SAINT LUCIA

No. 10 of 2016

ARRANGEMENT OF SECTIONS

Section

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ENFORCEMENT

I ASSENT

[L.S.] MAC DONALD DIXON,
Deputy to the Governor-General.

April 19, 2016.

SAINT LUCIA

No. 10 of 2016

AN ACT to establish a clinical trials framework and to institute good clinical practice principles in the design, conduct, documentation and reporting of clinical trials in Saint Lucia, and for related matters.

[ON ORDER]

BE IT ENACTED by the Queen's Most Excellent Majesty, by and with the advice and consent of the House of Assembly and the Senate of Saint Lucia, and by the authority of the same, as follows:

PRELIMINARY

Short title and commencement

1.—(1) This Act may be cited as the Clinical Trials Act, 2016.

(2) This Act shall come into operation on a day to be fixed by the Minister by Order published in the *Gazette*.

Interpretation

2. In this Act —

"adverse event" means any untoward medical occurrence in a subject to whom an investigational medicinal product or investigational medical device is administered including occurrences which are not necessarily caused by or related to that investigational medicinal product or investigational medical device;

"adverse reaction" means any untoward and unintended response in a subject to an investigational medicinal product or investigational medical device which is related to any dose administered to that subject;

"Appeals Board" means the Appeals Board established under section 30;

"applicant" means —

(a) in relation to an application for an ethical opinion, the chief investigator;

(b) in relation to an application for an authorization, the sponsor;

"application" means —

(a) an application for an ethical opinion under section 11; or

(b) an application for an authorization under section 13;

"authorization" means an authorization issued under section 15(2);

"chief investigator" means –

(a) in relation to a clinical trial conducted at a single trial site, the person who takes primary responsibility for the conduct of the clinical trial for the trial site; or

(b) in relation to a clinical trial conducted at more than one trial site, the authorized health practitioner, whether or not he or she is an investigator at any particular trial site, who takes primary responsibility for the conduct of the clinical trial;

"clinical data" means the safety or efficacy information that is generated from the use of a medicinal product or medical device sourced from —

(a) a clinical trial of an investigational medicinal product or medical device;

(b) a clinical trial or other study reported in the scientific literature, on a similar investigational medicinal product or investigational medical device for which equivalence to the investigational medicinal product or investigational medical device in question can be demonstrated; or

(c) a published or an unpublished report on other clinical experiences of the medicinal product or medical device in question or a similar equivalent;

"clinical trial" means —

(a) any investigation in human subjects, other than a non-interventional trial, intended —

(i) to discover or verify the clinical, pharmacological or other pharmacodynamic effects of one or more medicinal products or medical devices,

(ii) to identify any adverse reactions to one or more medicinal products or medical devices,

(iii) to study absorption, distribution, metabolism and excretion of one or more medicinal products or medical devices,

with the object of ascertaining the safety or efficacy of the medicinal products or medical devices;

(b) includes a post-market clinical follow-up;

"conditions and principles of good clinical practice" means the conditions and principles of good clinical practice under section 19(1);

"conducting a clinical trial" includes —

(a) administering, or giving directions for the administration of, an investigational medicinal product or investigational medical device to a subject for the purposes of the clinical trial;

(b) giving a prescription for an investigational medicinal product or investigational medical device for the purposes of the clinical trial;

(c) carrying out any other medical or nursing procedure in relation to a clinical trial; and

(d) carrying out any test or analysis—

(i) to discover or verify the clinical, pharmacological or other pharmacodynamic effects of the investigational medicinal product or investigational medical device administered in the course of a clinical trial,

(ii) to identify any adverse reactions to an investigational medicinal product or investigational medical device, or

(iii) to study absorption, distribution, metabolism and excretion of the investigational medicinal products or investigational medical device;

but does not include any activity undertaken prior to the commencement of the clinical trial which consists of making such preparations for the clinical trial as are necessary or expedient;

"confidentiality" means prevention of disclosure, other than to authorized individuals, organizations or legal entities, of —

(a) an applicant's proprietary information;

(b) a trial subject's personal identity;

(c) personal medical information and other personal data;

"day" means a calendar day;

"Ethics Committee" means the Ethics Committee appointed under section 6;

"informed consent" means a trial subject's free and voluntary expression of his or her willingness to participate in a particular clinical trial, after having been informed of its nature, significance, implications and risks and other aspects of the clinical trial that are relevant to the trial subject's decision to participate;

"investigational medical device" means the medical device being tested or used as a reference in a clinical trial;

"investigational medicinal product" means a pharmaceutical form of an active substance or placebo being tested, or to be tested, or used, or to be used, as a reference in a clinical trial, and includes a medicinal product or medical device which has a marketing approval but is, for the purposes of the clinical trial—

(a) used or assembled, formulated or packaged in a way different from the form of the product or device authorized under the marketing approval;

(b) used for an indication not included in the summary of product or device characteristics under the marketing approval for that product or device; or

(c) used to gain further information about the form of that product or device as authorized under the marketing approval;

"investigator" means a person responsible for the conduct of the clinical trial at a trial site;

"investigator's brochure" means a document containing a summary of the clinical data and non-clinical data on the investigational medicinal product or investigational medical device, which are relevant to the clinical trial;

"*in vitro* diagnostic medical device" means any medical device which is intended to be used, alone or in combination with others, as a reagent, reagent device, calibrator, control material, kit, instrument, apparatus, equipment or system, according to the intended purpose specified by the manufacturer, for the *in vitro* examination of specimens derived from the human body, including blood and tissue donations;

"manufacturer" means a person with responsibility for the design, manufacture, packaging and labelling of an investigational medical device with a view to placing it on the market for the first time under his or her own name, regardless of whether those operations are carried out by the person himself or herself or on his or her behalf by a third party;

"marketing approval" means the authorization to market a medicinal product or medical device in the United States of America, the European Union and any other jurisdiction recognized by the National Competent Authority;

"medical device" means any instrument, apparatus, implement, implant, machine, appliance, software, material or other similar or related article, whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings for one or more of the following purposes —

(a) diagnosis, prevention, monitoring, treatment or alleviation of disease;

(b) diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap;

(c) investigation, replacement, modification or support of the anatomy or of a physiological process;

(d) supporting or sustaining life; or

(e) control of conception,

and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means;

"medicinal product" —

(a) means —

(i) any substance or combination of substances presented as having properties for treating or preventing disease in human beings, and

(ii) any substance or combination of substances which may be used in or administered to human beings with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis;

(b) does not include a medical device;

"Minister" means the Minister responsible for health;

"minor" means a person under the age of sixteen years;

"monitoring" means the act of overseeing the progress of a clinical trial, and of ensuring that it is conducted, recorded, and reported in accordance with the protocol, good clinical practice and the laws of Saint Lucia;

"National Competent Authority" means the National Competent Authority designated under section 7;

"non-interventional trial" means a study of one or more medicinal products or medical device which have a marketing approval, where the following conditions are met —

(a) the products are prescribed in the usual manner in accordance with the terms of the marketing approval;

