

SENATE PUBLIC AFFAIRS COMMITTEE SUBSTITUTE FOR  
SENATE BILL 313

**51ST LEGISLATURE - STATE OF NEW MEXICO - FIRST SESSION, 2013**

AN ACT

RELATING TO HEALTH; ENACTING THE BIOMEDICAL RESEARCH ACT;  
PERMITTING BIOMEDICAL RESEARCH ON LIMITED CATEGORIES OF HUMAN  
EMBRYONIC STEM CELLS; REQUIRING OVERSIGHT; PROHIBITING HUMAN  
CLONING; IMPOSING PENALTIES; AMENDING THE MATERNAL, FETAL AND  
INFANT EXPERIMENTATION ACT; MAKING THE DEFINITION OF "EMBRYO"  
THE SAME UNDER BOTH ACTS.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF NEW MEXICO:

**SECTION 1.** [NEW MATERIAL] SHORT TITLE.--Sections 1  
through 7 of this act may be cited as the "Biomedical Research  
Act".

**SECTION 2.** [NEW MATERIAL] DEFINITIONS.--As used in the  
Biomedical Research Act:

A. "cell lines" means a permanently established  
cell culture that will proliferate indefinitely given the

1 appropriate laboratory conditions;

2 B. "embryo" means a fertilized human egg from the  
3 time that cell division begins to the end of the eighth week  
4 after conception;

5 C. "fertilization" means the process whereby the  
6 male sperm and female ovum unite to form an embryo;

7 D. "human adult stem cell" means an  
8 undifferentiated cell found in differentiated tissue that can  
9 renew itself and differentiate to yield specialized cell types;

10 E. "human reproductive cloning" means the asexual  
11 creation of an embryo;

12 F. "in vitro" means in a laboratory or clinical  
13 environment, including a test tube or culture medium, and also  
14 refers to a process or reaction occurring in a laboratory or  
15 clinical environment;

16 G. "in vitro fertilization" means an assisted  
17 reproduction technique in which fertilization is accomplished  
18 outside the human body;

19 H. "placental cells" means cells obtained from the  
20 placenta;

21 I. "pre-implantation embryo" means an embryo formed  
22 and maintained outside the human body, by in vitro  
23 fertilization, that has not experienced more than fourteen days  
24 of development, excluding time the embryo was cryopreserved or  
25 frozen; and

1 J. "umbilical cord stem cells" means cells derived  
2 from an umbilical cord.

3 SECTION 3. [NEW MATERIAL] BIOMEDICAL RESEARCH PERMITTED--  
4 LIMITATIONS--RESEARCH PROHIBITIONS.--

5 A. Research and clinical applications conducted in  
6 accordance with the Biomedical Research Act that involve the  
7 derivation and use of pre-implantation human embryonic stem  
8 cells are permitted; provided that they are derived from:

- 9 (1) embryos that are produced by in vitro  
10 fertilization clinics and designated for destruction;  
11 (2) stem cell lines;  
12 (3) human adult stem cells from any source;  
13 (4) umbilical cord stem cells; and  
14 (5) placental cells.

15 B. Research involving the derivation of human  
16 embryonic stem cells, as permitted by Subsection A of this  
17 section, shall only be conducted with the informed consent of  
18 the original progenitors or recipients pursuant to a sperm or  
19 egg donation agreement and in accordance with guidelines and  
20 policies promulgated by an institutional review board as  
21 provided in Section 4 of the Biomedical Research Act, which  
22 shall take into account the recommendations of the United  
23 States department of health and human services' office for  
24 human research protections, the national research council and  
25 the institute of medicine of the national academies.

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1           SECTION 4. [NEW MATERIAL] INSTITUTIONAL REVIEW BOARD  
2           OVERSIGHT REQUIRED.--A person or institution conducting stem  
3           cell research shall submit its activities to the oversight of  
4           an institutional review board. The institutional review board  
5           shall:

6                     A. provide oversight over all issues related to  
7                     derivation and use of stem cells;

8                     B. review and approve the scientific merit of  
9                     research protocols;

10                    C. review compliance of all stem cell research with  
11                    all relevant regulations and guidelines; and

12                    D. perform such other activities as may be  
13                    necessary or appropriate and consistent with nationally  
14                    recognized institutional review board standards or protocols or  
15                    as may be provided by law.

