

HB 1571

2004

A bill to be entitled

An act relating to consent to experimental research; amending s. 381.026, F.S.; providing an exception for receiving patient consent for certain treatment for certain federally approved experimental research; amending s. 458.331, F.S.; providing an exception to disciplinary action for certain experimentation without consent for certain federally approved research; amending s. 743.065, F.S.; providing for an unwed pregnant minor to consent to participation in certain federally approved research; providing for an unwed minor mother to consent to her child's participation in certain federally approved research; providing an effective date.

Be It Enacted by the Legislature of the State of Florida:

Section 1. Paragraph (e) of subsection (4) of section 381.026, Florida Statutes, is amended to read:

381.026 Florida Patient's Bill of Rights and Responsibilities.--

(4) RIGHTS OF PATIENTS.--Each health care facility or provider shall observe the following standards:

(e) Experimental research.--In addition to the provisions of s. 766.103, 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 unless such research has been approved by a federally approved institutional review board in accordance with 45 C.F.R. part 46 or 21 C.F.R. part 56 with a waiver of informed consent as

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30 permitted under such parts. For any patient, regardless of
 31 ability to pay or source of payment for his or her care,
 32 participation must be a voluntary matter; and a patient has the
 33 right to refuse to participate. The patient's consent or refusal
 34 must be documented in the patient's care record.

35 Section 2. Paragraph (u) of subsection (1) of section
 36 458.331, Florida Statutes, is amended to read:

37 458.331 Grounds for disciplinary action; action by the
 38 board and department.--

39 (1) The following acts constitute grounds for denial of a
 40 license or disciplinary action, as specified in s. 456.072(2):

41 (u) Performing any procedure or prescribing any therapy
 42 which, by the prevailing standards of medical practice in the
 43 community, would constitute experimentation on a human subject,
 44 without first obtaining full, informed, and written consent
 45 unless such research has been approved by a federally approved
 46 institutional review board in accordance with 45 C.F.R. part 46
 47 or 21 C.F.R. part 56 with a waiver of informed consent as
 48 permitted under such parts.

49 Section 3. Subsections (1) and (2) of section 743.065,
 50 Florida Statutes, are amended to read:

51 743.065 Unwed pregnant minor or minor mother; consent to
 52 medical services for minor or minor's child valid.--

53 (1) An unwed pregnant minor may consent to the performance
 54 of medical or surgical care or services relating to her
 55 pregnancy by a hospital or clinic or by a physician licensed
 56 under chapter 458 or chapter 459 and for her participation in
 57 research approved by a federally approved institutional review
 58 board in accordance with 45 C.F.R. part 46 or 21 C.F.R. part 56,

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59 and such consent is valid and binding as if she had achieved her
60 majority.

61 (2) An unwed minor mother may consent to the performance
62 of medical or surgical care or services for her child by a
63 hospital or clinic or by a physician licensed under chapter 458
64 or chapter 459 and for her child's participation in research
65 approved by a federally approved institutional review board in
66 accordance with 45 C.F.R. part 46 or 21 C.F.R. part 56, and such
67 consent is valid and binding as if she had achieved her
68 majority.

69 Section 4. This act shall take effect upon becoming a law.