

LONGEVITY AND REGENERATIVE THERAPIES BILL, 2024

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LONGEVITY AND REGENERATIVE THERAPIES BILL, 2024

A BILL FOR AN ACT TO PROVIDE FOR THE APPROVAL AND REGULATION OF LONGEVITY AND REGENERATIVE THERAPIES AND RELATED MATTERS

Enacted by the Parliament of The Bahamas

1. Short title and commencement.

- (1) This Act may be cited as the Longevity and Regenerative Therapies Act, 2024.
- (2) This Act shall come into force on such date as the Minister may specify by Notice published in the Gazette.

2. Interpretation.

In this Act—

“**approved therapy**” means any therapy granted full, provisional or research approval;

“**Board**” means the Board established pursuant to section 6;

“**efficacy**” means the ability of a therapy to achieve the intended therapeutic effect based on substantial evidence;

“**Ethics Committee**” means the Committee established pursuant to section 9;

“**Field**” means the global scientific domain of research and administration of therapies that aim to enhance human healthy longevity, including but not limited to, gene therapies, stem cell therapies and/or

biological materials derived from stem cells, advanced longevity therapies, immunotherapies, cancer therapies, regenerative therapies, functional medicines, and gerontology;

“**foetus**” means the stage in development from the end of the embryonic stage to birth;

“**gene therapy**” means any product that modifies a person’s targeted genes to treat or cure a disease or act on the underlying cause of a disease or aging and includes—

- (a) replacing a disease-causing gene with a healthy copy of the gene;
- (b) inactivating a disease-causing gene that is not functioning adequately; and
- (c) introducing a new or modified gene into the body to help treat a disease or the underlying cause of the disease;

“**health**” is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity;

“**health care facility**” includes a clinic, a walk-in clinic, a surgical centre, a birth centre, a dialysis centre, a maternity hospital, a diagnostic facility, a health practitioner’s office, a medical practitioner’s office, Blood Bank, therapeutic facility, laboratory or radiology facility, diagnostic imaging facility or any other facility which offers medical or surgical care as defined in the Hospitals and Health Care Facilities Act (*Ch. 235*);

“**Hospitals and Health Care Facilities Licensing Board**” means the body established under section 4 of the Hospitals and Health Care Facilities Act (*Ch. 235*);

“**human embryo**” means the stages of a human development from the first cleavage of the fertilized ovum to the end of the first nine weeks gestation;

“**immunotherapy**” means any product that uses a person’s own immunological agents, such as cells, antibodies, and growth factors, to fight diseases, guide, boost or activate the immune system, or prevent rejection of a transplanted organ or tissue;

“**informed consent**” is the voluntary decision about whether to undergo a therapy after a process in which a health care provider or his representative educates a patient about the risks, benefits, and alternatives of a given procedure or intervention;

“**longevity**” means a long and healthy duration of individual life as measured by the capability to survive beyond the species-specific average age of death, the individual’s ability to live past their life expectancy at birth;

- “**manufacture**” means all steps in propagation, processing, and preparation of therapies;
- “**manufacturing facility**” means any facility engaged in the manufacture of any therapy;
- “**Minister**” means the Minister responsible for Health and Wellness;
- “**Monitoring Body**” means the body established pursuant to section 18;
- “**Nomination Committee**” means the committee referred to in section 5;
- “**precedent condition**” means any condition upon which the Ethics Committee grants a provisional approval, including but not limited to additional data requirements, post-marketing studies, risk mitigation requirements, and monitoring and reporting obligations;
- “**record**” means any physical, electronic or other information created in the course of carrying out activities regulated under this Act, including documentation of processes, procedures, tests, inspections and other activities related to therapies;
- “**regenerative therapy**” means a cell therapy, immunotherapy, therapeutic tissue engineering product, human cell and tissue product, stem cell and/or biological materials derived from stem cells, or a combination product using any such therapies or products;
- “**research**” means any clinical investigation involving a therapy required to be approved by the Ethics Committee under this Act;
- “**safety**” means the relative freedom from harmful effect to persons affected, directly or indirectly, by a product when taking into consideration the character of the product in relation to the condition of the recipient at the time;
- “**stem cell therapy**” means stem cell products or stem cell derivatives administered to human patients to prevent, mitigate or treat a disease or condition;
- “**therapy**” means any product regulated under this Act, including any regenerative therapy or longevity treatment.

