fully executed interstate data sharing contract, other state cancer registries shall complete and return the TDOH Request for Data form (PH-3599 Rev. 7-03) beginning on page 30.

U.S. federal agencies will be handled on a case by case basis and will generally follow the same guidelines presented in this document for external data requests.

The United States Department of Labor, Employment Standards Administration, Energy Employees Occupational Illness Compensation will occasionally fax a claim for Survivor Benefits under the Energy Employees Occupational Illness Compensation Program Act. The signed survivor declaration is sufficient for release of information, as per Deputy General Counsel, TDOH, Office of General Counsel. Upon the death of an individual, the confidentiality “key” he/she possessed devolves to the next-of-kin and/or legal representative, if applicable. A letter authorizing release of public health information (PHI) from a person requesting his/her own records is sufficient to release such information to that person.



STATE OF TENNESSEE

Department Of Health
Policy, Planning and Assessment
Office of Cancer Surveillance
Tennessee Cancer Registry
Cordell Hull Building, 6th Floor
425 Fifth Avenue North
Nashville, TN 37243

Request for Data

Name of Person Making Request		Organization	
Street Address			
City	State	Zip	Phone Number () - -
Type of Organization: Governmental <input type="checkbox"/> Commerical <input type="checkbox"/> Non-Profit <input type="checkbox"/> Other – Specify <input type="checkbox"/> _____			
Type of Activities Conducted by the Person/Organization:			
Type of Record and Time Period Requested:			
Purpose for Which Records Are Requested:			
Project Approval by an Institutional Review Board? <input type="checkbox"/> No <input type="checkbox"/> Yes (if yes, please attach copy)			
If you plan to use confidential information to contact the registrant, his/her family, or any other person or entity named on the record, complete the following:			
Procedure Used for Contact:			
Method for Maintenance and Protection of Identifying Information:			

The undersigned certifies that he/she has read, understands, and agrees to the conditions described above that apply to the use of data provided by the State of Tennessee, Department of Health. Please initial each item and provide the information requested below.

Data Release Agreement:

- 1. All information provided by the requestor is correct.
- 2. All fees shall be paid prior to the receipt of information.
- 3. Records released by the Tennessee Department of Health will not be sold, transferred, or used for any purpose other than those stated in this request.
- 4. Strict standards of confidentiality of records and information, including, but not limited to, patient medical records and other similar records shall be maintained in accordance with applicable state and federal law. All data provided will be kept confidential and will be used for the specific purpose described above.
- 5. The requestor affirms it is familiar with the requirements of the Health Insurance Portability and Accountability Act (HIPAA) requirements and its accompanying regulations, and will comply with all HIPAA requirements.
- 6. The appropriate source, reference, and acknowledgement will always accompany any use of these data. The guidelines specified by the Reference Guidelines document will be followed.
- 7. A copy of any results generated using these data will be provided to the Tennessee Department of Health, Office of Policy, Planning and Assessment.
- 8. All copies of confidential data provided for research purposes in response to this request will be destroyed at the end of the study. Paper copies should be burned or shredded and electronic records should be erased or returned to the Tennessee Department of Health.
- 9. The Tennessee Department of Health may choose to take legal action if confidentiality is breached. Breaches of confidentiality will require that you immediately cease use of the data; return all data to the Tennessee Department of Health; and forfeit all rights to access data in the future.
- 10. The Tennessee Department of Health does not warrant the accuracy of any information in the records that will be provided and shall not be held liable for any inaccuracies in such records or any damages from the use thereof. Provisional data is incomplete and may contain inaccuracies.

Signature: _____ Date: _____

Name (print): _____

Title: _____

Telephone Number (of person signing): () - _____

All electronic data can be supplied in a fixed format text file. Data will be supplied via CD. Questions concerning the completion of this form or the request for information may be directed to the Tennessee Department of Health, Tennessee Cancer Registry, telephone 1-800-547-3558.

