ANTIGUA AND BARBUDA

STEM CELL RESEARCH AND THERAPY REGULATIONS, 2020

STATUTORY INSTRUMENT

2020, No. 49

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THE STEM CELL RESEARCH AND THERAPY REGULATIONS 2020 made by the Minister in exercise of the powers contained in section 32 of the Stem Cell Research And Therapy Act 2019, No. 11 of 2019.

PRELIMINARY

1. Citation

These Regulations may be cited as the Stem Cell Research And Therapy Regulations 2020.

2. Interpretation

Unless the context otherwise requires, the following definitions of terms shall apply to all rules promulgated pursuant to these Regulations –

"Act" means the Stem Cell Research And Therapy Act 2019

"blood" means whole human blood collected from a donor and includes any substance derived from blood or derived from any part of the human body which can be used as a source from which to derive a constituent of blood and processed either for transfusion or for further manufacturing, or for therapeutic use or for the preparation of a substance for therapeutic use;

"blood transfusion" means the transfusion of blood, or any of the constituents of blood, into a person and includes the operation of removing all or part of the blood of a person and replacing it with blood taken from another person;

"building" means a structure, whether permanent or temporary, intended for human habitation; and where two or more buildings are situated on adjacent pieces of land and are occupied by the same person, they shall constitute a single building for the purposes of the Stem Cell Research and Therapy Act 2019;

"Committee" means the National Stem Cell Oversight Committe established under section 4 of the Stem Cell Research And Therapy Act 2019;

"Coroner" has the same meaning as in the Coroners Act, Cap. 105;

"diagnostic facility" means any facility used for the purpose of providing information for the diagnosing of sickness or disease, or the extent of injuries suffered by persons and includes any Blood Bank, laboratory or radiology facility including a facility in which diagnostic imaging is done;

"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;

"health practitioner" means a person who is registered to practice under the Medical Practitioners Act 2009, the Midwifery Act Cap 281, and the Pharmacy Act;

"human reproductive cloning" means attempting to establish a pregnancy or the reproduction of a human by transferring a human embryo containing a diploid set of chromosomes obtained from a human being, whether alive or dead, a foetus or a humanembryo;

"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 7 of the Act;

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

"laboratory" means a place for the admission of persons requiring medical or surgical treatment for any sickness, injury or infirmityor nursing care;

"licence" means a licence issued by the Committee under regulation 6;

"Licence Holder" means a person who has been granted a licence to operate a facility or laboratory or to carry out any activity for which a licence is required under these Regulations;

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

"medical practitioner's office" means a facility where persons suffering from sickness, injury or infirmity may be examined and treated by a licensed medical practitioner;

"minor" means a person under eighteen years of age, but does not include a person who is married or a parent;

"Minister" means the Minister with responsibility for Health;

"nearest relative" means in strict order of priority—

(a) spouse;

(b) a child who is not a minor;

(c) parent or guardian; or

(a) a brother or sister over eighteen years of age;

"non-regenerative tissue" means tissue other than regenerative tissue;

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

"ovum" means s female reproductive cell, weather 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;

"relative" means a spouse, child, parent, brother or sister;

"research facility" includes a clinic, a walk-in clinic, a surgical centre, a birth centre, a dialysis centre, a maternity laboratory, a diagnostic facility, a therapeutic facility, a health practitioner's office, a medical practitioner's office or any other facility which offers medical or surgical care to any person;

"Serious adverse events" means any untoward occurrence which may be associated with the procurement, testing, processing, storage or distribution of tissue or cells intended for human application and which, in relation to a donor of tissue or cells intended for human application or a recipient of tissue or cells:

(a) might lead to the transmission of a communicable disease, to death or life-threatening, disabling or incapacitating conditions, or

(b) might result in, or prolong, laboratoryisation or morbidity.

"Serious adverse reactions" means An unintended response, including a communicable disease, in a donor of tissue or cells intended for human application or a recipient of tissue or cells, which may be associated with the procurement or human application of tissue or cells and which is fatal, life-threatening, disabling, incapacitating or which results in, or prolongs, laboratoryisation or morbidity.

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

"spouse" means either a man who is married to a woman or a woman who is married to a man;

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

"stem cell research" means –

(c) 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

(a) 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.

"therapeutic purposes" includes transplant purposes;

"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;

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

3. Enforcement of the Act and of these Regulations

(1) The Committee has the legal authority to enforce the requirements of the principal Act and of these Regulations in relation to any facility or laboratory licenced in accordance with the principal Act or these Regulations and in relation to any person who is in breach of a duty imposed by the principal Act or these Regulatios.

(2) The Committee may, as part of its enforcement mechanism, issue administrative fines against a License Holder or Administrator of any facility or laboratory licenced under these Regulations for breach of these Regulations.

(3) An administrative fine levied against a Licence Holder pursuant to subregulation (2) shall not exceed –

(a) $10,000.00 for a single or one-off occurrence where the breach is remedied within five (5) business days of the laboratory or facility receiving notice from the Committee of the breach and requiring the facility or laboratory to remedy the breach; or

(b) $50,000.00 in total or $5,000.00 per day if the breach is a continuing breach or the breach is not remedied within five (5) business days of the facility receiving notice from the Committee of the breach and requiring the facility or laboratory to remedy the breach.

(4) The Committee may, on the application of the Licence Holder, extend the time given in subregulation (3)*(a)*, if in the opinion of the Committee, five (5) business days is not sufficient time within which a the breach can be reasonably remedied.

(5) The Committee may waive all or part of any administrative fine levied under these Regulations.