3. Purpose of Act.

The purpose of this Act is —

- (a) to create in the Commonwealth of The Bahamas a legal framework for research and approval of therapies, as defined in this Act;
- (b) to ensure that therapy related research is conducted safely, ethically, with scientific rigor and with regard to emerging scientific developments worldwide; and

- (c) to foster global research, innovation and treatment in regenerative, holistic or/and functional therapies, including cancer therapy and plant-based or/and innovative treatments and medicines that enhance the mental and physical state necessary for healthy longevity.

4. Policy.

- (1) The Minister shall prepare a Longevity and Regenerative Therapy Policy (“the Policy”) which shall be approved by the Cabinet and laid in the House of Assembly.
- (2) The Policy shall be reviewed every two years and updated and approved by the Cabinet and laid in the House of Assembly.
- (3) The Board and the Ethics Committee shall carry out their duties and powers under this Act in accordance with the Policy.

5. Nomination Committee.

- (1) There shall be a body called the “Nomination Committee”.
- (2) The Board shall select a ‘Nomination Committee’ comprised of 3 appropriately qualified persons with the knowledge, experience and expertise in the Field and following consultation with the Minister.
- (3) The Nomination Committee shall be responsible for—
 - (a) providing to the Minister a list of persons qualified to serve on the Ethics Committee after consultation with the relevant local and international medical bodies, scientific bodies, religious and faith-based organizations and patient advocacy groups based on the criteria for composition of the Ethics Committee outlined in the Act; and
 - (b) maintaining a list of 25 persons qualified to serve on the Ethics Committee including obtaining resumes and references of persons included on the list.

6. Establishment of National Longevity and Regenerative Therapy Board.

There shall be a Board called the “National Longevity, and Regenerative Therapy Board”.

7. Members of the Board.

- (1) The members of the Board shall be appointed by the Minister.

- (2) The Board shall consist of seven members—
 - (a) three members shall be qualified and experienced in the Field;
 - (b) one member shall be qualified as having had experience in or having shown capacity and competency in matters relating to law or compliance;
 - (c) one member shall be qualified as having had experience in information technology in the Field;
 - (d) one member shall be qualified as having had experience in or having shown capacity and competency in matters relating to business and investment; and
 - (e) one member shall be an internationally known scientist or medical specialist in the Field.
- (3) All members of the Board shall be appointed for three years, and shall be eligible for re-appointment.
- (4) The Minister shall appoint one of the members to be Chairperson of the Board.
- (5) The Chairperson may nominate any member to perform the function of Chairperson at any meeting of the Board at which the Chairperson is absent.
- (6) The Chairperson and four other members shall constitute a quorum.

8. Responsibilities and powers of the Board.

- (1) The Board shall be responsible for —
 - (a) fostering innovation in the Field;
 - (b) encouraging the advancement of medical tourism and translational sciences in the Field;
 - (c) working with the Ministry of Finance, Ministry responsible for Health, and others to create innovative financial and tax incentives for companies to enter the Field, in The Bahamas, these incentives may include, but are not limited to: regulatory exclusivity, patent protections, expedited programs, VAT tax and tariffs, and exemptions from application or other therapy-related fees;
 - (d) negotiating and entering into agreements or partnerships which further the purposes of this Act in consultation with the Minister of Health;
 - (e) obtaining and maintaining resources required to ensure that best practices and standards are upheld in all in-vivo and ex-vivo therapy and research operations/programs in the Field;