16           SECTION 5. [NEW MATERIAL] HUMAN REPRODUCTIVE CLONING  
17           PROHIBITED.--

18                     A. It is unlawful to knowingly engage or assist in  
19                     human reproductive cloning or attempted human reproductive  
20                     cloning of a human being.

21                     B. A person shall not knowingly purchase, sell,  
22                     transfer or otherwise obtain human embryonic, gametic or  
23                     cadaveric tissue for the purpose of human reproductive cloning.

24           SECTION 6. [NEW MATERIAL] SCIENTIFIC RESEARCH--EXEMPT  
25           EMPLOYEES.--An employee shall not be required to conduct

1 scientific research, experimentation or study that involves the  
2 creation or use of pre-implantation embryos in relation to  
3 human embryonic stem cell research to the extent that such  
4 research conflicts with the sincerely held religious practices  
5 or beliefs of the employee.

6 SECTION 7. [NEW MATERIAL] PENALTIES.--Violation of a  
7 provision of the Biomedical Research Act is a misdemeanor and  
8 shall be punishable by a fine of not more than twenty-five  
9 thousand dollars (\$25,000) or imprisonment for not more than  
10 one year or both.

11 SECTION 8. Section 24-9A-1 NMSA 1978 (being Laws 1979,  
12 Chapter 132, Section 1, as amended) is amended to read:

13 "24-9A-1. DEFINITIONS.--As used in the Maternal, Fetal  
14 and Infant Experimentation Act:

15 A. "viability" means that stage of fetal  
16 development when the unborn child is potentially able to live  
17 outside the mother's womb, albeit with artificial aid;

18 B. "conception" means the fertilization of the egg  
19 of a human female by the sperm of a human male;

20 C. "health" means physical or mental health;

21 D. "clinical research" means any biomedical or  
22 behavioral research involving human subjects, including  
23 embryos, conducted according to a formal procedure. The term  
24 is to be construed liberally to embrace research concerning all  
25 physiological processes in human beings and includes research

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1 involving human in vitro fertilization, but shall not include  
2 diagnostic testing, treatment, therapy or related procedures  
3 conducted by formal protocols deemed necessary for the care of  
4 the particular patient upon whom such activity is performed and  
5 shall not include human in vitro fertilization performed to  
6 treat infertility; provided that this procedure shall include  
7 provisions to ensure that each living fertilized ovum, zygote  
8 or embryo is implanted in a human female recipient, and no  
9 physician may stipulate that a woman must abort in the event  
10 the pregnancy should produce a child with a disability; and  
11 provided further that emergency medical procedures necessary to  
12 preserve the life or health of the mother or the fetus shall  
13 not be considered to be clinical research;

14 E. "subject at risk", "subject" or "at risk" means  
15 any person who may be exposed to the likelihood of injury,  
16 including physical or psychological injury, as a consequence of  
17 participation as a subject in:

18 (1) any research, development or related  
19 activity that departs from the application of those established  
20 and accepted methods deemed necessary to meet the person's  
21 needs;

22 (2) controlled research studies necessary to  
23 establish accepted methods designed to meet the person's needs;  
24 or

25 (3) research activity that poses a significant

1 risk to the subject;

2 F. "significant risk" means an activity that is  
3 likely to cause disfigurement or loss or impairment of the  
4 function of any member or organ;

5 G. "embryo" means a fertilized human egg from the  
6 time that cell division begins to the end of the eighth week  
7 after conception;

8 [~~G.~~] H. "fetus" means the product of conception  
9 from the [~~time of~~] end of the eighth week after conception  
10 until the expulsion or extraction of the fetus or the opening  
11 of the uterine cavity, but shall not include the placenta,  
12 extraembryonic membranes, umbilical cord, extraembryonic fluids  
13 and their resident cell types, [~~and~~] cultured cells or products  
14 of conception produced by in vitro fertilization clinics and  
15 designated for destruction;

16 [~~H.~~] I. "live-born infant" means an offspring of a  
17 person that exhibits heartbeat, spontaneous respiratory  
18 activity, spontaneous movement of voluntary muscles or  
19 pulsation of the umbilical cord if still attached to the infant  
20 ex utero; provided that the Maternal, Fetal and Infant  
21 Experimentation Act does not apply to a fetus or infant absent  
22 the characteristics set forth in this subsection;

23 [~~I.~~] J. "infant" means an offspring of a human  
24 being from the time it is born until the end of its first  
25 chronological year;

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