CHAPTER 235B

STEM CELL RESEARCH AND THERAPY

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CHAPTER 235B

STEM CELL RESEARCH AND THERAPY

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CHAPTER 235B

STEM CELL RESEARCH AND THERAPY

STEM CELL RESEARCH AND THERAPY REGULATIONS

S I 62/2014

(SECTION 14)

[Commencement 8th October, 2014]

PART I - PRELIMINARY

Citation.

1. These Regulations may be cited as the Stem Cell Research and Therapy Regulations.

Application.

2. These Regulations shall apply to all stem cell research and therapy conducted in The Bahamas.

Interpretation.

3. In these Regulations —

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

"autologous" means derived or transferred from the same individual's body;

"allogenic stem cell procedures" means a procedure whereby stem cells or the product of stem cells are transferred from one individual into a different individual;

"clinical" means performed in humans;

"experimental stem cell therapy" means stem cell therapy not accepted as standard medical practice;

"minimal manipulation" or "minimally manipulated" means the extraction of autologous stem cells maintained under non-proliferating conditions for short periods of time, normally less than 48 hours;

"non-clinical" means not performed in humans;

"Review Entities" means the National Committee, the Science and Compliance Subcommittees, and the Local Review Boards, collectively;

"the National Committee" means the National Stem Cell Ethics Committee.

PART II - SCIENTIFIC AND ETHICS OVERSIGHT AND REVIEW

The National Committee.

4. (1) The National Committee shall have nine members appointed by the Minister and shall include —

(a) the Chairman; and

(b) eight persons,

who shall satisfy international standards for membership on an Ethics Committee.

(2) The National Committee shall ensure that all research and therapy involving human derived stem cells receives the appropriate level of prior approval and on-going oversight, which may include review by —

(a) a National Stem Cell Science Subcommittee of the National Committee ("Science Subcommittee");

(b) a National Stem Cell Compliance Subcommittee of the National Committee ("Compliance Subcommittee");

(c) Local Stem Cell Ethical Review Boards ("Local Ethical Review Boards"); and

(d) Local Stem Cell Scientific Review Boards ("Local Scientific Review Boards").

(3) The National Committee, with assistance as needed from the Science Subcommittee and the Compliance Subcommittee, shall review and approve the membership of each Local Review Board, upon its formation and annually, to ensure the proper composition and expertise of each Board.

(4) The National Committee shall issue guidelines for stem cell research and therapy, which, at a minimum, shall address —

(a) which Review Entities shall review specified categories of stem cell research and therapy; and

(b) what is the preferred format and content for reports from Local Review Boards to the National Committee and its two Subcommittees to avoid unnecessary duplicative review and to provide the National Committee and its Subcommittees with the factual information and

context necessary to resolve in an efficient manner the National-level issues requiring their review.

(5) For proposed stem cell research or therapy requiring the National Committee's review, the National Committee may —

(a) grant an approval;

(b) grant a conditional approval; or

(c) disapprove the proposal.

(6) Where the National Committee has disapproved a proposal for stem cell research or therapy, such disapproval shall be documented in its records and the National Committee may in its discretion give any relevant reasons for the disapproval.

(7) Where there is a proposal to conduct research or therapy using previously-derived human embryonic stem cell lines, the National Committee —

(a) will review the procurement history and other related documentation for such stem cell lines to ensure that no new human embryonic stem cell lines will be derived for purposes of the research or therapy;

(b) will grant an approval only in exceptional circumstances in which participation of The Bahamas in important international research or international therapy initiatives requires agreement to permit use of previously-derived human embryonic stem cell lines, or will disapprove the proposal; and

(c) may issue further guidelines for such research and therapy.

(8) Where there is a proposal to conduct research or therapy using Somatic Cell Nuclear Transfer, the National Committee —

(a) will review all details of the proposal;

(b) will grant an approval, or will grant a conditional approval, or will disapprove the proposal; and

(c) may issue further guidelines for such research and therapy.

(9) All submissions to Review Entities shall be treated as proprietary and confidential, and shall be

protected from public disclosure or use in any manner other than as necessary to perform the relevant review, absent written consent from the submitter.

(10) The Review Entities may submit information from within a submission to the Minister of Health or to other Review Entities, but only to the extent necessary to perform the review within their duty.

