Government Notice No. 63 of 2021

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 (Registration of Contract Research Organisations) Regulations 2021.

2. In these regulations –

"Act" means the Clinical Trials Act;

"CRO" means Contract Research Organisation.

3. (1) No CRO shall conduct, or assist in, a clinical trial in Mauritius unless it is registered with the Council.

(2) A CRO seeking registration with the Council shall make an application to the Council, in the form set out in the First Schedule to these regulations, at least 2 months before the CRO is to begin to operate.

(3) An application made under paragraph (2) shall –

(a) be accompanied by such documents and information as the Council may determine; and

(b) include the documents set out in the First Schedule.

(4) The CRO shall not be registered unless –

(a) paragraph (3) has been complied with;

(b) it complies with such conditions as may be imposed by the Council or any other relevant authority.

(5) (a) Where the Council grants an application, it shall, on such terms and conditions as it may determine and on payment of the

appropriate fee specified in Part I of the Second Schedule, register the CRO.

(b) Where the Council registers a CRO under paragraph (a), it shall issue a registration certificate in the form set out in the Third Schedule.

(c) A registration certificate issued under subparagraph (b) shall be valid for –

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

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

(6) The Council may reject an application made under paragraph (2) where –

(a) the applicant does not –

(i) comply with paragraphs (3) and (4);

(ii) pay the appropriate fee specified in Part I of the Second Schedule;

(b) the Council –

(i) is not satisfied that it is in the public interest to register the CRO;

(ii) is not satisfied that the applicant complies, or has the capacity to comply, as may be applicable, with the Guidelines for Contract Research Organisation set out in the Fourth Schedule;

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

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

4. (1) An application for the extension of a registration certificate of a CRO shall be –

(a) made to the Council, at least one month before the date of expiry of the registration certificate, in the form set out in the First Schedule; and

(b) accompanied by –

(i) the documents referred to in regulation 3(3);

(ii) the appropriate fee specified in Part II of the Second Schedule.

(2) The Council may extend the registration of a CRO for such further periods of 24 months and on such other terms and conditions as it may determine.

(3) Where the Council extends the registration certificate, it shall issue a certificate in the form set out in the Third Schedule.

5. (1) Every CRO shall keep such information or document as the Council may determine.

(2) The Council may issue such direction as it may determine to the person in charge for the effective running of the CRO which he administers and the person in charge shall comply with such direction.

6. Every registered CRO shall at all times comply with the Guidelines set out in the Fourth Schedule.

7. Any person may, at all reasonable times and on good cause shown, inspect the register of contract research organisations on payment of the fee set out in Part III of the Second Schedule.

8. These regulations shall come into operation on 29 March 2021.

Made by the Minister on 29 March 2021.

FIRST SCHEDULE
(Regulations 3(2) and 4(1))

APPLICATION FOR REGISTRATION OF CONTRACT RESEARCH ORGANISATIONS

NAME OF APPLICANT

CONTACT DETAILS OF APPLICANT

ADDRESS .....
.....
.....
PHONENUMBER:.....
FAX NO:.....
EMAIL:.....
WEBSITE:.....

FOR OFFICIAL USE Applicants Should Not Write Below This Line	
Date of Application:	2 0
Date of Receipt:	2 0
Reference Number	

Note –

(a) The information/documents required vide this Application Form must not be considered exhaustive. The Council may request for such other information as it deems necessary with respect to the Application.

(b) The Council reserves the right to amend the Application Form to reflect any change in relevant laws, regulations, rules and policy guidelines.

(c) Additional sheet(s) may be used, if necessary, to submit the required information.

LEGAL STATUS OF THE APPLICANT

1. REGISTERED OFFICE

	ADDRESS: .... PHONE /FAX /EMAIL:.....

2. PLACE OF BUSINESS IN MAURITIUS

	ADDRESS: .... PHONE /FAX /EMAIL:.....

