Clinical Trials (Medical Devices Trials) Regulations 2021

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THE CLINICAL TRIALS ACT

Regulations made by the Minister under section 35 of the Clinical Trials Act

1. These regulations may be cited as the **Clinical Trials (Medical Devices Trials) Regulations 2021**.

2. In these regulations —

"Act" means Clinical Trials Act.

3. No person shall conduct a clinical trial in respect of a medical device unless he is registered with the Council for this purpose.

4. (1) Any person who intends to conduct clinical trials in respect of a medical device shall make an application for a trial licence to the Council.

(2) An application under paragraph (1) shall be made in such form as the Council may determine.

(3) An application made under paragraph (2) shall be accompanied by such documents and information as the Council may determine.

(4) The Council may grant or refuse the application.

(5) (a) Where the Council grants the application, it shall issue a trial licence —

(i) on such terms and conditions as it may determine; and

(ii) on payment of the appropriate fee specified in the First Schedule.

(b) The licence shall be as set out in the Second Schedule.

(6) A trial licence issued under paragraph (5) shall be valid for—

(a) a period of 60 months from the date of issue; or

(b) such shorter period as the Council may determine.

(7) The Council may reject an application made under paragraph (2) where —

(a) the applicant does not comply with paragraph (3);

(b) the Council is not satisfied that it is in the public interest to grant the licence;

(c) the Council has reason to believe that —

(i) the health, welfare, safety or protection of a subject is likely to be compromised; or

(ii) any document or information submitted by the applicant is false or misleading.

5. (1) Any licence holder who intends to renew his licence shall, at least 60 days before the expiry of the licence, make an application, in writing, to the Council.

(2) Where the Council is satisfied that the licence holder still satisfies with the terms and conditions referred to in regulation 4, it may, on payment of the appropriate fee specified in the First Schedule, renew the licence for further periods of 24 months.

6. (1) Where a trial licence is lost, defaced or destroyed, the licence holder shall, as soon as possible, report such loss, damage or destruction to the Police and make an application to the Council for the issue of a duplicate licence.

(2) The Council shall, on receipt of an application under paragraph (1) and payment of the appropriate fee specified in the First Schedule, issue a duplicate licence to the person in charge of the licence holder and that licence shall be marked "DUPLICATE".

7. For the purpose of section 15 of the Act, the fee for an amended trial licence shall be as specified in the First Schedule.

8. (1) For the purpose of section 29 of the Act, every licence holder shall keep a register.

(2) The register shall contain the following information —

(a) the date and time the clinical trial is conducted;

(b) the clinical trial conducted and its purpose;

(c) the name of the person who conducts the clinical trial;

(d) the outcome of the clinical trial; and

(e) such other information as the Council may determine.

9. Every licence holder shall, at all times, comply with the rules set out in the Third Schedule.

10. (1) The class of the medical device shall be as set out in the Third Schedule.

(2) The fee in respect of each class of the medical device shall be as specified in the First Schedule.

11. Any person may —

(a) at all reasonable times and on good cause shown; and

(b) on payment of the fee specified in the First Schedule,

inspect the register of a licence holder.

12. Any person who contravenes these regulations shall commit an offence and shall, on conviction, be liable to a fine not exceeding 500,000 rupees and to penal servitude for a term not exceeding 8 years.

13. These regulations shall come into operation on 7 May 2021.

Made by the Minister on 6 May 2021.

FIRST SCHEDULE

[Regulations 4(5), 5, 6, 9, 10(2) and 11]

FEES

		(Rs)	Pilot study (Rs)	Pivotal study (Rs)	Post-approval (Rs)
1.	Issue of trial licence	10,000			
2.	Issue of amended trial licence	20,000			
3.	Issue of duplicate licence	10,000			
4.	Annual service fee	20,000			
5.	Class I medical device with low risk		10,000	20,000	10,000
6.	Class IIa medical device		20,000	40,000	20,000

	with moderate risk			
7.	Class IIb medical device with moderate risk	40,000	80,000	40,000
8.	Class III medical device with high risk	100,000	200,000	75,000

SECOND SCHEDULE

[Regulation 4(5)(b)]

TRIAL LICENCE

(Issued under Part V of the Clinical Trials Act)

This is to certify that ……... (name), a private limited company duly incorporated in Mauritius on ……. (date), holder of a certificate of incorporation bearing no. ……., issued by the Registrar of Companies, registered under Business Registration no. ……, and having satisfied the requirements of the Clinical Trials Act, is hereby issued a trial licence.

This trial licence certifies that the company is duly registered as a person licensed to carry out a 'clinical trial in relation to a medical device operating at ……. and is governed by the Clinical Trials Act.

This trial licence shall be valid for a period of ……..... months from the date of this certificate and is subject to the following conditions —

(a) ……..…..

(b) ……..……..

(c) ……..……..

Given under the hand of the Chairperson of the Clinical Research Regulatory Council

…… ……

Name Signature

THIRD SCHEDULE
[Regulations 9 and 10(1)]

RULES

1. Definitions specific to classification rules

(1) Duration of use

"long-term" means normally intended for continuous use for more than 30 days;

"short-term" means normally intended for continuous use for between 60 minutes and 30 days;

"transient" means normally intended for continuous use for less than 60 minutes.