(11) Every review by the National Committee, the Science Subcommittee, or the Compliance Subcommittee shall be completed within sixty days from receipt of an application seeking review.

(12) A review will be deemed to be complete when the National Committee or the reviewing Subcommittee issues, in writing, either —

(a) an approval of the research or therapy under review;

(b) a conditional approval; or

(c) a disapproval.

(13) Notwithstanding the foregoing, the National Committee may issue guidelines exempting specific categories of applications from the sixty-day review deadline.

The Science Subcommittee.

5. (1) The Science Subcommittee shall have seven members, which shall include —

(a) the Chairman and two members of the National Committee; and

(b) four expert scientists, with expertise in the particular stem cell research or therapy under review, who shall be selected from the pool of scientists appointed under subsection (2).

(2) The Minister shall on the advice of the National Committee appoint a pool of expert scientists, which shall not exceed twenty-one, who will include basic scientists, translational scientists, clinician scientists and physician disease experts and any other scientists recommended by the National Committee.

(3) Where a member has an interest in the research or therapy under review, he shall make a declaration of conflict and shall recuse himself from participating in the review, except to provide information requested by the Science Subcommittee.

(4) The Science Subcommittee shall review recommendations from Local Scientific Review Boards regarding proposed protocols for stem cell research and therapy in categories designated by the National Committee —

(a) to ensure that there is sufficient scientific merit and justification for initiating the stem cell research or therapy, as appropriate for the proposed activity;

(b) to ensure that there is sufficient scientific merit and justification for continuing the stem cell research or therapy, as appropriate for the proposed activity;

(c) to ensure that all health care providers administering stem cells or stem cell derivatives to humans in such categories have appropriate scientific qualifications and experience.

The Compliance Subcommittee.

6. (1) There shall be a Compliance Subcommittee with the primary responsibility of ensuring that the monitoring and quality assurance of all stem cell research and therapy initiatives in The Bahamas are adhered to in accordance with what is approved by the applicable Review Entities.

(2) There shall be seven members on the Compliance Committee, appointed by the Minister, who shall include —

(a) a Chairman, who shall be the Chairman of the Hospitals and Health Care Facilities and Licensing Board under the Hospitals and Health Care Facilities Act; and Ch. 235.

(b) six persons, who shall be a physician and persons in the fields of nursing, allied health, engineering, architecture, and law.

(3) The Compliance Subcommittee's duties shall, among other things, be to —

(a) ensure that all clinical stem cell research and therapy is conducted pursuant to written policies and procedures addressing all aspects of the operations, including, but not limited to —

(i) screening, consent, treatment, patient confidentiality;

(ii) emergency and safety procedures, accidents and adverse reactions;

(iii) outcome analysis to maintain, monitor and evaluate the effective management, safety and operations of the institution and of services provided therein;

(b) ensure that the policies and procedures referred to in sub-paragraph (a) are designed to —

(i) ensure public safety;

(ii) maximise the quality of stem cell care;

(iii) minimise risks to patients, personnel and the public; and

(iv) ensure that all personnel involved in stem cell research and therapy have the appropriate qualifications required by the respective bodies in The Bahamas, and that the corresponding stem cell research and therapy takes place in appropriate facilities.

Local Stem Cell Ethical Review Boards.

7. (1) Every Local Ethical Review Board shall —

(a) have sufficient diversity among its members, including consideration of race, gender and background to ensure that different perspectives are given a voice;

(b) be sensitive to issues, such as community attitudes, in order to promote respect for the advice and counsel of the Local Ethical Review Boards;

(c) be composed of qualified persons of both sexes;

(d) include at least one scientist with relevant expertise and one ethicist.

(2) Each Local Ethical Review Board shall encourage different perspectives and voices in its discussion of protocols and in its proceedings.

(3) Each Local Ethical Review Board must be recognised by the National Committee as having the requirements to function in the capacity of an Ethical Review Board.

(4) A Local Ethical Review Board may have partially or completely overlapping membership with a Local Scientific Review Board, and may have combined meetings and combined procedures, as long as the requirements for each Board are satisfied and each Board fulfils its duties sufficiently.

Ethical conduct and oversight.

8. (1) Every person who performs stem cell research or therapy shall have the responsibility of ensuring that activities are carried out with the highest ethical standards and in accordance with these Regulations and with guidelines issued by the National Committee.