PART I

Licensing of Activities uder the Act

4. Licensing requirement

(1) No person shall use any building as a laboratory or research or clinical facility or the purpose of conducting any research, medical procedure or therapy using Stem Cell technology except under the authority of a licence issued in accordance with these Regulations.

(2) Subject to subregulation (4) no person shall conduct or engage in the conduct of any activity in the area of stem cell research and therapy in Antigua and Barbuda except such a person is licenced in accordance with the requirements of these Regulations.

(3) Subregulation (2) includes activites aimed at procuring, importing, testing, processing, or distributing human tissues or cells for human application, the storing of human tissues and cells and the use of human tissue or cells in the treatment of any person or in any procedure or activity permitted to be done under a licence issued in accordance with these Regulations.

(4) The Committee may authorise any person to import, without a licence, human tissue or cells for human application if the Committee is satisfied that –

(a) the human tissue or cell is being imported directly from a facility licenced to export human tissue or cells;

(b) the human tissue or cell will be received directly by a facility licensed under these Regulations to import human tissue or cells;

(c) the importationof the human tissue or cells is necessary for clinical purposes; and

(a) the case is one of emergency.

5. Application for Licence

(1) An application for a licence to operate a laboratory or facility for the purpose of conducting stem cell research or therapy may be made by the intended Licence Holder in Form A of Schedule I

(2) Where the applicant for a licence is not the intended Administrator of the laboratory or facility, the application must be accompanied by a notarised letter of Consent given by the intended Administrator and two (2) valid Government issued photo identification of the intended Administrator.

(3) If the applicant for a licence is a body corporate, in addition to the information required by subregulation (2), the application must be accompanied by a Statutory Declaration in which shall be clearly stated –

(a) the name, qualification and contact details of the intended Administrator;

(b) th name, position and contact details of the authorised representative of the body corporate;

(c) the name, address and contact details of the Shareholders and Directors of the body corporate;

(a) the name, address and contact details of every person who owns 5% or more of the interest in the body corporate

(4) The Committee may not grant a licence unless it is satisfied that the intended Administrator –

(a) is aware of the duties and functions of an intended Adminintrator;

(b) is a suitable person to be an Administrator of a Licence facility or laboratory.

(5) The Committee may not grant a licence unless it is satisfied that the applicant is a suitable person to hold a licence.

(6) The Committee may not grant a licence unless the premises in respect of which the licence is to be granted is suitable for the activity authorized by the licence.

(7) The application for a licence must be accompanied by the appropriate application fee as set out in Schedule II (Fees).

6. Characteristics of a Licence

(1) A Licence issued under this regulation must be in Form B of Schedule I and must –

(a) specify the name of the Administrator;

(b) specify the name of the licensee, if different from the Administrator;

(c) specify the name and location of the facility or laboratory and give a brief description of the premises to which the licence apply;

(a) specify the activity that the laboratory or facility is licensed to conduct;

(e) contain the conditions, if any, pursuant to which the licence is granted;

(f) specify the expiration date of the licence;

(g) bear the seal of the Committee and be authenticatd by the signature of the Chairman of the Committee and of the Minister.

(2) It shall be a condition of every licence granted under regulation 5 that –

(a) the licensed activity shall be carried out only by persons suitably qualified to perform these activities;

(b) the licensed activity shall be carried out only on the premises specified in the licence.

7. Validity and renewal of licence

A licence granted under these Regulations shall be valid for a period of five (5) years from the date of issue subject to the payment to the Committee of an Annual Licence Fee as set out in Schedule II (Fees).

8. Duties of the Administrator

(1) An Adminstrator shall ensure that –

(a) the persons who perform any activity in relation to the licence are suitably qualified to undertake the activity;

(b) the conditions of the licence are complied with;

(c) the laboratory or facility has in place adequate mechanisms for tracing donations;

(a) tissues and cells for human application are procured, tested, processed, stored, distributed, imported or exported and handled in accordance with best practices;

(e) the laboratory or facility has in place or adopts a proper coding system;

(f) licensed activites are carried out using best practices;

(g) patients are informed of their right of access to their information held by the laboratory or facility and to be informed of their treatment and care and their rights to receive a copy of any information health by the laboratory or facility with respect to their treatment and care;

(h) there are protocols in place to prevent cross-contamination;

(i) regular risk assessments are conducted of the laboratory or facility;

(2) Where the Administrator and the License Holder are separate persons, both shall be under a duty to ensure that –

(a) the staff, procedures and operations at the laboratory and facility comply with the Act and these Regulations;

(b) there is a system in place for the training of staff and persons to whom the licence applies to ensure that they are aware of and utilise best practices;

(c) there is a clear system in place governing the documentation and processing of patient information;

(d) there is a direct line of contact maintained between the Committee and the Administrator or Licence Holder;

(e) procedures are established for the reporting of serious adverse events and serious adverse reactions and that the Committee is notified of any such occurrence within 24 hours of the facility or laboratory becoming aware of the serious adverse event or serious adverse reaction.

(f) the Committee is provided with semi-annual reports of the activities of the laboratory or facility on the 30th April and the 30thOctober each year;

9. Register of Licences

(1) The Committee shall maintain a register recording the grant, suspension or revocation of every licence granted under these Regulations.

(2) The register shall contain the following information –

(a) the name of the Licence Holder;

(b) the name of the Administrator;

(c) the name and current address of the facility;

(d) laboratory ;

(e) the activities authorised by the licence;

(f) any variation of the information referrd to in paragraph *(a)* or *(a)*.

(3) The Committee shall make the information contained in the register available to the public in such manner as it considers appropriate.

