**Florida (State) Law and Human Subjects Research:**

There are State of Florida laws that intersect with the federal regulations governing the protections of human subjects, that researchers working with human subject need to be aware of, depending on the nature of the researcher’s proposed research.

**Legal Age of Consent** - In Florida, the legal age of consent is 18 years of age. All under the age of 18 are considered children or minors. Note the following exceptions:

- **Emancipated Minors** - In Florida, the following categories of children are legally authorized to consent to participation in research on their own behalf:
  
  - Children who have had the "disability of nonage" (e.g. considered a child) removed by a circuit court. (See Chapter 743, Florida Statutes).
  - Children who are married or have been married may consent to medical care and treatment, including participation in experimental procedures.
  - An unwed pregnant child may consent to the performance of medical or surgical care of services relating to her pregnancy by a hospital or clinic or by a licensed physician. This category includes research relating to her pregnancy.

Except for emancipated minors, FSU’s IRB will not approve the enrollment in research of persons under the age of 18 without parental permission unless the investigator can demonstrate that enrollment is permissible under and consistent with Florida law and meets the requirements set forth in 45 CFR 46, Subpart D and 21 CFR 50 Subpart D.

**Genetic Testing** - State law (Section 760.40) provides that informed consent must always be obtained prior to DNA testing and notice given whenever the results are received.

**Diagnosis and/or treatment of STDs (including HIV and AIDS)** - State law (Section 384.25, F.S.) requires that practitioners report evidence of sexually transmitted diseases, including HIV and AIDS, to the county health department.

**HIV Testing** - State law (Section 381.004) governs informed consent requirements for HIV testing and disclosure of HIV testing and results to third parties.

**Treatment of persons who are developmentally disabled** - State law (Section 393.13(6)) provides certain rights to individuals who are developmentally disabled. Prior to instituting a plan of experimental medical treatment, express and informed consent shall be obtained from a developmentally disabled individual, if competent, or the individual's parent or legal guardian.
Rights of persons determined to be incapacitated - State law (Section 744.3215) provides that persons determined to be incapacitated retain protected rights; however, a guardian may consent on behalf of a ward to the performance on the ward of any experimental biomedical or behavioral procedures or to the participation by the ward in any biomedical or behavioral experiment.

Foster Children - Children in foster care may not have had parental rights legally severed. Thus, while State law is clear regarding consent for medical treatment, it is silent regarding consent for biomedical or behavioral research. The Department of Health has informally opined that it will not approve research involving foster children without parental permission, unless the parental rights have been severed. Any researchers considering research with this vulnerable population should consult with the Florida Department of Health for more specific guidance.

When the Subject Cannot Consent (incapacitated/incompetent adults) - Florida recognizes that the following individuals (in order presented) may consent to the enrollment of an individual in medical research that has been approved by an IRB:

- Surrogate (competent adult expressly designated by the patient/individual to make health care decisions on behalf of the patient). Designation should be in writing.
- Court Appointed Guardian (in the absence of a Surrogate, or where a court revokes the authority of the Surrogate). All persons who have been adjudged incompetent should have a judicially appointed guardian.
- A person holding a valid power of attorney (durable POA) which contains language giving the right to make health care decisions from a patient:
- A proxy (in the event the patient is incompetent or incapacitated) Pursuant to Section 765.401 a proxy may consent (where the patient has not executed an advance directive, or designated a Surrogate to make heath care decisions) to experimental treatment, provided, the experimental treatment has been approved by and IRB, and the proxy reasonably believes that the patient would have made the decision under the circumstances.

What is a proxy? A substitute, competent decision maker in the following order of priority:

- Patient's spouse
- An adult child, or if the patient has more than 1 child, a majority of the adult children reasonably available for consultation
- A parent of the patient
- The adult sibling of the patient (if more than 1, then a majority of such adult siblings)
- An adult relative of the patient who has exhibited special care and concern for the patient and maintained regular contact with the patient
- A close friend of the patient
- A clinical social worker

**Researchers working with confidential governmental records:** Please be advised that there are Florida Statutes that mandate that certain records be kept confidential and exempt from Chapter 119, Public Records Law, such as reports of abuse, neglect, or exploitation of a vulnerable adult. However, for example, in Section 415.107, F.S. there is an exemption for any person engaged in bona fide research or auditing; however, information identifying the subjects of the report must not be made available to the researcher.

It is very important to determine with a governmental agency whether certain information that the researcher is seeking is confidential by law, and whether there are any exemptions or exceptions that would permit the researcher to lawfully access the information, the manner of de-identification, and any other requirements that the governmental agency must comply with in order for the researcher to lawfully access and utilize confidential information or data.

**Note:** that many records maintained by the Florida Department of Health, or Department of Children and Families are confidential and exempt from Chapter 119. Some of those confidentiality clauses contain specific research exemptions, but it is key that the researcher determine the agency requirements, whether confidentiality agreements or data use agreements must be in place, and any other requirements that the Florida Department of Health may impose prior to releasing any information for bona fide research use.

**Educational/School records**- Section 1002.22, Florida Statutes protects the rights of students and their parents in respect to student records and reports as created, maintained, and used by public educational institutions in the state. In general, student records are confidential and may not be released without parental consent. However, once a child reaches the age of 18, or is attending a postsecondary educational institution, the permission or consent of the parent is accorded to the student. This right to privacy with respect to educational records is protected by Chapter 119.07(1).

Any personally identifiable information is confidential and exempt from the Public Records Laws of Chapter 119, Florida Statutes. However, the information may be released without the consent of the student or the student’s parent in certain circumstances, such as individuals or organizations conducting studies for or on behalf of an institution or a board of education for the purpose of developing, validating, or administering predictive tests, administering student aid programs, or improving instruction, if such studies are conducted in such a manner as will not permit the personal identification of the students and their parents by persons other than representatives of such organizations and if such information will be destroyed when no longer
needed for the purpose of conducting such studies. See Section 1002.(3)(d), F.S. for more detail and other exceptions.

**Fetal research restriction** - Section 390.0111(6), Florida Statutes provides that no personal 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 procedures except as necessary to protect or preserve the life and health of such fetus or premature infant.

**Experimental Research** - Section 381.026(4)(e), Florida Statutes provides that 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. The 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 records.