(2) The National Committee shall authorise Local Ethical Review Boards to conduct ethical reviews of all stem cell research and therapy.

(3) Every person who conducts stem cell research or therapy shall obtain review by a Local Ethical Review Board, before beginning such research or therapy.

(4) Where review by the National Committee or one or both of its Subcommittees is required, the Local Ethical Review Board shall make a recommendation to any Review Entity performing a subsequent review.

Local Scientific Review Boards.

9. (1) Every Local Scientific Review Board shall —

(a) be composed of persons with expertise in the particular stem cell research or therapy under review;

(b) be recognised by the National Science Subcommittee as having the requirements to function in the capacity of a Scientific Review Board.

(2) Every person who performs stem cell research or therapy shall have the responsibility of ensuring that activities are carried out with the highest degree of scientific rigour and in accordance with these Regulations and with guidelines issued by the National Committee.

(3) To ensure that persons fulfil the obligations under paragraph (2) a Local Scientific Review Board shall —

(a) review the credentials of every person who conducts stem cell research and therapy;

(b) ensure that all health care providers administering stem cells or stem cell derivatives to humans have appropriate scientific qualifications and experience;

(c) review protocols for the conduct of all stem cell research and therapy before initiation;

(d) ensure that there is sufficient scientific merit and justification for initiating the stem cell research

or therapy, as appropriate for the proposed activity, such as, without limitation, preclinical and clinical data and data gathered from animal models;

(e) ensure that there is sufficient scientific merit and justification for continuing the stem cell research or therapy, as appropriate for the proposed activity.

(4) Where review by the National Committee or one or both Subcommittees is required, the Local Science Review Board shall make a recommendation to any Review Entity performing a subsequent review.

(5) A Local Scientific Review Board may have partially or completely overlapping membership with a Local Ethical Review Board, and may have combined meetings and combined procedures, as long as the requirements for each Board are satisfied and each Board fulfils its duties sufficiently.

Written policies requirements.

10. (1) Every Review Entity shall create and follow written policies —

(a) that preclude a member from participating in the initial or continuing review of any project that the member has an interest in, except to provide information requested by any Review Entity;

(b) on record keeping requirements for —

(i) its activities; and

(ii) the research activities which it reviews,

to ensure compliance with international best practices in relation to ethical practices and regulatory requirements;

(c) for maintaining records, on the research it reviews, relating to the history of all stem cell lines, biological material donors, applicable ethical research standards, and reports of adverse or unexpected outcomes that pose a threat to the health or safety of any individual or raise new ethical issues;

(d) that establish safeguards to protect the rights, health and general welfare of patients;

(e) that ensure the confidentiality of trade secrets and other confidential commercial and financial information submitted to the Review Entity.

(2) Records relating to the stem cell research and therapy activities and the review of such activities by the Review Entities shall be retained for at least ten years after completion of the activity.

(3) All records shall be accessible for inspection and copying by authorized representatives of the Ministry of Health at reasonable times and in a reasonable manner.

(4) The safeguards referred to in paragraph (l)(d) shall include the requirement to report immediately to the National Committee any serious adverse event or unexpected adverse event associated with stem cell therapy or clinical research.

Requirements for reporting to the National Committee.

11. (1) Upon formation each Local Review Board shall submit a report to the National Committee setting forth the name and credentials of its members.

(2) By the 31st day of March of each year, each Local Review Board shall submit updated reports to the National Committee.

(3) The report referred to in paragraph (2) shall include —

(a) the name and credentials of its members;

(b) updates on the conduct of research and therapy;

(c) new scientific benefits or knowledge gained from research and therapy;

(d) the impact that research and therapy may have on the social fabric of the Society.

PART III - REQUIREMENTS FOR CONDUCTING NON- CLINICAL AND CLINICAL STEM CELL RESEARCH AND STEM CELL THERAPY

Consent to donation of biological materials.

12. (1) Local Ethical Review Boards shall conduct a rigorous review of the procurement process in order to ensure that the donor's participation in the research is preceded by the donor having been —

(a) fully informed of the impact of the research;

(b) advised that participation is voluntary; and

(c) properly taken through the informed consent process and having given his informed consent.

(2) A researcher shall exercise care in communicating the concept of "informed consent" to ensure that such consent has actually been obtained.

(3) The informed consent process shall take into account language barriers and the educational level of the donor.