10. Qualification of the Administrator

(1) The Administrator shall at a minimum possess –

(a) A minimum of ten (10) years experience at a senior management level; and

(b) A first degree in biological sciences or a related field.

(2) The Committee may, if it considers it necessary for the licensed activity to be conducted by a facility or laboratory, request that the intended Adminsitrator possess such additional qualifications or skills as are satisfactory to the Committee.

(3) No person may be appointed as Administrator of a laboratory or facility unless the Committee is satisfied with his or her qualifications.

11. Register of serious adverse events and serious adverse reactions

(1) The Committee shall maintain a register containing information provided to it under these Regulations regarding serious adverse events and serious adverse reactions.

(2) The Committee may, if it deems it appropriate to do so, make the information contained in the register available to the public.

(3) The Committee shall require a Licence Holder to adopt –

(a) a system to report, investigate, register and transmit information about serious adverse events and serious adverse reactions;

(b) an accurate, rapid and verifiable procedure for addressing and containing the impact of serious adverse events and serious adverse reactions.

12. Confidentiality

Information that is provided by a patient or that is collected in the course of pursuing a licenced activity under these Regulations, and from which a donor (living or deceased) or a recipient of tissue or cells may be identified, shall be regarded as confidential and shall not be disclosed except where the disclosure –

(a) is of information that has been rendered anonymous so that neither the donor nor the recipient is identifiable;

(b) is made pursuant to an order of the High Court;

(c) is made to the Committee or a member of the Committee acting in the course or his or her duties under the Act or these Regulations;

(d) is made to a tissue establishment for the purpose of tracing a donation from donor to recipient or recipient to donor;

(e) is made to a Licence Holder or a member of staff of the laboratory or facility or some other person to whom the licence applies for the purpose of his or her functions under the licence;

(f) is necessary for the purpose of proceedings, whether or not such proceedings have started or are being contemplated, between the Licence Holder or Administrator and the Committee or between the Licence Holder or

Administrator and some other person with a recognised interest in a licensed activity;

(g) is with the written consent of the donor or the recipient whose identity would be disclosed.

PART II

INSPECTION, SEARCH AND SEIZURE

13. Inspection of documents

(1) An inspector appointed by the Committee may, upon giving two (2) days' written notice, require a person to produce for inspection any document relevant to compliance with these Regulations.

(2) Where records or documents to which subregulation (1) applies are stored in any electronic form, the power under this regulation includes power to require the records or documents to be made available for inspection in a visible and legible form or in a form from which they can readily be produced in a visible and legible form.

(3) An inspector may inspect and take copies of any documents produced for inspection in pursuance of a requirement under subregulation (1).

14. Entry and inspection of premises

(1) The Committee may arrange for any premises in respect of which a licence is in force to be inspected on its behalf, and for a report on the inspection to be made to it for any of the purposes referred to in subregulation (6).

(2) The Committee shall arrange for an inspection under subregulation (1) of any premises in respect of which a licence is in force not less than once per year.

(3) The Committee may arrange for any premises to be inspected on its behalf, and for a report on the inspection to be made to it for the purpose of satisfying itself that—

(a) the premises are suitable for use for the carrying-on of a licensed activity;

(b) the laboratory or facility has the equipment and materials necessary to effectively cary out the activities for which ir is licensed;

(c) the facility is fit for the purpose and conforms to the acceptable standards for health and safety requirements; and

(a) policies and procedures are in place for the maintenance of the premises and facility.

(4) For the purpose of carrying out an inspection under paragraph (1) or (3), a duly authorised person may at any reasonable time enter and inspect any premises specified in a licence, or proposed to be used as premises where licensed activities are authorised to be carried on.

(6) The purposes for which an inspection may be carried out under subregulation (1) are for—

(a) ensuring compliance by the Licence Holder with—

(i) these Regulations; or
(ii) the conditions of the licence;

(b) ensuring compliance by the Administrator with the duty under regulation 8; and

(c) investigating a report of the occurrence of a serious adverse event or a serious adverse reaction.

15. Entry and search in connection with suspected offence

(1) An Inspector or a member of the Committee may apply to the Magistrate in Form C of Schedule I for a warrant to enter any premises, by force if necessary, and search the premises if there are reasonable grounds for believing—

(a) that an offence under these Regulations is being, or has been, committed on any premises, and

(b) that any of the conditions in subregulation (2) is met in relation to the premises.

(2) The conditions referred to at subregulation (1) are—

(a) that entry to the premises has been, or is likely to be, refused and notice of the intention to apply for a warrant under this regulation has been given to the occupier;

(b) that the premises are unoccupied;

(c) that the occupier is temporarily absent; or

(d) that an application for admission to the premises or the giving of notice of the intention to apply for a warrant under this paragraph would defeat the object of entry.

(3) A warrant under this regulation shall continue in force until the end of the period of 31 days beginning with the day on which it is issued.

(4) A warrant issued under this part must be Form D of Schedule I

16. Execution of warrants

(1) Entry and search under a warrant under regulation 15 is unlawful if the person executing the warrant fails to comply with the provisions of subregulations (2) to (4) and (6).

(2) Entry and search shall be at a reasonable time unless the person executing the warrant thinks that the purpose of the search may be frustrated on an entry at a reasonable time.

(3) If the occupier of the premises to which the warrant relates is present when the person executing the warrant seeks to enter them, the person executing the warrant shall—

(a) produce the warrant to the occupier, and

(b) give him—

(i) a copy of the warrant, and

(ii) an appropriate statement.