- (f) recommending to the Ministry of Health local standards for clinical research in the Field and contributing to the creation of international standards for the same;
 - (g) developing and implementing policies to monitor compliance with all aspects of the Act and any regulations;
 - (h) authorizing the Monitoring Body to develop and or procure services to ensure that the therapies approved by the Ethics Committee comply with all relevant standards described in this Act and any Regulations promulgated based on authority delegated in this Act; and
 - (i) preparing a report, at the end of each year, on its activities and on the impact that the research and administering of longevity therapy, stem cell therapy, immunotherapy and gene therapy has had on The Bahamas and submitting the report to the Minister.
- (2) The Board may approve a foreign practitioner to perform research and treatments in the Field, provided that the foreign practitioner is operating with a Bahamian citizen or local resident partner or associate that possesses sufficient technical, scientific, medical, nursing or research expertise in the Field.
- (3) The Board may, from time to time, appoint a subcommittee from amongst its members for any purpose the Board deems fit.
- (4) For the purpose of this section —
- “**foreign practitioner**” means a person who currently holds and maintains a licence in good standing to engage in a medical profession and or healthcare profession in a jurisdiction other than The Bahamas and who is not the subject of a pending disciplinary action in any jurisdiction; and
- “**good standing**” means a person, provider, organization, or facility who has complied with all obligations of the regulatory body in his or its jurisdiction and is not being subject to any form of sanction, suspension of disciplinary censure.

9. Establishment of National Longevity and Regenerative Therapy Ethics Review Committee.

There shall be a Committee called the “National Longevity and Regenerative Therapy Ethics Review Committee”.

10. Members of the Ethics Committee.

- (1) The members of the Ethics Committee shall be appointed by the Minister following recommendations of the Nomination Committee.

- (2) The Ethics Committee shall consist of seven members—
 - (a) the Chief medical Officer, *ex officio*
 - (b) two members shall be qualified and experienced in the Field;
 - (c) two members shall be qualified as having had experience in or having shown capacity and competency in matters relating to business, science, medicine, bioethics, patient advocacy, scientific research ethics, law or education; and
 - (d) two members shall be internationally known specialists in the Field.
- (3) A member of the Ethics Committee shall not be a member of the Board.
- (4) All members shall be appointed for a period of up to 3 years and shall be eligible for re-appointment.
- (5) The Minister shall appoint one of the members of Ethics Committee to be the Chairperson of the Ethics Committee.
- (6) The Chairperson may nominate any member to perform the function of Chairperson at any meeting of the Ethics Committee at which the Chairperson is absent.

11. Responsibilities and powers of the Ethics Committee.

- (1) The Ethics Committee shall be responsible for —
 - (a) approving applications for research and administration of therapies in the Field;
 - (b) ensuring that research and administration of therapies in the Field are safely, ethically, and scientifically rigorously implemented;
 - (c) ensuring that research and administration of therapies in the Field are designed with regard to emerging scientific developments worldwide; and
 - (d) preparing a report and submitting the report to the Board, at the end of each year, on its activities; and on the impact that longevity, stem cell therapy, immunotherapy, gene therapy and research has had on the affairs of The Bahamas.
- (2) The Ethics Committee may invite any person who is not a member of the Ethics Committee to attend any meeting of the Ethics Committee whenever it considers it desirable to do so for the purpose of providing information or expert advice.

12. Application.

- (1) Any person or entity ("applicant") seeking full, provisional or research approval of a therapy for any intended use, shall submit an application in writing to the Board with the prescribed fee.