(4) Whenever possible, the person conducting the informed consent process shall have no vested interest in the research protocol and where a member of the research team who has such an interest participates in the informed consent process, the member's role must be disclosed to the donor and care must be taken to ensure that information is provided in a transparent and accurate manner.

Mandatory disclosures.

13. (1) The informed consent document and the process for obtaining the consent shall contain the following statements —

(a) that the biological materials may be used in the derivation of totipotent or pluripotent cells for research;

(b) where applicable, the biological materials will be destroyed during the process of deriving totipotent or pluripotent cells for research (unless the specific research protocol aims to preserve the integrity of the research material);

(c) that derived stem cells or stem cell lines might be kept for many years and used for future studies, many of which may not be predictable at this time;

(d) that the donation is made without any restriction or direction regarding who may be the recipient of transplants of the cells derived, except in the case of allogeneic transplantation;

(e) that the donation is —

(i) limited to specific research purposes only;

(ii) for broadly stated purposes, including research not presently anticipated, in which case the informed consent process shall notify donors that a Local Ethical Review Board may later grant permission for those unanticipated broadly stated uses and may waive the donor's consent where it is prohibitively difficult to obtain that consent;

(f) disclosure of what donor medical or other information and what potential donor identifiers will be retained; specific steps taken to protect donor privacy and the confidentiality of retained

information; and whether the identity of the donor will be readily ascertainable to those who derive or work with the resulting stem cell lines, or any other entity or person, including specifically any oversight bodies and government agencies;

(g) disclosure of the possibility that any resulting cells or cell lines may have commercial potential, and whether the donor will or will not receive financial benefits from any future commercial development;

(h) disclosure of any present or potential future financial benefits to the researcher, the employer of the researcher, or any affiliated organizations;

(i) that the research is not intended to provide direct medical benefit to anyone including the donor, except in the sense that research advances may benefit everyone;

(j) that neither consenting nor refusing to donate materials for research will affect the quality of care provided to potential donors;

(k) that there are alternatives to donating human materials for the research at issue, and an explanation of what these alternatives are.

(2) The consent process shall explore whether donors have objections to the specific forms of research outlined in the research protocol.

Documentation of informed consent.

14. (1) Informed consent shall be documented by the use of a written consent form approved by a Local Ethical Review Board, signed and dated by the donor or his legally authorised representative at the time of consent and a copy shall be given to the person signing the form.

(2) The consent form may be either of the following documents —

(a) a written consent form that embodies the elements of informed consent required under regulation 13, which form —

(i) may be read to the donor or his legally authorised representative; and

(ii) shall be given to either the donor or his legally authorised representative with adequate opportunity to read it before it is signed; or

(b) a short written consent form that summarizes the elements of informed consent required under regulation 13, and when this form is used —

(i) the form shall indicate that it has been presented orally to the donor or to his legally authorised representative;

(ii) there shall be a witness to the oral presentation, who shall sign the short form;

(iii) a Local Ethical Review Board shall approve a written summary of what must be included in the short form and what is orally presented to the donor or his representative;

(iv) it shall be signed by the donor or his representative;

(v) the person actually obtaining the consent shall sign a copy of the short form; and

(vi) a copy of the short form and the written consent form under paragraph (a) shall be given to the donor of his representative.

(3) Consent to donate shall be obtained at the time of the proposed transfer of the biological materials to the research team.

(4) A Local Ethical Review Board may grant permission to use biological materials, obtained under paragraph (3), for broadly stated purposes including research not presently anticipated. However the Local Ethical Review Board shall make every reasonable effort to obtain the consent of the donor, but shall proceed to grant such permission if the consent is prohibitively difficult to obtain.

Withdrawal of consent.

15. All donors shall be informed that they retain the right to withdraw consent until the biological materials are actually used in research or until information which could link the identity of the donors with the biological material is no longer retained (*if applicable*).

Reimbursement for costs of research related injuries.

16. (1) A researcher shall be responsible for the medical costs of a donor, including the costs of treating injuries, that arise directly and proximately from the act of donating.

(2) Appropriate professional liability insurance shall be current for all professionals participating in the said research and therapy initiatives.

(3) In addition, the National Committee, may require that the sponsor of the respective stem cell research or therapy put in place a special fund, in instances where the Committee deems it justifiable in the interest of participants.

Recruitment practices.

