# F I S C A L  I M P A C T  R E P O R T

**SPONSOR** Park **ORIGINAL DATE** 02/05/10 **LAST UPDATED** 02/11/10 **HB** 166/aHJC

**SHORT TITLE** Biomedical Research Act **SB**

**ANALYST** Hanika-Ortiz

## ESTIMATED ADDITIONAL OPERATING BUDGET IMPACT (dollars in thousands)

| | FY10 | FY11 | FY12 | 3 Year Total Cost | Recurring or Non-Rec | Fund Affected |
|---|---|---|---|---|---|---|
| **Total** | | $5.0 - $50.0 | | | Recurring | Various |

(Parenthesis ( ) Indicate Expenditure Decreases)

## SOURCES OF INFORMATION
LFC Files

Responses Received From
Health Policy Commission (HPC)
Office of the Attorney General (AGO)
New Mexico Medical Board (MB)
Department of Health (DOH)

## SUMMARY

Synopsis of HJC Amendment

The House Judiciary Committee Amendment to House Bill 166 adds a new section requiring that stem cell research be approved by an Institutional Review Board (IRB). The IRB would provide oversight related to derivation and use of stem cells; review and approve research protocols; review regulatory compliance of stem cell research; and, perform such other activities as may be appropriate and consistent with nationally recognized IRB protocols or as provided by law.

## SIGNIFICANT ISSUES

An IRB is a committee designated to approve, monitor, and review biomedical and behavioral research involving humans. The Food and Drug Administration and Department of Health and Human Services (specifically Office for Human Research Protections) regulations have empowered IRB's to approve, modify or disapprove research. An IRB performs critical oversight functions for research conducted on human subjects that are scientific, ethical, and regulatory.

Some IRB reviews are conducted by for-profit organizations known as independent or commercial IRB's. The responsibilities of these IRB's are identical to those based at academic or medical institutions, and they are governed by the same federal regulations.

Synopsis of Original Bill

House Bill 166 expands the scope of prohibited activities in the Maternal, Fetal and Infant Experimentation Act and enacts the "biomedical research act" permitting limited biomedical research on certain embryonic stem cells while at the same time prohibiting human reproductive cloning. Punishment for violation of the new covered activities is a misdemeanor.

Sections 1: cites the title of the act as the "biomedical research act".

Section 2: defines terms used in the act, such as:

- "*cell lines* mean a permanently established cell culture that will proliferate indefinitely…";
- "*embryo* means a fertilized human egg that has begun cell division";
- "human reproductive cloning means the asexual creation of an embryo";
- "*pre-implementation embryo* means an embryo formed and maintained outside the body…that has not experienced more than fourteen days of development…"; and
- "*primitive streak* means a structure that forms…around the fourteenth day of existence".

Section 3: permits certain research and clinical applications involving the use of pre-implantation human embryonic stem cells designated for destruction. The research shall only be conducted with the informed consent of the original progenitors or recipients pursuant to a sperm or egg donation agreement and in accordance with guidelines promulgated by the United States Department of Health and Human Services Office for Human Research Protection, the National Research Council and the Institute of Medicine of the National Academies. The act prohibits research on a human embryo for longer than 14 days or until formation of the primitive streak begins, whichever occurs first.

Section 4: prohibits human reproductive cloning; which includes purchasing, selling, transferring or obtaining human embryonic, gametic or cadaveric tissue for the purpose of reproductive cloning.

Section 5: exempts an employee from participating if in conflict with their sincerely held religious practices or beliefs.

Section 6: provides that a violation is a misdemeanor punishable by a fine of up to $25,000 and/or imprisonment for not more than 1 year or both.

Section 7: amends the Maternal, Fetal and Infant Experimentation Act, Section 24-9A-1 NMSA 1978, to include in the definition of *fetus* "…the product of conception from the end of the eighth week after conception" and exclude within the definition of fetus "…products of conception produced by in vitro fertilization clinics and designated for destruction". The bill also updates the definition of *in vitro fertilization* to mean "an assisted reproduction technique in which fertilization is accomplished outside the human body".

## FISCAL IMPLICATIONS

The bill imposes a fine of not more than $25,000 or imprisonment for not more than one year or both, for violation of the biomedical research act.

Proponents of the bill believe stem cell research over time has the potential to increase jobs, stimulate economic activity and improve health outcomes within the state.

The bill does not provide for nor authorize state funding for any research activities or clinical applications made possible by this bill.

The bill does not provide an appropriation for enforcement of the provisions in the act.

## SIGNIFICANT ISSUES

The bill creates guidelines for researchers studying human stem cells in New Mexico toward the goal of fostering such biomedical research within the state.

The bill would permit limited stem cell research using embryos produced by in vitro fertilization clinics and targeted for disposal.

Scientists harvest embryonic stem cells from embryos left over in fertility clinics after in vitro fertilization procedures (IVF). When people undergo IVF, there are many more embryos created than can be implanted. Sometimes surplus embryos are discarded. Other times, they are donated to help other infertile couples, or used for research.

The *primitive streak* is an important concept in bioethics, where some experts have argued that experimentation with human embryos is permissible only until the primitive streak develops, generally around the fourteenth day of existence. The development of the primitive streak is taken by such bioethicists, to signify the creation of a unique, potential human being.

## PERFORMANCE IMPLICATIONS

HPC notes that on March 9, 2009, President Obama issued Executive Order 13505, entitled *Removing Barriers to Responsible Research Involving Human Stem Cells*. Pursuant to the Executive Order, the National Institutes of Health (NIH) published the National Institutes of Health Guidelines for Human Stem Cell Research (Guidelines), effective on July 7, 2009. These Guidelines apply to the expenditure of NIH funds for research using human embryonic stem cells and certain uses of human induced pluripotent stem cells. The Guidelines are based on the principles that responsible research with human embryonic stem cells has the potential to improve our understanding of human biology and aid in the discovery of new ways to prevent and treat illnesses, and individuals donating embryos for research purposes should do so freely, with voluntary and informed consent.

## ADMINISTRATIVE IMPLICATIONS

There is no state agency identified in the bill to provide oversight for these activities.

## OTHER SUBSTANTIVE ISSUES

HPC further notes that some states are funding stem cell research in order to remain competitive and prevent the relocation of scientists and biotechnology firms to other states or overseas.

## WHAT WILL BE THE CONSEQUENCES OF NOT ENACTING THIS BILL

Future opportunities for federally funded and approved stem cell research may conflict with existing state statute.

AHO/svb:mew