(b) the assignment of any patient involved in the study to a particular therapeutic strategy is not decided in advance by a protocol but falls within current practice;

(c) the decision to prescribe a particular medicinal product or medical device is clearly separated from the decision to include the patient in the study;

(d) no diagnostic or monitoring procedures are applied to the patients included in the study, other than those which are ordinarily applied in the course of the particular therapeutic strategy in question; and

(e) epidemiological methods are to be used for the analysis of the data arising from the study;

"post-market clinical follow-up" means a clinical trial carried out following the marketing approval of a medicinal product or medical device and intended to answer specific questions relating to clinical safety or performance of a medicinal product or medical device when used in accordance with the marketing approved labelling for the medicinal product or medical device;

"protocol" means a document that describes the objective, design, methodology, statistical considerations and organisation of a clinical trial and includes successive versions of the protocol and modifications to the protocol;

"Regulations" means Regulations made under section 35;

"serious adverse event" means an adverse event that requires inpatient hospitalization or prolongation of existing hospitalization that –

(a) results in persistent or significant disability or incapacity;

(b) consists of a congenital anomaly or birth defect;

(c) is life-threatening; or

(d) results in death;

"sponsor" means the person who takes responsibility for the start, management or financing of a clinical trial;

"subject" means an individual, whether a patient or not, who participates in a clinical trial —

(a) as a recipient of an investigational medicinal product or investigational medical device or of some other treatment or product; or

(b) without receiving any treatment or product, as a control;

"trial site" means a hospital, health centre, surgery or other institution, site or facility at or from which a clinical trial or any part of a clinical trial is conducted;

"unexpected adverse reaction" means an adverse reaction the nature and severity of which is not consistent with the information about the medicinal product or medical device set out —

(a) in the case of a product or device with a marketing approval, in the summary of product or device characteristics for that product or device;

(b) in the case of any other investigational medicinal product or investigational medical device, in the investigator's brochure relating to the clinical trial.

Act binds the Crown

3. This Act binds the Crown.

Application and non-application

4.—(1) This Act applies to clinical trials in Saint Lucia.

(2) This Act does not apply to —

(a) *in vitro* diagnostic medical devices; or

(b) cosmetic products.

Application of other laws

5. Unless otherwise specifically provided under this Act, this Act does not derogate from the operation of any other Act in so far as that other Act relates to a clinical trial.

PART I
ADMINISTRATION

Ethics Committee

6.—(1) The Minister may, with the approval of Cabinet, appoint an Ethics Committee under this section.

(2) Subject to subsections (3) and (4), the Ethics Committee consists of no less than seven or more than eleven members to be appointed by the Minister after consultation with:

(a) the Allied Health Council;

(b) the Medical and Dental Council;

(c) the Bar Association;

(d) the General Nursing Council;

(e) the Pharmacy Council.

(3) The Ethics Committee consists of—

(a) an allied health practitioner;

(b) a medical practitioner;

(c) a dental practitioner;

(d) an attorney-at-law of at least eight years standing;

(e) a nurse;

(f) a pharmacist;

(g) persons possessing special qualifications, substantial experience or proven capacity in one or more of the fields of finance, science, clinical research ethics, quality and risk management and consumer affairs.

(4) The Minister shall designate a person appointed under subsection (3) to serve as Chairperson and Deputy Chairperson of the Ethics Committee.

(5) The Minister shall cause to be published in the *Gazette* the names of all members of the Ethics Committee as first appointed, including the Chairperson and Deputy Chairperson and every change in the membership of the Ethics Committee.

(6) The functions of the Ethics Committee is to ensure the protection of the rights, safety, dignity, well-being and confidentiality of subjects and provide public assurance of that protection, by reviewing applications for opinions and conducting an assessment from an ethical point of view to determine whether a favourable opinion is warranted for a clinical trial.

(7) Subject to subsection (8), the Ethics Committee may by writing delegate its functions to —

(a) any member; or

(b) a sub-committee.

(8) Subsection (7) does not authorize the Ethics Committee to delegate its power to make rules.

(9) A delegation under subsection (7) may—

(a) be made in respect of any particular matter or class of matters or generally, or may be made subject to such terms and conditions as the Ethics Committee determines;

(b) at any time, be revoked by the Ethics Committee and while in force shall not prevent the discharge by the Ethics Committee of any function that it has delegated under subsection (7).

(10) A delegate must comply with any written directions of the Ethics Committee.

(11) In carrying out its functions, the Ethics Committee may —

(a) subject to this section, make rules for its procedure at meetings;

(b) co-opt additional persons for the purpose of a meeting who hold office only in relation to the meeting for which he or she is co-opted and does not count as a member at that meeting;

(c) exercise any other powers as are specified by any other written law; and

(d) do all such things as may in its opinion be necessary or conducive to the proper discharge of its functions.

(12) Subject to subsection (15), a member holds office for a period of three years from the date of his or her appointment, and is eligible for re-appointment for not more than one consecutive term.

(13) Notwithstanding subsection (12), a person may be appointed to serve as a member for a period of less than three years so as to assist in providing continuity of experience as a member.

(14) Where for any reason the Chairperson, Deputy Chairperson or any other member is unable to carry out his or her functions under this Act, the Minister may appoint a member to act in the place of the Chairperson, Deputy Chairperson or other member —

(a) until the Chairperson, Deputy Chairperson or other member is again able to carry out such functions; or

(b) until another person is appointed as a Chairperson, Deputy Chairperson or member under this section.

(15) The Minister may, at any time, revoke the appointment of a member if —

(a) the member is incapable for any reason of performing his or her functions as a member;

(b) the member has been absent from three consecutive regular meetings of the Ethics Committee;

(c) the member fails to disclose his or her interest in an application for an opinion; or

(d) the Minister, on reasonable grounds, thinks it expedient to do so.

(16) A member, other than the Chairperson, may at any time resign his or her office by notice in writing addressed to the Minister and transmitted through the Chairperson and the resignation takes effect on the date the notice is received by the Minister or, if a later date is specified in the resignation, on that later date and the member ceases to be a member of the Ethics Committee.

(17) The Chairperson may at any time resign his or her office by notice in writing addressed to the Minister and the resignation takes effect on the date the notice is received by the Minister or, if a later date is specified in the resignation, on that later date and the Chairperson ceases to be Chairperson of the Ethics Committee.

(18) The members shall be paid remuneration as may be determined by Cabinet.

National Competent Authority

7.—(1) The Ministry of Health is designated as the National Competent Authority for the purposes of this Act.

(2) Notwithstanding subsection (1), the Minister may, by order published in the *Gazette*, designate a body as the National Competent Authority as the Minister considers necessary.

(3) The National Competent Authority shall—

(a) issue authorizations in accordance with this Act;

(b) monitor and enforce this Act;

(c) carry out any other function assigned under this Act.

Electronic database system on clinical trials

8.—(1) The National Competent Authority shall keep an electronic database system on clinical trials in accordance with this section.

