Alabama Statewide Cancer Registry
Release of Cancer Information
Procedures for Researchers

I. Introduction

The Alabama Statewide Cancer Registry (ASCR) has responsibility for the registry of cancer information for the State of Alabama. Confidentiality is maintained by the ASCR through the provisions of the Alabama Statewide Cancer Act. On request from researchers, the ASCR will consider the release of four types of data, outlined below. All requests for data must be in writing through a letter of intent, and in the form of at least a summary research protocol, accompanied by the enclosed *Research Application/Agreement for Disclosure of Confidential Information from the Alabama Statewide Cancer Registry for Research Purposes (*herein referred to as *Research Application/Agreement*.)

Depending upon the category of data needed, requests may be reviewed by the Program Manager, the ASCR Advisory Committee and/or the Alabama Department of Health (ADPH) Institutional Review Board (IRB.) The ASCR will ensure that personal health information will only be disclosed for research purposes if the following conditions are met:

- The objective of the research project cannot be reasonably accomplished using other non-personal information.
- The research project is not contrary to the public interest.
- The approval of an IRB has been obtained, if the approval is required by law or by the research funding agency or by the ASCR.
- The person to whom the personal health information is to be disclosed has entered into an agreement with the ASCR, according to the terms and conditions set forth in the *Research Application/Agreement* and the *Confidentiality Agreement*.

Further, the request for information must address the following points:
a. The purpose of the project.
b. The relevance and importance of the project
c. The research methods to be employed (i.e. sample size, selection criteria.)
d. The feasibility of the project.
e. Details as to how the information provided by the ASCR will be used (e.g. transfer of data to third parties, publications).
f. The methods of ensuring the retention of confidentiality of patient information in both the short and the long term, and
g. The names of those connected with the project that will have access to the data.
h. The potential risks and benefits to study subjects/participants/department.

II. Types of Research Requests

Requests may be grouped into the following categories generally in an ascending order of sensitivity:

1. No person-specific information is included in the data provided to the researcher. For example, a study to validate the reported accuracy and completeness of diagnostic information about cancer cases may require the linkage of a study file to the ASCR, in order to create an "agreement table" for each data element of interest. Thus, no person-specific data would be disclosed. Requests for aggregate statistics and descriptive/trend information do not require the

submission of a *Research Application/Agreement*; rather, a data request form should be submitted to the Research Coordinator. However, any drafts or reports based on these statistics must be submitted for review to the Program Manager prior to publication or public release.

2. Patient-specific or case-specific or event-specific information is included in the data provided to the researcher, but all individual identifiers are first removed.
For example, a researcher may be interested in the patient care referral patterns for certain subsets of the cancer patient population. This type of request involves a residual risk of disclosure. For example, there might be an interest in retaining zip code information in order to impute area indicators of social class. Researchers must submit a *Research Application/Agreement* and *Confidentiality Agreement*. ASCR Advisory Committee approval is required.

3. Person-specific information with identifiers are included in the data provided to the researcher, but there is no subsequent contact with these subjects, and they are not expected to be directly affected in any way by the research. In this instance, the researcher needs to have a clear reason for requiring information. Often the researcher needs identifiers back to permit closer review of records. ASCR Advisory Committee and ADPH IRB approval is required.

4. Person-specific information and personal identifiers are included in the data provided to the researcher, who intends to use the information for subsequent contact with subjects or their families.
Individuals may have been selected and identified through other data held, legitimately, by the applicant, or may have been selected as a result of an individual cancer history contained in the ASCR. It must be emphasized that the purpose of any contact and follow-up would be research; no person would be contacted for administrative follow-up alone. This type of request requires sensitive and careful handling. Initial contact with these individuals must, in all instances, be made by the ASCR staff who would obtain written consent prior to any information-gathering or contact by non-ASCR investigators. ASCR Advisory Committee and ADPH IRB approval is required.

ASCR Advisory Committee
The management authority for providing ASCR data for research purposes, whether used within the ASCR, or by external researchers, is delegated to the Program Manager. The Advisory Committee will provide advice and recommendations to the Program Manager, in accordance with established policies and procedures. This committee will report to the State Health Officer, to whom appeals of ASCR access decisions may be directed.

The request for information must address the following issues:

a. The scientific merit of the research question and proposed methods.
b. The ethical acceptability of the research question and proposed methods.
c. The public interest value of the research.
d. Security of data.
e. Compliance with relevant legislation.

With respect to scientific merit, the ADPH IRB will consider whether a request is associated with a research project that has undergone scientific peer review through a recognized research funding agency. Most peer-review granting agencies will also require that a research proposal be reviewed by the Institutional Review Board (IRB) of the institutional "home" of the principal investigator. In cases where requests originate without having gone through a scientific or ethical review, the Advisory Committee will retain the right to commission an independent review prior

to consideration. Applicants must explain their proposed data security measures when they apply for access (see *Research Application/Agreement.*)

III. Control of information after its release by the ASCR

The ASCR requests that all reports or manuscripts using information directly supplied by the ASCR be submitted to the ASCR Program Manager for review prior to publication. Acknowledgement of the Alabama Statewide Cancer Registry in supplying the information should be made in all publications and papers. A pledge of confidentiality will be sworn and witnessed for any individual who receives patient identifying information from the ASCR. Release of identifiable cancer patient information by the researcher to a third party may not be made without prior written permission of the ASCR. Requests for further release of these data must be made in writing.

IV. Mechanics of the release of information

Upon the notification of a request for information, the ASCR will send to the requestor a copy of this document, *The Release of Cancer Information from the Alabama Statewide Cancer Registry for Research Purposes Procedures for Researchers.* The requestor will submit a scientific protocol in full, or a proposal summary, which addresses the points in section I above, together with the completed *Research Application/Agreement* Form enclosed. Additional information about the research project may be required by the ASCR. If the research proposal is approved, the ASCR will send to the requestor a *Confidentiality Agreement.* The data will be released for research purposes only after receipt of these signed agreements.

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