17. Every Local Ethical Review Board is responsible for conducting rigorous review of all protocols to ensure the safety and the informed and voluntary choice of all donors, in accordance with the following principles —

(a) that there must be monitoring of recruitment practices to ensure that no vulnerable populations, for example, economically disadvantaged women, are disproportionately encouraged to participate as donors or other research subjects;

(b) where reimbursement for research participation is offered, the relevant Review Entity or Review Entities shall carry out a detailed and rigorous review to ensure that reimbursement of direct expenses or financial considerations of any kind do not constitute an undue inducement;

(c) that biological samples intended for donation must be collected only by medically qualified and experienced clinicians.

General requirements applicable to clinical research and therapy. Ch. 235.

18. (1) All clinical use of stem cells for research or therapy shall be conducted in a licensed hospital or health care facility, and such facility must comply with the Hospital and Healthcare Facilities Act and any regulations made thereunder.

(2) All stem cells for clinical research or therapeutic use shall meet the donation and procurement requirements established in this Part.

(3) A clinical researcher or a physician conducting stem cell research or administering therapy shall be responsible for the medical costs of a donor, including the costs of treating injuries that arise directly and proximately from the act of donating.

Requirements for clinical research using stem cells.

19. (1) Clinical research using autologous, minimally manipulated adult stem cells will require the prior approval of a Local Scientific Review Board and a Local Ethical Review Board.

(2) Clinical research using autologous stem cells requiring more than minimal manipulation requires the approval of the Science Subcommittee, following recommendations from Local Scientific Review and Ethical Review Boards.

(3) Clinical research employing allogeneic stem cell procedures must obtain the approval of the National Committee; which shall assess and ensure that —

(a) experimental products satisfy the guidelines of the International Conference on Harmonisation of Human Medicinal Products (ICH) for Good Manufacturing Practice; and

(b) clinical research is conducted in accordance with the ICH guidelines for the Good Clinical Practice.

(4) Where clinical investigators participating in a multinational clinical trial employing allogeneic stem cell procedures propose to include clinical sites located in The Bahamas, the clinical trial shall also be previously approved by an internationally recognised and sanctioned authority, unless the National Committee expressly waives any prior-approval requirement in writing.

(5) The internationally recognised and sanctioned authority must be recognised by the National Committee as demonstrating excellence in both scientific competence and in ethical standards.

Informed consent requirements for clinical research.

20. (1) No person conducting research on the effect of stem cells in a human (hereinafter referred to as a "clinical researcher") may involve a human being as a subject in research covered by these Regulations unless the clinical researcher has obtained the legally effective informed consent of the subject or his legally authorised representative.

(2) A clinical researcher shall seek such consent only under circumstances that provide the prospective subject or his legally authorised representative sufficient opportunity to consider whether or not to participate and that minimises the possibility of coercion or undue influence.

(3) The information that is given to the subject or his legally authorised representative shall be in language understandable to the subject or his legally authorised representative.

(4) No informed consent, whether oral or written, shall include any exculpatory language through which the subject or his representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the clinical researcher, the sponsor, the institution, or its agents from liability for negligence.

(5) In seeking informed consent, the following information shall be provided to each subject —

(a) a statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;

(b) a description of any reasonably foreseeable risks or discomforts to the subject;

(c) a description of any benefits to the subject or to others which may reasonably be expected from the research;

(d) a disclosure of appropriate alternative procedures or courses of therapy, if any, that might be advantageous to the subject;

(e) a statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained and that notes the possibility that the government may inspect the records;

(f) an explanation as to whether any compensation or medical treatment is available if injury occurs during research involving more than minimal risk and if so, what the compensation or medical treatment consists of, or where further information may be obtained;

(g) an explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject;

(h) a statement that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may discontinue participation at any time without penalty or loss

of benefits to which the subject is otherwise entitled.

(6) When appropriate, one or more of the following elements of information shall also be provided to each subject —

(a) a statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or foetus, if the subject is or may become pregnant) which are currently unforeseeable;

(b) anticipated circumstances under which the subject's participation may be terminated by the clinical researcher without regard to the subject's consent;

(c) any additional costs to the subject that may result from participation in the research;

(d) the consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;

(e) a statement that significant new findings developed during the course of the research, which may relate to the subject's willingness to continue participation, will be provided to the subject;

(f) the approximate number of subjects involved in the study.