For Health Department Use Only:

This data was released on _____ based on IRB approval and/or Health Data Policy Committee policy.
(Date)

Signature: _____ Date: _____

APPENDIX

Contents page

1.	Data Access Review Committee Member List.....	31
2.	Data Access Review Committee Guidelines	32
3.	Data Access Review Committee Summary Report.....	33
4.	Request for Individual-Level Data Procedure Outline	34
5.	Reference Guidelines	35
6.	Tennessee Code for Cancer Reporting Systems (T.C.A. 68-1-1001).....	36
7.	Tennessee Cancer Registry Reporting Rules (Chapter 1200-7-2).....	41
8.	Glossary of Terms.....	47

Tennessee Cancer Registry
Data Access Review Committee

Member list and contact information

Updated 05/2008

<p>Martin Whiteside, DC, PhD, MSPH Director of Office of Cancer Surveillance Office of Policy, Planning and Assessment Tennessee Department of Health 6th floor, Cordell Hull Bldg 425 5th Ave North Nashville, TN 37243 615-532-7903 Email: Martin.Whiteside@tn.gov</p>	<p>Qiong Li, Ph.D. Epidemiologist Office of Cancer Surveillance Office of Policy, Planning and Assessment Tennessee Department of Health 6th floor, Cordell Hull Bldg 425 5th Ave North Nashville, TN 37243 615-741-9079 Email: Qiong.Li@tn.gov</p>	<p>David J. Law, Ph.D. Director of Division of Health Research Office of Policy, Planning and Assessment Tennessee Department of Health 4th floor, Cordell Hull Bldg 425 5th Ave North Nashville, TN 37243 615-253-4702 Email: David.Law@tn.gov</p>
<p>Ellen Omohundro, Ph.D. Statistical Research Specialist Division of Health Research Office of Policy, Planning and Assessment Tennessee Department of Health 4th floor, Cordell Hull Bldg 425 5th Ave North Nashville, TN 37243 615-253-6862 Email: Ellen.Omohundro@tn.gov</p>	<p>Yinmei Li, MD, Ph.D. Director of Surveillance, Epidemiology & Evaluation Section Division of Health Research Office of Policy, Planning and Assessment Tennessee Department of Health 6th Floor, Cordell Hull Bldg 425 5th Ave North Nashville, TN 37243 615-741-8190 Email: Yinmei.Li@tn.gov</p>	<p>Patrick A. Turri, M.S. Director of Data Analysis Tennessee Hospital Association 500 Interstate Blvd. South Nashville, TN 37210-4634 615-401-7449 Email: pturri@tha.com</p>



State of Tennessee
Department of Health
Office of Policy, Planning & Assessment
Office of Cancer Surveillance
Tennessee Cancer Registry
Cordell Hull Building, 6th Floor
425 Fifth Avenue North
Nashville, TN 37243-5262

Data Access Review Committee Guidelines

I. Introduction

The TDOH Data Policy Committee has established the Data Access Review Committee (DARC) as a formal subcommittee with delegated authority to conduct its business as defined below. The chair of the DARC subcommittee, the TCR epidemiologist, shall be responsible for preparing and submitting an annual fiscal year written report not later than July 30 of each year. The report shall contain information regarding data requests, committee disposition of requests, and minutes of subcommittee proceedings.

The DARC subcommittee shall be staffed by the TCR epidemiologist and membership will be selected by the TCR program. Meetings will be set by the TCR program. Committee data requests shall be guided by the policy and procedures herein.

II. Purpose of Data Access Review Committee is to ensure the confidentiality of data collected and ensure the validity of research projects utilizing TCR data. For a list of current committee members see Appendix (page 31).

III. Criteria for Committee Decision Making:

- 1) Follow the specific requirements of the Tennessee Cancer Reporting System Act of 1983 (TCA 68-1-1001), the accompanying TDoH rules and the HIPAA Privacy Rules applicable to the release of individual-level data.
- 2) Determine if the research is an appropriate use of TCR data.
- 3) Determine if the proposed methods are appropriate for the study.
- 4) Verify that the study has an ending date. The TCR will not release data on an ongoing basis to supply research entities with a pool of data from which they may conduct future studies.
- 5) Ensure that there are adequate provisions to maintain the confidentiality of the data before, during and after the study. The data must be destroyed upon completion of the study.
- 6) Return decision to TCR within 15 work days of receiving.

IV. Review Procedure – see page 34.

