CHAPTER 235B

STEM CELL RESEARCH AND THERAPY

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ARRANGEMENT OF SECTIONS

CHAPTER 235B

STEM CELL RESEARCH AND THERAPY

An Act to provide for the conduct and regulation of stem cell research and therapy in The Bahamas and for connected purposes. *37 of 2013*

[Assent - 25th September, 2013]

[Commencement 25th September, 2013]

Short title.

1. This Act may be cited as the Stem Cell Research and Therapy Act.

Purpose of Act.

2. The purpose of this Act is —

(a) to create a legal framework for stem cell research and therapy in The Bahamas to ensure that stem cell research and therapy is conducted safely and ethically having regard to emerging scientific developments;

(b) to foster innovation in stem cell research and therapy with the goal of encouraging the advancement of medical cures and regenerative medicine.

Interpretation.

3. In this Act —

"Act" means the Stem Cell Research and Therapy Act; Ch. 235B.

"chimera" means an animal created by transplanting cells or tissues from an organism of one species into an organism of another species; the resulting chimeric animal being mosaic, with some cells or tissues containing DNA only from the host and others containing DNA only from the donor, but no cells or tissues with combined DNA from both the host and the donor;

"DNA" means deoxyribonucleic acid;

"extra-embryonic tissues" means intrauterine tissues that support the embryo's placenta, umbilical cord, and amniotic sac;

"foetus" means the stage in development of the organism from the end of the embryonic state through birth;

"genome" means the totality of the DNA sequence of a particular cell or individual;

"human reproductive cloning" means attempting to establish a pregnancy or the birth of a human by transferring a human embryo containing a diploid set of chromosomes obtained from a single-living or deceased human being, foetus or embryo;

"human embryo" shall mean the stages of human development from the first cleavage of the fertilized ovum to nine weeks of gestation;

"hybrid" means an animal formed from interbreeding species or fusing genetic material of two distinct species;

"in vitro embryo" means a human embryo that exists outside the body of a human being;

"Minister" means the Minister responsible for Health;

"nucleus" means a membrane-bound cell structure that contains the genetic information of the cell;

"ovum" means a female reproductive cell, whether mature or not;

"pluripotent cells" means stem cells that can become all cell types, except cells of extra embryonic tissues;

"primitive streak" means a stage in early human development when the first sign of a nervous system appear;

"Somatic Cell Nuclear Transfer" means the insertion of a nucleus of a somatic (or, differentiated) cell into an ovum from which the nuclear material (chromosomes) has been removed, and its subsequent activation;

"sperm" means a male reproductive cell, whether mature or not;

"stem cell" means an undifferentiated cell of a multicellular organism that is capable of self-replication, proliferation and differentiation;

"stem cell research" means —

(a) any manipulation of stem cells or stem cell derivatives for the purpose of learning about the stem cells' function, structure, effect, or other characteristic and includes *in vivo* (human and animal) and *in vitro* investigations; or

(b) any medical experiments, or scientific or psychological investigation involving stem cells or stem cell derivatives, which involves physical or psychological intervention by the researcher upon the body of a human or animal subject and which is undertaken for the purpose of gaining generalizable knowledge rather than undertaken in the normal course of the subject's medical treatment or diagnosis,

but shall not include the mere storage or transport of stem cells;

"stem cell therapy" or "therapy" means administering stem cells or stem cell derivatives to human patients to treat, prevent, or mitigate a disease or condition;

"totipotent cells" means stem cells that can become all cell types, including cells of extra embryonic tissues.

Establishment of National Stem Cell Ethics Committee.

4. (1) There shall be a committee to be known as the "National Stem Cell Ethics Committee" (hereinafter referred to as "the Committee") which shall be responsible for —

(a) ensuring that all stem cell research and therapy conducted in The Bahamas meet best practices and international standards;

(b) developing and implementing policies to monitor compliance with this Act and any regulations thereunder.

(2) The members of the Committee shall be appointed by the Minister for such period as he shall specify and shall be persons qualified as having had experience of or having shown capacity in matters relating to science, medicine, commerce, religion, education, ethics or law.

(3) At least one member of the Committee shall be recognised internationally as a leader in stem cell science.

(4) The Minister shall appoint one of the members to be the Chairman of the Committee.

(5) The Chairman may nominate any member to perform the functions of Chairman at any meeting of the Committee at which the Chairman is absent, and such nomination may be either general or in relation to a specific occasion.

(6) The Chairman may after consultation with the Minister summon any person who is not a member of the Committee to attend any meeting of the Committee whenever he considers it desirable to do so.

(7) For the purpose of any proceedings, the Committee has the power of summoning before it any witnesses and requiring them to give evidence on oath, or on solemn affirmation if there are persons entitled to affirm, and to produce such documents and things as the committee deems requisite.

(8) For the purposes of subsection (1), the Committee shall approve such Review Committees as may be prescribed by regulations.