(4) If the occupier of the premises to which the warrant relates is not present when the person executing the warrant seeks to enter them, but some other person is present who appears to the person executing the warrant to be in charge of the premises, the person executing the warrant shall—

(a) produce the warrant to that other person,

(b) give him—

(i) a copy of the warrant,

(ii) an appropriate statement, and

(c) leave a copy of the warrant in a prominent place on the premises.

(5) In subregulations (3)*(b)*(ii) and (4)*(b)*(ii) the references to an appropriate statement are to a statement in writing containing the information set out in Schedule III.

(6) If the premises to which the warrant relates are unoccupied, the person executing the warrant shall leave a copy of it in a prominent place on the premises.

(7) Where the premises in relation to which a warrant under regulation 23 is executed are unoccupied, or the occupier is temporarily absent and no other person is present who appears to the person executing the warrant to be in charge of the premises, the person executing the warrant, shall, when leaving the premises, leave them as effectively secured as he found them.

17. Seizure in the course of inspection or search

(1) An Inspector or a duly authorised person entering and inspecting premises under a warrant issued under this Part may seize anything on the premises which he has reasonable grounds to believe may be required for purposes of the Committee's functions relating to the grant, revocation, variation and suspension of licences and to the investigation of serious adverse events and serious adverse reactions.

(2) An Inspector or a duly authorised person entering and searching premises under a warrant issued under this Part may seize anything on the premises which he has reasonable grounds to believe may be required for the purpose of being used in evidence in any proceedings for an offence under these Regulations.

(3) Where a person has power under paragraph (1) or (2) to seize anything, he may take such steps as appear to be necessary for preserving the thing or preventing interference with it.

(4) The power under subregulation (1) or (2) includes power to retain anything seized in exercise of the power for so long as it may be required for the purpose for which it was seized.

(5) Where by virtue of subregulation (1) or (2) a person seizes anything, he shall leave on the premises from which the thing was seized a statement giving particulars of what he has seized and stating that he has seized it.

18. Powers: supplementary

(1) Any power under this Part to enter and inspect or search any premises includes power to take such other persons and equipment as the person exercising the power reasonably considers necessary.

(2) Any power under this Part to inspect or search any premises includes, in particular—

(a) power to inspect any equipment found on the premises,

(b) power to inspect and take copies of any records found on the premises,

(c) in the case of premises named on a licence as the premises where the licensed activity will be conducted, power to observe the carrying-on on the premises of the licensed activity.

(3) Any power under this Part to enter, inspect or search premises includes power to require any person to afford such facilities and assistance with respect to matters under that person's control as are necessary to enable the power of entry, inspection or search to be exercised.

19. Requirements when exercising power of inspection or search

(1) A person's right to exercise a power under this Part is subject to his producing evidence of his entitlement to exercise it, if required.

(2) As soon as reasonably practicable after having exercised a power under this Part to inspect or search premises, the Inspector or a duly authorised person shall—

(a) prepare a written report of the inspection or search, and

(b) if requested to do so give a copy of the report to the Administrator or Licence Holder.

20. Enforcement

(1) A person commits an offence if he or she fails without reasonable excuse to comply with a request of the Inspector or a duly authorized person to –

(a) make records or documents available in a legible form as required by regulation 12(2);

(b) offer the Inspector or duly authorised person such assistance with matters under his or her control as is necessary to enable the entry, inspection and search to be carried out; or

(c) he or she intentionally obstructs the exercise of any right under this Part.

(2) A person guilty of an offence under this regulation is liable on summary conviction to the penalty specified in section 26 of the Act.

21. Meaning of duly authorised person

In this Part, a "duly authorised person", in the context of any provision, means a person authorised by the Committee to assist an Inspector in carrying out any function for the purposes of that provision.

PART III

DONATION OF TISSUE

A. DONATION OF TISSUE BY ADULTS

22. Donation of regenerative tissue by adults

(1) A person who—

(a) is not a minor;

(b) is of sound mind; and

(c) agrees with the medical advice given to him by a medical practitioner,

may, in writing signed by him in the presence of a designated officer consent to the removal from his body of the regenerative tissue specified in the consent and to do so—

(i) for the purpose of the transplantation of the tissue to the body of another living person, or

(ii) for use for other therapeutic purposes or for medical or scientific purposes.

(2) A person who has given a consent referred to in subregulation (1), may, at any time before the removal of the regenerative tissue to which the consent applies, revoke in writing, his consent to such removal.

(3) The designated officer shall, before removal of the regenerative tissue, certify in writing, that—

(a) all requirements referred to in subregulation (1) have been complied with;

(b) he or she explained to the donor the implications of the removal of regenerative tissue from the body; and

(c) the donor understood the implications of the removal of the regenerative tissue from the body.

(4) The Consent referred to in subregulation (1) and the certification referred to in subregulation (3), shall be in the manner set out in Form E of Schedule I.

23. Consent under regulation 22

A subsisting consent under regulation 22(1) and the certification under regulation 22(3), shall be sufficient authority for a medical practitioner, other than the designated officer and the medical practitioner referred to in regulation 22(1)), to remove the regenerative tissue referred to in the consent.

24. Donation of non-regenerative tissue by adults

(1) A person who—

(a) is not a minor;

(b) is of sound mind; and

(c) agrees with the advise given to him by a medical practitioner,

may, in writing signed by him in the presence of a designated officer, consent to the removal of non-regenerative tissue from his body after the expiration of a period of at least twenty-four hours from the time at which the consent is signed, for the purpose of the transplantation of the tissue to the body of another living person.

(2) A person who has given a consent referred to in subregulation (1), may, at any time before the removal of the non-regenerative tissue to which the consent applies, revoke in writing, his consent to such removal.

