Republic of Mauritius

ECONOMIC DEVELOPMENT BOARD MAURITIUS

CLINICAL RESEARCH

GUIDELINES FOR THE APPLICATION PROCEDURE IN MAURITIUS

AUGUST 2022

TABLE OF CONTENTS

Page No

1 Introduction

The promulgation of the Clinical Trial Act 2011 has paved the way for the development of the life sciences sector. The Act provides the legal framework for the conduct of clinical trials. These clinical research work can provide solutions to a broad range of genetic, infectious and lifestyle diseases like diabetes, cardiovascular diseases, cancer, hypertension amongst others prevailing in Mauritius and countries of the region.

1.1 Definition

"Clinical trial" means an investigation in a subject intended to:

(a) discover or verify the clinical or pharmacological effect of an investigational medicinal product;
(b) identify any adverse reaction to such a product; or
(c) study the absorption, distribution, metabolism and excretion of such a product, for the purpose of ascertaining the safety or efficacy of the product, after its administration to the subject;

The Mauritian government has identified life sciences and clinical trial as a promising sector for Mauritius and appropriate legislation has been introduced with a view to encourage the development of this sector.

The Clinical Trials Act provides for the setting up of the Clinical Research Regulatory Council, Ethics Committee and the Pharmacovigilance Committee.

The CRRC is mandated by law, *inter alia,* to:

- Consider and grant or refuse applications for a trial licence;
- Issue, amend, extend, review, suspend or cancel trial licences;
- Examine and approve the qualifications of every investigator;
- Exercise control over licensees and on sites by inspection and examination of any reports received
- Consult regularly with, and consider reports and recommendations from, the Ethics Committee, the Pharmacovigilance Committee and the Trade and Therapeutics Committee.

The CRRC is additionally responsible for the registration of CROs and the regulation and control of trial licenses which are issued.

As at date, there are 5 Contract Research Organisations (CROs) based in Mauritius. These CROs are carrying various clinical trials on a number of diseases such as diabetes, HIV, hepatitis, amongst others and are leading to knowledge transfer and job creation. Also fuelling the trend is a multi-ethnic, drug naive population and ageing population which presents enormous opportunities to position Mauritius as a hub for clinical trial for the region.

2 Good Clinical Practice

Clinical trials shall be conducted in accordance with the conditions and principles of good clinical practice. In this respect, the below mentioned rule must be followed:

- The rights, safety and well-being of a subject shall prevail over the interests of science and society.
- Every sponsor shall ensure that any person involved in conducting a clinical trial is qualified by education, training and experience to perform his tasks.
- Every sponsor and investigator shall comply with guidelines prepared or approved by the Council.

The Clinical Research Regulatory Council and Ethics Committee are abiding to the ICH European Guidelines to permit the conduct of Clinical Research in Mauritius:

- ICH E6: Good Clinical Practice: Consolidated guidelines (https://www.ema.europa.eu/en/ich-e6-r2-good-clinical-practice)

- ICH Harmonised Tripartite Guidelines E8: General Considerations for Clinical Trials (https://www.ema.europa.eu/en/ich-e8-general-considerations-clinical-studies)

- ICH Harmonised Tripartite Guidelines E10: Choice of Control Group and related issues in Clinical Trials (https://www.ema.europa.eu/en/ich-e10-choice-control-group-clinical-trials)

3 Incentives

The table below lists the incentives applicable to companies engaged in clinical research and testing activities:

Activity	Incentives
Life Sciences	• 8-year income tax holiday on income derived from healthcare, biotechnology and life sciences from year of incorporation • VAT exemption on construction of medical Research & Development centers • VAT exemption on plants and equipment • Accelerated depreciation of 50% in respect of capital expenditure incurred on Research & Development, that is the investment cost is fully amortised in 2 years • Exemption of registration duty on acquisition of immovable property • Double deduction in respect of qualifying expenditure on R&D directly related to the entity's trade or business and provided the R&D is carried out in Mauritius.

Table 1: Incentives for Life Sciences sector

4 Registration of a Contract Research Organisation

The *Clinical Trials (Registration of Contract Research Organisations) Regulations 2021 made under section 35 of the Clinical Trial Act* took effect from 29 March 2021. It establishes the registration process for Contract Research Organisation (CROs) before undertaking any clinical trials in Mauritius. Under these regulations, application by a CRO must be made with the Council at least 2 months prior to the commencement of its activities.