- (2) The Board shall, within thirty (30) days, inform the applicant in writing of the information required to process the application including —
 - (a) scientific description of the therapy to be administered or researched, including the specific intended use for the therapy;
 - (c) applicable legal requirements under Bahamian law;
 - (d) evidence of adequate funding;
 - (e) details of all persons or institutions providing the funding for administration of therapy or the research;
 - (f) details of establishment of facilities for administration of therapy or the research;
 - (g) details of the medical or healthcare professionals or scientists involved in administration of therapy or the research;
 - (h) any application requirements prescribed in regulations; and
 - (i) any other information the Board deems necessary in the circumstances.
- (3) The Board shall forward applications referred to in subsection (1) to the Chairperson of the Ethics Committee.
- (4) The Ethics Committee shall review the application to determine if the therapy meets all required standards for safety, efficacy and ethics.
- (5) The Ethics Committee may request any additional information required to conduct its review under this Act.
- (6) The Board shall ensure that applicants are appraised of the progress of their application.

13. Approvals.

- (1) All applications referred to in section 12(1) conducted in The Bahamas shall be approved by the Ethics Committee prior to the initiation of distribution or research, as applicable.
- (2) The Ethics Committee may determine that an application referred to in section 12(1) for which approval is being sought —
 - (a) has full approval;
 - (b) has provisional approval with precedent conditions;
 - (c) has research approval; or
 - (d) is not approved.
- (3) Once the Ethics Committee is satisfied the precedent conditions have been met the Ethics Committee may then grant full approval to the applicant.
- (4) The Chairperson of the Ethics Committee shall notify the Chairperson of the Board of the Ethics Committee decisions and the application shall be

referred back to the Board once the Ethics Committee review process has been completed.

- (5) The Board shall ensure that the Permanent Secretary of the Ministry responsible for Health is notified of the Ethics Committee approvals.
- (6) The Board shall notify an applicant, in writing, of the Ethics Committee decision.
- (7) Where the application is 'not approved' the applicant may re-submit a revised version of the application for the therapy or research referred to in Section 12(1) up to 3 times.
- (8) An approval under this section does not permit the applicant to start to administer the approved therapy or conduct the approved research until a written notice authorizing the applicant to start is issued by the Board to the applicant pursuant to this section.

14. Authorization to begin research or administer therapy.

Once the Board is satisfied that the applicant has satisfied all requirements to operate a healthcare facility or medical research facility in The Bahamas, the Board shall issue a written notice to the applicant that the applicant is authorized to start.

15. Power to require information.

- (1) The Board may, for purposes of the administration and enforcement of this Act, by notice in writing require any person to —
 - (a) furnish such documents, records and other information as the Board specifies in the notice concerning himself or any other person the Board considers is carrying out any therapy or research covered by this Act;
 - (b) attend at such time and place as the Board specifies in the notice to be examined on oath before the Board concerning the carrying out of any therapy or research covered by this Act by himself or any other person;
 - (c) for the purposes of paragraph (b), produce any record in his custody or control that the Board may require him to produce; and
 - (d) provide the Board with access to the premises where any therapy or research approved under this Act is carried on by him, or records of the therapy or research approved under this Act are kept in order to —
 - (i) examine the records or any other documents, which relate to the therapy or research;
 - (ii) inspect any materials being used;

- (iii) inspect the processes used;
 - (iv) otherwise inspect the premises.
- (2) An applicant for therapy approved under this Act, or the employee or agent of such applicant, who has been given notice under subsection (1) (d) that access to the premises is required shall —
 - (a) give the Board such reasonable assistance in connection with the examination or inspection; and
 - (b) answer, orally or in writing, any questions relating to the examination or inspection.
- (3) Without prejudice to the generality of the Board's powers under subsection (1), the Board may by notice in writing, require a healthcare facility or other institution to —
 - (a) furnish the Board with details of any test or procedure ordered by or on behalf of an applicant for an approved therapy under this Act or related person;
 - (b) cause an officer of the healthcare facility or other institution to appear before the Board to give evidence related to a test or procedure ordered by or on behalf of an applicant for an approved therapy under this Act or related person.

16. Registry.

- (1) The Board shall maintain a registry for all approved therapies under this Act.
- (2) The details, content, and accessibility of this registry shall be prescribed in regulations.

