



<b>Policy Name: State Laws Affecting Human Subjects Research</b>			
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**I. POLICY**

**A. Introduction**

In addition to federal laws and regulations, human research activities conducted by MUSC investigators must comply with all laws in the state in which the research is being conducted. In general, when federal and state laws differ, the more restrictive law prevails.

**B. Consent of an Incompetent Person**

South Carolina is specific in addressing who may consent on behalf of an incompetent person. The IRB must approve the informed consent process and the person who will provide consent for research procedures.

**C. Disclosure of Genetic Test Results**

Disclosure of genetic testing results is covered by SC law and disclosure of test results requires written informed consent from the individual or his/her legal representatives. IRB informed consent templates provide suggested language for investigator’s guidance when preparing informed consent documents involving genetic testing.

**D. Possibility of Mandatory Reporting**

When research involves the possibility of mandatory reporting to a third party, regardless of the research subject’s consent, the participant must be informed of the information that may be disclosed.

**II. RELEVANT SECTION DETAIL**

**A. SECTION 15-1-320 – Age of Consent**

Minors in State laws mean persons under age of 18 years.

**B. SECTION 44-66-30 – Adult Health Care Consent**

1. Persons unable to consent:

Persons who are unable, whether temporarily or permanently, to make an informed consent, may have their health care decisions made by another within a legally prescribed priority listing, and with the patient's wishes and best interests (to the extent possible known and determined) as the basis for consent of health care decision-making.

The following is a summary of the priority listing for persons able to make health care decisions for those unable to consent (either to provide or withhold consent);

- a) Court appointed guardian;
- b) Attorney with durable power of attorney related to health care decisions;
- c) Individual authorized by another statute;
- d) Spouse – unless legally separated, with provisions;
- e) Parent or adult child;
- f) Adult sibling, grandparent, adult grandchild; and
- g) Other relative (by blood or marriage) believed by health care professional, to have close personal relationship.

2. Exceptions:

- a) Where persons of equal decision-making priority disagree, another authorized person may petition the court for further action including appointment of a new guardian;
- b) Where it is known that the persons as prescribed in the priority listing are not available, able or willing to decide on behalf of the patient; and
- c) Where there is actual knowledge that the persons as prescribed in the priority listing were not approved by the patient to act on their behalf.

**C. SECTION 38-93-30 (2006) Privacy of Genetic Information**

1. Confidentiality; disclosure restrictions and exceptions.

All genetic information must be confidential and must not be disclosed to a third party in a manner that allows identification of the individual tested without first obtaining the written informed consent of that individual or a person legally authorized to consent on behalf of the individual.

2. Genetic tests; informed consent required; exceptions.

It is unlawful to perform a genetic test on tissue, blood, urine, or other biological sample taken from an individual without first

obtaining specific informed consent to the test from the individual, or a person legally authorized to consent on behalf of the individual, unless the test is performed for use in a study in which the identities of the persons from whom the genetic information is obtained are not disclosed to the person conducting the study

3. Tissue from live donor

South Carolina law mandates that genetic information obtained from any tests or from this research be kept confidential. Results of the research will not be given to the individual or his/her doctor. To help protect the individual's privacy, these reports will not be put in his/her health record. South Carolina law prohibits any insurer using this information in a discriminatory manner against the individual or any member of his/her family in issuing or renewing insurance coverage for the individual or his/her family. South Carolina state law further prohibits sharing genetic information with anyone except in a few narrow circumstances, one of these being a research project of this type, approved by the Institutional Review Board and then all steps must be taken to protect the individual's identity.

4. Tissue from nonliving donor.

South Carolina law mandates that genetic information obtained from any tests or from this research be kept confidential. Results of the research will not be given to individual. To help protect privacy, these reports will not be put in the deceased's health record. South Carolina law prohibits any insurer using this information in a discriminatory manner against the individual or any member of his/her family in issuing or renewing insurance coverage for the individual or his/her family. South Carolina state law further prohibits sharing genetic information with anyone except in a few narrow circumstances, one of these being a research project of this type, approved by the Institutional Review Board and then all steps must be taken to protect the individual's identity.

### III. CONFLICT BETWEEN FEDERAL AND STATE STATUES

In areas of conflict between federal and state statutes, the more stringent statute will be prevail

### IV. REFERENCES

- A. [SECTION 15-1-320 – Age of Consent.](#)
- B. [SECTION 44-66-30 – Adult Healthcare Consent Act](#)
- C. [SECTION 38-93-30 \(2006\) Privacy of Genetic Information](#)