(3) The designated officer shall, before removal of non-regenerative tissue, certify in writing, that—

(a) all requirements referred to in subregulation (1) have been complied with;

(b) he or she explained to the donor the implications of removal of the non-regenerative tissue from the body; and

(c) the donor understood the implications of removal of the non-regenerative tissue from the body.

(4) The certification referred to in subregulation (3), shall be in the manner set out in Form E of Schedule I.

25. Consent under regulation 24

A subsisting consent under regulation 24(1) and certification under regulation 24(3), shall be sufficient authority for a medical practitioner, other than the designated officer and the medical practitioner referred to in regulation 24(1), to remove the non-regenerative tissue referred to in the consent.

B. DONATION OF TISSUE AFTER DEATH

26. Authority to remove tissue after death

Subject to regulation 27(1), a designated officer may authorise, for the purpose and use stated in this regulation, the removal of tissue from the body of a person who has died in the laboratory or facility or whose body has been brought into the laboratory or facility for—

(a) the transplantation of the tissue to the body of a living person; or

(b) the use of the tissue for other therapeutic purposes or for medical or scientific purposes.

27. Conditions under which designated officer may exercise authority

(1) The authorisation referred to in regulation 26 shall only be given where, after making such inquiries as are reasonable in the circumstances, a designated officer—

(a) is satisfied that the deceased person during his lifetime expressed the wish for, or consented to, the removal of tissue from his or her body after his or her death, for the purpose or a use referred to in regulation 26 and had not withdrawn the wish or revoked the consent; or

(b) has no reason to believe that the deceased person has expressed an objection to the removal of tissue from his body after his death for the purpose or a use referred to in regulation 26; and

(c) is satisfied that the nearest relative of the deceased person consents to the removal of tissue from the body of the deceased person for the purpose or a use referred to in regulation 26 .

(2) The consent referred to in regulation 27(1)*(c)* shall be in Form F as set out in Schedule I.

(3) The authorisation of a designated officer under regulation 26 shall be restricted by the expressed terms of the wishes or consent of the deceased person, or the consent of his nearest relative, as the case may be, both as to the tissue which may be removed and as to the purpose or use of such tissue.

(4) The nearest relative of a person may make it known to a designated officer at any time when the person is unconscious and before death that he consents to the removal, after the death of the person, of tissue from the body of the person for the purpose or a use referred to in regulation 26, but the designated officer shall not act on such an indication if such person recovers consciousness.

28. Removal of tissue only after death

No tissue may be removed from the body of the donor under this Part until death has occurred.

29. When death occurs

(1) For the purposes of this Part, a person is considered dead when there has occurred—

(a) irreversible cessation of all functions of the brain stem of that person; or

(b) irreversible cessation of circulation of blood in the body of that person.

(2) Subject to the stipulations set out in subregulation (3), death shall be determined by two medical practitioners on the staff of the relevant laboratory, in accordance with internationally accepted standards for determination of death of someone who is comatose.

(3) The stipulations referred to in subregulation(2) are –

(a) no medical practitioner who has a familial or professional relationship with the proposed recipient shall take any part in the determination of the fact of the death of the donor of the tissue;

(b) no medical practitioner who had taken part in the determination of death under subregulation (2) shall participate in the transplantation of the tissue to the recipient; and

(c) where the tissue is to be removed for therapeutic purposes, no medical practitioner who is due to remove or transplant the tissue, may determine the occurrence of death or may be a part of any team or process by whom or which death is determined.

30. Concurrence of Coroner

(1) Where a designated officer has reason to believe that the circumstances applicable to the death of a person are such that a coroner has jurisdiction to hold a preliminary inquiry or an inquest into the manner and cause of death of the person under the provisions of the Coroner's Act, the designated officer shall not authorise the removal of tissue from the body of the deceased person unless the coroner has stated that he has no objection to the removal.

(2) A statement by a coroner under this regulation may be given orally but shall be confirmed in writing within 24 hours of the making of the oral statement and shall be subject to such conditions, if any, as are specified in the statement.

SCHEDULE 1

FORMS

(These Forms have been approved by the National Stem Cell Oversight Committee to be used for the purposes of the Stem Cell Research and Therapy Act, 2019 and these Regulations)

FORM A

ANTIGUA AND BARBUDA
Stem Cell Research and Therapy Act, 2019

APPLICATION FOR A LICENCE TO OPERATE A STEM CELL RESEARCH AND THERAPY LABORATORY OR FACILITY

TO: The National Stem Cell Oversight Committee (nscoc)

SECTION 1: PERSONAL INFORMATION

Name of Applicant: (Individual or Company)
.....

Address:

Physical Address:
.....

Mailing Address:
.....

Contact Details:

Telephone contact information: (H) ..... (W) ..... (C).....

Email address:..... Fax .....

Name of authorised Company Representative: .....

Position: .....

Address:

Home Address: .....

Mailing Address: .....

Contact Details:

Telephone contact information: (H) .. .. (W) .. .. (C) .. ..

Email address .. .. Fax .. ..

List the names, addresses and contact details of ALL Directors and of all Shareholders owning 5% or more of the interest in the Company or Business.

Name Address and contact details Position

.. ..

.. ..

.. ..

Is the Applicant the Intended Administrator of the Facility/Laboratory? [Yes] [No]*

NB: If the Applicant is NOT the Intended Administrator, this Application MUST be accompanied by a letter of consent signed by the Administrator and two (2) forms of photo identification of the Administrator.