17. Prohibited acts.

- (1) No person or entity shall —
 - (a) genetically modify a human embryo with the intent of that embryo becoming a living human;
 - (b) test gene therapies on patients without informed consent;
 - (c) purposely modify the germline of an adult human;
 - (d) transplant an edited human embryo into a non-human life form;
 - (e) use a replicative virus to deliver therapies, except if specifically approved for a specific treatment by the Ethics Committee.
- (2) No person shall abort or attempt to abort a foetus for the purpose of conducting research.

- (3) No person shall offer to do, or advertise the doing of, anything prohibited by subsections (1) and (2).
- (4) No person or entity shall—
 - (a) cause an approved therapy to be adulterated or misbranded;
 - (b) cause the receipt of any therapy that is adulterated or misbranded; or
 - (c) falsely or fraudulently purport to have any approval from the Ethics Committee or the Board for any therapy regulated under this Act.
- (5) No person or entity shall pay or offer to pay a consideration to a person for doing anything prohibited by this section.

18. Monitoring Body.

- (1) The Board may appoint not less than three persons and not more than five persons to a body called a Monitoring Body.
- (2) The Monitoring Body or their designees, including Monitoring Body inspectors shall —
 - (a) inspect the premises, equipment, and procedures of the owner of an application of any approved therapy or a person acting on behalf of the owner of an application under this Act;
 - (b) examine any records or documents related thereto;
 - (c) track and monitor materials and methods of advertising and marketing approved therapies in the public domain; and
 - (c) make such enquiries
as may be necessary to ascertain whether the research, marketing, operations, manufacturing or other distribution practices related to therapies are in compliance with all directives, terms of approvals, regulations, policies and guidelines of the Ministry of Health, the Board and the Ethics Committee that relate to this Act.
- (3) The Monitoring Body acting pursuant to subsection (2) shall produce evidence of its authority to act under subsection (2).
- (4) The Monitoring Body shall obtain the information under subsection (2) necessary for monitoring and evaluation of therapies under the Act.
- (5) The Monitoring Body shall report its findings to the Board.
- (6) Members of a Monitoring Body shall be compensated on terms as the Board determines.

19. Inspection reports.

- (1) The Board shall inform the Hospitals and Health Care Facilities Licensing Board of any healthcare facility engaging in activities covered by this Act.
- (2) The Hospitals and Health Care Facilities Licensing Board may review the inspection report produced by a Monitoring Body inspector after an inspection is conducted in accordance with this Act and the inspection report relates to a healthcare facility carrying out covered by this Act.
- (3) The Board may make a request to the Hospitals and Health Care Facilities Licensing Board to conduct an inspection in accordance with section 25 of the Hospitals and Health Care Facilities Act (Ch. 235) on any healthcare facility engaged in activities covered by this Act and the Hospitals and Health Care Facilities Licensing Board shall provide a copy of the inspection report to the Board.

20. Use and Licensing Requirements.

- (1) Any healthcare facility used for the purpose of providing therapy or conducting research shall be licensed as a healthcare facility in accordance with the provisions of the Hospitals and Health Care Facilities Act (Ch. 235)
- (2) The Hospitals and Health Care Facilities Licensing Board shall inform the Board of any changes to the licence of any healthcare facility referred to in subsection (1).

21. Powers of The Minister.

- (1) The Minister may, acting on the advice of the Board, make the determination –
 - (a) that a healthcare facility is operating in a manner that is detrimental to the public health or public safety; or
 - (b) that a healthcare facility is otherwise in violation of this Act,and by Order published in the Gazette, suspend with immediate effect the operation of that healthcare facility.
- (2) The Minister shall within seventy-two hours after suspending the operation of a healthcare facility, inform the licensee or Administrator of the healthcare facility, of any conditions that must be complied with prior to the lifting, by Order, of any suspension made under subsection (1).
- (3) A person aggrieved by a decision of the Minister made under subsection (1) may appeal to the Supreme Court but such an appeal shall not operate as a stay of the decision of the Minister.
- (4) The advice of the Board referred to in subsection (1) shall be based on—

- (a) the findings from an inspector who conducted an inspection under section 25 of the Hospitals and Health Care Facilities Act (Ch. 235);
- (b) a report from the Monitoring Body; or
- (c) any other credible information.