3. DIRECTORS

	Full Name *(surname in block letters)*	**Citizen of Mtius (Y/N)**	**Contact Details** *(Phone/Fax/Email)*

4. SECRETARY (as applicable)

	Full Name	**Address**	**Contact Details** *(Phone/Fax/Email)*

5. AUDITOR

	Full Name	**Address**	**Contact Details** *(Phone/Fax/Email)*

6. OFFICERS (Person in Charge, Investigators, Medical Practitioners, Nurses, Pharmacists) [as applicable]

	Full Name & Position *(surname in block letters)*	**Citizen of Mtius (Y/N)**	**Contact Details** *(Phone/Fax/Email)*

7. SHAREHOLDERS (as applicable)

	Full Name *(surname in block letters)*	**Address**	**Citizen of Mtius (Y/N)**	**Percentage Share****

*** To also specify Types and Classes of Shares*

8. ULTIMATE BENEFICIAL OWNERS* *(if different from details provided under Section 7)*

	Full Name ***(surname in block letters)***	**Address**	**Citizen of Mtius (Y/N**

** Means the ultimate owners/beneficiaries of the Applicant*

9. DOCUMENTS TO BE SUBMITTED FOR THE APPLICANT

	Tick as appropriate	√
	Certified copy of the Certificate of Incorporation	
	Certificate of Current Standing	
	Corporate Profile, Latest Annual Return and Audited Financial Statements	
	Organogram	
	Floor Plan of Research Offices (demonstrate adequate equipment and infrastructure)	
	Fire Certificate	
	Evidence of compliance to Good Clinical Practice and other relevant trainings	
	Certificates of Insurance (public liability, professional indemnity, cyber protection)	
	ISO Certification	
	Procedures for dealing with non-compliances	
	Adequate Standard Operating Procedures and associated documents (templates and forms)	
	Relevant policies as per the law	

	Quality Management Plan	
	Business Continuity Plan	
	Adequate IT systems	
	Good Data Handling policies (including compliance with Data Protection Act 2017)	
	Confidentiality Procedures in place	
	Provision for Pharmacovigilance (system in place for safe reporting)	

10. DOCUMENTS TO BE SUBMITTED FOR EACH OFFICER

	Tick as appropriate	√
	Person in Charge	
	Curriculum Vitae	
	Certificates	
	Evidence that the Person in Charge complies with the requirements of paragraph 2 (1) of the Guidelines for Contract Research Organisation	
	Minimum of 5 years experience in clinical research field	
	Investigator	
	Curriculum Vitae	
	Certificates	
	Evidence of Registration with the Medical Council of Mauritius	
	Evidence of Fitness to practice	
	Minimum of 5 years experience in clinical research field	
	Medical Practitioner	
	Curriculum Vitae	

	Certificates	
	Evidence of Registration with the Medical Council of Mauritius	
	Certificate of good standing from the Medical Council of Mauritius	
	Minimum of 5 years experience in clinical research field	
	Pharmacists	
	Curriculum Vitae	
	Certificates	
	Evidence of Registration with the Pharmacy Council	
	Minimum of 5 years experience in clinical research field	
	Nurses	
	Curriculum Vitae	
	Certificates	
	Evidence of Fitness to Practice	
	Minimum of 5 years experience in clinical research field	

11. TEST OF FITNESS AND PROPRIETY

** Each question below is to be responded to with regards to the applicant, the officers, the employees, shareholders and directors and refers to any jurisdiction*

		Yes**	**No**
1.	Have you* ever been subject to any proceedings of a disciplinary or criminal nature, or have been notified of any impending proceedings or of any investigation, which might lead to such proceedings?		
2.	Have you*, or any business in which you* have had controlling interest or have exercised significant influence, been investigated, disciplined, suspended or criticised by a regulatory or professional body, a court or tribunal, whether publicly or privately?		

3.	Have you* ever been associated, in ownership or management capacity, with a company, partnership or other business association that has been refused registration, authorisation, membership or a licence to conduct trade, business or profession, or has had that registration, authorisation, membership or licence revoked, withdrawn or terminated?		
4.	As a result of the removal of the relevant licence, registration or other authority mentioned in question 3 above, have you* ever been refused the right to carry on a trade, business or profession requiring a licence, registration or other authorisation?		
5.	Have you* ever been subject of any justified complaint relating to regulated activities?		
6.	Have you* ever been charged or convicted of a criminal offence?		
7.	Have you* ever contravened any of the requirements and standards of a regulatory body, professional body, government or its agencies?		
8.	Have you* ever been dismissed, asked to resign or resigned, from employment or from a position of trust, fiduciary appointment or similar because of questions about your honesty and integrity?		
9.	Have you* ever been disqualified, under the Companies legislation or any other legislation or regulation from acting as a director or serving in a managerial capacity?		
10.	Have you* ever been diagnosed as being mentally ill or unstable?		
12.	Have you* ever been disciplined by a professional, trade or regulatory body; or dismissed or requested to resign from any position or office for negligence, incompetence or mismanagement?		