The Regulations provide for a list of a user-friendly documents that must be submitted to the Council with an application form, including both for the organisation as a whole and individually for staff. Once the Council approves the registration, a Certificate is issued to the CRO.

4.1 Documents Required

4.1.1 Applicant

1. Certified copy of the Certificate of Incorporation
2. Certificate of Current Standing
3. Corporate Profile, Latest Annual Return and Audited Financial Statements
4. Organigram
5. Floor Plan of Research Offices (demonstrate adequate equipment and infrastructure)

6. Fire Certificate
7. Evidence of compliance to Good Clinical Practice and other relevant trainings
8. Certificates of Insurance (public liability, professional indemnity, cyber protection)
9. ISO Certification
10. Procedures for dealing with non-compliances
11. Adequate Standard Operating Procedures and associated documents (templates and forms)
12. Relevant policies as per the law
13. Quality Management Plan
14. Business Continuity Plan
15. Adequate IT systems
16. Good Data Handling policies (including compliance with Data Protection Act 2017)
17. Confidentiality Procedures in place
18. Provision for Pharmacovigilance (system in place for safe reporting)

4.1.2 Others

Person in Charge

1. Curriculum Vitae
2. Certificates
3. Evidence that the Person in Charge complies with the requirements of paragraph 2 (1) of the Guidelines for Contract Research Organization
4. Minimum of 5 years' experience in clinical research field

Investigator

1. Curriculum Vitae
2. Certificates
3. Evidence of Registration with the Medical Council of Mauritius
4. Evidence of Fitness to practice
5. Minimum of 5 years' experience in clinical research field

Medical Practitioner

1. Curriculum Vitae
2. Certificates
3. Evidence of Registration with the Medical Council of Mauritius
4. Certificate of good standing from the Medical Council of Mauritius

4.2 Application Fees

Registration of CRO	MUR 50,000
Application for extension of certificate of CRO	MUR 25,000
Inspection Fee	MUR 5,000

5 Clinical Trial Licence

The application of a Clinical Trial Licence is governed by section 12 of the Clinical Trials Act.

The application for the Trial Licence must be made with the Council and accompanied by the prescribed fee and relevant documents.

5.1 Application Process for a Clinical Trial Licence

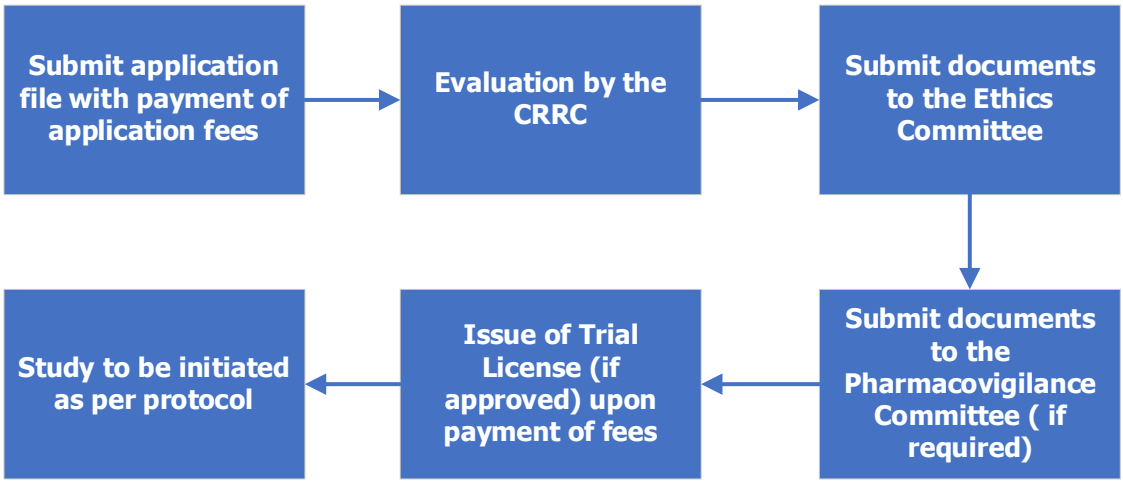


Figure 1: Main steps for the issue of a Clinical Trial Licence

As per section 12 of the Clinical Trials Act 2011, an application for a Trial Licence should be accompanied by the application fee and the following documents:

- Protocol;
- An investigator's brochure;
- Brief CV and proof of registration with the medical council for each investigator;
- Proof of registration with other regulatory bodies, if applicable;

- A GMP certificate and a Certificate of Pharmaceutical Product (COPP) in relation to every investigational product or device from the country of origin;
- Bilingual forms to be used for the purpose of patient/subject information, informed consent, recruitment of subjects, adverse event reports and adverse reaction reports; and
- Proof of local insurance coverage.

