420-7-3-.01 General Provisions

(1) These rules apply to the reporting of cancer or benign brain-related tumors to the Alabama Statewide Cancer Registry.

(2) Statutory Authority. These rules are promulgated and adopted pursuant to the authority of Act 95-275.

(3) Definitions (a list of selected terms often used in connection with these Rules):

(a) "Accuracy" means the correctness of data reported on cancer or benign brain-related tumor cases submitted to the ASCR according to established national standards.

(b) "Advisory Council" means the council appointed by the State Health Officer consisting of healthcare professionals, university representatives, and other interested parties from various health associations.

(c) "ASCR" means the Alabama Statewide Cancer Registry.

(d) "Behavior Code" means a one-digit code which indicates whether a tumor is malignant, benign, in situ, or of uncertain behavior.

(e) "Cancer Registry" means a collection of cancer or benign brain-related tumor data on patients that is maintained as an identified repository of such data for, or within any hospital, medical clinic, or centralized institution.
(f) "Cancer Registrar" means any person appropriately trained for the collection of cancer or benign brain-related tumor data for a cancer registry.

(g) "Cancer Patient" means any person who is undergoing diagnosis or treatment for cancer or benign brain-related tumor.

(h) "Clinical Records" means any records, hard copy or patient abstract, containing information which could lead to the identification of cancer patients, cancer diagnosis or treatment facilities, independent clinical laboratories, or health care providers.

(i) "Clinical Information" means any information which could lead to the identification of cancer or benign brain-related tumor patients, cancer or benign brain-related tumor diagnosis or treatment facilities, independent clinical laboratories, or health care providers.

(j) "Completeness" means the complete reporting of all confirmed cases of cancer or benign brain-related tumor.

(k) "Data Acquisition Manual" means the manual developed by the ASCR which specifies the rules and guidelines used when abstracting a confirmed cancer or benign brain-related tumor case to be reported.

(l) "Death Match" means the matching of confirmed cases of cancer or benign brain-related tumor reported to the central registry with a listing of deceased individuals.

(m) "Direct Reporting" means the reporting of all cancers or benign brain-related tumors from the facility or provider to the central registry via paper or electronic submission.

(n) "Electronic data submission" means transferring data from a computer used by a reporting entity to a computer specified by the ASCR through the use of a modem, magnetic tape, magnetic disk, or secure Internet connection.

(o) "Healthcare Facilities" means all public, private, federal, or military hospitals, surgical centers, outpatient radiation therapy centers, outpatient medical oncology centers, or any other facilities where cancer or benign brain-related tumor cases are diagnosed or treated.

(p) "Healthcare Providers" means a person who is licensed by the Alabama Board of Medical Examiners to practice medicine or the Alabama Board of Dental Examiners to practice dentistry.
"Indirect Reporting" means reporting of all cancers or benign brain-related tumors to the central registry via paper or electronic submission by a facility through contract with an outside facility or registrar.

"Primary Cancer" means any confirmed cancer or benign brain-related tumor not determined to be a metastasis from another primary site.

"Primary Site" means the site of origin of a confirmed cancer or benign brain-related tumor.

“Researcher” means the primary investigator, co-investigator, or project director of a research project or proposal.

"Research Review Committee" means the committee appointed by the State Health Officer consisting of representatives from the ASCR Advisory Council and the ADPH.

"Statistical Data" means collected aggregate data which does not lead to the identification of cancer or benign brain-related tumor patients, cancer or benign brain-related tumor diagnosis or treatment facilities, independent clinical laboratories, or health care providers.

"Timeliness" means the reporting of all confirmed cases of cancer or benign brain-related tumor within 180 days of admission or diagnosis.

