

# HUMAN SUBJECTS RESEARCH AND FLORIDA LAWS

## CONSENT CONSIDERATIONS

### INFORMED CONSENT LAW LANGUAGE AND PROCESS REQUIREMENTS

Florida Law requires language that a reasonable individual, from the information provided by the practitioner under the circumstances, would have a general understanding of the procedure/treatments as well as the substantial risks and hazards inherent in the proposed procedure/treatment. See [Fla. Stat. § 766.103](#). The consent must be in writing and signed by the individual (or their authorized representative) that is mentally and physically competent to give consent.

Additionally, by statute, a patient has the right to know if medical treatment is for purposes of experimental research and to consent prior to participation in such experimental research. For any patient, regardless of ability to pay or source of payment for his or her care, participation must be a voluntary matter; and a patient has the right to refuse to participate. The patient's consent or refusal must be documented in the patient's care record. See [Fla. Stat. § 381.026\(4\)\(e\)](#).

Performing any procedure or prescribing any therapy which, by the prevailing standards of medical practice in the community, would constitute experimentation on a human subject, without first obtaining full, informed, and written consent may constitute grounds for denial of a license or disciplinary action. See [Fla. Stat. § 458.331](#).

### MINORS

#### **LEGAL AGE OF CONSENT**

The legal age of consent in Florida is 18 years of age. See [Fla. Stat. § 743.07](#). Otherwise, the individual is considered a minor (or child) unless they qualify as an emancipated minor. A legal guardian (including natural or adoptive parents who currently hold parental rights) must consent for the minor in Florida.

For minors enrolled in a study, consent must be sought immediately from the individual when they turn 18 or otherwise reach the age of majority through emancipation (as defined below). Failure to do so may result in disciplinary action, even if limited to on data analysis.

#### **EMANICIPATED MINORS**

Emancipation in Florida may either be complete emancipation, or emancipation for only limited purposes, as defined by state law.

- Complete Emancipation. Florida, a minor is considered emancipated for *all purposes*, and may consent to participation in research when:
  - A court order declares the minor to be emancipated.
    - The disability of nonage of a minor adjudicated as an adult and in the custody or under the supervision of the Department of Corrections is removed, as such disability relates to health care services, except in regard to medical services relating to abortion and sterilization. [Fla. Stat. § 743.066](#).

- A copy of the court order should be obtained and reviewed closely to ensure the court granted emancipation that includes the ability to consent to research.
  - The minor is married.
    - The disability of nonage of a minor who is married or has been married or subsequently becomes married, including one whose marriage is dissolved, or who is widowed, or widowed, is removed. The minor may assume the management of his or her estate, contract and be contracted with, sue and be sued, and perform all acts that he or she could do if not a minor. [Fla. Stat. § 743.01](#).
    - Proof of marriage (copy of the marriage license) should be obtained.
- Limited Emancipation. In limited and statutorily defined situations, a minor may consent on their own behalf or on behalf of their child, as follows:
  - Pregnant minors or minor parent of child. In some situations, an unwed minor may consent to medical or surgical care relating to her pregnancy, or her child. Such situations should be evaluated closely to ensure a specific study is compliant with state law consent requirements if it involves a pregnant minor or a child whose mother is a minor. Note that a minor may consent for their child, but not themselves if no they are not pregnant. See [Fla. Stat. §743.065](#) which provides:
    - An unwed pregnant minor may consent to the performance of medical or surgical care or services relating to her pregnancy by a hospital or clinic or by a physician licensed under chapter 458 or chapter 459, and such consent is valid and binding as if she had achieved her majority.
    - An unwed minor mother may consent to the performance of medical or surgical care or services for her child by a hospital or clinic or by a physician licensed under chapter 458 or chapter 459, and such consent is valid and binding as if she had achieved her majority.
    - Nothing in this act shall affect the provisions of s. 390.0111.
  - Other limited areas where minors may consent. Florida law also provides minors with limited authority to consent to their own medical treatment if the treatment is specific to STDs or substance abuse treatment. These areas have specific requirements and parameters for the minor to be able to consent, and Florida law should be carefully considered with respect to such studies to ensure such requirements are met if consent is sought from the minor.
    - Substance abuse treatment: See [Fla. Stat §397.501](#).
    - Sexually transmitted diseases: Any minor may consent to examination for and treatment of sexually transmissible diseases. See [Fla. Stat. § 384.30](#).

