

Nebraska's History in Stem Cell Research

By David Crouse, Ph.D.

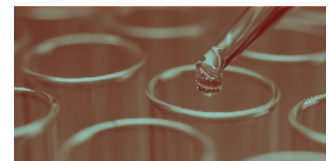
President, Nebraska Coalition for Lifesaving Cures



NOVEMBER 10, 2017 The University of Nebraska Medical Center has a long and distinguished national and international reputation in stem cell transplantation for a variety of diseases. Following some 20 years of basic science research around the world and gradual refinement of clinically applied transplantation, the first patients at UNMC were transplanted with bone marrow cells in 1983 and sometime later, using techniques pioneered at UNMC with peripheral blood

derived stem cells. During most of this time and continuing today, basic science research related to stem cells has been an important part of UNMC's research portfolio.

After the first description of the isolation and characterization of human embryonic stem cells (hESC) in 1998, the President of the University of Nebraska established a committee to develop guidelines for hESC research conducted by the University of Nebraska in 2000. The resulting recommendations, adopted by the Board of Regents in 2001, required the university to follow federal guidelines, among other things (see: <http://nebraska.edu/docs/reports/bioethicsreport2001.pdf>). Therefore, when President Bush restricted the use of federal funds for hESC research to stem cell lines created prior to August 9, 2001, the university was duly limited to using the "Bush" approved hESC lines.



LB 606 allows the university to conduct research on hESC lines as long as the cell lines were developed elsewhere.

The Nebraska Legislature similarly grappled with hESC research legislation for many years, but no legislation was enacted until a compromise was reached in 2008. The compromise, supported by both proponents and opponents of the research, was entitled the Stem Cell Research Act (LB 606). It allows the university to conduct research on hESC lines as long as the cell lines were developed elsewhere. In other words, the university may not create or destroy embryos nor participate in any form of human cloning (see: <http://nebraskalegislature.gov/FloorDocs/100/PDF/Final/LB606.pdf>).

LB 606 did not alter the Board of Regents' policy requiring UNMC to adhere to federal policy and thus use only federally approved hESC lines. At that time there were 21 listed and available hESC lines in the NIH Stem Cell Registry.

Updated Status

On March 6, 2009, the White House announced that President Obama would be issuing an Executive Order changing stem cell research policy. That same day, representatives from the Nebraska Coalition for Ethical Research and others testified before the University of Nebraska, Board of Regents that stem cell research in Nebraska should not be expanded beyond the Bush-approved hESC lines and urged the Board to revisit its policy.

On March 9, 2009 President Obama signed an Executive Order reversing limitations on federally funded hESC research to lines created before Aug. 9, 2001. The executive order did not permit



the creation or destruction of human embryos using federal funds and also called for the NIH to issue new policy for management of this issue within 120 days. The current NIH "Guidelines for Human Stem Cell Research" were released in final form on July 7, 2009 (Fed Register 74, No. 128, pages 32170-32175, July 7, 2009). Those guidelines were based on the National Academies of Sciences recommendations and contained criteria for hESC line inclusion that were much more strict than the criteria employed at the time of approval of the "Bush hESC lines." In October and November of 2009,

the BOR considered the University policy regarding Embryonic Stem Cells in some detail and with lengthy discussion. Finally, in a 4 to 4 split vote, the current policy was retained.

As of November 10, 2017, 489 hECS lines had been submitted and 388 hESC lines had been approved by the Advisory Committee to the NIH Director for inclusion in the NIH Human ESC Registry (http://grants.nih.gov/stem_cells/registry/summary_data.htm). Only five of the approved group came from the approved "Bush hESC lines." Also as of November 10, 2017, three approved lines are "on hold" with respect to use while pending revision to the NIH hESC Guidelines to clarify the definition of "eligible cell lines" are under consideration (<http://edocket.access.gpo.gov/2010/pdf/2010-3527.pdf>).

As it now stands, the Federal law, which does not permit use of federal funds to support the creation or destruction of embryos or participation in cloning, is parallel to the Nebraska law with respect to use of state resources for the same hESC activities. The BOR policy requiring the University of Nebraska be compliant with federal policy in this area is fully aligned with federal and state laws.

The University of Nebraska Medical Center developed a Regenerative Medicine Initiative in 2010 to bring together investigators and recruit new faculty take advantage of the many opportunities this area offers for research and clinical development. That program has continued to develop and expand. As part of that effort, investigators at UNMC will continue ongoing work with many kinds of stem cells, all strictly adhering to the federal and state guidelines and laws.

Other Compelling Reasons to Keep the Current Law

- Nebraska and national polls show overwhelming support for embryonic stem cell research.
- If additional restrictions were implemented, Nebraska would be stigmatized as one of only six states that severely restrict hESC research (along with ND, SD, AR, IN, and LA). In some of these states, the laws are vague and potentially unenforceable.
- In recent years, Iowa and Michigan overturned state bans related to hESC research and Missouri, after a long battle, has protected researchers' ability to pursue projects within federal guidelines and limitations.
- More than 10 states are using state taxpayer dollars to support hESC research.
- hESC research gives life-affirming hope to countless patients and their families who seek cures for diabetes, Parkinson's disease, ALS, spinal cord injuries, cancer, vision loss, and other debilitating diseases.
- Adult stem cells, though very valuable and widely applied to a number of blood related cancers and genetic diseases, have never completed clinical trials for use in diabetes, Parkinson's, ALS, spinal cord injuries, macular degeneration or many other diseases as claimed by some.
- Clinical Trials with human ESC are now in progress in the United States as well as abroad.
- Curative treatments could be denied to Nebraska patients and families with some of the restrictive laws and regressive policies that have been proposed in the Nebraska Legislature and at Board of Regents meetings, respectively.
- There are at least 400,000 excess embryos at fertility clinics that will be destroyed if not used for research purposes. More embryos are added every year.
- Public policy at a public university should not be based on religious views of a minority.
- One way Nebraska can retain researchers, attract new scientists and create new high-tech jobs is to promote research in stem cells and other life sciences, which would be impossible with stricter limits on hESC research at the University or Legislative level.



hESC research gives life-affirming hope to countless patients and their families who seek cures for diabetes, Parkinson's disease, ALS, spinal cord injuries, cancer, vision loss, and other debilitating diseases.