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THE GENERAL ASSEMBLY OF PENNSYLVANIA

HOUSE BILL

No. 1730 Session of 2007

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

AS REPORTED FROM COMMITTEE ON HEALTH AND HUMAN SERVICES, HOUSE OF REPRESENTATIVES, AS AMENDED, MAY 5, 2008

AN ACT

~~Prohibiting use of coercion and undue influence to gain participation of special needs persons in certain research; and imposing a penalty.~~ <—

REQUIRING THE DEPARTMENT OF HEALTH TO ESTABLISH STANDARDS GOVERNING PROTECTIONS FOR HUMAN SUBJECTS OF RESEARCH IN THIS COMMONWEALTH; AND REQUIRING RESEARCHERS TO OBTAIN LEGALLY EFFECTIVE INFORMED CONSENT FROM EACH RESEARCH SUBJECT OR THE SUBJECT'S LEGALLY AUTHORIZED REPRESENTATIVE. <—

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

~~Section 1. Short title.~~ <—

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

~~Section 2. Definitions.~~

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

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

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

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

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

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

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

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

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

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

(2) identifiable private information.

~~Section 3. Undue influence and coercion prohibited.~~

~~No investigator may involve a special needs individual as a subject in research unless the investigator has obtained the informed consent of the subject or the subject's legally authorized representative in accordance with the provisions of this act. An investigator shall seek consent only under circumstances that provide the prospective subject or representative sufficient opportunity to consider whether or not to participate and minimize the possibility of coercion or undue influence. Information given to the subject or representative shall be in language understandable to the subject or representative. No consent or consent form, whether oral or written, may include exculpatory language through which the subject or representative waives or appears to waive a legal right or releases or appears to release the investigator, sponsor, institution or an agent from liability for negligence.~~

~~Section 4. Penalty.~~

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

~~Section 5. Effective date.~~

~~This act shall take effect in 60 days.~~

SECTION 1. SHORT TITLE. <——

THIS ACT SHALL BE KNOWN AND MAY BE CITED AS THE PROTECTIONS FOR HUMAN SUBJECTS OF RESEARCH ACT.

SECTION 2. DEFINITIONS.

THE FOLLOWING WORDS AND PHRASES WHEN USED IN THIS ACT SHALL HAVE THE MEANINGS GIVEN TO THEM IN THIS SECTION UNLESS THE CONTEXT CLEARLY INDICATES OTHERWISE:

"DEPARTMENT." THE DEPARTMENT OF HEALTH OF THE COMMONWEALTH.

"HUMAN RESEARCH SUBJECT." A LIVING INDIVIDUAL ABOUT WHOM AN

INVESTIGATOR CONDUCTING RESEARCH OBTAINS DATA THROUGH INTERVENTION OR INTERACTION.

"INFORMED CONSENT." THE PROCESS OF PROVIDING THE KEY FACTS ABOUT RESEARCH BEFORE HUMAN RESEARCH SUBJECTS DECIDE WHETHER OR NOT TO PARTICIPATE. IT IS ALSO A CONTINUING PROCESS THROUGHOUT THE RESEARCH TO PROVIDE INFORMATION TO HELP HUMAN RESEARCH SUBJECTS DECIDE WHETHER OR NOT TO CONTINUE PARTICIPATION. INFORMED CONSENT MUST BE SOUGHT UNDER CIRCUMSTANCES THAT MINIMIZE THE POSSIBILITY OF COERCION OF UNDUE INFLUENCE.

"INVESTIGATOR." A PERSON CONDUCTING RESEARCH ON BEHALF OF ANY ORGANIZATION CONDUCTING RESEARCH, INCLUDING, BUT NOT LIMITED TO, PHARMACEUTICAL COMPANIES, UNIVERSITIES, HOSPITALS AND GOVERNMENT ENTITIES.

"RESEARCH." A SYSTEMATIC INVESTIGATION, INCLUDING DEVELOPMENT, TESTING AND EVALUATION DESIGNED TO DEVELOP OR CONTRIBUTE TO GENERALIZED KNOWLEDGE. ACTIVITIES WHICH MEET THIS DEFINITION CONSTITUTE RESEARCH FOR PURPOSES OF THIS ACT, WHETHER OR NOT THEY ARE SUPPORTED UNDER A PROGRAM WHICH IS CONSIDERED RESEARCH FOR OTHER PURPOSES.

