

By Senator Aronberg

27-1605-04

See HB

1                                   A bill to be entitled  
2           An act relating to consent to experimental  
3           research; amending s. 381.026, F.S.; providing  
4           an exception for receiving patient consent for  
5           certain treatment for certain federally  
6           approved experimental research; amending s.  
7           743.065, F.S.; providing for an unwed pregnant  
8           minor to consent to participation in certain  
9           federally approved research; amending s.  
10          458.331, F.S.; providing an exception to  
11          disciplinary action for certain experimentation  
12          without consent for certain federally approved  
13          research; providing an effective date.

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

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17           Section 1. Paragraph (e) of subsection (4) of section  
18 381.026, Florida Statutes, is amended to read:

19           381.026 Florida Patient's Bill of Rights and  
20 Responsibilities.--

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

23           (e) Experimental research.--In addition to the  
24 provisions of s. 766.103, a patient has the right to know if  
25 medical treatment is for purposes of experimental research and  
26 to consent prior to participation in such experimental  
27 research with a waiver of informed consent as permitted under  
28 45 C.F.R. part 46 or 21 C.F.R. part 56, unless such research  
29 has been approved by a federally approved institutional review  
30 board in accordance with such sections. For any patient,  
31 regardless of ability to pay or source of payment for his or

1 her care, participation must be a voluntary matter; and a  
2 patient has the right to refuse to participate. The patient's  
3 consent or refusal must be documented in the patient's care  
4 record.

5 Section 2. Subsection (1) of section 743.065, Florida  
6 Statutes, is amended to read:

7 743.065 Unwed pregnant minor or minor mother; consent  
8 to medical services for minor or minor's child valid.--

9 (1) An unwed pregnant minor may consent to the  
10 performance of medical or surgical care or services relating  
11 to her pregnancy by a hospital or clinic or by a physician  
12 licensed under chapter 458 or chapter 459 and for her  
13 participation in research approved by a federally approved  
14 institutional review board in accordance with 45 C.F.R. part  
15 46 or 21 C.F.R. part 56 with a waiver of informed consent as  
16 permitted under such sections, and such consent is valid and  
17 binding as if she had achieved her majority.

18 Section 3. Paragraph (u) of subsection (1) of section  
19 458.331, Florida Statutes, is amended to read:

20 458.331 Grounds for disciplinary action; action by the  
21 board and department.--

22 (1) The following acts constitute grounds for denial  
23 of a license or disciplinary action, as specified in s.  
24 456.072(2):

25 (u) Performing any procedure or prescribing any  
26 therapy which, by the prevailing standards of medical practice  
27 in the community, would constitute experimentation on a human  
28 subject, without first obtaining full, informed, and written  
29 consent with a waiver of informed consent as permitted under  
30 45 C.F.R. part 46 or 21 C.F.R. part 56, unless such

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1 experimentation has been approved by a federally approved  
2 institutional review board in accordance with such sections.  
3       Section 4. This act shall take effect upon becoming a  
4 law.  
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