ANTIGUA AND BARBUDA

STEM CELL RESEARCH AND THERAPY BILL, 2019

No. of 2019

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ARRANGEMENT OF CLAUSES

CLAUSES

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ANTIGUA & BARBUDA

STEM CELL RESEARCH AND THERAPY BILL, 2019

NO. OF 2019

AN ACT to provide for the conduct and regulation of Stem Cell Research and Therapy and the licensing of laboratory and facilities suited for conducting stem cell research and therapy and for connected purposes.

ENACTED by the Parliament of Antigua and Barbuda as follows:

PART I

PRELIMARY

1. Short title and commencement

(1) This Act may be cited as Stem Cell Research and Therapy Act, 2019.

(2) This Act comes into operation on a day to be appointed by the Minister by Notice published in the official *Gazette*.

2. Purpose of the Act

The purpose of this Act is—

(a) to create a legal framework for stem cell research therapy in Antigua and BarbudA;

(b) to ensure that stem cell research and therapy is conducted safely and ethically having regard to emerging scientific developments;

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

(d) to provide for the licensing of buildings as laboratories or facilities and for matters incidental thereto.

3. Interpretation

In this Act—

"Administrator" means the person who is responsible for the operations and management of a laboratory or research facility;

"clinic" means a facility where persons suffering from any sickness, injury or infirmity may be retained for less than twenty-four hours for the purpose of diagnosing and treating the sickness, injury or infirmity, but does not include a licensed laboratory;

"Committee" means the National Stem Cell Oversight Committee established under section 4

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

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

"guardian" means a person appointed by a will or by order of a Court to be guardian of child;

"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 a 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;

"inspector" means a person employed by the Committee and any person designated or appointed under section 37;

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

"licence" means a licence issued by the Committee under section 19;

"medical practitioner" means a person who is registered to practice under the Medical Practitioners Act 2009;

"Minister" means the Minister responsible for Health;

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

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

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

"regenerative tissue" means tissue that, after injury within or after removal from the body of a living person, is replaced in the person's body by natural processes;

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

"stem cell research" means–

(a) any manipulation of stem cells or stem 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 untaken 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 cell or stem cell derivatives to human patients to treat, prevent, or mitigate a disease or condition;

"therapeutic facility" includes a building or place used for the treatment by means of therapy, of persons suffering from any sickness, disease or injury;

"tissue" includes an organ, a part of a human body and a substance extracted from the human body or a part of the human body, but does not include—

(a) spermatozoa or ova;

(b) an embryo or a foetus or a part of an embryo or a foetus; or

(c) blood or a blood constituent;

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

"transplant" means the removal of tissue from a human body, whether living or dead, and its implantation into another living human body.

PART II

STEM CELL RESEARCH AND THERAPY

4. Establishment of National Stem Cell Oversight Committee

(1) For the purposes of this Act, there is hereby established a Committee consisting of five persons to be known as the "National Stem Cell Oversight Committee", hereinafter referred to as "the Committee".

(2) The Committee is constituted as follows—

(a) the Chief Medical Officer or his or her nominee;

(b) the Director of Analytical Services or his or her nominee;

(c) a person nominated by the Minister responsible for Legal Affairs and approved by the Cabinet; and

(d) four persons with extensive knowledge in stem cell research nominated by the Minister responsible for Health and approved by the Cabinet.

(3) The names of all members appointed to the Committee as first constituted and every change in membership shall be published in the official *Gazette*.

(4) A person appointed to be a member of the Committee shall vacate his seat at the expiration of three years from the date of his appointment, but he is eligible to be reappointed.

(5) The Chief Medical Officer or his or her nominee shall be the Chairperson of the Committee.

(6) A member who fails to attend three consecutive meetings of the Committee without the permission of the Chairman shall vacate his seat.

(7) Three members of the Committee shall constitute a quorum.

(8) The Committee shall set its own procedures of operation.

5. Functions of the National Stem Cell Oversight Committee

(1) The Committee shall be responsible for –

(a) developing regulations for the practice of stem cell research and therapy;

(b) develop and implement policies to monitor compliance with this Act and any regulations thereunder;

(c) issuing licences for the use of buildings as laboratories, or facilities;

(d) issuing licences to providers to engage in the activity of conducting stem cell research and therapy;

(e) inspection of laboratories and facilities;

(f) initiating investigations into any matter affecting the diagnosis, treatment and care of a patient within a laboratory or research facility licensed under this Act;

(g) appointing inspectors for the purposes of this Act; and

(h) to do such other things as may be prescribed by this Act or any other relevant written law.

(2) On the advice of the Committee, the Minister, may appoint or employ any person or company on such terms and conditions as the Minister thinks fit to assist the Committee with the proper carrying out of the provisions of this Act.