## **FOSTER CHILDREN**

In Florida, a foster parent generally does not have the authority to consent to research for foster children in their care. In the cases where parental rights have not been terminated, the biological parent or legal guardian, as applicable, would need to consent. Otherwise, a court order should be obtained. In some cases, the Department of Children and Families may consent to medical treatment only to the extent of the time necessary to obtain a court order. Additionally, in cases where a parent or legal guardian refuses to consent to necessary treatment, a court order may be obtained.

See [Fla. Stat. § 39.407](#).

## **PREGNANCY TESTING FOR RESEARCH**

As noted above, an unmarried, pregnant minor may consent to medical and surgical care related to her pregnancy by a hospital, clinic, or physician. She cannot, however, consent to medical treatment for herself that is not related to her pregnancy. [Fla. Stat. §743.065](#). Additionally, the Florida Constitution and case law supports that minors have a right to consent to pregnancy testing without the consent of her parents. In such cases, the minor would also have to consent to disclosure of the pregnancy test information.

## **TREATMENT OF INDIVIDUALS WITH DEVELOPMENTAL DISABILITIES**

Prior to instituting a plan of experimental medical treatment or carrying out any necessary surgical procedure, express and informed consent shall be obtained from the individual, if competent, or the individual's parent or legal guardian. Information upon which the individual shall make necessary treatment and surgery decisions shall include, but not be limited to:

- The nature and consequences of such procedures.
- The risks, benefits, and purposes of such procedures.
- Alternate procedures available.

See [Fla. Stat. § 393.13\(6\)](#).

## **CONSENT FOR INDIVIDUALS DETERMINED/ADJUDICATED INCAPACITATED (LEGAL GUARDIANSHIP)**

In cases wherein a formal guardianship has been established through the court system, court approval is required for participation in a research study. Specifically,

- Without specific authority of the court, a guardian may not consent on behalf of the ward to the performance on the ward of any experimental biomedical or behavioral procedure or to the participation by the ward in any biomedical or behavioral experiment. The court may permit such performance or participation only if:
  1. It is of direct benefit to, and is intended to preserve the life of or prevent serious impairment to the mental or physical health of the ward; or
  2. It is intended to assist the ward to develop or regain his or her abilities.

See [Fla. Stat. § 744.3215](#)

## **CONSENT FOR INCAPACITATED OR DEVELOPMENTALLY DISABLED ADULTS**

### **DETERMINING CAPACITY**

Florida Law presumes that an individual (adult) has appropriate capacity to consent to medical treatment for themselves unless it is affirmatively determined that they are incapacitated. Incapacity may not be inferred from the individual's voluntary or involuntary hospitalization for mental illness or from her or his intellectual disability. Prior to initiating the proxy process for consent purposes, two physicians must find (and document) that the individual lacks capacity. Specifically, if an individual's capacity to make health care decisions or provide informed consent is in question, the primary or attending physician must evaluate the individual's capacity and, if the evaluating physician concludes that the individual lacks capacity, enter that evaluation in the medical record. If the evaluating physician has a question as to whether the individual lacks capacity, another physician shall also evaluate the individual's capacity, and if the second physician agrees, the health care facility must enter both physician's evaluations in the individual's medical record.

See [Fla. Stat. § 765.204](#).

### **WHO MAY CONSENT/CONSENT BY PROXY**

If the individual has designated a health care surrogate or has delegated authority to make health care decisions to an attorney in fact under a durable power of attorney, the health care facility must notify such surrogate or attorney in fact in writing that her or his authority under the instrument has commenced, as provided in chapter 709 or s. [765.203](#).

If an incapacitated or developmentally disabled individual has not executed an advance directive, or designated a surrogate to execute an advance directive, or the designated or alternate surrogate is no longer available to make health care decisions, health care decisions may be made for the individual by any of the following individuals (proxies), in the following order of priority, if no individual in a prior class is reasonably available, willing, or competent to act:

- The judicially appointed guardian of the individual or the guardian advocate of the person having a developmental disability as defined in s. 393.063, who has been authorized to consent to medical treatment, if such guardian has previously been appointed; however, there is no requirement that such appointment be made before a treatment decision can be made;
- The individual's spouse;
- An adult child of the individual, or if the individual has more than one adult child, a majority of the adult children who are reasonably available for consultation;
- A parent of the individual;
- The adult sibling of the individual or, if the individual has more than one sibling, a majority of the adult siblings who are reasonably available for consultation;
- An adult relative of the individual who has exhibited special care and concern for the individual and who has maintained regular contact with the individual

and who is familiar with the individual's activities, health, and religious or moral beliefs; or

- A close friend of the individual.