5.2 Sponsor

The sponsor shall also provide:

- information as to the quantity of every investigational medicinal product to be used in the clinical trial;
- Information relating to the measures to be taken for the health, welfare, safety and protection of subjects;
- Information relating to the financial aspects of the clinical trial, in particular:
  - (i) Sources of funding for the clinical trial and information on the financial or other interests of the sponsor relevant to the clinical trial;
  - (ii) The arrangements for the reimbursement of expenses incurred by the subjects;
  - (iii) Any provision for compensation in the event of injury or death resulting from the clinical trial, including details of any insurance cover to be contracted for the protection of subjects;
  - (iv) Details of any insurance or indemnity to cover the liability of the sponsor and investigator; and
  - (v) Summary details of any financial arrangements between:

(A) the sponsor and the investigator; and

(B) the sponsor and the owner or occupier of the site;

- Information relating to the anticipated benefits and risks of the clinical trial;
- Information relating to the location, structure and amenities of any site where the clinical trial is to be conducted; and
- Such other information as the Council may require.

If all relevant documents/information are provided and any conditions imposed are complied with, a trial licence is deliverable within 60 days where the Council grants the licence.

5.3 Application Fees (Medicinal Products)

Application Fee	• MUR 10,000
Fee payable for the issue of an amended licence	• MUR 20,000
Clinical trial (Phase I) licence	• MUR 100,000
Clinical trial (Phase II with a known product) licence	• MUR 150,000
Clinical trial (Phase II with an unknown product) license	• MUR 200,000
Clinical trial (Phase III with a known product) license	• MUR 150,000
Clinical trial (Phase III with an unknown product) licence	• MUR 200,000
Clinical trial (Phase IV) license	• MUR 20,000
Annual Service Fee	• MUR 20,000

Clinical Trials (Licence and Fees) Regulations 2011

6 Progress and Completion of Clinical Trial Report

Every sponsor shall furnish to the Council a written report on the progress of a clinical trial, containing such particulars as the Council deems necessary, not later than 6 months after:

- the date on which the trial license is issued;
- the end of every subsequent period of 6 months; and
- the completion of the clinical trial.

7 Completion and Discontinuance of Clinical Trial

A sponsor shall, not later than 90 days after a clinical trial is completed, notify the Council of the completion.

Where a clinical trial is discontinued, its sponsor shall forthwith notify the Council in writing of the discontinuance and the reasons thereof.

8 Classification of Medical Devices

The Clinical Trials (Medical Devices Trials) Regulations was introduced in 2021 under section 35 of the Clinical Trial Act and caters for the provision of medical devices trials.