(7) Nothing in these Regulations is intended to limit the authority of a physician to provide emergency medical care to the extent the physician is permitted to do so.

(8) Informed consent shall be documented by the use of a written consent form approved by a Local Ethical Review Board and signed and dated by the subject or his legally authorised representative at the time of consent and a copy thereof shall be given to the person signing the form.

(9) The consent form may be either of the following documents —

(a) a written consent form that embodies the elements of informed consent required by paragraph (5), which form —

(i) may be read to the subject or his legally authorised representative; and

(ii) shall be given to either the subject or his representative with adequate opportunity to read it before it is signed; or

(b) a short written consent form that summarises the elements of informed consent required under paragraph (5), and when the short form is used —

(i) it shall indicate that the information thereon must be presented orally to the subject or his legally authorised representative;

(ii) there shall be a witness to the oral presentation, who will sign the short form;

(iii) a Local Ethical Review Board shall approve the written summary of what must be included in the short form and what must be orally presented to the donor or his representative;

(iv) it shall be signed by the subject or his representative;

(v) the person actually obtaining the informed consent will sign a copy of the short form; and

(vi) a copy of the short form and the written consent form under paragraph (a) shall be given to the subject or his representative.

Stem cell therapy.

21. (1) All stem cell therapy shall have the prior approval of the appropriate Review Entities.

(2) The National Committee may, in its discretion, review any costs for therapy where it has received a written request for the review of such costs.

(3) Stem cell therapy using autologous minimally manipulated adult stem cells will require the approval of a Local Scientific Review Board and a Local Ethical Review Board.

(4) Pre-clinical and clinical data, including data derived from peer-reviewed published studies, may be used to substantiate the safety and efficacy of a proposed autologous, minimally manipulated stem cell therapy, and such evidence must be credible and substantial to support approval of the therapy.

(5) Approval is required for each treatment protocol; however once approved, the protocol may be administered to treat additional patients without having to

obtain approval for each patient or course of treatment, provided —

(a) all of the other regulations regarding stem cell use continue to be met;

(b) the protocol is not altered, except where altered in order to permit the use of different cell types of a given patient;

(c) outcomes are reported to the Local Scientific Review and Ethical Review Boards on a schedule determined at the time of approval.

(6) Any changes to an approved stem cell therapy protocol must be reviewed by the Local Scientific Review and Ethical Review Boards before therapy is administered to patients.

(7) Stem cell therapy employing more than minimal manipulation requires the approval of the National Committee upon recommendation of the Local Scientific Review and Ethical Review Boards.

(8) Non-clinical and clinical data, including those derived from peer-reviewed published studies, may be used to substantiate the safety and efficacy of a proposed autologous stem cell therapy employing more than minor manipulation, and such evidence must be credible and substantial to support approval of the therapy.

(9) Substantial evidence that stem cells and their derivatives for such therapy have been handled according to Good Manufacturing Practice as established by ICH guidelines is required.

(10) The outcome of every clinical trial must be reported to the Local Scientific Review and Ethical Review Boards, and the National Committee if required by the terms of the approval.

(11) Stem cell therapy using allogeneic stem cell procedures requires the approval of the National Committee in consultation with international experts and the approval shall be granted on a per protocol per patient basis.

(12) Any experimental stem cell therapy must have prior approval by a Local Scientific Review Board and a Local Ethical Review Board, or may be referred for a decision by the National Committee upon the discretion of the Local Scientific Review or Ethical Review Committee.

(13) A clinician may provide experimental stem cell therapy to, at most, a very small number of patients, outside the context of a formal clinical trial, provided —

(a) a written plan and protocol for the procedure that includes —

(i) sufficient scientific rationale and justification explaining why the procedure has a reasonable chance of success, including any preclinical evidence of proof-of-principle for efficacy and safety;

(ii) an explanation of why the proposed therapy should be attempted rather than using existing therapy;

(iii) a full characterisation of the types of cells being transplanted and their characteristics;

(iv) a description of how the cells will be administered, including adjuvant drugs, agents, and surgical procedures; and

(v) a plan for clinical follow-up and data collection to assess the effectiveness and adverse effects of the cell therapy;

(b) voluntary informed consent is provided by the patient and he understands that the intervention is unproven and he demonstrates his understanding of the risks and benefits of the procedure;

(c) there is a commitment by the clinician to use his experience with individual patients to contribute to generalisable knowledge which include —

(i) ascertaining outcomes in a systematic and objective manner;

(ii) plan for communicating outcomes, including negative outcomes and adverse events, to the scientific community to enable critical review through abstracts, professional meetings, peer-reviewed publications and such other publications as directed by the Committee; and

(iii) transferring to a formal clinical trial in a timely manner after experience with, at most, a few patients.

