



**FRIENDS RESEARCH INSTITUTE, INC.
INSTITUTIONAL REVIEW BOARD (IRB)**

**State of Maryland Requirements Pertaining to the
Review of Human Subjects Research**

A. Human Subjects Research Act

Maryland law incorporates the Federal Regulations governing human subjects research and expands their application to all research in Maryland, not only federally funded research. In addition, Maryland law provides access to the minutes of IRB meetings, with confidential or privileged information redacted; and grants power to the Attorney General to enforce the law. [Health-General §13-2001 to 2004]

B. Age of Consent

In Maryland, for purposes of consent to medical treatment, a minor is an individual under the age of 18 years. Parental permission must be sought for minor subjects to participate in research; exceptions to this must be granted by the IRB. The age of majority is 18 years. [General Provisions § 1-401]

A minor has the same capacity as an adult to consent to medical treatment if the minor is married, or is the parent of a child. [Health-General §20-102]

A minor has the same capacity as an adult to consent to medical treatment if, in the judgment of the attending physician, the life or health of the minor would be affected adversely by delaying treatment to obtain the consent of another individual. [Health-General §20-102]

A minor has the same capacity as an adult to consent to:

- (1) Treatment for or advice about drug abuse;
- (2) Treatment for or advice about alcoholism;
- (3) Treatment for or advice about venereal disease;
- (4) Treatment for or advice about pregnancy;
- (5) Treatment for or advice about contraception other than sterilization;
- (6) Physical examination and treatment of injuries from an alleged rape or sexual offense;
- (7) Physical examination to obtain evidence of an alleged rape or sexual offense; and
- (8) Initial medical screening and physical examination on and after admission of the minor into a detention center. [Health-General §20-102]

A minor who is 16 years old or older has the same capacity as an adult to consent to consultation, diagnosis, and treatment of a mental or emotional disorder by a physician, psychologist, or a clinic. [Health-General §20-104]

C. Who Can Give Informed Consent for Research

- (1) A competent adult;
- (2) The parent of a minor; or
- (3) A legal guardian for the individual, if one has been appointed

D. Reporting Suspected Neglect and Abuse of Children, Vulnerable Adults, and Others

Under Maryland law, a health practitioner, police officer, educator, or human service worker acting in a professional capacity in the State, who has reason to believe that a child has been subjected to abuse or neglect, is required to notify the local department or the appropriate law enforcement agency. [Family Law §5-704]

A health practitioner, police officer, educator, or human service worker who contacts, examines, attends, or treats an alleged vulnerable adult, and who has reason to believe that the alleged vulnerable adult has been subjected to abuse, neglect, self-neglect, or exploitation should notify the local department. [Family Law §14-302]

E. Reporting Infectious or Contagious Diseases

Under Maryland law, a physician with reason to suspect that a patient under the physician's care has an infectious or contagious disease that endangers public health and is designated as reportable is required to report this information to appropriate authorities. There is an exception for reporting of human immunodeficiency virus or acquired immunodeficiency syndrome. [Health-General §18-201]

F. Reporting Threats to Harm Oneself or Others

Under Maryland law, mental health care providers and administrators of facilities that provide treatment for mental disorders have a duty to report threats made to harm oneself or others, to appropriate officials. [Courts and Judicial Proceedings §5-609]

A cause of action or disciplinary action may not arise against any mental health care provider or administrator for failing to predict, warn of, or take precautions to provide protection from a patient's violent behavior unless the mental health care provider or administrator knew of the patient's propensity for violence and the patient indicated to the mental health care provider or administrator, by speech, conduct, or writing, of the patient's intention to inflict imminent physical injury upon a specified victim or group of victims.

To fulfill the duty to report the threats, the mental health care provider or administrator should make reasonable and timely efforts to:

- (1) Seek civil commitment of the patient;
- (2) Formulate a diagnostic impression and establish and undertake a documented treatment plan calculated to eliminate the possibility that the patient will carry out the threat; or
- (3) Inform the appropriate law enforcement agency and, if feasible, the specified victim or victims of:
 - a. The nature of the threat;
 - b. The identity of the patient making the threat; and
 - c. The identity of the specified victim or victims.

No cause of action or disciplinary action may arise under any patient confidentiality act against a medical health care provider or administrator for confidences disclosed or not disclosed in good faith to third parties in an effort to discharge the duty to report threats.

G. Confidentiality of Medical Records

In addition to other provisions regarding confidentiality of health care records under Maryland law, a health care provider may disclose a medical record without the authorization of a person in interest if the person given access to the medical record signs an acknowledgment of the duty not to re-disclose any patient identifying information, to a person for educational or research purposes, subject to the applicable requirements of an institutional review board. [Health-General §4-305(b) (2)]