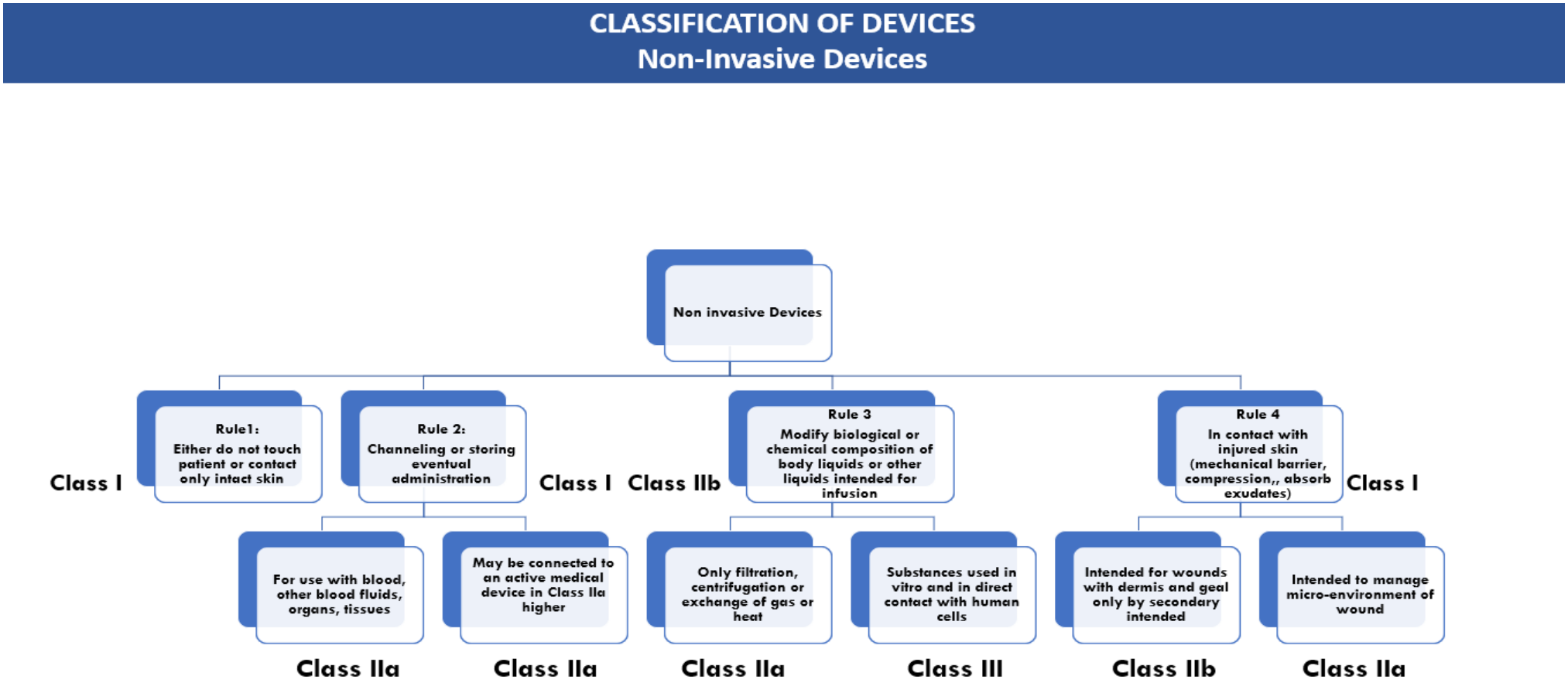
Under these regulations, trials must be authorized together with the process of licensing a trial and payment of relevant fee. The regulations also mention specific rules on device classification.

In line with the Clinical Trials (Medical Devices Trials) Regulations 2021, the following apply:

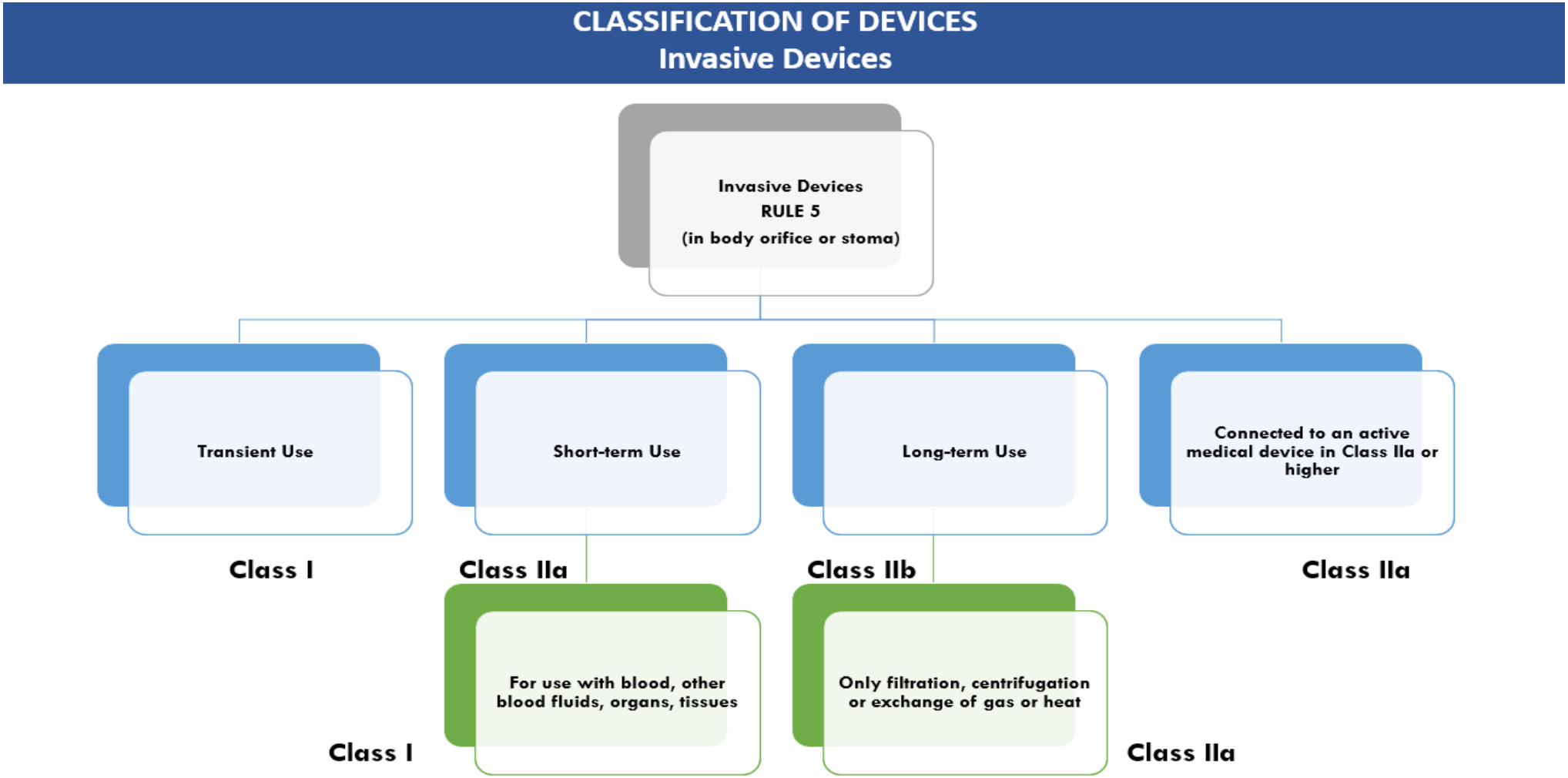
- No person shall conduct a clinical trial in respect of a medical device unless he is registered with the Council for this purpose;
- Any person who intends to conduct clinical trials in respect of a medical device shall make an application for a trial licence to the Council;
- Application form and documents to be submitted as per requirements of the Council;
- Full details of Rules and Classification are available in the Regulations.