**** IF THE ANSWER TO ANY OF THESE QUESTIONS IS 'YES' PLEASE PROVIDE DETAILS ON SEPARATE PAGES WITH PROPER REFERENCING**

DECLARATION BY APPLICANT

I, the undersigned, certify that I have been duly authorised to submit this application and sign this undertaking on behalf of the Applicant and accordingly –

(a) confirm that the information furnished in this application is complete, correct and accurate and that the documents submitted along with this application form are genuine and that there are no other documents or information which would affect the validity or accuracy of the information or document submitted;

(b) undertake to notify the Clinical Research Regulatory Council of any material change in information/documents submitted with respect to the application;

(c) confirm that I have been informed that it is a criminal offence under the Clinical Trials Act to conduct or assist in a clinical trial without a valid registration certificate, or to fail to comply with a condition of a registration certificate.

....

Name Signature

.....

Date

SECOND SCHEDULE

[Regulations 3(5)(a), 4(1)(b)(ii) and 7]

PART I

FEES

	(Rs)
Registration of CRO	50,000

PART II

FEES

	(Rs)
Application for extension of certificate of CRO	25,000

PART III

FEES

	(Rs)
Inspection fee	5,000

THIRD SCHEDULE

[Regulations 3(5)(b) and 4(3)]

REGISTRATION CERTIFICATE

Issued under Part V the Clinical Trials Act

This is to certify that **XXX**, a private limited company duly incorporated in Mauritius on **XXX**, holder of a certificate of incorporation bearing no **XXX** issued by the Registrar of Companies, registered under Business Registration Number **XXX**, and having satisfied the requirements of the Clinical Trials Act, is hereby granted a **Registration Certificate**.

This certificate is issued to

XXX

and attests that the company is duly registered as a Contract Research Organisation operating at XXX

and is governed by the Clinical Trials Act.

This certificate shall be valid for a period of [ ] months from the date of this certificate [and is subject to the following conditions:

1. xxx

2. xxx*

The attention of the Contract Research Organisation is drawn to sections 16A, 16B,16C, 16D and 29A of the Clinical Trials Act.

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

....

Name Signature

This XXX

Clinical Research Regulatory Council
2nd Floor, Les Bacha Building, Port Louis, Tel: 2143972

**Delete as appropriate*

FOURTH SCHEDULE
[Regulation 6]

GUIDELINES FOR CONTRACT RESEARCH ORGANISATION

1. Scope

These guidelines apply to all Contract Research Organisations.

2. Criteria for registration

(1) The CRO shall be under the leadership of a person in charge who shall be:

(a) responsible for the overall activities of the organization.

(b) thoroughly familiar with –

(i) the investigational product(s);

(ii) the protocol;

(iii) informed consent forms or other information provided to the subjects;

(iv) the standard operating procedures by the sponsors; and

(v) Good Clinical Practice guidelines and other rules applicable to the conduct of clinical trials.

(2) The CRO shall, at all times –

(a) have adequate resources, equipment and infrastructure;

(b) have qualified and trained staff for oversight, conduct and assisting of clinical trials including such officers having a minimum of 5 years of experience in clinical research field as the Council may determine; and

(c) ensure that its officers are trained regularly to update their skills in their field.

(3) The CRO shall ensure that trials are adequately monitored, and the trial related responsibilities transferred to it, partially or fully, by the sponsor are discharged effectively and efficiently.

(4) (a) The CRO shall implement quality assurance and quality control as per standard operating procedures designed for the purpose.

(b) The standard operating procedures referred to in paragraph (a) shall be well documented.

(5) (a) The CRO shall have training programmes to help its investigators carry out the research studies as per guidelines applicable to such trials.

(b) Training shall include protocol adherence, free and fair informed consent.

3. Record Keeping

(1) All records (including, but not limited to, written documents, electronic, magnetic or optical records, scans) such as protocols, Clinical Research Regulatory Council approvals, investigator particulars, consent forms, monitor reports, audit certificates and final reports shall be maintained for a period of at least 15 years.

(2) All documentation and communication are to be dated, filed and preserved according to written procedures.