(9) The Committee may appoint and employ on such terms and conditions as it thinks fit any officer, servant or agent as it considers necessary for the proper carrying out of the provisions of this Act.

Minister may give directions.

5. The Minister may give the National Committee written directions as to government's policy that is to be applied by the National Committee in the performance of its duties and the National Committee shall comply with such directions.

Prohibited procedures.

6. (1) No person shall engage in research or therapy that seeks to —

(a) create a human reproductive clone by using any technique, or transplant a human reproductive clone into a human being or into any non-human life form or artificial device;

(b) create a human *in vitro* embryo for any purpose other than human reproduction;

(c) derive a new stem cell line from a human embryo;

(d) maintain a human embryo for any purpose other than human reproduction outside the body or conduct research involving an *in vitro* embryo for more than fourteen days following its creation, or after the appearance of the primitive streak, excluding any time during which its development has been suspended;

(e) alter the genome of a cell of a human being or *in vitro* embryo such that the alteration is capable of being transmitted to descendants;

(f) transplant a sperm, ovum, embryo or foetus of a non-human life form into a human being;

(g) implant human totipotent or pluripotent cells into a human or non-human primate uterus, except in the context of *in vitro* fertilization;

(h) breed animal chimeras that have the potential to form sperm or eggs containing human DNA;

(i) create a hybrid containing any human genetic material, or transplant a hybrid into a human being or a non-human life form.

(2) No person shall offer to do, or advertise the doing of, anything prohibited by subsection (1).

(3) No person shall pay or offer to pay consideration to any person for doing anything prohibited by this section.

Licensing requirements.

7. (1) Any facility or laboratory used for the purpose of providing stem cell therapy or conducting stem cell research shall be licensed as a facility in accordance with the provisions of the Hospital and Health Care Facilities Act.

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(2) The Hospital and Health Care Facilities Act shall, save as provided herein and any regulations applicable thereto and subject to such modifications, adaptations, qualifications and exceptions as may be necessary, apply to the provisions relating to licensing and inspection of such facilities.

Power of Minister.

8. (1) The Minister may, acting on the advice of the Committee or on the basis of findings from an inspector, make a determination —

(a) that a facility or laboratory is operating in a manner that is detrimental to the public health or public safety; or

(b) that it is otherwise in violation of this Act, and

based on that determination, by order published in the *Gazette*, suspend with immediate effect the operation of that facility or laboratory.

(2) The Minister shall within seventy-two hours after suspending the operation of a facility or laboratory, inform the licensee or Administrator of that facility or laboratory, of any conditions that must be complied with prior to the lifting of any order made under subsection (1).

(3) A person who fails to comply with an order made pursuant to subsection (1) is guilty of an offence and is liable on summary conviction to a fine of fifty thousand dollars or to imprisonment for three years or to both that fine and imprisonment.

(4) A person aggrieved by a decision of the Minister made under subsection (1), may appeal to a judge of the Supreme Court, but such appeal shall not operate as a stay of the decision of the Minister.

Offences by bodies corporate.

9. (1) Where an offence under this Act committed by a body corporate is proved —

(a) to have been committed with the consent or connivance of; or

(b) to be attributable to any neglect on the part of,

any director, manager, secretary or other similar officer of the body corporate, or any person who was purporting to act in any such capacity, such director, manager, secretary or other similar officer or person, as well as the body corporate, shall be guilty of that offence and shall be liable to be proceeded against and punished accordingly.

(2) Where the affairs of a body corporate are managed by its members, subsection (1) shall apply in relation to the acts and defaults of a member in connection with his functions of management as if he were a director of the body corporate.

Report to be submitted to Minister.

10. (1) The Committee shall, at the end of each year, prepare a report on its activities and on the impact that stem cell research and therapy has had on the fiscal affairs of The Bahamas and shall furnish such report to the Minister.

(2) The Minister shall cause a copy of the report to be laid on the table of both Houses of Parliament.

Fees.

11. The Minister may prescribe fees to be paid in respect of matters arising under this Act

Offences and penalty.

12. A person who fails to comply with any of the provisions of this Act or any regulations made hereunder commits an offence and is liable on summary conviction to a fine of two hundred and fifty thousand dollars or to a term of imprisonment for ten years or to both that fine and imprisonment.

Consent to prosecute.

13. No prosecution for an offence under this Act shall be commenced without the consent of the Attorney-General.

Regulations.

14. The Minister may, after consultation with the Committee, make regulations for prescribing anything which may be prescribed under this Act and generally to give effect to the provisions of this Act and in particular those Regulations may provide for —

(a) the conduct and approval of non-clinical research and clinical research;

(b) the review and approval of stem cell therapy protocol;

(c) the storage, manipulation, transport and disposal of stem cells and stem cell derivatives;

(d) the qualification of inspectors;

(e) the treatment and care of patients;

(f) carrying out the purposes and provisions of this Act.