SECTION 3. DEPARTMENT.

(A) ADOPTION OF STANDARD.--WITHIN SIX MONTHS OF THE EFFECTIVE DATE OF THIS ACT, THE DEPARTMENT SHALL ADOPT A PROTECTIONS FOR HUMAN SUBJECTS OF RESEARCH STANDARD. THE STANDARD SHALL BE AT LEAST AS PRESCRIPTIVE AS THE STANDARD PROMULGATED BY THE DEPARTMENT OF HEALTH AND HUMAN SERVICES AND SHALL INCLUDE THE FOLLOWING, EXCEPT IN CASES WHERE THE DEPARTMENT SPECIFICALLY APPROVES A WAIVER IN ACCORDANCE WITH FEDERAL REGULATIONS OR SUBSECTION (D). NO INVESTIGATOR MAY INVOLVE A HUMAN BEING AS A SUBJECT IN RESEARCH IN THIS COMMONWEALTH UNLESS THE INVESTIGATOR HAS OBTAINED THE LEGALLY

EFFECTIVE INFORMED CONSENT OF THE HUMAN RESEARCH SUBJECT OR THE SUBJECT'S LEGALLY AUTHORIZED REPRESENTATIVE. AN INVESTIGATOR SHALL SEEK SUCH CONSENT ONLY UNDER CIRCUMSTANCES THAT PROVIDE THE PROSPECTIVE HUMAN RESEARCH SUBJECT OR THE SUBJECT'S REPRESENTATIVE SUFFICIENT OPPORTUNITY TO CONSIDER WHETHER OR NOT TO PARTICIPATE AND THAT MINIMIZE THE POSSIBILITY OF COERCION OR UNDUE INFLUENCE. THE INFORMATION THAT IS GIVEN TO THE HUMAN RESEARCH SUBJECT OR THE SUBJECT'S REPRESENTATIVE SHALL BE IN LANGUAGE UNDERSTANDABLE TO THE SUBJECT OR THE SUBJECT'S REPRESENTATIVE. NO INFORMED CONSENT, WHETHER ORAL OR WRITTEN, MAY INCLUDE ANY EXCULPATORY LANGUAGE THROUGH WHICH THE HUMAN RESEARCH SUBJECT OR THE SUBJECT'S REPRESENTATIVE IS MADE TO WAIVE OR APPEAR TO WAIVE ANY OF THE SUBJECT'S LEGAL RIGHTS OR RELEASE OR APPEAR TO RELEASE THE INVESTIGATOR, THE SPONSOR, THE INSTITUTION OR ITS AGENTS FROM LIABILITY FOR NEGLIGENCE.

(B) INFORMATION REQUIRED.--IN SEEKING INFORMED CONSENT, ALL OF THE FOLLOWING INFORMATION SHALL BE PROVIDED TO EACH HUMAN RESEARCH SUBJECT, EXCEPT AS PROVIDED IN SUBSECTION (D):

(1) A STATEMENT THAT THE STUDY INVOLVES RESEARCH, AN EXPLANATION OF THE PURPOSES OF THE RESEARCH, THE EXPECTED DURATION OF THE SUBJECT'S PARTICIPATION, A DESCRIPTION OF THE PROCEDURES TO BE FOLLOWED AND THE IDENTIFICATION OF ANY PROCEDURES WHICH ARE EXPERIMENTAL.

(2) A DESCRIPTION OF ANY REASONABLY FORSEEABLE RISKS OR DISCOMFORTS TO THE SUBJECT.

(3) A DESCRIPTION OF ANY BENEFITS TO THE SUBJECT OR TO OTHERS WHICH MAY REASONABLY BE EXPECTED FROM THE RESEARCH.

(4) A DISCLOSURE OF APPROPRIATE ALTERNATIVE PROCEDURES OR COURSES OF TREATMENT, IF ANY, THAT MIGHT BE ADVANTAGEOUS TO THE SUBJECT.

(5) A STATEMENT DESCRIBING THE EXTENT, IF ANY, TO WHICH CONFIDENTIALITY OF RECORDS IDENTIFYING THE SUBJECT WILL BE MAINTAINED.