SECTION 2: ADMINISTRATOR INFORMATION

(I) Name and personal details of the Administrator:

Full name of the Administrator: .. ..
(BLOCK LETTERS)

Date of Birth: Country of Birth: Nationality:

.. ..

Address of the Administrator:

Home Address: .. ..

Mailing Address: .. ..

Contact information: Tel.:(H) .. .. (W) .. .. (C) .. ..

Email address .. ..

(II) Qualifications:

Please attach to this application evidence of academic qualifications and experience, as well as, other qualifications of the Intended Administrator, including any Fellowship or Professional Membership and Current Medical Licence, Certificate of Good Standing from practising authority.

(III) Employment Profile

Present Employer (if applicable) .. ..

Employer's Address .. ..

Phone/Fax .. .. Email address .. ..

Previous Employers:

(List names and contact information for the three (3) most recent past employers and the Position held by you prior to leaving the employment)

.. ..

.. ..

.. ..

Have you ever been disciplined by a Medical Board/Council for anything in connection with the practice of medicine?

[Yes] [No]

Have your licence to practice medicine ever been suspended or revoked in any territory/jurisdiction/state?

[Yes] [No]

NB: If you answer [Yes] to any of the above questions, you MUST provide details of the matter on a separate form.

CERTIFICATE OF THE ADMINISTRATOR

I, ... certify that I have read and understood the duties that I am required to perform as Administrator pursuant to regulation 8 and I am competent and able to undertake my duties in a responsible manner and in accordance with acceptable best practices.

Signature of Administrator

SECTION 3: FACILITY INFORMATION

(I) Name and location of the Facility

Name of the Facility: .. ..

Physical location: .. ..

Mailing Address .. ..

Contact Information:

Main Phone Number(s) for Public Use .. ..

Administration Phone Number .. ..

Email .. ..

(II) Nature of Service to be provided: *(list the services to be offered to clients of the facility)*

(III) Type of Patient Accommodation:

Please specify the number of patients that the facility may accommodate at any one time for more than 24 hours, not more than 24 hours and day only)

____ number of patients may be admitted at any one time for MORE than 24 hours.

____ number of patients who are not discharged on the same day, may be admitted for not more than 24 hours.

____ number of patients may be admitted and discharged on the same day.

SECTION 4: Documents and Information to be included with this Application

This application must be completely filled out and must be accompanied by the following supporting documentation:

1. Where the Applicant is not the intended Administrator, a notarised letter of consent from the Intended Administrator consenting to being the Administrator of the Facility, certified copies of two (2) Government issued identification documents and an Affidavit that he or she is aware of

the duties of Administrator and consents to carry out those duties in accordance with best practices.

2. Fitness and Probity Check Forms completed by the Applicant and the Administrator (if different from the Applicant)

3. Certificate of Incorporation where the Applicant is a company, as well as the Certificate of Good Standing of the Company, and the Company Resolution appointing the representative of the company.

SECTION 5: SUBMISSION

The completed application and the non-refundable application fee should be submitted to the National Stem Cell Oversight Committee, Ministry of Health, Wellness and the Environment, St. John's, Antigua and Barbuda

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SECTION 6: DECLARATION

I, ... , the Intended Administrator/Licence Holder/ duly appointed authorised representative of the company hereby declare that the information that I have given herein is truthful, complete and accurate to the best of my knowledge.

I understand that the National Stem Cell Oversight Committee reserves the right to request/review any additional information that the Committee considers necessary to determining my suitability/the suitability of the Applicant to hold a licence and/or to be the Administrator of a licensed facility.

.. ..

Signature of Applicant Date

FOR USE BY THE NATIONAL STEM CELL OVERSIGHT COMMITTEE ONLY

Application No.

Amount of Fee Paid:

Application Complete: [Yes] [No]

Qualifications of the Administrator:	R [ ]	NR[ ]	A [ ]	NA[ ]
Copy of Adminstrator's Medical Licence(s)	R [ ]	NR[ ]	A [ ]	NA[ ]
Consent of the Administrator	R [ ]	NR[ ]	A [ ]	NA[ ]
Fitness and Probity Check Form for Administrator and the Applicant	R [ ]	NR[ ]	A [ ]	NA[ ]
Facility Inspection	R [ ]	NR[ ]	A [ ]	NA[ ]
System in place for tracing donations:	R [ ]	NR[ ]	A [ ]	NA[ ]
Coding System identified:	R [ ]	NR[ ]	A [ ]	NA[ ]
Procedure in place for reporting SAE/SAR:	R [ ]	NR[ ]	A [ ]	NA[ ]

NB: R=Required, NR=Not Required; A+Approved; NA=Not Approved

Application Approved: [Yes] [No]

Licence No .. ..

Issue Date .. .. Expiration Date .. ..

FORM B (I) - Licence

NSCOC
Stem Cell Research
and Therapy Act, 2019

[Regulation 6(1)]
Licence No.:.....

[NAME OF FACILITY/LABORATORY]
(Address)

is licensed under the Stem Cell Research and Therapy Regulations 2020 as a Stem Cell Laboratory/Clinic/Hospital

Authorised Activities:

Name of Administrator .....
Name of Licence Holder .....
.....
Valid from _____ to _____ . .....[Seal of NSCOC].....
.....
.....

_____ _____
Chairman NSCOC *Minister of Health*

FORM B (2) – Temporary Licence

NSCOC
Stem Cell Research
and Therapy Act, 2019
TEMPORARY LICENCE

[Regulation 6(1)]
Licence No.:.....