(2) Invasive and active devices

"active device intended for diagnosis and monitoring" means any active device used, whether alone or in combination with other devices, to supply information for detecting, diagnosing, monitoring or treating physiological conditions, states of health, illnesses or congenital deformities;

"active therapeutic device" means any active device used, whether alone or in combination with other devices, to support, modify, replace or restore biological functions or structures with a view to treatment or alleviation of an illness, injury or disability;

"body orifice" means any natural opening in the body, as well as the external surface of the eyeball, or any permanent artificial, such as a stoma;

"central circulatory system" means the following blood vessels: arteriae pulmonales, aorta ascendens, arcus aortae, aortae descendens to the bifurcation aortae, arteriae coronariae, arteria carotis communis, arteria carotis externa, arteria carotis interna, arteriae cerebrales, truncus brachiocephalicus, venae cordis, venae pulmonales, vena cava superior and vena cava inferior;

"central nervous system" means the brain, meninges, and spinal cord;

"injured skin or mucous membrane" means an area of skin or a mucous membrane presenting a pathological change or change following disease or a wound;

"reusable surgical instrument" means an instrument intended for surgical use in cutting, drilling, sawing, scratching, scraping, clamping, retracting, clipping or similar procedures, without a connection to an active device and which is intended by the manufacturer to be reused after appropriate procedures such as cleaning, disinfection and sterilisation have been carried out;

"surgically invasive device" means —

(a) an invasive device which penetrates inside the body through the surface of the body, including through

mucous membranes of body orifices with the aid or in the context of a surgical operation; and

(b) a device which produces penetration other than through a body orifice.

2. Implementing rules

(1) The application of the classification rules shall be governed by the intended purpose of the devices.

(2) If the device in question is intended to be used in combination with another device, the classification rules shall apply separately to each of the devices.

(3) (a) The software, which drives a device or influences the use of a device, shall fall within the same class as the device.

(b) If the software is independent of any other device, it shall be classified in its own right.

(4) If the device is not intended to be used solely or principally in a specific part of the body, it shall be considered and classified on the basis of the most critical specified use.

(5) If several rule, or if, within the same rule, several subrules, apply to the same device based on the device's intended purpose, the strictest rule and subrule resulting in the higher classification shall apply.

(6) A device is considered to allow direct diagnosis when it provides the diagnosis of the disease or condition in question by itself or when it provides decisive information for diagnosis.

3. Classification rules

(1) Non-invasive devices

(1) All non-invasive devices are classified as class I, unless one of the rules set out hereinafter applies.

(2) All non-invasive devices intended for channeling or storing blood, body liquids, cells or tissues, liquids or gases for the purpose of eventual infusion, administration or introduction into the body are classified as class IIa —

(a) if they may be connected to a class IIa, class IIb or class III active device; or

(b) if they are intended for use for channeling or storing blood or other body liquids, body cells and tissues, except for blood bags; blood bags are classified as class IIb;

(c) In all other cases, such devices are classified as class I.

(3) (a) All non-invasive devices intended for modifying the biological or chemical composition of human tissues or cells, blood, other body liquids or other liquids intended for implementation or administration into the body are classified as class IIb, unless the treatment for which the device is used consists of filtration, centrifugation or exchanges or gas, heat, in which case they are classified as class IIa.

(b) All non-invasive devices consisting of a substance or a mixture of substances intended to be used in vitro in direct contact with human cells, tissues or organs taken from the human body or used in vitro with human embryos before their implantation or administration into the body are classified as class III.

(4) (a) All non-invasive devices which come into contact with injured skin or mucous membrane are classified as —

(i) Class I if they are intended to be used as a mechanical barrier, for compression or for absorption of exudates;

(ii) Class IIb if they are intended to be used principally for injuries to skin which have breached the dermis or mucous membrane and can only heal by secondary intent;

(iii) Class IIa if they are principally intended to manage the micro-environment of injured skin or mucous membrane; and

(iv) Class IIa in all other cases.

(b) This rule also applies to the invasive devices that come into contact with injured mucous membrane.

(2) Invasive devices

(1) (a) All invasive devices with respect to body orifices, other than surgically invasive devices, which are not intended for connection to an active device or which are intended for connection to a class I active device are classified as —

(i) Class I if they are intended for transient use;

(ii) Class IIa if they are intended for short term use, except if they are used in the oral cavity as far as the pharynx, in an ear canal up to the ear drum or in the nasal cavity, in which case they are classified as Class I; and

(iii) Class IIb if they are intended for long-term use, except if they are used in the oral cavity as far as the pharynx, in an ear canal up to the ear drum or in the nasal cavity

and are not liable to be absorbed by the mucous membrane, in which case they are classified as class IIa.

(b) All invasive devices with respect to body orifices, other than surgically invasive devices, intended for connection to a class IIa, class IIb or class III active device, are classified as class IIa.