Informed consent requirements for stem cell therapy.

22. (1) No patient may be treated with therapy covered by these Regulations unless the medical provider

has obtained the legally effective informed consent of the subject or the subject's legally authorised representative.

(2) Informed consent shall include a clear description of the potential benefits and risks of the stem cell therapy.

(3) The informed consent process must emphasise the novel and experimental aspects of stem cell therapy.

PART IV - REQUIREMENTS FOR FACILITIES

Storage.

23. (1) In order to maintain, monitor and evaluate the effective management, safety and operations of the facility and the services provided therein, every facility which stores stem cells and stem cell derivatives shall have written policies and procedures addressing all aspects of the operation, including but not limited to collection, duration of and conditions for storage, labelling, indications for discard, patient confidentiality, equipment and supplies, cleaning and sanitation.

(2) The policies and procedures referred to in paragraph (1) shall be so designed as to —

(a) ensure public safety;

(b) maximise the quality of care of stem cells and of stem cell derivatives; and

(c) minimise patient, personnel and public risks.

Equipment.

24. Equipment used in the collection and storage of stem cells and stem cell derivatives shall be —

(a) maintained sanitised and kept in a clean manner;

(b) located so as to facilitate cleaning, calibration and maintenance;

(c) observed, standardised and calibrated on a regular basis, and in accordance with recommendations of the manufacturer.

Labelling and storage of stem cells and stem cell derivatives.

25. (1) A facility shall be required to put a comprehensive system in place to prevent labelling errors.

(2) All stem cells and stem cell derivatives must, prior to being stored, have affixed to their containers a clear and legible label showing the —

(a) proper label; and

(b) appropriate modifiers.

(3) Storage temperatures for all stem cells and stem cell derivatives shall be maintained in accordance with internationally recognised protocols.

(4) Where stem cells or stem cell derivatives are required to be utilised after a forty-eight hour period, such cells must be stored in a liquid state maintained within a temperature range of -80 degrees Celsius and -196 degrees Celsius in accordance with recommended protocols.

(5) Material that may adversely affect stored stem cells and stem cell derivatives shall not be stored in the same appliance or equipment.

Transport.

26. (1) When transporting stem cells and stem cell derivatives, a facility shall take steps to ensure that it does so in a manner that protects the integrity of the stem cells and stem cell derivatives.

(2) All containers used in the transportation process shall be made of materials which can withstand leakage, pressure changes and any other conditions incidental to ordinary handling during transportation.

(3) All standards governed by the International Air Transportation Association regarding the handling and transportation of such materials must be observed.

Disposal.

27. (1) Any facility that handles stem cells and stem cell derivatives shall have a written policy for their disposal and transfer.

(2) There shall be a written agreement between any facility that stores stem cells or stem cell derivatives and the donor (or patient) of those stem cells or derivatives, which shall specify the circumstances for disposal or transfer of the stem cells or stem cell derivatives.

(3) Any facility that handles stem cells or stem cell derivatives shall prior to disposing of them inform the relevant Review Entity in writing stating —

(a) whether the patient or donor has died or that there is no further need for the cells;

(b) the cells or derivatives being discarded;

(c) the date of discard; and

(d) the method of disposal.

(4) Where bio-hazardous materials are required to be disposed of, the method of disposal shall meet internationally recognised standards.

Fees.
Schedule.

28. (1) The fees specified in the *Schedule* shall be payable in respect of each facility.

Schedule.

(2) The Minister may by Order amend the fees in the *Schedule*.

SCHEDULE

FEES

Application Fees	
Initial application fee for stem cell related research	$2,500.00
Fee for review and modification of application	$ 1,000.00
License Fees	
Annual license fee for stem cell therapy (minor procedures)	$15,000.00-$25,000.00
Annual license fee for stem cell therapy (major procedures)	$25,000.00-$50,000.00.