(2) The electronic database must contain —

(a) name and contact details of the investigator or sponsor;

(b) description of the investigational medicinal product or investigational medical device;

(c) purpose of the clinical trial;

(d) status of the clinical trial;

(e) reports on serious adverse events; and

(f) any other information required by this Act.

Annual report

9.—(1) Not later than three months after the end of each financial year, the Ethics Committee and the National Competent Authority shall submit to the Minister an annual report on the work and activities of the Ethics Committee and the National Competent Authority and the Minister shall lay the same at the next sitting of Parliament after receipt of the report.

(2) A summary of an annual report under subsection (1) shall be published in the *Gazette* and the entire annual report shall be available to the public on payment of the prescribed fee.

PART II
CLINICAL TRIALS

Restriction on clinical trial

10.—(1) A person shall not—

(a) start a clinical trial or cause a clinical trial to be started;

(b) conduct a clinical trial;

(c) recruit an individual to be a subject in a clinical trial; or

(d) issue an advertisement for the purpose of recruiting individuals to be subjects in a clinical trial,

unless that person receives a favourable opinion from the Ethics Committee and an authorization from the National Competent Authority under this Act.

(2) A person who contravenes subsection (1) commits an offence and is liable on summary conviction to a fine not exceeding ten thousand dollars or to imprisonment for a period not exceeding two years or to both fine and imprisonment.

Application for opinion of Ethics Committee

11.—(1) An application for an Ethics Committee opinion in relation to a clinical trial shall be made by the chief investigator for the clinical trial.

(2) An application under subsection (1) must be—

(a) in writing;

(b) signed by the chief investigator making the application;

(c) accompanied by the particulars and documents specified in Schedule 1.

Opinion of Ethics Committee

12.—(1) Subject to subsections (3) and (4), the Ethics Committee shall within ninety days following receipt of an application, give an opinion in relation to the clinical trial to which the application relates.

(2) Where following receipt of an application it appears to the Ethics Committee that further information is required in order to give an opinion on a clinical trial, the Ethics Committee may, before giving an opinion, send a notice in writing to the applicant requesting that he or she furnishes the information.

(3) Where the Ethics Committee sends a request under subsection (2), the period specified in subsection (1) is suspended pending receipt of the information requested.

(4) Where any subject of the clinical trial is a minor and the Ethics Committee does not have a member with professional expertise in paediatric care, the Ethics Committee shall, before giving an opinion, obtain advice on the clinical, ethical and psychosocial problems in the field of paediatric care which may arise in relation to that clinical trial.

(5) Where any subject to the clinical trial is an adult incapable by reason of physical and mental incapacity to give informed consent to participation in the clinical trial and the Ethics Committee does not have a member with professional expertise in the treatment of —

(a) the disease to which the clinical trial relates; and

(b) the patient population suffering from that disease;

the Ethics Committee shall, before giving its opinion, obtain advice on the clinical, ethical and psychosocial problems in the field of that disease and patient population which may arise in relation to that clinical trial.

(6) The Ethics Committee shall consider, and give an opinion on, any other issue relating to the clinical trial, where —

(a) the Ethics Committee has been asked by the applicant to consider the issue;

(b) it is, in the opinion of the Ethics Committee, relevant to the other matters considered under this section.

(7) An opinion by the Ethics Committee must include —

(a) the relevance of the clinical trial and its design;

(b) whether the evaluation of the anticipated benefits and risks as required under paragraph 2 of Part 2 of Schedule 2 is satisfactory and whether the conclusions are justified;

(c) the protocol;

(d) the suitability of the investigator and supporting staff;

(e) the investigator's brochure;

(f) the quality of the trial site for the clinical trial;

(g) the adequacy and completeness of the written information to be given, and the procedure to be followed, for the purpose of obtaining informed consent of the subject to participate in the clinical trial;

(h) if the subject includes a person incapable of giving informed consent, whether the research is justified having regard to the conditions and principles specified in Part 5 of Schedule 2;

(i) details of provision for indemnity or compensation in the event of injury or death attributable to the clinical trial;

(j) details of any insurance or indemnity to cover the liability of the investigator or sponsor;

(k) the amounts, and, where appropriate, the arrangements, for rewarding or compensating investigators and subjects;

(l) the terms of any agreement between the sponsor and the owner or occupier of the trial site which are relevant to the arrangements referred to in paragraph (k); and

(m) the arrangements for the recruitment of subjects.

(8) Where the Ethics Committee gives an opinion under this section, it shall make a summary of that opinion available on the electronic database under section 8.

Application for authorization

13.—(1) Where a favourable opinion is provided to the chief investigator under section 10, the sponsor of the clinical trial may make an application for the authorization to conduct a clinical trial.

(2) An application under subsection (1) must —

(a) be in writing and signed by or on behalf of the sponsor; and

(b) be accompanied by —

(i) the particulars and documents specified in Schedule 3;

(ii) the prescribed fee.

Consideration of application for authorization

14.—(1) Subject to subsection (3) and section 15, the National Competent Authority shall consider an application for the conduct of a clinical trial and grant, or refuse to grant, an authorization within thirty days from the date of receipt of the application for authorization of a clinical trial.

(2) Upon receipt of an application, the National Competent Authority may give notice in writing to the applicant requesting him or her to provide further information relating to the particulars referred to in section 13(2)(b)(i).

(3) Where the National Competent Authority gives a notice under subsection (2), the period specified in subsection (1) is suspended from the date the notice is given and recommences on receipt of the information requested.

Grant or refusal of application for authorization

15.—(1) The National Competent Authority may grant an authorization for a clinical trial where —

(a) the applicant —

(i) has complied with the requirements of section 13,

(ii) has at his or her disposal suitable and sufficient trial sites, technical equipment and control facilities as to the storage of the investigational medicinal product or investigational medical device,

(iii) if a notice has been given under section 14(2), has provided the information requested by the National Competent Authority;

(b) the National Competent Authority has established that the particulars under section 13(2)(b)(i) are accurate.

(2) Where the National Competent Authority grants an authorization for a clinical trial, the National Competent Authority shall issue a written authorization, without conditions or subject to conditions upon payment by the sponsor of the prescribed fee.

(3) Where the National Competent Authority refuses an application, the National Competent Authority shall give a notice in writing to the sponsor setting out the grounds for refusing the application for authorization to conduct the clinical trial.

(4) Where a sponsor is given a notice under subsection (3), he or she may, within a period of fourteen days, or such extended period as the National Competent Authority may in any particular case allow, from the date on which the notice was received, send an amended application to the National Competent Authority for further consideration.

(5) The National Competent Authority shall consider an amended application and, not later than sixty days from the date on which the original application was received —

(a) issue a written authorization to the sponsor under subsection (2); or

(b) give a notice in writing to the sponsor setting out the grounds for refusing the application.

(6) Where an authorization is granted with conditions or refused, the applicant may, within thirty days from receipt of the written authorization, appeal in writing to the Appeals Board, setting out the grounds on which the appeal is made.

Withdrawal of application

16.—(1) An applicant may withdraw his or her application at any time before the opinion or authorization and the reason for such withdrawal shall be expressly disclosed to the Ethics Committee or National Competent Authority.