22. Reports to be submitted to the Minister.

- (1) The Board shall, at the end of each year, prepare a report and submit the report to the Minister.
- (2) The report shall include details on its activities and on the impact that research and administration of therapies under this Act has had on the affairs of The Bahamas.
- (3) The Minister shall cause a copy of the report to be laid on the table of both Houses of Parliament.

23. Offence.

A person who fails to comply with any of the provisions of this Act or is in violation of any regulations made hereunder commits an offence and is liable to a fine of a minimum of twenty-five thousand dollars or to a term of imprisonment minimum of two years, or to both a fine and imprisonment.

24. Offences by bodies corporate.

- (1) When an offence under this Act committed by a body corporate is proved –
 - (a) to have been committed with consent or connivance of; or
 - (b) to be attributed 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, the person concerned, 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.

25. Regulations.

The Minister may, after consultation with the Board, 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 requirements or clarifications related to —

- (a) the conduct and approval of non-clinical research and clinical research;
- (b) the registration and listing of facilities, entities, and therapies regulated under the Act;
- (c) the review and approval of therapies;
- (d) the establishment of special designation and priority programs for therapies;
- (e) the withdrawal of any full, provisional, or research approval of a therapy;
- (f) the definition of terms referenced in this Act, but not explicitly defined in this Act;
- (g) the interpretation of terms defined in this Act;
- (h) the development, testing, manufacturing, storage, manipulation, transport, disposal, sale, and distribution of any therapy, therapy reagents, components and equipment;
- (i) advertising and promotion of therapies;
- (j) safety and quality deviation reporting;
- (k) recalls and market action;
- (l) storage and shipping of therapies to and within The Bahamas;
- (m) pharmacovigilance and chemistry, manufacturing, and controls of therapies;
- (n) data management, data storage, and recordkeeping related to therapies;
- (o) the qualification of inspectors;
- (p) the treatment and care of patients;
- (q) fees to be paid in respect of the matters arising under this Act;
- (r) confidentiality of information included as part of any application or obtained through any inspection;
- (s) details, content, and accessibility of the registry of approved therapies under this Act;
- (t) administrative penalties for failure to comply with provisions of this Act; and
- (u) carrying out the purposes and provisions of this Act.

26. Repeal.

The Stem Cell Research and Therapy Act (Ch. 235B) is repealed.

27. Savings.

- (1) Notwithstanding the Stem Cell Research and Therapy Act (Ch. 235B) anything done or any action taken in exercise of any power conferred by or under that Act shall continue to be valid.
- (2) Any approvals obtained under the Stem Cell Research and Therapy Act (Ch. 235B) shall be recognized under this Act and shall be treated as if it was obtained from the National Longevity and Regenerative Therapy Ethics Review Committee, provided the owners of applications are in good standing.

OBJECTS AND REASONS

This Bill seeks to establish The Bahamas as a world leader in medical and wellness tourism in the field of longevity and regenerative medicine will provide significant economic, educational, social and health and job opportunities for Bahamian citizens and residents.

Clauses 1 and 2 of the Bill provides for the short title, commencement and interpretation.

Clause 3 of the Bill outlines the purpose of the Bill.

Clause 4 of the Bill provides for the Minister to prepare a policy on longevity stem cell and gene therapy to be approved by cabinet and laid in the House of Assembly and the policy shall guide the decisions of the Board and Ethics Committee.

Clause 5 of the Bill provides for the appointment of a Nomination Committee.