(2) All surgically invasive devices intended for transient use are classified as class IIa unless they —

(a) are intended specifically to control, diagnose, monitor or correct a defect of the heart or of the central circulatory system through direct contact with those parts of the body, in which case they are classified as class III;

(b) are reusable surgical instruments, in which case they are classified as class I;

(c) are intended specifically for use in direct contact with the heart or central circulatory system or the central nervous system, in which case they are classified as class III;

(d) have a biological effect or are wholly or mainly absorbed in which case they are classified as class IIb; or

(e) are intended to administer medicinal products by means of a delivery system, if such administration of a medicinal product is done in a manner that is potentially hazardous taking into account the mode of application, in which case they are classified as class IIb.

(3) All surgically invasive devices intended for short-term use are classified as class IIa unless they —

(a) are intended specifically to control, diagnose, monitor or correct a defect of the heart of the central circulatory system through direct contact with those parts of the body, in which case they are classified as class III;

(b) are intended specifically for use in direct contact with the heart or central circulatory system or the central nervous system, in which case they are classified as class III;

(c) have a biological effect or are wholly or mainly absorbed in which case they are classified as class III;

(d) are intended to undergo chemical change in the body in which case they are classified as class lib, except if the devices are placed in the teeth; or

(e) are intended to administer medicines, in which case they are classified as class IIb.

(4) All implantable devices and long-term surgically invasive devices are classified as class IIb unless they —

(a) are intended to be placed in the teeth, in which case they are classified as class IIa;

(b) are intended to be used in direct contact with the heart, the central circulatory system or the central nervous system, in which case they are classified as class III;

(c) have a biological effect or are wholly or mainly absorbed, in which case they are classified as class III;

(d) are intended to undergo chemical change in the body in which case they are classified as class III, except if the devices are placed in the teeth;

(e) are intended to administer medicinal products, in which case they are classified as class III;

(f) are active implantable devices or their accessories, in which case they are classified as class III;

(g) are breast implants or surgical meshes, in which cases they are classified as class III;

(h) are total or partial joint replacements, in which case they are classified as class III, with the exception of ancillary components such as screws, wedges, plates and instruments; or

(i) are spinal disc replacement implants or are implantable devices that come into contact with the spinal column, in which case they are classified as class III with the exception of components such as screws, wedges, plates and instruments.

(3) Active devices

(1) (a) All active therapeutic devices intended to administer or exchange energy are classified as class IIa unless their characteristics are such that they may administer energy to or exchange energy with the human body in a potentially hazardous way, taking account of the nature, the density and site of application of the energy, in which case they are classified as class IIb.

(b) All active devices intended to control or monitor the performance of active therapeutic class IIb devices, or intended directly to influence the performance of such devices are classified as class IIb.

(c) All active devices that are intended for controlling, monitoring, or directly influencing the performance of active implantable devices are classified as class III.

(2) Active devices intended for diagnosis and monitoring are classified as class IIa —

(a) if they are intended to supply energy which will be absorbed by the human body, except for devices intended to illuminate the patient's body, in the visible spectrum, in which case they are classified as class I;

(b) if they are intended to allow direct diagnosis or monitoring of vital physiological processes, unless they are specifically intended for monitoring of vital physiological parameters and the nature of variations of those parameters is such that it could result in immediate danger to the patient, for instance variations in cardiac performance, respiration, activity of the central nervous system, or they are intended for diagnosis in clinical situations where the patient is in immediate danger, in which cases they are classified as class IIb.

(3) (a) All active devices intended to administer and/ or remove medicinal products, body liquids or other substances to or from the body are classified as class IIa, unless this is done in a manner that is potentially hazardous, taking account of the nature of the substances involved, of the part of the body concerned and of the mode of application in which case they are classified as class IIb.

(b) All other active devices are classified as class I.

4. Special rules

(1) All devices used for contraception or prevention of the transmission of sexually transmitted diseases are classified as class IIb, unless they are implantable or long-term invasive devices, in which case they are classified as class III.

(2) (a) All devices intended specifically to be used for disinfecting, cleaning, rinsing or, where appropriate, hydrating contact lenses are classified as class IIb.

(b) All devices intended specifically to be used for disinfecting or sterilizing medical devices are classified as class IIa, unless they are disinfecting solutions or washer-disinfectors intended specifically to be used for disinfecting invasive devices, as the end point of processing, in which case they are classified as class IIb.

(c) This rule does not apply to devices that are intended to clean devices other than contact lenses by means of physical action only.

(3) Devices specifically intended for recording of diagnostic images generated by X-ray radiation are classified as class IIa.

(4) All devices incorporating or consisting of nanomaterial are classified as —

(a) class III if they, or their products of metabolism, are systemically absorbed by the human body in order to achieve the intended purpose;

(b) class III if they achieve their intended purpose in the stomach or lower gastrointestinal tract and they, or their products of metabolism, are systemically absorbed by the human body;

(c) class IIa if they are applied to the skin or if they are applied in the nasal or oral cavity as far as the pharynx, and achieve their intended purpose on those cavities; and

(d) class IIb in all other cases.

(5) Active therapeutic devices with an integrated or incorporated diagnostic function which significantly determines the patient management by the device, such as closed loop systems or automated external defibrillators, are classified as class III.