HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 1571 Consent to Experimental Research
SPONSOR(S): Zapata
TIED BILLS: None. **IDEN./SIM. BILLS:** SB 2332 (s)

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR
1) Health Services (Sub)		Bench	Collins
2) Health Care			
3) Judiciary			
4)			
5)			

SUMMARY ANALYSIS

The doctrine of informed consent requires that a physician inform a patient or research subjects of the benefits, risks, and alternatives to medical treatment or experimental procedures before such treatment is administered. Without the patient's informed consent, both the physician and the institution may be liable under both state and federal law.[1] However, 45 C.F.R. part 46 and 21 C.F.R. part 56 create informed, written consent exceptions for experimental research when approved by federal institutional review boards. Florida laws have no such exception.

HB 1571 provides a waiver for informed consent of human subjects in experimental research when a federally-approved institutional review board has approved the research project. It also creates an exception to disciplinary actions for certain experimentation without consent for certain federally-approved research. Finally, this bill allows unwed, pregnant minors to give informed consent to participate in experimental research. It allows these unwed pregnant minor mothers to give consent for their children to participate in experimental research as well.

Currently, research institutions conduct experimental studies in time sensitive situations, such as the emergency room. The intent of this bill is to allow researchers, after receiving federal approval, the ability to conduct research in emergency room settings when there is not sufficient time to receive informed consent. The bill also grants an unwed minor mother the right to give consent for her child to participate in experimental research, when currently this right does not extend to anyone.

Federal law currently allows these waivers under particular circumstances as determined by an Institutional Review Board (IRB). The Food and Drug Administration (FDA) regulations grant exceptions in some research situations. Under the regulations, an exception may be granted if the IRB finds that four requirements are met.[2]

This bill aligns the state statutes with the federal statutes in respect to experimental research on human subjects.

HB 1571 takes effect upon becoming law.

FULL ANALYSIS

[1] Kathryn A. Tuthill, *Human Experimentation*, 18 J. Legal Med. 221 (June 1997).
[2] Protection of Human Subjects, 21 C.F.R. § 50.23 (1996); Tuthill, *supra*, at 242.

I. SUBSTANTIVE ANALYSIS

A. DOES THE BILL:

1. Reduce government?	Yes[]	No[]	N/A[X]
2. Lower taxes?	Yes[]	No[]	N/A[X]
3. Expand individual freedom?	Yes[X]	No[X]	N/A[]
4. Increase personal responsibility?	Yes[]	No[]	N/A[X]
5. Empower families?	Yes[]	No[]	N/A[X]

For any principle that received a "no" above, please explain:

This bill allows researchers to experiment with patients under strict federal guidelines without the patient's consent. However, it does expand the individual freedom of unwed, pregnant minors by allowing them the right to consent to participate in experimental research and the right to consent to their child's participation.

B. EFFECT OF PROPOSED CHANGES:

PRESENT SITUATION

Currently, research institutions conduct studies on the performance of medicines and medical treatments in time sensitive situations. The intent of this bill is to allow researchers, after receiving federal approval, the ability to conduct research in emergency room settings when there is not sufficient time to receive informed consent. The bill also grants an unwed minor mother the right to give consent for her child to participate in experimental research, when currently this right does not extend to anyone.

The Department of Health (DOH) maintains an Institutional Review Board that approves all research involving patients that use DOH resources. The DOH maintains a Federal Wide Assurance and complies with 45 C.F.R. part 46, 21 C.F.R. parts 56 and 50 as applicable. According to DOH, the exceptions provided by this bill are currently observed. DOH currently complies with all federal regulations involving exceptions; therefore, there is no impact on DOH.

Federal Law

Federal regulations provide greater protection to experimental subjects than is normally afforded patients receiving medical treatment. Federal law requires that informed consent to experimentation be documented in writing.[3] Also, if medical treatment is experimental, then all reasonably foreseeable risks must be disclosed to the patient. In addition, an experimental procedure must first be approved by an Institutional Review Board (IRB). After the IRB has determined that risks to subjects are reasonable and that informed consent will be obtained, approval can be given.[4] The U.S. Department of Health and Human Services, through the Office of Human Subject Research monitors this process.