6. Minister may give directions

The Minister may give the Committee written directions of a general nature as to Government's policy that is to be applied by the Committee in the performance of its duties and the Committee shall comply with such directions in so far as such directions are consistent with this Act and with the regulations made hereunder governing the quality and safety of stem cells research and therapy.

7. The Committee to appoint inspectors

(1) The Committee shall appoint persons to be inspectors for the purposes of this Act.

(2) Every inspector may be assisted by a team of qualified persons, appointed by the Committee to make an inspection and evaluation of any laboratory or research facility or any aspect of the administration or management thereof.

(3) Any inspector or person appointed to assist such inspector who has a direct or indirect pecuniary interest in any laboratory or research facility shall as soon as possible, disclose the nature of his interest to the Committee and that inspector or person shall not be permitted to inspect or evaluate the laboratory or research facility on which he has a pecuniary interest.

(4) Every laboratory or research facility shall be inspected and evaluated as often as required and at least once a year and the laboratory or research facility, the operation thereof, and its registers and record shall at all times be open to such inspection and evaluation, and upon completion thereof an inspector shall forward a report to the Committee.

(5) Where an inspector has reasonable grounds to believe or to suspect that any building or place is used as a laboratory or research facility without being licensed under this Act, the inspector may upon presentation of his certificate or appointment, at any time, by himself, or with such assistance as he may require, enter and inspect that building or place and every part thereof.

(6) Any person who prevents or obstructs the entry, inspection or examination of a laboratory or research facility by an inspector or any person assisting an inspector, is guilty of an offence and is liable on summary conviction to a fine of thirty thousand dollars or to imprisonment for two years or to both that fine and imprisonment.

8. Funds and resources of the Committee

(1) The funds and resources of the Committee shall consist of —

(a) any moneys as from time to time are provided by Parliament; and

(b) any moneys or other property as from time to time may in any manner be lawfully paid to or vested in the Committee whether or not in respect of any matter incidental to its functions.

9. Accounts and audit

(1) The Committee shall keep proper accounts of all transactions and shall prepare in respect of each financial year a statement of accounts in a form that the Minister may with the approval of the Minister of Finance direct.

(2) The accounts shall be audited annually by an auditor appointed by the Committee with the approval of the Minister.

10. Annual report

(1) The Committee shall, as soon as possible after the expiration of each financial year and in any event not later than the 30th June in any year, submit to the Minister a report containing —

(a) an account of its transactions throughout the preceding financial year in such detail as the Minister may direct; and

(b) a statement of the accounts of the Committee audited in accordance with section 27.

(2) The Minister shall cause a copy of the report together with a copy of the audited financial statements and the auditor's report to be laid on the table of both Houses of Parliament.

(3) The Committee shall, as soon as possible after the expiration of each financial year submit to the Minister a report dealing with the activities of the Committee during the preceding financial year.

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

PART III

REQUIREMENT FOR LICENCE

11. Laboratories or facilities to be operated only under a licence

(1) After the commencement of this Act, no person shall use any building as a laboratory or a research facility for the purpose of conducting any stem cell research, procedure or therapy except under and in accordance with the terms of a licence issued under this Act.

(2) A person who contravenes subsection (1) is guilty of an offence and is liable on summary conviction to a fine of one hundred and fifty thousand dollars or to imprisonment for three years or to both such fine and imprisonment.

12. Application for a licence to use a building as a laboratory or research facility

(1) An application for a licence to use any building as a laboratory or research facility for the purpose of stem cell research or therapy shall be made to the Committee in the prescribed form.

(2) The Committee may, upon receipt of an application under subsection (1) grant a licence in the prescribed form if it is satisfied —

(a) that the applicant is a fit and proper person to operate a laboratory or research facility;

(b) that the applicant has paid the prescribed fee; and

(c) that the laboratory or research facility would be operating in the interest of the public health or in a manner that is not injurious to the public health.

(3) A licence to use a building as a laboratory or research facility may be granted subject to such terms and conditions as the Committee sees fit to impose.

(4) A licence issued under this Act in respect of any laboratory or research facility shall be kept affixed displayed in a conspicuous place in the laboratory or research facility.

(5) A licensee who fails to comply with subsection (3) is guilty of an offence and liable on summary conviction to a fine of one thousand dollars and in addition to the fine, a sum of five hundred dollars for each day the offence continues subsequent to the date to which the conviction relates.

13. Licensing of existing laboratories and facilities

(1) The Committee shall issue a temporary licence valid for a period of six months to any occupier of a laboratory or research facility that was, prior to the passing of this Act by the Parliament, used for the purpose of stem cell research and therapy.

(2) The occupier of a laboratory or research facility meeting the requirements of subsection (1) shall apply to the Committee within 30 days of the passing of this Act for the grant of a licence to continue to use the laboratory or research facility for the purpose of stem cell research and therapy.