Statutory Authority: Code of Alabama, 1975, §22-13-1
Author: Reda Wilson

420-7-3-.02 Reporting Date and Submission

(1) Effective January 1, 1996, all cases of confirmed cancer diagnosed or treated in the state are to be reported via electronic submission to the Alabama Statewide Cancer Registry (ASCR) within 180 days of admission or diagnosis as prescribed by these rules. Effective January 1, 2005, all cases of benign brain-related tumors diagnosed or treated in the state from January 1, 2004 and forward are to be reported via electronic submission to the ASCR. Benign brain-related tumors diagnosed or treated between January 1, 2004 and June 30, 2004 are to be reported no later than March 31, 2005. All subsequent benign brain-related tumors within 180 days of admission or diagnosis as prescribed by these rules.

(a) Healthcare facilities are to directly report each case of confirmed cancer or benign brain-related tumor, or indirectly report through contract with an established cancer registry or cancer registrar, via electronic submission.
(b) Healthcare facilities with 50 or less cases per year may elect to report each confirmed case of cancer or benign brain-related tumor via paper abstract on a quarterly basis or through the ASCR Casefinding Auditor system.

(c) Healthcare providers are to report each confirmed case of cancer or benign brain-related tumor identified as having not been previously reported by a healthcare facility at which there was an inpatient admission. These reports may be reported directly to the ASCR or indirectly reported through contract with an established cancer registry or cancer registrar.

(2) The reporting facility and/or provider is solely responsible for providing complete and accurate data as required in the ASCR Data Acquisition Manual. If data does not meet established quality of data standards in any or all of three areas: completeness, accuracy, and timeliness, the reporting facility and/or provider will respond to queries from the ASCR and submit original and/or corrected data. If this measure is necessary, then notification shall be sent to the facility or provider in the form of a letter regarding specific discrepancies between facility/provider and ASCR. The facility/provider shall have sixty (60) days to reply and resubmit data. No fees shall be charged facilities and/or providers to implement these rules.

(3) If the healthcare facility or provider fails to report in the prescribed format, the State Health Officer's authorized representative shall be permitted access to all records which would identify confirmed cases of cancer or benign brain-related tumor, or would establish characteristics of the cancer or benign brain-related tumor, treatment of the cancer or benign brain-related tumor, or medical status of any identified cancer or benign brain-related tumor patient.

Statutory Authority: Code of Alabama, 1975, §22-13-1
Author: Reda Wilson

420-7-3-.03 Data to be Reported

(1) All confirmed cancers with a behavior code of "2" (in situ) or "3" (malignant) or benign brain-related tumors with a behavior code of “0” (benign) or “1” (uncertain behavior) in the current International Classification of Diseases for Oncology (ICD-O) edition, and subsequent editions, must be reported. However, the following skin cancers and carcinoma in situ of the cervix uteri, as coded in ICD-O, are excluded from reporting:

(a) 8000-8004 Neoplasms, malignant, NOS (not otherwise specified) of the skin (C44.0-C44.9)
(b) 8010-8045 Epithelial carcinomas of the skin (C44.0-C44.9)
(c) 8050-8082 Papillary and squamous cell carcinomas of the skin (C44.0-C44.9)
(d) 8090-8110 Basal cell carcinomas of any site except genital sites
   NOTE: Skin cancers in the genital sites (vagina, clitoris, labium, vulva, prepuce, penis, and scrotum) ARE REPORTABLE since they are more likely to metastasize than the usual carcinomas of the skin. (These cancers are reportable both nationally and internationally.)
(e) 8010/2 Carcinoma in situ, NOS and intraepithelial carcinoma, NOS of the cervix uteri (C53.0-C53.9)
(f) 8070/2 Squamous cell carcinoma in situ, NOS, epidermoid carcinoma in situ, NOS, intraepidermal carcinoma, NOS, and intraepithelial squamous cell carcinoma of the cervix uteri (C53.0-C53.9)

(2) A report shall also be given for each subsequent primary cancer or benign brain-related tumor diagnosed in an individual. If it cannot be decided whether a case should be reported, the ASCR should be contacted for guidance.