(6) FOR RESEARCH INVOLVING MORE THAN MINIMAL RISK, AN EXPLANATION AS TO WHETHER ANY COMPENSATION AND ANY MEDICAL TREATMENTS ARE AVAILABLE IF INJURY OCCURS AND, IF SO, WHAT THEY CONSIST OF OR WHERE FURTHER INFORMATION MAY BE OBTAINED.

(7) AN EXPLANATION OF WHOM TO CONTACT FOR ANSWERS TO PERTINENT QUESTIONS ABOUT THE RESEARCH AND THE SUBJECT'S RIGHTS, AND WHOM TO CONTACT IN THE EVENT OF A RESEARCH-RELATED INJURY TO THE SUBJECT.

(8) A STATEMENT THAT PARTICIPATION IS VOLUNTARY AND THAT REFUSAL TO PARTICIPATE WILL INVOLVE NO PENALTY OR LOSS OF BENEFITS TO WHICH THE SUBJECT IS OTHERWISE ENTITLED.

(C) ADDITIONAL ELEMENTS OF INFORMED CONSENT.--WHEN APPROPRIATE, ONE OR MORE OF THE FOLLOWING ELEMENTS OF INFORMATION SHALL ALSO BE PROVIDED TO EACH HUMAN RESEARCH SUBJECT:

(1) A STATEMENT THAT THE PARTICULAR TREATMENT OR PROCEDURE MAY INVOLVE RISKS TO THE SUBJECT OR TO THE EMBRYO OR FETUS, IF THE SUBJECT IS OR MAY BECOME PREGNANT, WHICH ARE CURRENTLY UNFORSEEABLE.

(2) ANTICIPATED CIRCUMSTANCES UNDER WHICH THE SUBJECT'S PARTICIPATION MAY BE TERMINATED BY THE INVESTIGATOR WITHOUT REGARD TO THE SUBJECT'S CONSENT.

(3) ANY ADDITIONAL COSTS TO THE SUBJECT THAT MAY RESULT FROM PARTICIPATION IN THE RESEARCH.

(4) THE CONSEQUENCES OF A SUBJECT'S DECISION TO WITHDRAW FROM THE RESEARCH AND PROCEDURES FOR ORDERLY TERMINATION OF PARTICIPATION BY THE SUBJECT.

(5) A STATEMENT THAT SIGNIFICANT NEW FINDINGS DEVELOPED DURING THE COURSE OF THE RESEARCH MAY RELATE TO THE SUBJECT'S WILLINGNESS TO CONTINUE PARTICIPATION.

(6) THE APPROXIMATE NUMBER OF SUBJECTS IN THE STUDY.

(D) WAIVER.--THE DEPARTMENT MAY APPROVE A CONSENT PROCEDURE WHICH DOES NOT INCLUDE OR WHICH ALTERS SOME OR ALL OF THE ELEMENTS OF INFORMED CONSENT SET FORTH IN SUBSECTIONS (B) AND (C) OR WAIVE THE REQUIREMENT TO OBTAIN INFORMED CONSENT, PROVIDED THAT:

(1) THE RESEARCH OR DEMONSTRATION PROJECT IS TO BE CONDUCTED BY OR SUBJECT TO THE APPROVAL OF STATE OR LOCAL GOVERNMENT OFFICIALS AND IS DESIGNED TO STUDY, EVALUATE OR OTHERWISE EXAMINE:

(I) PUBLIC BENEFIT OR SERVICE PROGRAMS;

(II) PROCEDURES FOR OBTAINING BENEFITS OR SERVICES UNDER THOSE PROGRAMS;

(III) POSSIBLE CHANGES IN OR ALTERNATIVES TO THOSE PROGRAMS OR PROCEDURES; OR

(IV) POSSIBLE CHANGES IN METHODS OR LEVELS OF PAYMENT FOR BENEFITS OR SERVICES UNDER THOSE PROGRAMS.

(2) THE RESEARCH COULD NOT BE PRACTICABLY CARRIED OUT WITHOUT THE WAIVER OR ALTERATION.

SECTION 4. RULES AND REGULATIONS.

THE DEPARTMENT SHALL PROMULGATE RULES AND REGULATIONS AS NECESSARY TO CARRY OUT THE PROVISIONS OF THIS ACT.

SECTION 5. EFFECTIVE DATE.

THIS ACT SHALL TAKE EFFECT JULY 1, 2008.