[NAME OF FACILITY/LABORATORY]
(Address)

is **temporarily** licensed under the Stem Cell Research and Therapy Regulations 2020 as a Stem Cell Laboratory/Clinic/Hospital for a period of **30 days** from _____ to _____

Authorised Activities:

Name of Administrator .....
Name of Licence Holder .....
.....
Valid from _____ to _____ .....[Seal of NSCOC].....
.....
.....

_____ _____
Chairman NSCOC *Minister of Health*

FORM C - Application for Warrant

IN THE MAGISTRATE'S COURT

Application for Warrant pursuant to section 15(1) of the
Stem Cell Research and Therapy Act 2019, No. 11 of 2019

I……..... of ……
in Antigua and Barbuda, an inspector appointed under the Stem Cell Reserch and Therapy Act, 2019 No. 11 .of 2019 on the……day of ……20….., before the undersigned Magistrate,……..……..in Antigua and Barbuda state that:

…….…… the Stem Cell Research and Therapy Act 2019, No. 11 of 2019
……..……
……..……
……..……
and I further state that by virtue of the above I have probable cause to suspect that an offence has been committed under the Stem Cell Research and Therapy Act 2019, No. 11.of 2019 and that there are books, records, documents or things with respect to that offence concealed by.....at.....
……..……
. in the parish of …….. in Antigua and Barbuda.

Sworn }
On the ..... day of ……20…..} ……
Before me: } Inspector
}
…… }
Magistrate.

FORM D - Warrant

WARRANT

Pursuant to section 15(4) of the Stem Cell Research and Therapy Act 2019, No. 11 of 2019

To.....

Evidence on oath has been given this .....day of ....., 20..... by ..... that there is reasonable cause to believe that an offence has been committed under the Stem Cell Research and Therapy Act, 2019 No 11 of 2019 and that there are books, records, documents or things with respect to that offence at..... .... in the Parish of ..... in Antigua and Barbuda.

I am satisfied that the before mentioned evidence on oath establishes reasonable cause to believe that the books, records, documents or things so described are at the premises above-described and establishes grounds for the issuance of this warrant.

You are therefore hereby commanded, with the assistance of ..... and ....., to enter the said premises, by force and breaking doors if necessary and to search the same and if any books, records, documents or things with respect to that offence are found therein to make copies of those books, records or documents or if necessary, to seize and take away those books, records, documents or things and retain the copies made or the books, records, documents or things at the office of the Medical Benefits Scheme until they are produced in proceedings and dealt with as the law directs. AND if any books, records, documents or things have been seized, the Chief Executive Officer shall cause to be put in place the requisite arrangements to permit the employer reasonable access to those books, records, documents or things seized if they are necessary for the continued operations of the employer's business.

Given under my hand this .....day of.....20.....

.....
Magistrate

National Stem Cell Oversight Committee
Stem Cell Research and Therapy Act, 2019

FITNESS AND PROBITY CHECK FORM

I HEREBY GIVE MY CONSENT TO THE NATIONAL STEM CELLS OVERSIGHT COMMITTEE TO CARRY OUT ALL RELEVANT SEARCHES THAT MAY INCLUDE (WITHOUT LIMITATION) CORPORATE SEARCHES, CHECKS WITH HEALTH PROFESSIONAL REGISTRATION BOARDS OF WHICH I AM OR HAVE BEEN A MEMBER (INCLUDING REGISTRATION STATUS AND RELEASE OF INFORMATION ON ANY CURRENT OR ONGOING INVESTIGATIONS) AND CRIMINAL RECORD CHECKS.

I ALSO UNDERSTAND THAT I MAY BE REQUESTED TO PROVIDE FURTHER INFORMATION RELEVANT TO DETERMINING FITNESS AND PROBITY.

_____	_____	_____
PRINT NAME	SIGNATURE	DATE

FORM E-I:
PART A: CONSENT BY ADULT DONOR TO REMOVAL OF REGENERATIVE TISSUE

[Regulation 22(1), (2), (3)]

I, ... certify that.....,

(Name of donor)

being an adult of sound mind, and who has been given relevant medical advice by a medical practitioner, with which advice I agree, CONSENTS to the removal from my body of the following regenerative tissue for the purpose of the transplantation of the tissue to the body of another living person for therapeutic/medical/scientific purposes:

.....

.....

I further certify that I have had explained to me the implications of the removal of the regenerative tissue from my body and I understand the implications and consent to proceed with the removal of the regenertative tissue.

Date..... .....

Donor

FORM E-I:

PART B: CERTIFICATE OF DESIGNATED OFFICER OF ADULT CONSENT TO REMOVAL OF REGENERATIVE TISSUE

[Regulation 22

I, ... certify that .....,

(Name of designated officer) (Name of donor)

being an adult of sound mind, and who has been given relevant medical advice by a medical

practitioner, with which advice he/she agrees, has consented in writing to the removal from his/her

body of the following regenerative tissue for the purpose of the transplantation of the tissue to

the body of another living person for therapeutic/medical/scientific purposes:

.....

I further certify that I have explained to..... the implications of

(Name of donor)

the removal of the regenerative tissue from his/her body and I am of the opinion that he/she understood the implications of the removal.

Date..... .....

Signature of designated officer

FORM E-II:

PART A: CONSENT BY ADULT DONOR TO REMOVAL OF NON-REGENERATIVE TISSUE

[Regulation 24]

I, ... certify that.....,

(Name of donor)

being an adult of sound mind, and who has been given relevant medical advice by a medical

practitioner, with which advice I agree, CONSENT to the removal from my body of the following

non-regenerative tissue for the purpose of the transplantation of the tissue to the body of another

living person for therapeutic/medical/scientific purposes:

.....

.....