(3) All reports of confirmed cases of cancer or benign brain-related tumor shall include but not be limited to the data items, including treatment and patient follow-up information, listed in the ASCR Data Acquisition Manual.

Statutory Authority: Code of Alabama, 1975, §22-13-1
Author: Reda Wilson

420-7-3-.04 Quality Control

(1) All health care facilities and/or providers shall permit periodic quality control reviews including casefinding, abstracting, coding, and data submission processing. Unless other arrangements are made with a facility or provider, no less than 15 working days' notice is established as the minimum notice period applicable whenever the ASCR wishes to have access to information on site at a facility.

(a) All healthcare facilities and/or providers should perform quality control reviews including casefinding, abstracting, coding, and data submission processing and, upon request of ASCR and advance notification, submit quality control data.

(2) The ASCR will ensure the provision of cancer registry training and consultation.
(3) Reporting facilities shall assist the ASCR in annual reconciliation of cancer mortality and incidence data.

Statutory Authority: Code of Alabama, 1975, §22-13-1
Author: Reda Wilson

420-7-3-.05 Confidentiality

(1) The clinical records of individual patients submitted to the ASCR shall be confidential and shall not be public records open to inspection. Only state personnel authorized by the State Health Officer and other individuals authorized by the State Health Officer or designee shall have access to the records.

(2) The information contained in the clinical records of individual patients submitted to the ASCR shall be transferred to computer-compatible means of data entry. Only personnel authorized by the ASCR to use computers, terminals, programs, data files, and other computer hardware or software involved in maintaining patient information shall have access to them.

(3) Clinical information in possession of the ASCR may be disclosed in the following circumstances when authorized by the State Health Officer or designee:

(a) Information may be disclosed as provided in the Access to Information for Research Purposes of these Rules;

(b) Information from death certificates may be released to a participating hospital or provider when the hospital or provider requests a death match for confirmation of the reported or suspected deaths of cancer patients treated at that hospital or by that provider. Death match information provided to hospitals or providers shall not be further released by that facility/provider unless it is a cancer control agency or clinical facility for the purpose of obtaining information necessary to complete the cancer or benign brain-related tumor record.

(c) Statistical information and data based on client information may be released by the ASCR as long as no information identifying an individual patient, facility, or provider is released.

(4) Photocopying or other reproduction of any clinical records or reports in the possession of the ASCR containing identifying information, except as may be required in the conduct of the official business of the ASCR, is prohibited.

(5) Any legible documents other than the original incidence reports and abstracts, such as computer printouts or photocopies of any documents containing
identifying information, shall also be considered confidential material while in active use, and shall be destroyed by incineration or shredding immediately upon termination of their use by the ASCR.

(6) Original incidence reports, abstracts, and follow-up information submitted shall be retained by the ASCR according to currently accepted practice. All individuals with access to patient information shall be made aware of the privileged and confidential nature of all information submitted to the ASCR.

(7) Patient-specific data may be exchanged with any other cancer control agency or clinical facility for the purpose of obtaining information necessary to complete a case record. This data shall not be further disclosed by that agency or clinical facility.

(8) Follow-up information which is not available from the healthcare facility or provider may be obtained by the ASCR. The healthcare facility/provider may obtain follow-up information from the ASCR.

Statutory Authority: Code of Alabama, 1975, §22-13-1
Author: Reda Wilson

420-7-3-.06 Access to Information for Research Purposes

(1) The ASCR may release statistical data only to any person or agency for the following purposes:

(a) medical research or education;

(b) epidemiologic studies;

(c) health education;

(d) health planning or administration;

(e) required statistical reports necessary for publication of an annual report;

(f) publication of the ASCR annual report; and

(g) other statistical reports not previously produced and/or published by written request for research, information or education.
(2) A medical researcher may request the release of clinical records from the ASCR by the submission of a written research proposal to the registry containing the following information:

(a) purpose of the research;

(b) research design;

(c) proposed benefits to be derived from such research;

(d) a statement of compliance with all applicable state and federal requirements regarding the confidentiality of patient records;

(e) a completed application to the ADPH Institutional Review Board for release of confidential data; and

(f) If the research is to be credited toward a degree to the researcher, or if the research is being otherwise conducted by an institution of higher learning, the proposal shall contain a statement, signed by the dean of the school, or designee, declaring that the proposed research is in compliance with all applicable research standards of the institution.