(3) The Committee shall provide a response to the occupier's application within 60 days of the application being received.

(4) The provisions of section 8 apply equally to an occupier under this section and a new laboratory or research facility.

14. Contents of licence

A licence shall specify—

(a) the name of the administrator;

(b) the name of the licensee where he is not the administrator;

(c) the description and address of the building in respect of which the licence is granted;

(d) the nature of the service that may be provided at the building; and

(e) such other particulars, if any, as may be prescribed.

15. Duration of licence

(1) A licence shall take effect on the date specified in the licence as the date on which it is to take effect, and shall expire on the thirty-first day of December of that year.

(2) A licence granted under sections 12 or 13 is subject to renewal every two years upon payment of the prescribed fee.

16. Register

(1) The Committee shall prepare and maintain a Register containing names, addresses and such other particulars as may be prescribed of all laboratories or facilities which are licensed under this Act.

(2) The Committee shall cause the Register to be published in the *Gazette* as soon as practicable after the expiration of thirty days after the commencement of this Act, and thereafter in

each year as soon as practicable, after the thirty-first day of January, and the thirty-first day of July, respectively.

(3) In each year after the Register is published under subsection (2), the Committee shall cause to be published in the Gazette as aforesaid a corrected edition of the Register or a list with additions made to the Register since it was last published.

(4) The Committee shall keep the Register open at all reasonable times for inspection by members of the public.

17. Committee's refusal to renew

(1) The Committee may refuse to renew the licence of a laboratory or a research facility if, in the opinion of the Committee –

(a) the laboratory or the research facility is not being operated in the interest of the public health;

(b) the laboratory or the research facility is being operated in a manner that is injurious to the public health;

(c) the licensee of such laboratory or research facility is not a fit and proper person under the Medical Practitioner's Act.

(2) Where the renewal of a licence is refused or where a licence is suspended or revoked, the licence shall not be displayed in a manner that may induce any person to believe that it is still in force.

(3) A person who displays a licence contrary to subsection (2) is guilty of an offence and is liable on summary conviction to a fine of a one hundred thousand dollars or to imprisonment for two years or to both such fine and imprisonment.

18. Variation of a licence

(1) The Committee may, at any time upon an application made by a licensee, or of its own motion, vary any of the terms or conditions of a licence.

(2) The Committee shall, in varying any terms or conditions of a licence, take into account any representations made to it by the licensee, or on behalf of the licensee.

(3) The Committee shall not vary the terms or conditions of a licence on its own motion unless the licensee has been given a reasonable opportunity to make representations on the matter.

19. Suspension or revocation of licence

(1) The Committee may, by notice in writing, suspend or revoke the licence of a laboratory or research facility if —

(a) the respective licensee or the Administrator of the laboratory or research facility has been convicted of an offence under this Act;

(b) the licensee or the Administrator wilfully neglects or refuses to comply with any of the provisions of this Act,

(c) the licensee or the Administrator obstructs, impedes or hinders any person carrying out any duties or responsibilities under this Act or the regulations;

(d) if in the opinion of the Committee, the laboratory or research facility's building is kept in an unsanitary condition or is without proper fire protection; or

(e) the business of the laboratory or research facility is conducted in a manner contrary to this Act, or in such a manner that the revocation of the licence is required in the interest of the public health.

(2) Before issuing a Notice under subsection (1), the Committee shall give to the licensee not less than fourteen days' notice of its intention to suspend or revoke the licence.

(3) The notice under subsection (1) shall –

(a) state the grounds on which the action is to be taken;

(b) contain a statement to the effect that the licensee has fourteen days after receipt of the notice to show cause, in person or by a representative, why the action should not be taken.

(4) If the Committee, shall take into consideration any representation that the licensee may make, and if the Committee decides that the reasons for suspending or revoling the licence subsist, it shall make the order suspending or revoking the licence.

(5) An order made under subsection (4) shall be served on the licensee in any manner acceptable by rules of court governing service of documents.

(6) A person aggrieved by an order suspending or revoking a licence may appeal to a judge of the High Court, but such appeal shall not operate as a stay of the decision of the Committee.

20. Suspension of operations

(1) Notwithstanding sections 12 and 15, the Minister, acting on the advice of the Committee, may by order published in the *Gazette* suspend with immediate effect the operation of the licence of any laboratory or research facility pending the outcome of an investigation

(2) A copy of the Order made under subsection (1) shall be served forthwith upon the licensee together with any conditions that must be complied with before the order may be llifted.

(3) A person who contravenes subsection (1) or (2) is guilty of an offence and is liable on summary conviction to a fine of one hundred and 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 High Court, but such appeal shall not operate as a stay of the decision of the Minister.