(2) The application may be resubmitted after a withdrawal or following the refusal or the application, and the resubmitted application must make reference to the previous application, highlight the changes as compared to the previous application and, if applicable, specify how any unresolved issues in the previous application have been addressed.

(3) Where an applicant intends to make any substantial modification subsequent to the opinion or authorization of the clinical trial, he or she shall consider how such changes may affect the rights, safety, dignity, well-being and confidentiality of the subject.

Notice of substantial modification

17.—(1) An investigator or sponsor shall immediately give notice in writing to the Ethics Committee or National Competent Authority of any substantial modification in the particulars or documents relating an opinion or authorization.

(2) A notice under subsection (1) must—

(a) include details on how the modification may affect the rights, safety, dignity, well-being and confidentiality of the subject; and

(b) be accompanied by the opinion or authorization to which the notice relates.

(3) Upon receipt of a notice under subsection (1), the Ethics Committee or National Competent Authority may pursuant to sections 12, 14 and 15 amend or issue another opinion or authorization.

Withdrawal, revocation and suspension

18.—(1) The Ethics Committee or National Competent Authority may —

(a) withdraw an opinion or authorization if the Ethics Committee or National Competent Authority subsequently becomes aware that grounds for refusal existed at the time of issuance of the opinion or authorization, if the conditions surrounding the clinical trials do not correspond with the information contained in the application or if facts give reason to doubt the safety or the scientific basis of the clinical trial;

(b) revoke an opinion or authorization if the Ethics Committee or National Competent Authority becomes aware that subsequent to the opinion or authorization, the requirements for clinical trials under this Act are no longer fulfilled; or

(c) suspend an opinion or authorization for a limited time in cases where the Ethics Committee or National Competent Authority believes that —

(i) any condition, restriction or limitation which applies to the conduct of the clinical trial and is set out in the application for an opinion or authorization or the particulars or documents accompanying the application, or

(ii) any condition imposed by the National Competent Authority under section 15, is no longer satisfied, generally or at a particular trial site; or

(iii) there is sufficient information to raise doubts about the safety or scientific validity of the clinical trial, or the conduct of the clinical trial at a particular trial site.

(2) Before withdrawing, revoking or suspending an opinion or authorization, the Ethics Committee or National Competent Authority shall by notice in writing —

(a) inform the sponsor or investigator that the Ethics Committee or National Competent Authority proposes to issue a notice —

(i) withdrawing, revoking or suspending the opinion or authorization, and

(ii) suspending or terminating the clinical trial, or the conduct of a clinical trial at a particular site, and of the reasons for the suspension or termination; and

(b) advise the sponsor or investigator that he or she may, within one week of the date of the notice, furnish the Ethics Committee or National Competent Authority with written representations as to whether opinion or authorization should not be withdrawn, revoked or suspended or the clinical trial, or the conduct of the clinical trial at a particular site, should not be suspended or terminated.

(3) Subsection (2) does not apply where it appears to the Ethics Committee or National Competent Authority that there is an imminent risk to the health or safety of any of the subjects of the clinical trial.

(4) Where a statement is not provided within one week or the statement does not adequately address the grounds for the withdrawal, revocation or suspension, the Ethics Committee or National Competent Authority may by notice —

(a) withdraw, revoke or suspend the opinion or authorization; and

(b) require that the clinical trial, or the conduct of the clinical trial at a particular trial site, be suspended or terminated.

(5) A notice under subsection (4)(b) shall be served —

(a) in a case where the suspension or termination applies to the clinical trial generally, on—

(i) the sponsor, or

(ii) the investigator at each trial site;

(b) in a case where the suspension or termination applies to the conduct of a trial at a particular trial site, on—

(i) the sponsor, or

(ii) the investigator at that trial site.

(6) A notice under subsection (4)(b) must specify—

(a) whether the notice applies to the clinical trial generally or to one or more of the trial sites;

(b) whether the notice requires suspension or termination of the clinical trial;

(c) if the notice requires suspension of the clinical trial—

(i) whether the suspension applies until further notice from the Ethics Committee or National Competent Authority or for such period as may be specified in the notice, and

(ii) any conditions which are to be satisfied before the clinical trial or the conduct of the clinical trial at a particular site, may be recommenced; and

(d) whether suspension or termination is to take effect immediately on receipt of the notice or on such date as may be specified in the notice.

(7) Where the Ethics Committee or National Competent Authority issues a notice under subsection (4)(b), the Ethics Committee or National Competent Authority shall immediately inform, where the notice has not been served on the sponsor, the sponsor.

(8) Any person who fails to comply with a withdrawal, revocation or suspension of an opinion or authorization or notice of suspension or termination served on him or her under this section, unless that notice has been withdrawn or revoked by the Ethics Committee or National Competent Authority, commits an offence and is liable on summary conviction to fine not exceeding five thousand dollars or to a term of imprisonment not exceeding six months or to both fine and imprisonment.

(9) Where an opinion or authorization is withdrawn, revoked or suspended under this section, an applicant may, within thirty days from receipt of the withdrawal, revocation or suspension, appeal in writing to the Appeals Board, setting out the grounds on which the appeal is made.

Conditions and principles of good clinical practice

19.—(1) A person shall not —

(a) conduct a clinical trial; or

(b) perform the functions of the sponsor of a clinical trial, whether that person is the sponsor or is acting under arrangements made with that sponsor,

otherwise than in accordance with the conditions and principles of good clinical practice specified in Schedule 2.

(2) The sponsor of a clinical trial shall put and keep in place arrangements for the purpose of ensuring that with regard to the clinical trial the conditions and principles of good clinical practice under subsection (1) are satisfied or adhered to.

(3) Subject to subsection (4), the sponsor of a clinical trial shall ensure that —

(a) the investigational medicinal products used in the clinical trial, and

(b) any devices used for the administration of such products, are made available to the subjects of the clinical trial free of charge.

(4) Where —

(a) a clinical trial is conducted at more than one trial site; and

(b) the application for authorization to conduct the clinical trial specifies that in relation to one or more trial sites the duties of the sponsor under subsections (2) and (3) are to be performed by a person other than the sponsor, those duties shall, in relation to that trial site, be performed by the person so specified.

Urgent safety measures

20.—(1) The sponsor and investigator may take appropriate urgent safety measures in order to protect the subjects of a clinical trial against any immediate hazard to their health or safety.

(2) Where measures are taken under subsection (1), the sponsor shall immediately and in any event no later than three days from the date the measures are taken, give written notice to the Ethics Committee or National Competent Authority of the measures taken and the circumstances giving rise to such measures.

Notification of serious adverse events

21.—(1) An investigator shall report any serious adverse event which occurs in a subject at a trial site at which he or she is responsible for the conduct of a clinical trial immediately to the sponsor.

(2) A report under subsection (1) may be made orally or in writing.

(3) Following the report of a serious adverse event, the investigator shall make a detailed written report on the event.

(4) Subsections (1) to (3) do not apply to serious adverse events specified in the protocol or the investigator's brochure as not requiring immediate reporting.