(3) The clinical records or reports of the individual patient may be disclosed to research staff for the purpose of medical research, provided that the registry has determined that:

(a) disclosure of this information is deemed necessary to accomplish the purposes of the research;

(b) the research warrants the risk to the individual patient of the potential disclosure of their medical records;

(c) adequate safeguards to protect the clinical records or identifying information are established and maintained.

(4) For the purposes of these rules, research is defined as any systematic investigation designed to answer a defined scientific question that requires collection and analysis of data in order to develop or contribute to generalizable knowledge. A researcher is defined as the primary investigator or project director.

(5) The ASCR shall submit all research proposals to the ASCR Research Review Committee in determining whether to release information as provided in this Rule. The consideration of all research proposals shall conform to the established Department of Public Health research policy.

(6) Any copies of reports or records provided to the researcher remain under the ownership of the ASCR and shall be returned to the ASCR upon termination of the research to be destroyed.
Upon completion of the study, the researcher shall submit one copy of the completed research paper to the ASCR. The ASCR shall transmit the paper to the ASCR Research Review Committee for review, to be returned to the ASCR for file. If the committee deems the research to be of importance to the practicing physicians of the state, then the committee may recommend, with the concurrence of the researcher, the research agency or institution, that the abstract of the research paper be published.

Statutory Authority: Code of Alabama, 1975, §22-13-1
Author: Reda Wilson

420-7-3-.07 ASCR Research Review Committee

(1) This committee shall be composed of representatives from the Alabama Department of Public Health and members of the ASCR Advisory Council.

(2) The ASCR Research Review Committee shall evaluate all research proposals based upon the following criteria.

(a) The proposed research has social and scientific merit that is directed primarily toward improving the diagnosis, treatment, defining of risks, or prevention of cancer.

(b) All co-investigators are qualified to undertake the proposed research by means of specific academic training or demonstrable, related experience in epidemiologic, medical, biomedical, or statistical research.

(c) The hypotheses to be tested are explicit, and are determined to be researchable and feasible.

(d) The methods proposed for testing the hypothesis clearly define:

1. The population or cancers to be studied;

2. The type and amount of data to be collected;

3. The source of the data;

4. The procedures for collecting and maintaining the data;

5. The specific measurement techniques to be employed in analysis of data, including discussion of: major variables, statistical methods, and expected endpoints of the analysis.
(e) The results of this study will be interpreted so that the findings can be used or
generalized to other populations and provide a timely substantive, and important
contribution to the understanding of cancer diagnosis, treatment, or prevention.

(3) This committee retains the right to refuse the release of data and the right to deny
approval of submitted research proposals.

Statutory Authority: Code of Alabama, 1975, §22-13-1
Author: Reda Wilson
History: Filed November 17, 1995; effective December 22, 1995. Amended: Filed November

420-7-3-.08 Assistance and Consultation for Public Health Work

(1) The ASCR shall provide assistance and consultation for public health work.

(2) The ASCR shall provide consultation for any agency, facility or organization
actively engaged in the effort to reduce the incidence of cancer or benign
brain-related tumors, whether through direct service to or the education of cancer
or benign brain-related tumor patients and their families, the public, or the
medical professions in accordance with the provisions of these Rules and the
availability of staff time and resources.

(3) The ASCR may accept requests from students needing assistance with research
projects in accordance with the provisions of these Rules and the availability of
staff time and resources.

Statutory Authority: Code of Alabama, 1975, §22-13-1
Author: Reda Wilson
History: Filed November 17, 1995; effective December 22, 1995. Amended: Filed November