#### HOUSE OF REPRESENTATIVES TWENTY-FOURTH LEGISLATURE, 2007 STATE OF HAWAII

H.B. NO. 364

### A BILL FOR AN ACT

RELATING TO MEDICAL RESEARCH.

#### BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF HAWAII:

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#### PART I

SECTION 1. The legislature finds that an estimated 2 3 128,000,000 Americans suffer from the crippling economic and psychological burden of chronic, degenerative, and acute 4 5 diseases, including diabetes, Parkinson's disease, cancer, and Alzheimer's disease. The costs of treatment and lost 6 7 productivity of chronic, degenerative, and acute diseases in the United States run into hundreds of billions of dollars every 8 9 year. Yet, the estimates of these economic costs do not account 10 for the extreme cost in human loss and suffering associated with 11 these conditions.

12 On the other hand, stem cell research could lead to 13 unprecedented treatments and potential cures for diabetes, 14 Alzheimer's disease, cancer, and other diseases. Stem cell 15 research offers immense promise for developing new medical 16 therapies for these debilitating diseases.

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1 The United States has historically been a haven for open 2 scientific inquiry and technological innovation; and this 3 environment, combined with the commitment of public and private 4 resources, has made the United States the preeminent world 5 leader in biomedicine and biotechnology. The biomedical 6 industry is a critical and growing component of Hawaii's 7 economy, and its development would be significantly hampered by 8 any limitation imposed on stem cell research. 9 Open scientific inquiry and research endeavors supported by 10 public funding will be essential to realizing the promise of

11 stem cell research. Publicly funded stem cell research,
12 conducted under established standards of open scientific
13 exchange, peer review, and public oversight, offers the most
14 efficient and responsible means of fulfilling the promise of the
15 use of stem cells in providing regenerative medical therapies.

16 The legislature further finds that stem cell research,
17 including the use of embryonic stem cells for medical research,
18 raises significant ethical and policy concerns. Public policy
19 on stem cell research must balance ethical and medical
20 considerations. While not unique, these ethical and policy
21 concerns associated with stem cell research must be well thought
22 out. The policy of this State must be based on an understanding



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1	of the science associated with stem cell research and grounded
2	on a thorough consideration of the ethical concerns regarding
3	this research. Public policy on stem cell research must be
4	crafted to ensure that researchers have the research and ethical
5	tools necessary to fulfill the promise of stem cell research.
6	SECTION 2. Chapter 321, Hawaii Revised Statutes, is
7	amended by adding a new part to be appropriately designated and
8	to read as follows:
9	"PART . STEM CELL RESEARCH; POLICY
10	<b>§321- Stem cell research; policy.</b> (a) The policy of
11	the State relating to stem cell research shall be as follows:
12	(1) Research involving the derivation and use of human
13	embryonic stem cells, human embryonic germ cells, and
14	human adult stem cells from any source, including
15	somatic cell nuclear transplantation, shall be:
16	(A) Permitted in this State;
17	(B) Conducted with full consideration of the ethical
18	and medical implications of this research; and
19	(C) Reviewed by an approved institutional review
20	board;
21	(2) A physician, or other health care provider, delivering
22	fertility treatment shall provide the patient with



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1		timely, relevant, and appropriate information to allow
2		the patient to make an informed and voluntary choice
3		regarding the disposition of any human embryos
4		remaining following the fertility treatment;
5	(3)	Any individual to whom information is provided
6		pursuant to paragraph (2) shall be presented with the
7		option of storing the individual's unused embryos at
8		the individual's own expense, donating them to another
9		individual, discarding the embryos, or donating the
10		remaining embryos for research;
11	(4)	Any individual who elects to donate embryos remaining
12		after fertility treatments for research shall provide
13		written consent;
14	(5)	A physician, or other health care provider
15		facilitating the donation of embryos, and any
16		physician or health care provider that may handle,
17		store, transport, or otherwise manipulate donated
18		embryos shall ensure that the confidentiality of an
19		embryo donor's identity, and the confidentiality of
20		any traceable information from a donor are protected;
21		and



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1 (5) A person may not knowingly, for valuable 2 consideration, purchase or sell embryonic or cadaveric 3 fetal tissue for research purposes pursuant to this 4 chapter. 5 For purposes of this section, "valuable consideration" (b) does not include reasonable payment for the removal, processing, 6 7 disposal, preservation, quality control, storage, 8 transplantation, or implantation of embryonic or cadaveric fetal 9 tissue. 10 (C) Embryonic or cadaveric fetal tissue may be donated for 11 research purposes pursuant to this part. (d) The director of health shall adopt rules in accordance 12 13 with chapter 91 to implement this part." 14 PART II 15 SECTION 3. The legislature finds that the reestablishment 16 of the University of Hawaii's school of medicine in the Kakaako 17 area is generating an enormous stimulus towards medical and scientific innovation and presents a tremendous opportunity for 18 19 the State to improve its position in the leading-edge field of 20 biotechnology and stem cell research. In conjunction with the 21 state policy on stem cell research, an institute for regenerative medicine located at the University of Hawaii school 22 HB LRB 07-0660.doc 5 