(5) Adverse events, other than adverse events under subsections (1) to (3), that are identified in the protocol as critical to evaluations of the safety of the clinical trial must be reported to the sponsor in accordance with the reporting requirements, including the time periods for such reporting, specified in that protocol.

(6) The reports made under subsections (1), (3) and (5) shall identify each subject referred to in the report by a number assigned to that subject in accordance with the protocol.

(7) The number assigned to a subject in accordance with the protocol must be different from the number of any other subject in that clinical trial.

(8) Where the event reported under subsection (1) or (5) consists of, or results in, the death of a subject, the investigator shall supply—

(a) the sponsor;

(b) the Ethics Committee; and

(c) the National Competent Authority, with any additional information requested by the sponsor, ethics committee or National Competent Authority.

(9) The sponsor shall keep detailed records of all adverse events relating to a clinical trial which are reported to him or her by the investigators for that clinical trial.

(10) The Ethics Committee or National Competent Authority may, by sending a notice in writing to the sponsor, require the sponsor to send the records referred to in subsection (9), or copies of such records, to it.

Notification of suspected unexpected serious adverse reactions

22.—(1) A sponsor shall ensure that all relevant information about a suspected unexpected serious adverse reaction which occurs during the course of a clinical trial that is fatal or life-threatening is—

(a) recorded; and

(b) reported as soon as possible to—

(i) the National Competent Authority, and

(ii) the Ethics Committee, and in any event not later than seven days after the sponsor was first aware of the reaction.

(2) A sponsor shall ensure that within eight days of a report under subsection (1)(b), any additional relevant information is sent to the Ethics Committee or National Competent Authority.

(3) A sponsor shall ensure that a suspected unexpected serious adverse reaction which occurs during the course of a clinical trial, other than those referred to in subsection (1), is reported as soon as possible to—

(a) the National Competent Authority;

(b) the Ethics Committee, and in any event not later than fifteen days after the sponsor is first aware of the reaction.

(4) For the purposes of subsections (1) to (3), the sponsor may fulfill his or her obligations to report or provide information to the Ethics Committee or National Competent Authority by entering the report or information in the database established under section 8.

(5) A sponsor shall ensure that, in relation to each clinical trial for which he or she is the sponsor, the investigators responsible for the conduct of a clinical trial are informed of any suspected unexpected serious adverse reaction which occurs in relation to an investigational medicinal product or investigational medical device used in that clinical trial, whether that reaction occurs during the course of that clinical trial or another clinical trial for which the sponsor is responsible.

(6) The Ethics Committee and the National Competent Authority shall —

(a) keep a record of all suspected unexpected serious adverse reactions relating to an investigational medicinal product or investigational medical device which are brought to its attention under subsection (1) or (3) or otherwise; and

(b) ensure that the details of those reactions are entered in the database established under section 8, whether by the sponsor, the Ethics Committee or National Competent Authority.

Annual list of suspected serious adverse reactions and safety report

23.—(1) As soon as practicable after the end of a reporting year, a sponsor shall, in relation to each investigational medicinal product or investigational medical device tested in clinical trials for which he or she is the sponsor furnish the Ethics Committee or National Competent Authority with—

(a) a list of all the suspected serious adverse reactions which have occurred during that year in relation to such clinical trials, including those reactions relating to any investigational medicinal product or investigational medical device used as a placebo or as a reference in the clinical trials; and

(b) a report on the safety of the subjects of the clinical trials.

(2) In subsection (1), "reporting year", in relation to an investigational medicinal product or investigational medical device, means the year ending on the anniversary of—

(a) in the case of a product which has a marketing approval, the earliest date on which any such authorization relating to the product or device was granted or issued; or

(b) in any other case, the earliest date on which any clinical trial—

(i) relating to the product or device, and

(ii) for which the person responsible for making the report was the sponsor.

PART III
ENFORCEMENT

Infringement notice

24.—(1) Where the National Competent Authority has grounds for believing that any person has contravened any provision of this Act or any Regulations made under this Act, it may serve upon that person an infringement notice in writing —

(a) informing the person of the grounds for considering that he or she has contravened one or more provisions of this Act or Regulations;

(b) specifying the relevant provision of this Act or Regulations;

(c) specifying the measures which the person must take in order to ensure that the contravention does not continue or does not recur;

(d) requiring the person to take those measures, within such period as may be specified in the notice;

(e) warning the person that unless the requirements of paragraph (d) are met, further action may be taken in respect of the contravention.

(2) An infringement notice may include directions as to the measures to be taken by the person on whom the notice is served to ensure that the contravention does not continue or, as the case may be, does not recur, including the different ways of securing compliance.

Sale or supply of investigational medicinal product or investigational medical device

25.—(1) A sponsor shall not sell or supply, or procure the sale or supply, of an investigational medicinal product or investigational medical device —

(a) to a subject for the purposes of a clinical trial; or

(b) to a person for the purpose of administering the product or device to such a subject.

(2) A person shall not sell or supply an investigational medicinal product or investigational medical device —

(a) to a subject for the purposes of a clinical trial; or

(b) to a person for the purpose of administering the investigational medicinal product or investigational medical device to a subject.

(3) A sponsor or person who contravenes subsection (1) or (2) commits an offence and is liable on summary conviction to a fine not exceeding ten thousand dollars or to a term of imprisonment not exceeding two years or to both fine and imprisonment.

False or misleading information

26.—(1) A person shall not in the course of making an application provide to the Ethics Committee or National Competent Authority any relevant information which is false or misleading in a material particular.

(2) Any person who—

(a) is conducting a clinical trial under an authorization;

(b) is a sponsor of a clinical trial;

(c) while acting under arrangements made with a sponsor of a clinical trial, performs the functions of that sponsor;

shall not provide to the Ethics Committee or National Competent Authority any relevant information which is false or misleading in a material particular.

(3) An applicant or person who contravenes subsection (1) or (2) commits an offence and is liable on summary conviction to a fine not exceeding five thousand dollars or to a term of imprisonment not exceeding one year or to both fine and imprisonment.

(4) In this regulation, "relevant information" means any information which is relevant to an evaluation of—

(a) the safety or scientific validity of a clinical trial; or

(b) whether, with regard to a clinical trial, the conditions and principles of good clinical practice are being satisfied or adhered to.

Limitation on prosecution

27.—An investigation or prosecution under this Act or the Regulations made under this Act may be commenced at any time within twelve months from the time when the subject matter of the information or prosecution arose or the offence was committed whichever is later.

Prosecution of offences

28. Proceedings for an offence under this Act or the Regulations made under this Act may be instituted, heard, tried or determined by a court of summary jurisdiction in whose district the offence was committed or in any place in which the defendant is apprehended or happens to be.

Payment of compensation

29. Any person convicted of an offence under this Act may, if the Court thinks fit, be ordered to pay, in addition to any penalty for which he or she is liable for the offence, a sum in compensation as assessed by the Court.

