Policy
Department: HUMAN RESEARCH PROTECTIONS PROGRAM
Policy Number: X.J
Section: Conduct of Research
Review Responsibility: HRPP Policy and Procedure Committee
Original Creation Date: August 30, 2004;
Revision Dates: July 1, 2015

Subject: Applicable State Laws

Policy:
The following are State laws that may be relevant to research conducted at Vanderbilt University (VU) and Vanderbilt University Medical Center (VUMC).

I. Mandatory Reporting of Abuse. Any person who has knowledge of or is called upon to render aid to any child who is suffering from or has sustained any wound, injury, disability, or physical or mental condition is required to report the harm immediately by telephone to the:
A. Judge having juvenile jurisdiction over the child;
B. County office of the department;
C. Sheriff of the county where the child resides; or
D. Chief law enforcement official of the municipality where the child resides.
E. The report will include (to the extent known) the name, address, and age of the child, the name address of the person responsible for the care of the child, and the facts requiring the report.

II. Mandatory Reporting of Sexually Transmitted Disease. Every physician or other person who makes a diagnosis of, treats or prescribes for a case of sexually transmitted disease designated as reportable is required to report the case immediately to the Department of Health. Reports include the name, address, age, sex, race, stage of disease, treatment, and control of the disease.
A. Children 13 years of age or younger must be reported to the Department of Health.
B. Reporting is required for children where sexual abuse is suspected regardless of injury to the Department of Health and the Department of Health will notify the Department of Children’s Services.

III. Mandatory Reporting of Sepsis. Any participant requiring screening, diagnostic, or therapeutic services with respect to sepsis is required to report such to the Department of Health. The information includes:
A. The pathological or serological findings;
B. The state of the disease;
C. Other contributing factors to the disease;
D. The methods of treatment utilized;
E. Any previous incidence of sepsis in the participant;
F. If there is a specialist in critical care medicine on staff; and
G. The continuing education programs provided to the medical staff during the past year focused on sepsis.

IV. Mandatory Reporting of Cancer. All laboratories, hospitals, facilities and practitioners are required to report to the Department of Health within 6 months of diagnosis any cancer in an individual if making the initial diagnosis. The report includes the diagnosis, occupation, family history and personal habits of the person diagnosed with cancer.
V. Responsibilities of IRB Members.
A. IRB members are to be aware of the state law that may be relevant to the conduct of human subject research and to apply to the consideration of whether research meets the criteria for approval.
B. IRB members are to be aware of the state law that may be relevant to the conduct of human subjects research and to consider whether disclosure of the implications of the law is required for legally effective informed consent.

References:
TCA § 68-1-1003
TCA § 37-1-403
TCA § 68-10-101
TCA § 68-1-2101