8.1 Non-Invasive

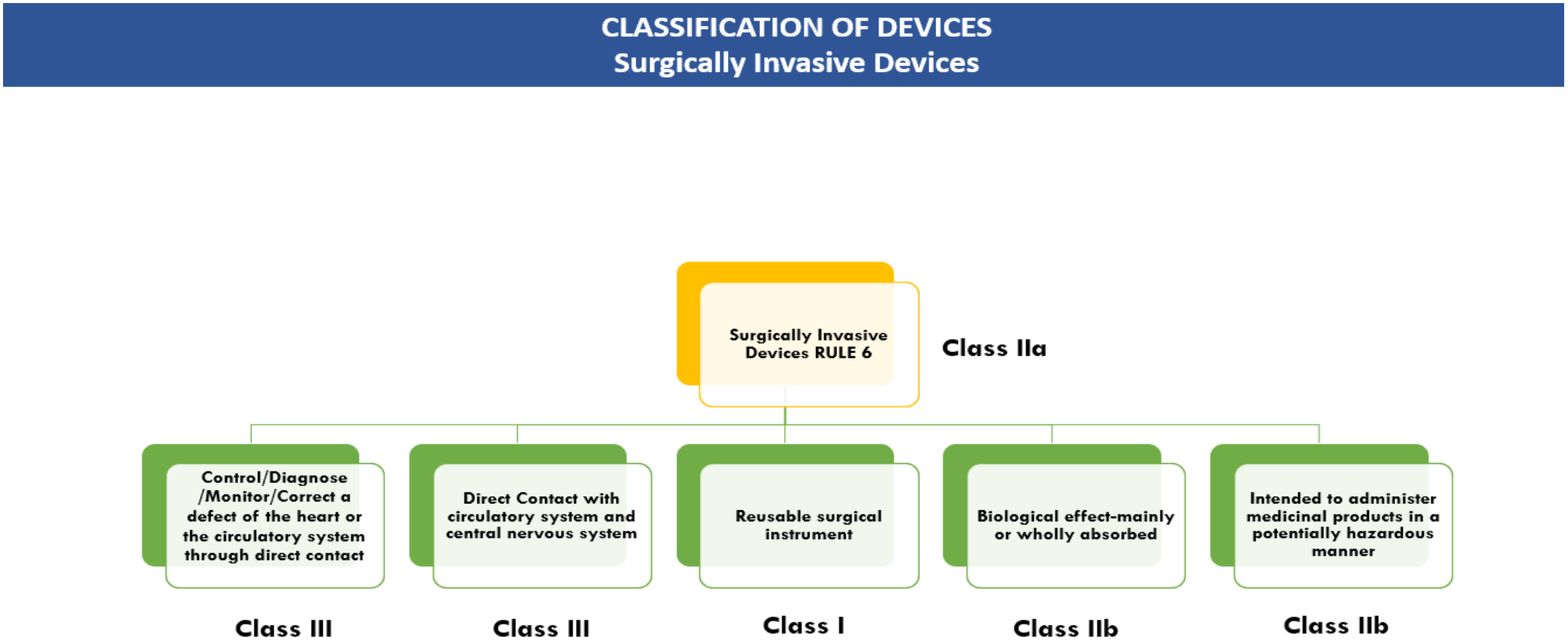
Reference is made to the Clinical Trials (Medical Devices Trials) Regulations (https://www.edbmauritius.org/sites/default/files/2022-08/medical%20devices%20trials%20regulations.pdf)