Clauses 6 and 7 of the Bill provide for the establishment of the National Longevity and Regenerative Therapy Board and its membership.

Clause 8 of the Bill provides for responsibilities and powers of the Board including—

- (a) ensuring that best practices and standards are upheld in all in-vivo and ex-vivo therapy and research operations/programs;
- (b) developing and implementing policies to monitor compliance with all aspects of the Act;
- (c) reporting to the Minister annually.

Clauses 9 and 10 of the Bill provide for the establishment of the National Longevity and Regenerative Therapy Ethics Review Committee and its members.

Clause 11 of the Bill provides for responsibilities and powers of the Ethics Committee including—

- (a) ensuring the therapy and research programs are safely, ethically, and scientifically implemented;
- (b) ensuring the therapy and research programs are designed with regard to emerging scientific developments worldwide; and
- (c) preparing a report and submitting the report to the Board annually.

Clause 12 of the Bill provides for the application process—

- (a) by a person wishing to engage in the administration or research of new therapies covered by the Act including submit his application in writing to the Board;
- (b) the Board informs the person of the information required to process the application;
- (c) the Board forwards the application to the Chairperson of the Ethics Committee;
- (d) the Ethics Committee shall review the application and may request further information from the applicant if necessary.

Clause 13 of the Bill provides for the determination of an application reviewed by the Ethics Committee which may be full approval, provisional approval or not approved and the Ethics Committee shall advise the Board of its determination and the Board shall advise the applicant, in writing, of the decision of the Ethics Committee. An approval by the Ethics Committee does not mean that the applicant may start to administer the approved therapy or conduct the approved research. The board must also issue, in writing, authorization to begin.

Clause 14 of the Bill provides that once the Board is satisfied that the approved applicant has also obtained all of the necessary licences and approvals for a medical or healthcare professional to operate the Board shall issue, in writing, authorization to begin.

Clause 15 of the Bill provides that the Board may require a person to attend and produce documents and give oral evidence under oath.

Clause 16 of the Bill provides that the Board maintain a registry of the therapies and research approved by the Ethics Committee.

Clause 17 of the Bill prohibits any therapy or research that seeks to –

- (a) genetically modify a human embryo with the intent of that embryo becoming a living human;
- (b) test gene therapies on patients without informed consent;
- (c) purposely modify the germline of an adult human;
- (d) transplant an edited human embryo into a non-human life form;
- (e) use a replicative virus to deliver therapies, except if specifically approved for a specific treatment by the Ethics Committee.

Clause 18 of the Bill provides for appointment by the board of a Monitoring Body.

Clause 19 of the Bill provides for the Hospitals and Health Care Facilities Licensing Board share the inspection reports relating to any facility where a therapy or research approved under this Act is being carried out.

Clause 20 of the Bill provides that any facility carrying out therapies or research under this Act must be licensed by the Hospitals and Health Care Facilities Licensing Board.

Clause 21 of the Bill provides the Minister with powers to suspend the operations of any laboratory, hospital or healthcare facility where it is determined that it is operating in a manner that is detrimental to the public health or public safety or is in violation of the Act.

Clause 22 of the Bill provides for a report to be prepared annually by the Board outlining the work of the board and submitted to the Minister who shall lay the report in Parliament.

Clause 23 of the Bill provides for offences where a person fails to comply with the provisions of the Act.

Clause 24 of the Bill provides the liability of persons a part of the company.

Clause 25 of the Bill provides for the Minister, after consultation with the Board to make regulations.

Clause 26 of the Bill repeals the Stem Cell Research and Therapy Act (Ch. 235B).

Clause 27 of the Bill provides anything done or any action taken in exercise of any power conferred by or under the Stem Cell Research and Therapy Act (Ch. 235B) shall continue to be valid and approvals obtained under the Stem Cell Research and Therapy Act (Ch. 235B) shall be recognized under this Act