PART IV

APPEALS

Establishment of Appeals Board

30. There is established an Appeals Board for the purpose of hearing appeals against decisions of the Ethics Committee or National Competent Authority.

Constitution and procedure

31.—(1) Subject to subsections (2) and (3), the Minister may make Regulations relating to the constitution and procedure of the Appeals Board.

(2) The names of the initial members, their titles, if any, and every change in membership, in the Appeals Board shall be published in the Gazette.

(3) At the hearing of an appeal, the Appeals Board may—

(a) confirm the decision of the Ethics Committee or the National Competent Authority; or

(b) set aside the decision of the Ethics Committee or the National Competent Authority.

Further appeal

32.—(1) A person who is dissatisfied with a decision made by the Appeals Board under section 31 may appeal to a judge in chambers.

(2) An appeal to a judge in chambers shall be lodged within ninety days after the decision against which the appeal is brought.

PART V
MISCELLANEOUS

General penalty

33. Any person who contravenes or fails to comply with any of the provisions of this Act for which no penalty is specifically provided commits an offence and is liable on summary conviction to a fine not exceeding ten thousand dollars or to a term of imprisonment not exceeding two years or to both fine and imprisonment.

Amendment of Schedules

34. The Minister may, by order, amend Schedule 1, Schedule 2 or Schedule 3.

Regulations

35.— (1) The Minister may make Regulations for the proper carrying out of the provisions of this Act.

(2) Without limiting the generality of subsection (1), the Minister may make Regulations —

(a) to make provision for any technical progress relating to clinical trials;

(b) to take account of international regulatory developments in the field of clinical trials;

(c) to improve the information on the safety of medicinal products or medical devices;

(d) to prescribe fees;

(e) to specify the procedure of the Ethics Committee at meetings of the Ethics Committee.

(3) Regulations made under this section may provide that the contravention of any provision constitutes an offence and may specify penalties for any offence on summary conviction to a fine not exceeding ten thousand dollars or to a term of imprisonment not exceeding two years or to both fine and imprisonment.

SCHEDULE 1

(Section 11(2)(c))

PARTICULARS AND DOCUMENTS FOR APPLICATION FOR OPINION OF ETHICS COMMITTEE

PARTICULARS

1. Particulars identifying the clinical trial including the full and short title of the clinical trial.

2. The following particulars relating to the trial design —

(a) a summary of the clinical trial, including justification and relevance, and the methodology to be used;

(b) the primary, and any secondary, research hypothesis;

(c) statistical analysis and justification for the numbers of subjects to be recruited for the clinical trial; and

(d) details of the process for peer review of the scientific value of the clinical trial.

3. The name and address of the sponsor.

4. Details of any arrangements under which the sponsor has delegated any of his or her responsibilities in relation to the proposed clinical trial.

5. The financial arrangements for the clinical trial, in particular —

(a) sources of funding for the clinical trial and information on financial or other interests of the applicant relevant to the clinical trial;

(b) the arrangements for remuneration of, or re-imbursement of expenses incurred by, subjects;

(c) any provision for compensation in the event of injury or death attributable to the clinical trial;

(d) details of any insurance or indemnity to cover the liability of the sponsor and investigator; and

(e) summary details of any financial arrangements between—

(i) the sponsor or person funding the clinical trial and the investigator, and

(ii) the sponsor or person funding the clinical trial and the owner or occupier of the trial site.

6. Arrangements for the recruitment of subjects, including the materials to be used.

7. The criteria for inclusion and exclusion of patients, including justification for recruiting from vulnerable groups including individuals whose willingness to volunteer in a clinical trial may be unduly influenced by the expectation, whether justified or not, of benefits associated with participation, or of a retaliatory response from senior members of a hierarchy in case of refusal to participate such as –

(a) individuals with lack of or loss of autonomy due to immaturity or through mental disability;

(b) persons in nursing homes;

(c) minors;

(d) impoverished persons;

(e) persons in emergency situations;

(f) ethnic minority groups;

(g) homeless persons;

(h) nomads;

(i) refugees;

(j) pregnant women;

(k) those incapable of giving informed consent;

(l) members of a group with a hierarchical structure such as university students, subordinate hospital and laboratory personnel, employees of the sponsor, members of the armed forces, and persons kept in detention.

8. Methods for recording and verifying health status for healthy volunteers.

9. Procedures for checking simultaneous or recent involvement of potential subjects in other trials.

10. Details of any relationship between subject and investigator which may be relevant for the purposes of an ethical opinion.

11. Details of —

(a) any proposed additional investigational procedures or other interventions over and above those required for normal clinical care,

(b) any aspect of normal clinical care to be withheld or other deviation from normal treatment, and

(c) the plan for treatment or care of subjects once their participation in the clinical trial has ended.

12. The procedures for—

(a) providing information to potential subjects, including a contact point where additional information can be obtained about the clinical trial and the rights of subjects;

(b) providing subjects with updated information during and where relevant after the clinical trial, and

(c) obtaining informed consent.

13. Details of the arrangements for access to confidential data about the subjects and the arrangements to protect subjects' privacy.

14. The rules for terminating or concluding the clinical trial before —
    (a) the date for the conclusion of the clinical trial specified in the protocol; or

    (b) the event specified in the protocol as the event which indicates that the end of the clinical trial has occurred.

15. Any agreement on —

    (a) the access by the investigator or his or her team to the data produced by the clinical trial; and

    (b) the policy for publication of that data.

16. An assessment of the ethical issues relating to the clinical trial, including —

    (a) the importance of the clinical trial and of the new knowledge to be gained;

    (b) an assessment of the potential benefits; and

    (c) an assessment of the possible risks for the subject.

17. details relating to the chief investigator and each investigator, including—

    (a) experience in conducting research, and

    (b) any potential conflicts of interest.

18. Details of any proposed trial site and its suitability for conducting the clinical trial.

DOCUMENTS

1. A document containing the particulars specified in paragraphs 1 to 4 and 6 to 9 of Part 2 of Schedule 3.

2. The following documents—

    (a) the protocol;

    (b) the investigator's brochure for the proposed clinical trial or, where the investigational medicinal product or investigational medical device has a marketing authorization and the product is to be used in accordance with the terms of that authorization, the summary of product characteristics relating to that product;

(c) any document providing evidence of any insurance to cover the liability of the sponsor and investigator;

(d) copies of the advertisement material for recruitment of subjects;

(e) in the case of advertising contained on video or audio cassettes, a copy of the script for that advertising;

(f) a copy of any letter inviting a subject to participate in the clinical trial;

(g) a copy of any questionnaire, diary or sample card to be completed by the subject in writing;

(h) a copy of all written information to be given to a potential subject or his or her legal representative prior to seeking informed consent;

(i) a copy of the form to be used to record the consent of a subject or their legal representative;

(j) a copy of any letters or other written information to be sent to any person who normally provides a subject's clinical care;

(k) a summary curriculum vitae for the chief investigator and each investigator.