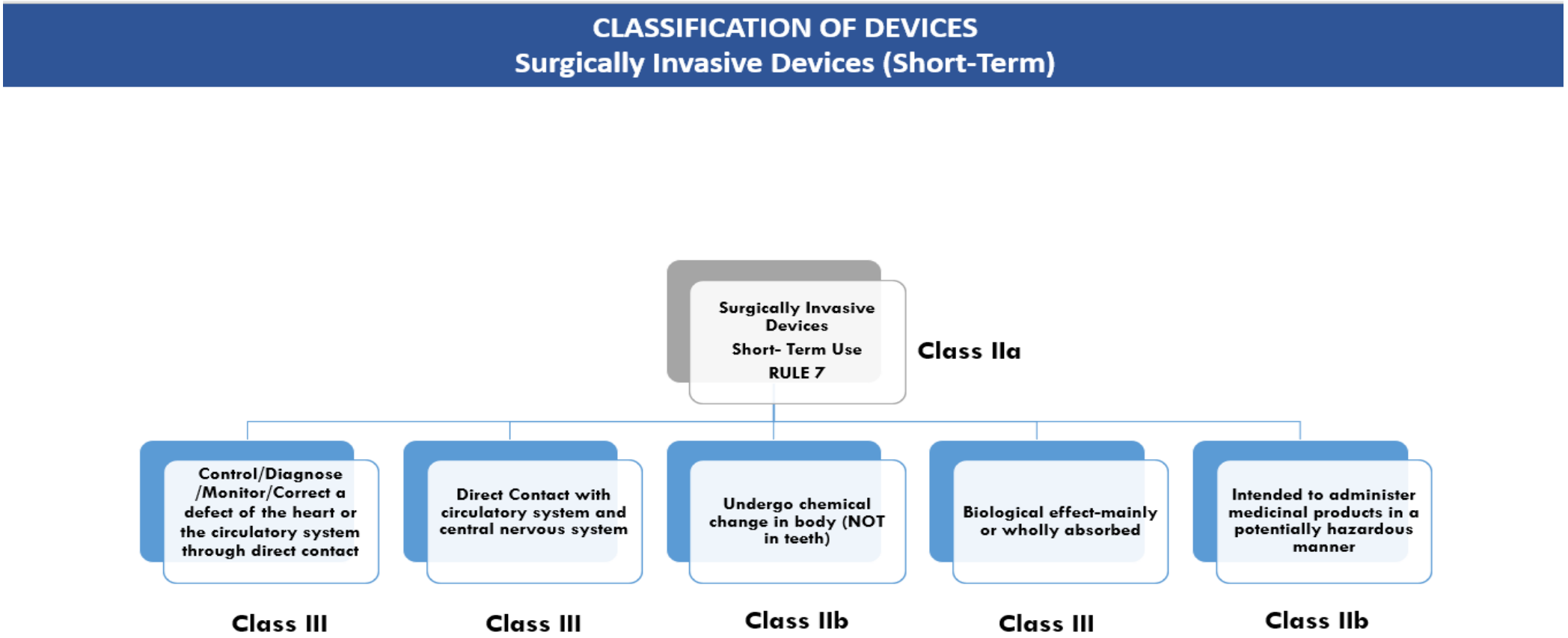
8.2 invasive Devices



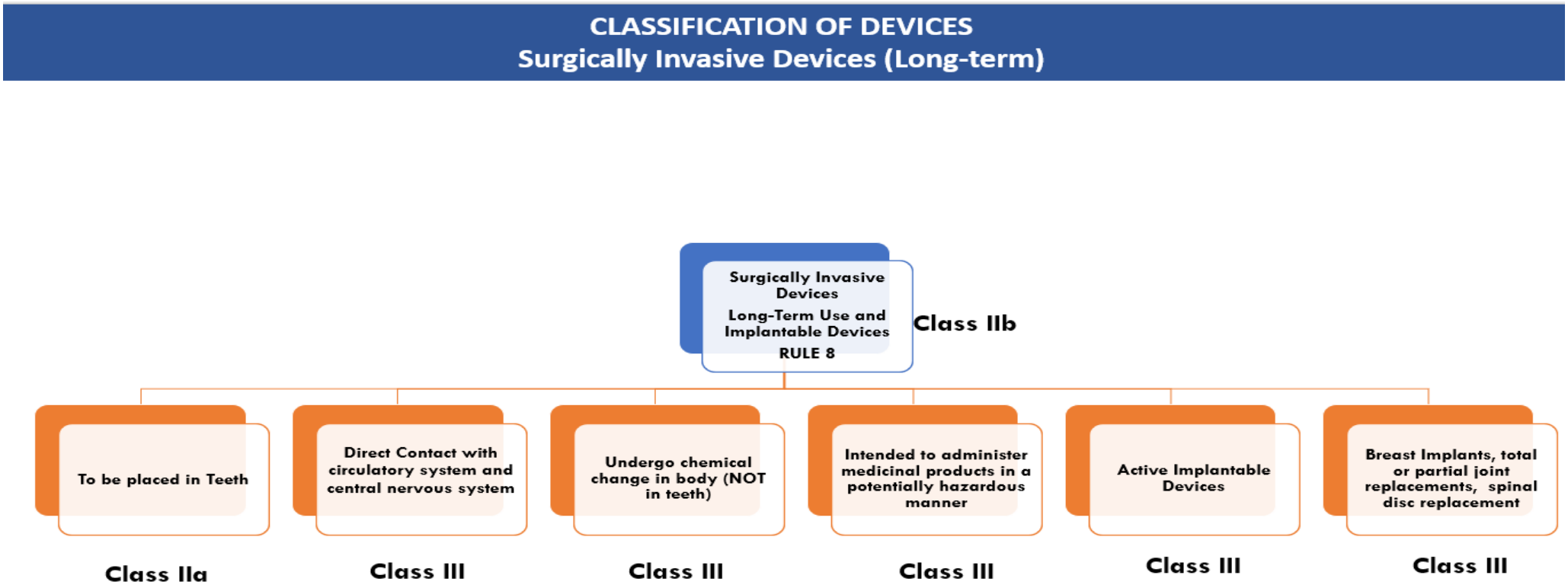
8.3 Surgically Invasive Devices



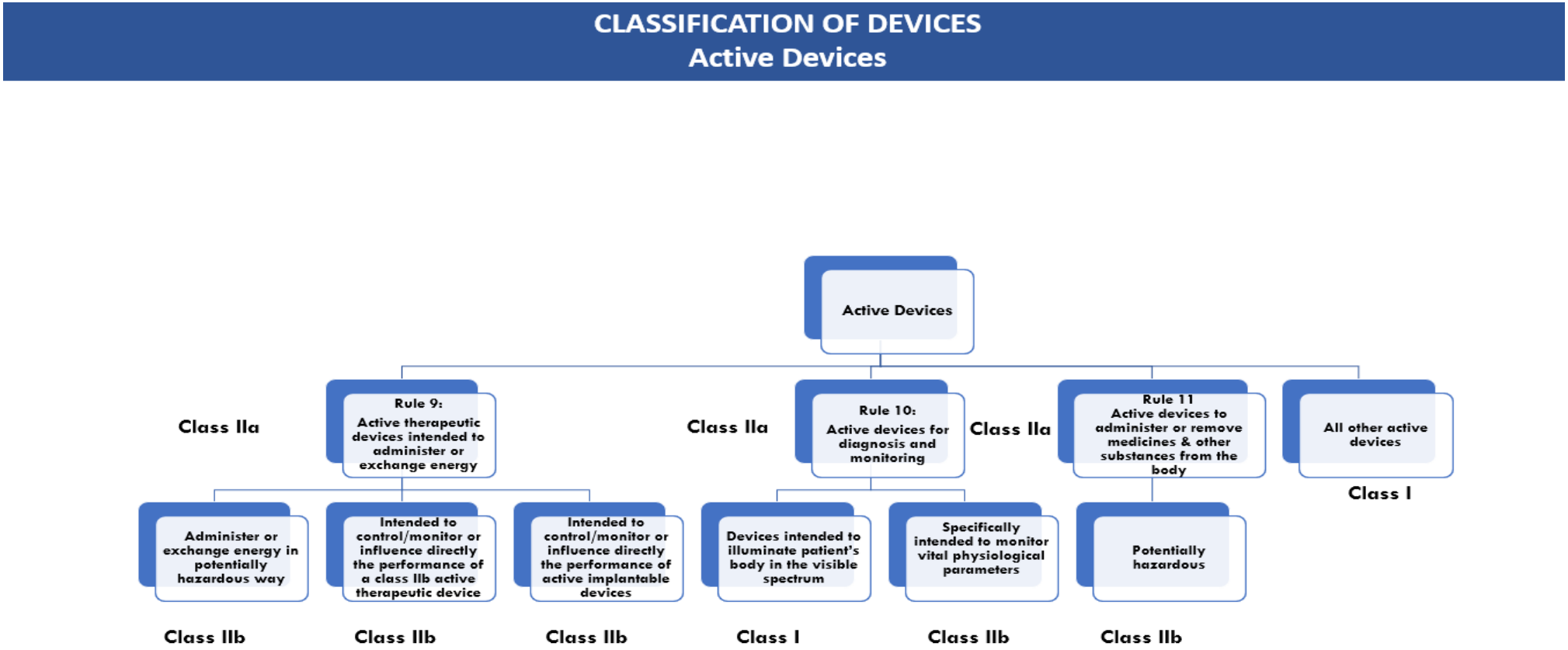
8.4 Surgically invasive Devices (Short-Term)



8.5 Surgically Invasive Devices (Long-Term)



8.6 Active Devices



8.7 Application Fees

	Rs	PILOT STUDY	PIVOTAL STUDY	POST APPROVAL STUDY
Issue of trial license	**10,000**			
Issue of amended trial license	**20,000**			
Issue of duplicate license	**10,000**			
Annual service fee	**20,000**			
Class I medical device with low risk		**10,000**	**20,000**	**10,000**
Class IIa medical device		**20,000**	**40,000**	**20,000**
Class IIb medical device with moderate risk		**40,000**	**80,000**	**40,000**
Class III medical device with high risk		**100,000**	**200,000**	**75,000**

9 Clearance of Samples and other materials for research purposes

Procedures prior to receipt of samples

The following steps are required for clearance of samples:

1. Submission of an official request to the Director Pharmaceutical Services (DPhS), Ministry of Health and Wellness, for import authorization of products for clinical research purposes.

2. Request for import authorization

   Submission of the following documents (first time applicant):

   - Approval from Clinical Research Regulatory Authority & Ethics Committee
   - Trial Licence
   - Brief of Applicant