All decisions by a proxy must be based on the proxy's informed consent and on the decision the proxy reasonably believes the individual would have made under the circumstances. If there is no prior indication of the individual's wishes, the proxy may consider the best interest of the individual. The process for determining the appropriate proxy should be clearly documented, including the efforts to identify each proceeding category of proxy.

See [Fla. Stat. § 765.401](#)

## **PRIVACY & CONFIDENTIALITY**

### **FLORIDA INFORMATION PROTECTION ACT**

The Florida Information Protection Act (“FIPA”) applies to “Personal Information” in electronic form and must be considered in addition to HIPAA with respect to any Personal Information in the research context. Personal Information includes an individual's first name or first initial and last name in combination with any one or more of the following data elements:

- (I) A social security number;
- (II) A driver license or identification card number, passport number, military identification number, or other similar number issued on a government document used to verify identity;
- (III) A financial account number or credit or debit card number, in combination with any required security code, access code, or password that is necessary to permit access to an individual's financial account;
- (IV) Any information regarding an individual's medical history, mental or physical condition, or medical treatment or diagnosis by a health care professional; or
- (V) An individual's health insurance policy number or subscriber identification number and any unique identifier used by a health insurer to identify the individual.

Personal Information also includes a user name or e-mail address, in combination with a password or security question and answer that would permit access to an online account. Additionally Covered Entities and their Third Party Agents must take reasonable measures to protect and secure data in electronic form containing Personal Information.

See [Fla. Stat. § 501.171](#).

### **HIV TESTING**

Florida Law extends additional protection to HIV testing and results, and the identity of people receiving such testing. Informed consent is required for HIV testing and disclosure of testing and results to third parties is only permitted as specified by the statute.

See [Fla. Stat. § 381.004](#).

### **SUBSTANCE ABUSE TREATMENT**

Florida law includes specific confidentiality requirements that need to be considered together with Federal law when substance abuse treatment information is involved. Additionally, specific consent to disclosure rules must be followed as defined by state law, including when a minor is involved as they may hold ultimate decision making with respect to both the treatment and disclosure of substance abuse information. See [Fla. Stat. § 397.501](#).

### **SEXUALLY TRANSMITTED DISEASES**

Information and records related to sexually transmitted diseases carry specific confidentiality requirements. Additionally, the fact of consultation, examination, and treatment of a minor for a sexually

transmissible disease is confidential and shall not be divulged in any direct or indirect manner, such as sending a bill for services rendered to a parent or guardian, unless specifically authorized by statute.

See [Fla. Stat. § 384.30](#).

## **MANDATORY REPORTING OBLIGATIONS**

### **CHILD ABUSE**

Any person who knows, or has reasonable cause to suspect, that a child is abused, abandoned, or neglected by a parent, legal custodian, caregiver, or other person responsible for the child's welfare, or that a child is in need of supervision and care and has no parent, legal custodian, or responsible adult relative immediately known and available to provide supervision and care shall report such knowledge or suspicion to the Department of Children and Families.

Any person who knows, or who has reasonable cause to suspect, that a child is abused by an adult other than a parent, legal custodian, caregiver, or other person responsible for the child's welfare shall report such knowledge or suspicion to the Department of Children and Families.

Any person who knows, or has reasonable cause to suspect, that a child is the victim of childhood sexual abuse or the victim of a known or suspected juvenile sexual offender shall report such knowledge or suspicion to the Department of Children and Families.

Reporters in the following occupation categories are required to provide their names to the hotline staff:

1. Physician, osteopathic physician, medical examiner, chiropractic physician, nurse, or hospital personnel engaged in the admission, examination, care, or treatment of persons;
2. Health or mental health professional other than one listed in subparagraph 1.;
3. Practitioner who relies solely on spiritual means for healing;
4. School teacher or other school official or personnel;
5. Social worker, day care center worker, or other professional child care, foster care, residential, or institutional worker;
6. Law enforcement officer; or
7. Judge.

All cases of known or suspected child abuse, abandonment will be made to the Florida Department of Children and Families central abuse hotline at 1-800-962-2873 or online at <https://reportabuse.dcf.state.fl.us/>. Reports involving juvenile sexual abuse or a child who has exhibited inappropriate sexual behavior will also be made to the central abuse hotline.

If the report is of an instance of known or suspected child abuse involving impregnation of a child under 16 years of age by a person 21 years of age, and the report is being made solely under § 827.04, Florida Statutes, then the report will be made immediately to the appropriate county sheriff's office or other appropriate law enforcement agency unless health care professionals are providing medical or counseling services to pregnant children when such reporting would interfere with the provision of medical services.