I further certify that I have had explained to me the implications of the removal of the non-regenerative tissue from my body and I understand the implications and consent to proceed with the removal of the regenertative tissue.

Date..... .....

Donor

FORM E-II:

PART B: CERTIFICATE OF DESIGNATED OFFICER OF ADULT CONSENT TO REMOVAL OF NON-REGENERATIVE TISSUE

I, ... certify that ....,

(Name of designated officer) (Name of donor)

being an adult of sound mind, and who has been given relevant medical advice by a medical

practitioner, with which advice he/she agrees, has consented in writing to the removal from his/her

body of the following non-regenerative tissue for the purpose of the transplantation of the tissue to

the body of another living person for therapeutic/medical/scientific purposes:

.....

I further certify that I have explained to..... the implications of

(Name of donor)

the removal of the non-regenerative tissue from his/her body and I am of the opinion that he/she understood the implications of the removal.

Date..... .....

Signature of designated officer

FORM F – AUTHORISATION OF REMOVAL AFTER DEATH

I, ... hereby authorise the removal of the

(Name of designated officer)

undermentioned tissue from the body of .....,

(Name of donor)

deceased, for transplantation to the body of a living person/use for therapeutic/medical/scientific

purposes:.....

.....I certify that I have made enquiries as are reasonable in

the circumstances and (delete as appropriate):

I am satisfied that the deceased during his/her lifetime expressed the wish for, or consented to, the removal of tissue from his/her body after death for any purpose or use referred to above and had not withdrawn the wish or revoked the consent; and

I have no reason to believe that the deceased had expressed an objection to the removal of tissue from his/her body after death for any purpose or use referred to above; and

I am satisfied that the nearest relative of the deceased consents to the removal of tissue from the body of the deceased for any such purpose or use.

Date ....

Signature of Designated Officer

FORM Z-I:

CONSENT BY PARENT/GUARDIAN OF A MINOR TO REMOVAL OF REGENERATIVE TISSUE FROM THE BODY OF A MINOR

I, ...parent/guardian of .....
(Name of donor)

(a minor), consent to the removal of the undermentioned Regenerative/Non-Regenerative tissue from his/her body for

the purpose of transplantation to the body of.....
(Name of recipient)

Who is his/her natural brother/sister/mother/father.....

I certify that: I have obtained advice from a medical practitioner, other than the practitioner due to

transplant the tissue, regarding the nature and effect of the removal of the tissue and the nature of

the transplantation. .

..... has the mental capacity to understand the nature
(Name of donor)

and effect of the removal and the nature of the transplantation and has agreed to the removal of

the regenerative tissue for the purpose of its transplantation to the body

of..... his/her natural brother/ sister/mother/father.
(Name of recipient)

Date..... .....

Signature of parent/guardian

FORM Z-II:

CERTIFICATE BY DESIGNATED OFFICER OF CONSENT

TO REMOVAL OF REGENERATIVE/NON-REGERNERATIVE TISSUE FROM THE BODY OF A MINOR

I, ...certify that .....
(Name of designated officer)

parent/guardian of ....., a minor, has consented to the removal

of the undermentioned regenerative/non-regenerative tissue from the body of the minor for the

purpose of transplantation to the body of ....., the minor's
name of recipient

natural brother/sister/mother/father:.....

I further certify that:

the parent/guardian of the minor has obtained medical advice from a medical practitioner, other than the practitioner due to transplant the tissue, regarding the nature and effect of the removal of the tissue and the nature of the transplantation

the minor has the mental capacity to understand the nature and effect of the removal and the nature of the transplantation and has agreed to the removal of the regenerative tissue for the purpose of its transplantation to the body of the person receiving the tissue

I explained to the parent/guardian the implications of the removal of the regenerative tissue from the body of the minor and the parent/ guardian appeared to understand the implications of the removal.

Date..... .....

Signature of designated Officer

FORM Z-III:

CERTIFICATE OF MEDICAL PRACTITIONER

I, ... medical practitioner, hereby certify that unless the undermentioned tissue, which is the same tissue specified in the consent of parent/guardian of, a minor, is transplanted to the body of .. .. (Name of recipient) the natural brother/sister/mother/father of the minor, he/she (the recipient) would die. I further certify that I will not participate in any of the medical procedures involved in transplantation of the tissue.

Date...

....
Signature of medical practitioner

SCHEDULE II

FEES

Nature of Fee	**Amount Payable**
Application Fee	$
Annual Licence Fee:	
Single year	$
Two years	$
Three years	$

SCHEDULE III

APPROPRIATE STATEMENTS

An appriopriate statement for the purposes of regulation 16 must contain the following information –

(a) a statement that the duly authorized person has authorised by the Authority for the purposes of regulation;

(b) a statement that the duly authorised person's rights of entry and search are subject to his producing evidence of his identity and entitlement to exercise the entry and search;

(c) a statement of the duly authorised person's powers under regulation 13 to search and seize anything which he believes on reasonable grounds to be required for his functions;

(a) a description of the requirement under regulation 17(5) for the duly authorised person to leave a sgtatement giving particulars of what he has seized and stating that he has seized it;

(e) a statement that a person commits an offence under regulation 20 if –

(i) he fails to make records or documents available in a legible form as required by regulation 13(2);

(ii) he fails to offer the Inspector or duly authorised person such assistance with matters under his or her control as is necessary to enable the entry, inspection and search to be carried out; or

(iii) he or she intentionally obstructs the exercise of any right under this Part.

Made this 30th day of July, 2020

Hon. Molwyn Joseph,
Minister of Health, Wellness & the Environment.