3. Submission of request for clearance in 3 copies (one to be kept by the Pharmacy Department and remaining two to be returned to the applicant after approval by the Pharmacy section).

4. Issuance of approval by the DPhS and same to be issued by the Deputy Director Pharmaceutical Services (DDPhS) in his absence.

5. List of pharmacists posted at point of entries will be submitted to applicant upon request. However, this list may change at any time.

6. Issuance of authorisation for import by the Pharmacy Department (either on the same day or within one day after request).

10 Contacts

10.1 Institutions / Regulatory Bodies

Economic Development Board
BIO Industry & Project Development
Tel: +230 203 3800
Email: bpd@edbmauritius.org

Clinical Research Regulatory Council
Tel: + 230 214 3972
Email : crrc@govmu.org

Pharmacy Board
Directorate of the Pharmacy Board
Tel: +230 201 1334
Email: moh-pharm@govmu.org

Customs Department
Tel: +230 202 0500
Email: customs@mra.mu

10.2 Contract Research Organizations

Name of Company	Telephone No.	Email	Contact Person
Cap Research Ltd	+2304602144	regine.rouzier@cap-research.com	Dr Regine Rouzier Chief Executive Officer
Centre D'Etudes Cliniques Ltee	+2302141405	sadiyah.joomun@centredetudescliniques.com	Mrs Sadiyah Joomun Operations Manager
Centre International De Developpement Pharmaceutique Ltee	+230 4012600	c.blazy@cidp-cro.com	Mrs Claire Blazy-Jauzac Chief Executive Officer
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