See [Fla. Stat. § 39.201](#).

### **VULNERABLE ADULTS**

"Vulnerable adult" means a person 18 years of age or older whose ability to perform the normal activities of daily living or to provide for his or her own care or protection is impaired due to a mental, emotional, sensory, long-term physical, or developmental disability or dysfunction, or brain damage, or the infirmities of aging.



Any person, including, but not limited to, any:

1. Physician, osteopathic physician, medical examiner, chiropractic physician, nurse, paramedic, emergency medical technician, or hospital personnel engaged in the admission, examination, care, or treatment of vulnerable adults;
2. Health professional or mental health professional other than one listed in subparagraph 1.;
3. Practitioner who relies solely on spiritual means for healing;
4. Nursing home staff; assisted living facility staff; adult day care center staff; adult family-care home staff; social worker; or other professional adult care, residential, or institutional staff;
5. State, county, or municipal criminal justice employee or law enforcement officer;
6. Employee of the Department of Business and Professional Regulation conducting inspections of public lodging establishments under s. [509.032](#);
7. Florida advocacy council or Disability Rights Florida member or a representative of the State Long-Term Care Ombudsman Program; or
8. Bank, savings and loan, or credit union officer, trustee, or employee, who knows, or has reasonable cause to suspect, that a vulnerable adult has been or is being abused, neglected, or exploited shall immediately report such knowledge or suspicion to the central abuse hotline.

To the extent possible, a report made pursuant to paragraph (a) must contain, but need not be limited to, the following information:

1. Name, age, race, sex, physical description, and location of each victim alleged to have been abused, neglected, or exploited.
2. Names, addresses, and telephone numbers of the victim's family members.
3. Name, address, and telephone number of each alleged perpetrator.
4. Name, address, and telephone number of the caregiver of the victim, if different from the alleged perpetrator.
5. Name, address, and telephone number of the person reporting the alleged abuse, neglect, or exploitation.
6. Description of the physical or psychological injuries sustained.
7. Actions taken by the reporter, if any, such as notification of the criminal justice agency.
8. Any other information available to the reporting person which may establish the cause of abuse, neglect, or exploitation that occurred or is occurring.

All cases of suspected abuse, neglect or exploitation of vulnerable adults will be made to the Florida Department of Children and Families central abuse hotline at 1-800-962-2873 or online at <https://reportabuse.dcf.state.fl.us/>.

See [Fla. Stat. § 415.1034](#).

#### **DIAGNOSIS AND TREATMENT OF STDS**

Each person who makes a diagnosis of or treats a person with a sexually transmissible disease and each laboratory that performs a test that concludes with a positive result for a sexually transmissible disease or a result indicative of human immunodeficiency virus (HIV) or acquired immune deficiency syndrome (AIDS) shall report such facts as may be required by the department by rule, within a time period as specified by rule of the department, but in no case to exceed 2 weeks.

See Fla. Stat. [§ 384.25](#).

## **OTHER CONSIDERATIONS**

### **GENETIC TESTING**

DNA analysis may be performed only with the informed consent of the person to be tested, and the results of such DNA analysis, whether held by a public or private entity, are the exclusive property of the person tested, are confidential, and may not be disclosed without the consent of the person tested. A person who performs DNA analysis or receives records, results, or findings of DNA analysis must provide the person tested with notice that the analysis was performed or that the information was received. The notice must state that, upon the request of the person tested, the information will be made available to his or her physician. The notice must also state whether the information was used in any decision to grant or deny any insurance, employment, mortgage, loan, credit, or educational opportunity. If the information was used in any decision that resulted in a denial, the analysis must be repeated to verify the accuracy of the first analysis, and if the first analysis is found to be inaccurate, the denial must be reviewed. Failure to comply with this law constitutes a first degree misdemeanor.

See [Fla. Stat. § 760.40](#).

### **FETAL RESEARCH**

No person shall use any live fetus or live, premature infant for any type of scientific, research, laboratory, or other kind of experimentation either prior to or subsequent to any termination of pregnancy procedure except as necessary to protect or preserve the life and health of such fetus or premature infant.

See [Fla. Stat. § 390.0111](#).

### **ILLEGAL LOTTERY**

The State of Florida has strict laws regarding what constitutes an illegal lottery. The use of a lottery or prize drawing as a form of compensation or method of encouraging participation in research would be a violation of these laws.