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THE GENERAL ASSEMBLY OF PENNSYLVANIA

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HOUSE BILL

No. 1730 Session of  
2007

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INTRODUCED BY BLACKWELL, PARKER, SHIMKUS, BRENNAN, KIRKLAND,  
JAMES, DePASQUALE, YOUNGBLOOD, MURT, SIPTROTH, HENNESSEY,  
CURRY, JOSEPHS, BOYD, MUNDY, PALLONE AND SWANGER,  
JULY 13, 2007

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REFERRED TO COMMITTEE ON HEALTH AND HUMAN SERVICES,  
JULY 13, 2007

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AN ACT

1 Prohibiting use of coercion and undue influence to gain  
2 participation of special needs persons in certain research;  
3 and imposing a penalty.

4 The General Assembly of the Commonwealth of Pennsylvania  
5 hereby enacts as follows:

6 Section 1. Short title.

7 This act shall be known and may be cited as the Research  
8 Consent Act.

9 Section 2. Definitions.

10 The following words and phrases when used in this act shall  
11 have the meanings given to them in this section unless the  
12 context clearly indicates otherwise:

13 "Interaction." Includes communication and interpersonal  
14 contact between an investigator and a subject.

15 "Intervention." Includes physical procedures by which data  
16 are gathered and manipulations of the subject's environment that  
17 are performed for research purposes.

1 "Investigator." A person conducting research directly or  
2 indirectly on behalf of any organization conducting  
3 experimentation upon humans including, but not limited to,  
4 pharmaceutical companies, universities, hospitals, whether  
5 public or private, and governmental entities.

6 "Poor." An individual whose personal or family income falls  
7 below two times the poverty level.

8 "Private information." Includes individually identifiable  
9 information about behavior that occurs in a context in which an  
10 individual can reasonably expect that no observation or  
11 recording is taking place and individually identifiable  
12 information provided for specific purposes by an individual  
13 which the individual can reasonably expect will not be made  
14 public.

15 "Research." A systematic investigation designed to develop  
16 or contribute to generalized knowledge. The term includes, but  
17 is not limited to, generalized research, development, testing  
18 and evaluation.

19 "Special needs person." An individual who suffers from a  
20 developmental disability, is mentally ill or poor, has substance  
21 abuse intervention issues or has been convicted of a felony and  
22 served time in prison as a result of committing the felony.

23 "Subject." A living individual about whom an investigator,  
24 whether professional or student, conducting research obtains:

25 (1) data through intervention or interaction with the  
26 individual; or

27 (2) identifiable private information.

28 Section 3. Undue influence and coercion prohibited.

29 No investigator may involve a special needs individual as a  
30 subject in research unless the investigator has obtained the

1 informed consent of the subject or the subject's legally  
2 authorized representative in accordance with the provisions of  
3 this act. An investigator shall seek consent only under  
4 circumstances that provide the prospective subject or  
5 representative sufficient opportunity to consider whether or not  
6 to participate and minimize the possibility of coercion or undue  
7 influence. Information given to the subject or representative  
8 shall be in language understandable to the subject or  
9 representative. No consent or consent form, whether oral or  
10 written, may include exculpatory language through which the  
11 subject or representative waives or appears to waive a legal  
12 right or releases or appears to release the investigator,  
13 sponsor, institution or an agent from liability for negligence.  
14 Section 4. Penalty.

15 A violation of any provision of this act constitutes a felony  
16 of the third degree.

17 Section 5. Effective date.

18 This act shall take effect in 60 days.