SCHEDULE 2

(Section 12(7)(b) and (h))

CONDITIONS AND PRINCIPLES OF GOOD CLINICAL PRACTICE

AND FOR THE PROTECTION OF CLINICAL TRIAL SUBJECTS

PART 1

APPLICATION AND INTERPRETATION

1.—(1) The conditions and principles specified in Part 2 apply to all clinical trials.

(2) If any subject of a clinical trial is—

(a) an adult able to give informed consent, or

(b) an adult who has given informed consent to taking part in the clinical trial prior to the onset of incapacity, the conditions and principles specified in Part 3 apply in relation to that subject.

(3) If any subject of a clinical trial is a minor, the conditions and principles specified in Part 4 apply in relation to that subject.

(4) If any subject—

(a) is an adult unable by virtue of physical or mental incapacity to give informed consent, and

(b) did not, prior to the onset of incapacity, give or refuse to give informed consent to taking part in the clinical trial,

the conditions and principles specified in Part 5 apply in relation to that subject.

(5) If any person—

(a) is an adult unable by virtue of physical or mental incapacity to give informed consent, and

(b) has, prior to the onset of incapacity, refused to give informed consent to taking part in the clinical trial,

that person cannot be included as a subject in the clinical trial.

2. In this Schedule —

"guardian" means a tutor or curator appointed under the Civil Code of Saint Lucia, Cap. 4.01;

"good manufacturing practice" means an international quality standard for manufacturing practices which ensures the quality of investigational medicinal products and investigational medical devices that provides assurance that active substances meet the requirements for quality and purity that the investigational medical products and investigational medical devices purport or represent to possess;

"person connected with the conduct of the trial" means—

(a) the sponsor of the trial,

(b) a person employed or engaged by, or acting under arrangements made with, the sponsor and who undertakes activities in connection with the management of the trial,

(c) an investigator for the trial,

(d) a health service worker who is a member of an investigator's team for the purposes of the clinical trial, or

(e) a person who provides health services under the direction or control of a person referred to in paragraphs (c) and (d) above, whether in the course of the clinical trial or otherwise;

"health service provider" includes—

(a) a person or body providing a health service;

(b) a person who manages a health care institution;

(c) any clinic, public hospital, private hospital, community health centre, mental health hospital; and

(d) the chief executive officer or person holding a similar position of a body listed in paragraph (c).

3.—(1) For the purposes of this Schedule, a person gives informed consent to take part, or that a subject is to take part, in a clinical trial only if his decision—

(a) is given freely after that person is informed of the nature, significance, implications and risks of the clinical trial; and

(b) either—

(i) is evidenced in writing, dated and signed, or otherwise marked, by that person so as to indicate his or her consent, or

(ii) if the person is unable to sign or to mark a document so as to indicate his or her consent, is given orally in the presence of at least one witness and recorded in writing.

(2) For the purposes of this Schedule, references to informed consent—

(a) shall be construed in accordance with paragraph (1); and

(b) include references to informed consent given or refused by an adult unable by virtue of physical or mental incapacity to give informed consent, prior to the onset of that incapacity.

PART 2

CONDITIONS AND PRINCIPLES WHICH APPLY TO ALL CLINICAL TRIALS

Principles based on International Conference on Harmonisation Good Clinical Practice Guideline

1. Clinical trials shall be conducted in accordance with the ethical principles that are consistent with good clinical practice and the requirements of this Act.

2. Before the clinical trial is started, foreseeable risks and inconveniences have been weighed against the anticipated benefit for the individual trial subject and other present and future patients. A clinical trial should be started and continued only if the anticipated benefits justify the risks.

3. The rights, safety, and well-being of the subjects are the most important considerations and prevails over interests of science and society.

4. The available non-clinical and clinical information on an investigational medicinal product or investigational medical device must be adequate to support the clinical trial.

5. Clinical trials must be scientifically sound, and described in a clear, detailed protocol.

6. A clinical trial shall be conducted in compliance with the protocol that has a favourable opinion from the Ethics Committee.

7. The medical care given to, and medical decisions made on behalf of, subjects shall always be the responsibility of an appropriately qualified health practitioner.

8. Each individual involved in conducting a clinical trial shall be qualified by education, training, and experience to perform his or her respective task.

9. Subject to the other provisions of this Schedule relating to consent, freely given informed consent shall be obtained from every subject prior to clinical trial participation.

10. All clinical trial information shall be recorded, handled, and stored in a way that allows its accurate reporting, interpretation and verification.

11. The confidentiality of records that could identify subjects shall be protected, respecting the privacy and confidentiality rules in accordance with the requirements of any law relating to data protection or confidentiality.

12. Investigational medicinal products or investigational medical devices used in the clinical trial must be—

(a) manufactured or imported, and handled and stored, in accordance with the principles and guidelines of good manufacturing practice, and

(b) used in accordance with the approved protocol.

13. Systems with procedures that assure the quality of every aspect of the clinical trial must be implemented.

14. A clinical trial shall be started only if the Ethics Committee and the National Competent Authority comes to the conclusion that the anticipated therapeutic and public health benefits justify the risks and may be continued only if compliance with this requirement is permanently monitored.

15. The rights of each subject to physical and mental integrity, to privacy and to the protection of the data concerning him or her in accordance with any law relating to data protection are safeguarded.

16. Provision has been made for insurance or indemnity to cover the liability of the investigator and sponsor which may arise in relation to the clinical trial.

PART 3

CONDITIONS WHICH APPLY IN RELATION TO AN ADULT ABLE TO CONSENT OR WHO HAS GIVEN CONSENT PRIOR TO THE ONSET OF INCAPACITY

1. The subject has had an interview with the investigator, or another member of the investigating team, in which he or she has been given the opportunity to understand the objectives, risks and inconveniences of the clinical trial and the conditions under which it is to be conducted.

2. The subject has been informed of his or her right to withdraw from the clinical trial at any time.

3. The subject has given his or her informed consent to taking part in the clinical trial.

4. The subject may, without being subject to any resulting detriment, withdraw from the clinical trial at any time by revoking his or her informed consent.

5. The subject has been provided with a contact point where he or she may obtain further information about the trial.

PART 4

CONDITIONS AND PRINCIPLES WHICH APPLY IN RELATION TO A MINOR

Conditions

1. Subject to paragraph 6, a parent of the minor or, if by reason of the emergency nature of the treatment provided as part of the clinical trial no such person can be contacted prior to the proposed inclusion of the subject in the trial, a guardian for the minor has had an interview with the investigator, or

another member of the investigating team, in which he or she has been given the opportunity to understand the objectives, risks and inconveniences of the clinical trial and the conditions under which it is to be conducted.

2. That parent or guardian has been provided with a contact point where he or she may obtain further information about the clinical trial.

3. That parent or guardian has been informed of the right to withdraw the minor from the clinical trial at any time.

4. That parent or guardian has given his informed consent to the minor taking part in the clinical trial.

5. That parent or guardian may, without the minor being subject to any resulting detriment, withdraw the minor from the clinical trial at any time by revoking his or her informed consent.

6. The minor has received information according to his or her capacity of understanding, from staff with experience with minors, regarding the clinical trial, its risks and its benefits.