A. Institutional Review Boards

Institutional Review Boards (IRB) exists in institutions where human subject research is performed. IRBs review, evaluate, and approve or disapprove investigations that include human research subjects. This responsibility is filled in several ways. First, the IRB ensures that risks to subjects are minimized by scrutinizing research procedures. Second, the IRB reviews both the informed consent document and the procedures for obtaining consent. Third, the criterion for subject selection is assessed to guard

[3] 21 C.F.R. § 50.25(2) (1996); 45 C.F.R. § 46.117 (1996).
[4] Tuthill, *supra*, at 231-232.

against exploitation of vulnerable subjects. "Vulnerable subjects" are defined to encompass: (1) minors; (2) prisoners; and (3) mentally disabled patients. Fourth, the IRB determines whether the potential risks to subjects are reasonable when compared to the anticipated benefits. Finally, the IRB reviews mechanisms for maintaining confidentiality of records.[5]

The initial proposal for research sets forth the design of the project. It includes the study's objectives and necessary background information, criteria eligibility for the subject population, the course of treatment the subjects will receive, and the data to be collected. The principal investigator, the person who wishes to perform the research, would submit the proposal to the IRB for its review and approval. A proposal consent form often accompanies this proposal. After evaluating each individual proposal, the IRB will approve, disapprove, or approve contingent on certain modifications.[6]

The IRB membership must comprise of at least five members whose backgrounds provide expertise and diversity. All the members may not share the same profession and there must be at least one member who is not affiliated with the institution and at least one non-scientist member.[7]

General criteria for IRB approval of research include the following:

1. The risks are minimal;
2. The risk-benefit balance is reasonable;
3. The selection of subjects is equitable;
4. Informed consent will be sought and documented;
5. Subjects' safety and privacy are adequately protected; and
6. The rights and welfare of particularly vulnerable subjects are respected. Research approved by the IRB can be subjected to additional review by the institution, but the institution may not approve research that has been disapproved by the IRB.[8]

The research subject's interests may be the least protected by the IRBs. The subject is the most vulnerable of the three parties protected (physician investigators, the institution, and research subjects) because the subject's well-being is directly and foreseeably affected by the research. The subjects may also be unrepresented on the IRB. Although, an IRB that regularly reviews proposals involving vulnerable subjects, such as minors, must have a member who represents that subject's interest participate in the IRB.[9]

B. Exceptions to Informed Consent by Research Subjects

Under current federal regulations, the IRB may waive the informed consent requirements if:

1. The research or demonstration project is to be conducted by state or local government officials and is designed to study, evaluate or otherwise examine public benefit or service programs;
2. The research could not practicably be carried out without waiver or alteration;
3. The IRB finds and documents that the research involves no more than minimal risks to the subjects;
4. The waiver or alteration will not adversely affect the rights and welfare of the subjects;
5. The research would not be practicably carried out without the waiver or alteration; and
6. Whenever appropriate, the subjects will be provided with additional pertinent information after participation.[10]

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[5] *Id*. at 232.
[6] 21 C.F.R. § 56.109(a) (1996); 45 C.F.R. § 46.109(a) (1996).
[7] 21 C.F.R. § 56.107(c), (d) (1996); 45 C.F.R. § 46.107(c), (d) (1996).
[8] 21 C.F.R. § 56.111, 56.112 (1996); 45 C.F.R. § 46.111, 46.112 (1996).
[9] 21 C.F.R. § 56.107(a) (1996); 45 C.F.R. § 46.107(a) (1996).
[10] 45 C.F.R. § 46.116(c)-(f) (1996).

The informed consent policy is not intended to preempt any applicable federal, state, or local laws that require disclosure of additional information before obtaining legally effective informed consent. The policy does not intend to limit the authority of a physician to provide emergency medical care that is permitted under applicable federal, state, or local law.[11]

C. Emergency Room Experimental Treatment

The FDA regulations grant exceptions in some research situations. The provision in the regulations that grants an exception has been applied in emergency room situations. Generally, an emergency situation is the most difficult time to obtain informed consent from a patient. In such a situation, the patient is likely to be unconscious and in a life-threatening situation. The patient's family may be unavailable to give consent for the patient. Physicians argue that emergency room treatment cannot be improved unless physicians are allowed to conduct research on patients who actually are in emergency, life-threatening situations. These are the patients the research is intended to benefit.

In response to these concerns, the FDA, on October 2, 1996, amended its informed consent regulations to allow physicians to test experimental drugs and devices on emergency room patients who are unable, because of a life-threatening condition, to give informed consent.[12]

Under the regulations, an exception may be granted if the IRB and a disinterested physician find that four requirements are met.[13]

1. The patient must be in a life-threatening situation, available treatment must be unproven or unsatisfactory, and research must be necessary to determine the safety and effectiveness of particular treatments;[14]
2. Obtaining the informed consent must be impracticable. Impracticability must result either from the patient's inability to give consent, because of a medical condition, or the need to administer treatment before a patient's legal representative may be notified;[15]
3. The risks related to the research must be reasonable to what is known about the medical condition of the potential class of subjects, the risks and benefits of standard therapy, if any, and what is known about the risks and benefits of the proposed intervention or activity;[16] and
4. The research cannot practicably be carried out without a waiver.