21. Transfer of a licence

A licensee shall, as soon as practicable, notify the Committee of any agreement for the transfer of a licence or of any circumstance that affects the information outlined in section 10.

22. Appeal to Minister

(1) A person aggrieved by —

(a) a decision of the Committee to refuse to grant, renew, transfer, or vary a term or condition of a licence;or

(b) any other decision of the Committee in the exercise or purported exercise of any power or authority conferred upon it by this Act,

may within fourteen days from the date on which the decision is communicated to him, appeal in respect thereof in writing to the Minister.

(2) Pursuant to an appeal under subsection (1), the Minister may confirm, modify or reverse the decision of the Committee complained of, or may make such other order as the Minister thinks just.

PART IV

PROHIBITED PROCEDURE

23. Prohibited procedures

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

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

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

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

(d) breed animal chimaeras that have the potential to form sperm or eggs containing human DNA.

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

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

(4) A person who contravenes this section commits an offence and is liable on conviction on indictment to a fine of one million dollars ($1,000,000) or to imprisionment for ten years or to both such fine and imprisonment.

PART V

OFFENCES

24. Offences involving bodies corporate

(1) A body corporate commits an offence and shall be liable to be proceeded against and punished accordingly if it is proved on the part of the body corporate that the offence —

(a) was committed with its consent or connivance; or

(b) is attributable to any gross negligence on the part of any employee of the body corporate, or any person who was purporting to act in any such capacity;

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

25. Offences and penalty

A person who fails to comply with any of the provisions of this Act or the regulations made under this Act, commits an offence.

26. Penalty for offences not otherwise provided for

(1) Any person who is guilty of an offence under this Act for which no penalty is provided elsewhere in this Act, shall be liable on summary conviction to a fine or five thousand dollars or to imprisonment for three months or to both that fine and imprisonment.

(2) Where the licensee is a company, every officer, director or agent of the company who directed, authorized, condoned or participated in the commission of any offence under this Act, is liable to the like penalties as the company and as if he had committed the like offence personally.

PART VI

MISCELLANEOUS

27. Report to be submitted to Minister

(1) The Committee shall, at the end of each calendar year, prepared a report on its activities and shall furnish such report to the Minister.

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

28. Administrator

(1) Every laboratory or research facility shall have at all times an Administrator whose name shall be registered with the Committee.

(2) Every Administrator and medical practitioner shall possess such qualifications as may be prescribed by regulations and such regulations may contain different qualifications for Administrators of different laboratories and facilities.

29. Administrator deemed to be the occupier for certain purposes

The Administrator of a laboratory or research facility shall be deemed to be the occupier of the building for the purpose of giving notice or information of the death of any person or of the birth of any child in that laboratory or research facility under the Births and Deaths (Registration) Act, Cap. 53.

30. Patient to be under care of medical practitioner

(1) Each patient admitted to a laboratory shall remain under the care of a medical practitioner.

(2) Each patient admitted to a research facility shall remain under the care and treatment of a health practitioner qualified to administer care and treatment for that patient's sickness or injury.

31. Register of patients and particulars in case of transfer or death

(1) The Administrator of a laboratory or research facility shall keep or cause to be kept a register of patients in which shall be recorded—

(a) the name, age, sex and usual place of abode of each patient, and the date of his admission, or attendance, as the case may be;

(b) the diagnosis of each patient;

(c) the name of the medical practitioner attending each patient;

(d) the date on which each patient leaves the laboratory or research facility and, if transferred to another laboratory or research facility, the name of the other laboratory or research facility, in the event of the death of a patient in the laboratory or research facility, the date of his death.

(2) The particulars required by subsection (1) to be recorded in the register shall be so recorded as soon as practicable after the occurrence of the act or event to which the entry relates.

(3) The Administrator of a laboratory or research facility shall, within forty-eight hours of the death of any patient, in the laboratory or research facility, forward to the Chief Medical Officer, a copy of the notification of the death of a patient and the name of the attending medical practitioner.

(4) Any person who knowingly makes a false entry in the register of patients is guilty of an offence and is liable on summary conviction to a fine of twenty thousand dollars or to imprisonment for one year or to both that fine and imprisonment.

(5) Any Administrator who fails to make any record in the register required by subsections (1) and (2) to be made therein or the notification as required by subsection (3) is guilty of an offence and is liable on summary conviction to a fine of five thousand dollars or to imprisonment for three months or to both that fine and imprisonment.

32. Regulations

The Minister may, after consultation with Committee, make regulations 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 conducted within Antigua and Barbuda;

(b) the treatment and care of patients;

(c) fees which are to bepaid upon application for a licence.

Passed the House of Representatives on the day of , 2019.

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Speaker.

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Clerk to the House of Representatives.

Passed the Senate on the day of , 2019.

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President.

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Clerk to the Senate.