7. The e xplicit wish of a minor who is capable of forming an opinion and assessing the information referred to in paragraph 6 to refuse participation in, or to be withdrawn from, the clinical trial at any time is considered by the investigator.

8. No incentives or financial inducements are given—

(a) to the minor; or
(b) to a parent of the minor or the guardian of the minor,

except provision for compensation in the event of injury or loss.

9. The clinical trial relates directly to a clinical condition from which the minor suffers or is of such a nature that it can only be carried out on minors.

10. Some direct benefit for the group of patients involved in the clinical trial is to be obtained from that clinical trial.

11. The clinical trial is necessary to validate data obtained—

(a) in other clinical trials involving persons able to give informed consent, or

(b) by other research methods.

Principles

13. Informed consent given by a parent or guardian to a minor taking part in a clinical trial shall represent the minor's presumed will.

14. The clinical trial has been designed to minimize pain, discomfort, fear and any other foreseeable risk in relation to the disease and the minor's stage of development.

15. The risk threshold and the degree of distress have to be specially defined and constantly monitored.

16. The interests of the patient always prevail over those of science and society.

PART 5
CONDITIONS AND PRINCIPLES WHICH APPLY IN RELATION TO AN INCAPACITATED ADULT

Conditions

1. The subject's guardian has had an interview with the investigator, or another member of the investigating team, in which he or she has been given the opportunity to understand the objectives, risks and inconveniences of the clinical trial and the conditions under which it is to be conducted.

2. The guardian has been provided with a contact point where he or she may obtain further information about the clinical trial.

3. The guardian has been informed of the right to withdraw the subject from the clinical trial at any time.

4. The guardian has given his informed consent to the subject taking part in the clinical trial.

5. The guardian may, without the subject being subject to any resulting detriment, withdraw the subject from the clinical trial at any time by revoking his or her informed consent.

6. The subject has received information according to his or her capacity of understanding regarding the clinical trial, its risks and its benefits.

7. The explicit wish of a subject who is capable of forming an opinion and assessing the information referred to in paragraph 6 to refuse participation in, or to be withdrawn from, the clinical trial at any time is considered by the investigator.

8. No incentives or financial inducements are given to the subject or their guardian, except provision for compensation in the event of injury or loss.

9. There are grounds for expecting that administering the medicinal product or medical device to be tested in the trial will produce a benefit to the subject outweighing the risks or produce no risk at all.

10. The clinical trial is essential to validate data obtained—

(a) in other clinical trials involving persons able to give informed consent, or

(b) by other research methods.

11. The clinical trial relates directly to a life-threatening or debilitating clinical condition from which the subject suffers.

Principles

12. Informed consent given by a guardian to an incapacitated adult in a clinical trial shall represent that adult's presumed will.

13. The clinical trial has been designed to minimize pain, discomfort, fear and any other foreseeable risk in relation to the disease and the cognitive abilities of the patient.

14. The risk threshold and the degree of distress have to be specially defined and constantly monitored.

15. The interests of the patient always prevail over those of science and society.

SCHEDULE 3

(Section 13(b)(i))

APPLICATION FOR AUTHORIZATION

1. The name and address of—

(a) the sponsor,

(b) if any person has been authorized by the sponsor to make the application on his or her behalf, that person,

(c) any other person to whom the sponsor has delegated any of his responsibilities in relation to the proposed clinical trial.

2. The address of each trial site and the names and address of the investigator responsible for the conduct of the trial at each site.

3. A copy of the opinion of the Ethics Committee opinion in relation to the clinical trial, if available.

4. A description of any investigational medicinal product or investigational medical device to be used in the clinical trial.

5. The name and address of the person responsible for the manufacture or importation of any finished investigational medicinal product or investigational medical device to be used in the clinical trial and the details of any authorization held by that person.

6. A description of the proposed clinical trial.

7. The protocol for the proposed clinical trial.

8.—(1) Information on each investigational medicinal product or investigational medical device to be used in the clinical trial in sub-paragraphs (2) to (8).

(2) A summary assessment of the potential risks and benefits of the use of the investigational medicinal product or investigational medical device in the proposed clinical trial.

(3) In the case of an investigational medicinal product or investigational medical device, other than an investigational medicinal product or investigational medical device referred to in sub-paragraphs (4) to (7), the application must contain—

(a) summaries of the chemical, pharmaceutical and biological data on the active substance and the finished product or device;

(b) summaries of the non-clinical pharmacology and toxicology data on that product or device, if available; and

(c) summaries of the available data from previous clinical trials of, and human experience with, that product or device.

(4) In the case of an investigational medicinal product or investigational medical device which has a marketing approval, the application must contain—

(a) a copy of the summary of product or device characteristics;

(b) if there has been a change —

(i) to the process of manufacture of the product or its active substance or device, or

(ii) of manufacturer of that product or substance or device, the summaries referred to in sub-paragraph (3)(a);

(c) if the product or device is to be used in the trial after it has been blinded, the summaries referred to in sub-paragraph (3)(a), in so far as they relate to the blinded product or device; and

(d) if the product or device is to be used other than in accordance with the terms of the summary of product or device characteristics under that authorization, the summaries referred to in subparagraphs (3)(b) and (c), in so far as that data relates to such use.

(5) In the case of an investigational medicinal product or investigational medical device which does not have a marketing approval, but where—

(a) another pharmaceutical form or strength of that product or device has a marketing approval; and

(b) the investigational medicinal product or investigational medical device is supplied by the holder of that approval, the application must contain the summaries referred to in sub-paragraph (3) (a), in so far as they relate to the finished product or device to be used in the clinical trial, and the summaries referred to in sub-paragraph (3)(b) and (c), in so far as they relate to the product or device to be used in the clinical trial.

(6) In the case of an investigational medicinal product or investigational medical device which does not have a marketing approval, but where —

(a) another medicinal product containing the same active substance or medical device has a marketing approval; and

(b) the investigational medicinal product or investigational medical device is supplied by the manufacturer of that other product,

the application must contain the summaries referred to in sub-paragraph (3) (a), in so far as the summaries relate to that other product, and the summaries referred to in sub-paragraph (3)(b) and (c), in so far as they relate to the product or device to be used in the clinical trial.

(7) Where the investigational medicinal product or investigational medical device is a placebo, the application must contain the summaries referred to in sub-paragraph (3)(a), in so far as they relate to that product or device.

(8) An application relating to an investigational medicinal product is not required if—

(a) the product has been used in a clinical trial that has been authorized, or is to be treated as having been authorized, by the National Competent Authority for the purposes of this Act; and

(b) the sponsor of that clinical trial authorizes the National Competent Authority to refer to the application submitted in relation to that clinical trial.

9. A description or sample of the labelling which is to appear on each investigational medicinal product or investigational medical device when supplied to a subject in the clinical trial.

Passed in the House of Assembly this 29th day of January, 2016.

PETER I. FOSTER,
Speaker of the House of Assembly.

Passed in the Senate this 9th day of February, 2016.

CLAUDIUS J. FRANCIS,
President of the Senate.

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