In addition, public disclosure of an investigation of a study proposal must be made to the community in which the research will be conducted. This may occur in a public forum setting. This disclosure must be made prior to commencement of the study and must include risks and expected benefits. Upon completion of the study, public disclosure of the results must be made.[17]

Florida Law

The Florida Patient's Bill of Rights and Responsibilities, s. 381.026, F.S., stipulates that a patient has the right to know if medical treatment is for purposes of experimental research and to consent prior to participation in this research. There is no waiver to this prior, informed, written consent right. It requires voluntary participation and the patient's consent or refusal must be accurately documented in the patient's record.

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[11] *Id.*
[12] 21 C.F.R. § 50, 56, 312, 314, 601, 812, & 814).
[13] Protection of Human Subjects, 21 C.F.R. § 50.23 (1996); Tuthill, *supra*, at 242.
[14] 21 C.F.R. § 50.24(a)(1).
[15] 21 C.F.R. § 50.24(a)(2) (I), (ii).
[16] 21 C.F.R. § 50.24(a)(3) (iii).
[17] 21 C.F.R. § 50.24(a)(4),(7) (ii)-(iv).

Section 458.331, F.S., creates grounds for denial of a license or disciplinary action if the patient's full, informed, and written consent is not obtained prior to human subject experimentation.

Section 743.065, F.S., allows unwed pregnant minors to consent to the performance of medical or surgical care relating to her pregnancy. This consent is held to be valid and binding as if she were not a minor. This section extends the consent right to the unwed minor mother granting consent for medical services and care for her child.

In Florida, there is no legally recognized waiver to informed, written consent for experimental research on patients, unwed pregnant minors, or an unwed minor mother's child. If consent is needed in an emergency setting, such as in the emergency room, the health care provider must withhold the experimental treatment until such consent can be granted by the patient or the patient's family.

EFFECT OF PROPOSED CHANGES

HB 1571 creates an exception to the requirement that the patient give an informed, written consent to all experimental research. This exception aligns the state statutes with the federal regulations outlined above. In order to obtain a consent waiver, the research institution has to follow the federal regulations and submit a proposal to the respective IRB. Each institution conducting experimental research on human subjects has an IRB. The institution also has to conduct a public forum to inform the community in which the research is intended to occur about the risks and benefits to the study.

This bill also allows the respective researchers the ability to follow this waiver exception without being susceptible to disciplinary actions, such as losing his or her license.

The second portion of HB 1571 allows an unwed pregnant minor the right to consent to participate in experimental research. An example of research in which pregnant minors may participate would be research in HIV transmission from a mother to her child through the course of pregnancy or delivery. This bill also allows the unwed minor mother to consent to her child's participation in experimental research. Currently, no one has this authority so long as the unwed minor mother remains a minor or unwed.

C. SECTION DIRECTORY:

Section 1. Amends s. 381.026, F.S., to allow a federally-approved institutional review board to grant a waiver of informed consent in accordance with 45 C.F.R. part 46 or 21 C.F.R. part 56 for patient experimentation.

Section 2. Amends s. 458.331, F.S., to exempt researchers from disciplinary action when they perform experimental research on patients if the institutional review board has granted a waiver of consent on that particular research project or situation.

Section 3. Amends s. 743.065, F.S., to extend an unwed pregnant minor's right to consent to medical care to also allow her consent to experimental research. It amends this section to also allow the unwed minor mother the right to consent to experimental research on her child.

Section 4. Provides an effective date of upon becoming law.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:

   None.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

   None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

To the extent that institutional review boards grant the waiver exception in case of greater than minimal risk, there is the cost of the requisite public forums. The anticipated number of such research projects is indeterminate. The bill does not state who bears the costs of these public forums; however, it is assumed that the physician/provider or health care facility would bear the cost of the requisite public forums.

D. FISCAL COMMENTS:

According to the Department of Health, this bill would not have a fiscal impact on the agency.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

   This bill does not require counties or municipalities to spend funds or to take an action requiring the expenditure of funds. This bill does not reduce the percentage of a state tax shared with counties or municipalities. This bill does not reduce the authority that municipalities have to raise revenue.

2. Other:

   STATE RIGHT TO PRIVACY

   There may be an impact on the State's explicit constitutional Right to Privacy. Unlike the Federal Constitution, Florida has an explicit Right to Privacy. This Right to Privacy encompasses several aspects of personal autonomy and liberty. According to *Parham v. J.R.*, 442 U.S. 584 (1979), the government may not arbitrarily restrict the right of parents to raise and educate their children or to make fundamental decisions regarding their children's welfare. Parents of unwed pregnant minors may view this bill as interfering with their right to choose whether or not their unwed pregnant minor daughter participates in experimental research. However, the bill would support the unwed minor mother's right to consent to experimental research with her child.

B. RULE-MAKING AUTHORITY:

None.

C. DRAFTING ISSUES OR OTHER COMMENTS:

Section 459.015(1)(y), F.S., should be amended to reflect that the provisions of the bill affect osteopathic physicians as well as allopathic physicians.

IV. AMENDMENTS/COMMITTEE SUBSTITUTE CHANGES