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1 of medicine could become a world leader in innovative stem cell 2 research. Not only will humanity benefit, but this type of 3 medical research will also significantly reduce state health 4 care costs in the future. The State will benefit from 5 royalties, patents, and licensing fees arising from discoveries 6 and innovations relating to stem cell research. This research 7 will create significant numbers of high-end jobs and generate 8 millions of dollars as it expands the State's tax base. 9 The purpose of this part is to lay the foundation for the establishment of an institute for regenerative medicine at the 10 11 University of Hawaii's school of medicine.

SECTION 4. (a) The president shall develop and the board of regents of the University of Hawaii shall approve for submission to the legislature a plan to establish an institute for regenerative medicine at the school of medicine. The institute for regenerative medicine shall have the following purposes:

18 (1) Support stem cell research and other vital research
19 opportunities to realize therapies, protocols, and
20 medical procedures that will result in, as speedily as
21 possible, the cure for or substantial mitigation of
22 major diseases, injuries, and orphan diseases;



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1 (2) Support all stages of the process of developing cures, 2 from laboratory research through successful clinical 3 trials; and 4 Establish the appropriate regulatory standards and (3) 5 oversight bodies for research and facilities 6 development. 7 The plan to be developed by the president and approved (b) 8 by the board of regents of the University of Hawaii concerning 9 the establishment of the institute for regenerative medicine 10 shall ensure that: 11 (1)Use of research funds made available to the institute 12 will be maximized by giving priority to stem cell 13 research that has the greatest potential for therapies 14 and cures, specifically focused on pluripotent stem 15 cell and progenitor cell research among other vital research opportunities that cannot, or are unlikely 16 17 to, receive timely or sufficient federal funding, 18 unencumbered by limitations that would impede the 19 research; provided that research shall be subject to 20 accepted patient disclosure and patient consent 21 standards;



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1 Research is conducted safely and ethically by (2)2 including provisions to require compliance with 3 standards based upon national models that protect 4 patient safety, patient rights, and patient privacy; 5 (3) The Hawaii health care system is improved and the 6 long-term health care cost burden on Hawaii is reduced 7 through the development of therapies that treat 8 diseases and injuries with the ultimate goal to cure 9 them; and Strict fiscal and public accountability is implemented 10 (4) 11 through mandatory independent audits, open meetings, 12 public hearings, and annual reports to the public. 13 The institute for regenerative medicine shall have the (C)14 right to conduct stem cell research, which includes research 15 involving adult stem cells, cord blood stem cells, pluripotent stem cells, and progenitor cells. For the purposes of this 16 section, "pluripotent stem cells" are cells that are capable of 17 18 self-renewal and have broad potential to differentiate into 19 multiple adult cell types. Pluripotent stem cells may be 20 derived from somatic cell nuclear transfer or from surplus 21 products of in vitro fertilization treatments, when such 22 products are donated under appropriate informed consent HB LRB 07-0660.doc

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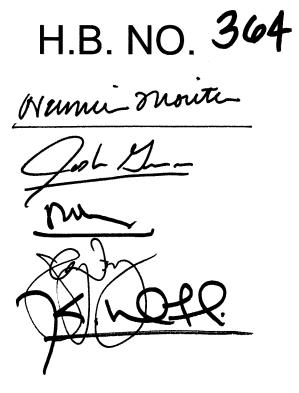
procedures. "Progenitor cells" are multipotent or precursor 1 2 cells that are partially differentiated, but retain the ability 3 to divide and give rise to differentiated cells. 4 No funds authorized for, or made available to, the (d) 5 institute for regenerative medicine shall be used for research 6 involving human reproductive cloning. 7 The University of Hawaii may issue general obligation (e) 8 bonds to fund the development and construction of the institute 9 for regenerative medicine. 10 (f) The president shall develop and the board of regents 11 shall approve the plan to establish the institute for 12 regenerative medicine no later than November 30, 2008, and 13 submit the finalized plan to the legislature no later than 14 December 31, 2008, together with any necessary proposed 15 legislation, such as funding needs, for introduction in the 16 regular session of 2009. 17 PART III SECTION 5. This Act shall take effect upon its approval. 18 19

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Report Title:

Human Stem Cell Research

#### Description:

Sets state policy for stem cell research in the State. Requires UH to develop plan to establish an institute for regenerative medicine at school of medicine no later than 12/31/2008.

