Florida Laws 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 subjects need to be aware of, depending on the nature of the researcher's proposed research. The information below is offered for informal guidance purposes only, and should not be considered as legal advice on a particular matter or as an exhaustive list of laws which may be applicable to any particular research project.

CHILDREN/MINORS AS SUBJECTS

In Florida, generally anyone who: (1) is under the age of 18; (2) is unmarried and has not been married (F.S. 743.01); and (3) has not been emancipated (i.e., had the "disability of nonage" removed) by order of the court is a minor. (F.S. 743.015). Except for emancipated minors, FIU's IRB will not approve the enrollment in research of persons under the age of 18 without parental or guardian permission, unless the investigator can demonstrate that enrollment is permissible consistent with Florida law and meets the requirements set forth in 45 CFR 46, Subpart D, and 21 CFR 50, Subpart D.

In Florida, the following categories of children are legally authorized to consent to participation in research on their own behalf:

- Persons who are 16 or older and who have had the "disability of nonage" removed by a circuit court. (743.015, Florida Statutes)
- Children who are married or have been married may consent to medical care and treatment, including participation in experimental procedures (743.01, Florida Statutes)
- An unwed, pregnant minor may consent to the performance of medical or surgical care of services relating to her pregnancy by a hospital, clinic, or a licensed physician. (743.065, Florida Statutes) This category includes research relating to her pregnancy.

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.

CONFIDENTIALITY

Florida Public Records Law - There are Florida Statutes that mandate that certain records be kept confidential and exempt from production pursuant to Chapter 119, Florida Statutes, the Florida Public Records Law, such as reports of abuse, neglect, or exploitation of a vulnerable

adult. Should a public records request be received by the University, any confidential records may not be produced.

Medical Records - Section 456.057(7)(a)4, Florida Statutes, provides that records may be furnished for statistical and scientific research, provided the information is abstracted in such a way as to protect the identity of the patient or provided written permission is received from the patient or the patient's legal representative.

Educational/School Records – Section 1002.22, Florida Statutes, states, in part, that the "rights of students and their parents with respect to education records created, maintained, or used by public educational institutions and agencies shall be protected in accordance with the Family Educational Rights and Privacy Act (FERPA)." 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 post-secondary 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 research which seeks to access FIU students' educational records must be approved as required by FIU BOT Regulation 108(9) at http://regulations.fiu.edu/regulation which provides:

> **9. Requests for Education Records in Research or Contracts.**
> a. All requests for academic research or contracts dealing with information from Education Records shall be referred to the University Registrar. Such requests must be in writing and specifically set forth the type(s) of information to which access is requested and the intended scope of the research project or contract.
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> b. The applicable Custodian of Records and the University Registrar shall determine whether to grant the request, in whole or in part, and may condition access upon a guarantee that the researcher or agent will appropriately safeguard the data, no Personally Identifiable Information is published or made available to others, or other reasonable conditions.

See the Educational Records and FERPA web page for further information on the requirements.

MANDATED REPORTING

Some study activities may result in researchers becoming aware of abuse or neglect of human subjects; this awareness may result during or from interactions or interventions with human subjects, or from disclosure by study subjects. Where abuse or neglect reporting is mandated by law or professional standards, the incident must be reported to the appropriate authorities. In Florida, FIU researchers may be considered mandatory reporters, and must follow applicable law for reporting abuse or neglect. See FIU Policy #140.130, Mandatory Reporting of Child Abuse, Abandonment and Neglect on the FIU Policies and Procedures Library for reporting obligations and how to report.

PARTICIPANT COMPENSATION

Use of Lotteries, Raffles or Drawings as Compensation – State law (Section 849.09) provides that it is illegal for a person to "[s]et up, promote, or conduct any lottery for money or for anything of value, [or to] assist in the setting up, promoting or conducting a lottery" or to "[a]id or assist in the setting up, promoting, or conducting of any lottery or lottery drawing." See Lotteries, Raffles, or Drawings for Participants for further information.

PREGNANCY OR FETAL RESEARCH

Pregnant Minor Subjects – Section 734.065, Florida Statutes, provides that pregnant minors do not need parental permission to participate in research related to the pregnancy or the fetus. Similarly, minors who are mothers do not need parental permission to participate in research related to their child.

Fetal Research Restrictions – 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.

TESTING OR TREATMENT

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.

Pregnancy Testing – State law (Article I, Section 23 of the Florida Constitution) provides a right to privacy. A minor has a right to privacy as it relates to whether she is pregnant or not, and thus a researcher can only tell the parent if the minor consents to that disclosure.

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

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.

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.

Experimental Treatment 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.