***BACKGROUND***

1. The Medicines and Related Substances Act, 1965 (Act 101 of 1965) as amended, read in conjunction with the General Regulations on Medical Devices, provides for the regulatory oversight of Medical Devices including In- Vitro Diagnostics (IVDs) in South Africa.
2. In terms of Regulation 18 of the General Regulations on Medical Devices

(1) A person desiring to initiate or conduct a—

(a) clinical trial in respect of a medical device; or

(b) clinical performance assessment in respect of an IVD,

must apply on an application form obtainable from the office of the Chief Executive Officer, to the Authority for authorisation to conduct such a clinical trial or clinical performance assessment.

1. A clinical evaluation, including a clinical investigation, clinical trial and/or clinical performance assessment of a medical device and/or IVD may not be initiated prior to obtaining authorisation from SAHPRA.
2. Application must be made to SAHPRA to obtain authorisation to conduct:
   1. A clinical trial or clinical investigation of a medical device
   2. Clinical performance assessment of a medical device
   3. A new intended purpose of a registered medical device
3. clinical trial means a study in or on human or animal subjects undertaken to assess the safety or clinical performance of the medical device
4. Clinical evaluation, clinical investigation, clinical trial and/ or clinical performance assessment must be conducted in accordance with the guidelines for good clinical practice.

***SUBMITTING AN APPLICATION FOR A NEW/AMENDMENT TO A CLINICAL EVALUATION OF A MEDICAL DEVICE***

1. Applications must be submitted via email to **mdct@sahpra.org.za** only. Applications submitted by any other means or to any other email address will not be processed.
2. Supportive documents, as listed in the annexure and application below, must be submitted by the applicant for each medical device to be evaluated
3. The fee for a new or amendment to a clinical evaluation application is payable upon application and proof of payment should be submitted together with the completed application.

***Note: Fees may be updated from time to time. The onus is on the applicant to ensure that payment is made in line with the current fees structures, as published in the Government Gazette.***

***TIMELINES FOR PROCESSING APPLICATIONS FOR CLINICAL EVALUATION OF A MEDICAL DEVICES/IVD***

1. Applications for clinical investigations of medical devices made to SAHPRA will be processed within 10-12 weeks.
2. A query letter will be issued to the applicant in the event that an application does not meet the submission or evaluation criteria. The deficiencies identified within the application will be documented in the query letter.
3. The applicant is required to respond to the deficiencies noted in the query letter **within five (5) working days.**

***NOTE: Only two (2) response cycles will be permitted, i.e. the applicant will have two opportunities to address the deficiencies identified in the application by submitting a response to SAHPRA within the defined timelines.***

1. If the response/s (limited to a maximum of two cycles) from the applicant does not adequately address the deficiencies identified in the application, the application will not be recommended and the application process will be concluded.

**DR B SEMETE-MAKOKOTLELA**

**CHIEF EXECUTIVE OFFICER OF SAHPRA**

**November 2024**

**UPDATE HISTORY**

|  |  |  |
| --- | --- | --- |
| **Date** | **Reason for Update** | **Version & Publication** |
| November 2024 | Published for public comment |  |

**ANNEXURE A**

**APPLICATION FORM**

|  |  |  |
| --- | --- | --- |
| **PART 1: Status** | | |
| Date Received ………………………… | |  |
| CIMD Application Number ………….. | |  |
| **Aim of Study** | *Pre-marketing approval for new device*  *Pre-marketing approval for new claims*  *Post-Marketing study*  *Non-Marketing study* | |
| **Type of Study** | Observational study  Interventional study | |
| **Does this clinical investigation involves first human use?** | Yes  No | |
| **Will the investigational device be imported to South Africa** | Yes (SAHPRA Establishment importation license is required).  No | |

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| **PART 2: GENERAL INFORMATION** | |
| ***Applicant*** | |
| **Applicant** |  |
| **Address** |  |
| **Contact person** |  |
| **Telephone no.** |  |
| **Cell no.** |  |
| **E-mail address** |  |
| **Date of application** |  |
| **PART 3:** **Sponsor details** | |
| **Type of Sponsorship** | Commercial  Non-commercial |
| **Type of sponsor** | Manufacturer  Authorized Representative  Hospital  Independent individuals  Foundation  University or Institution  Other, please specify:  ------------------------------------------- |
| **Type of aid** | Material support  Funding support  Other, please specify:  --------------------------------------- |
| **Sponsor Details** | Name \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  NRA account (if applicable) \_\_\_\_\_  Address \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Phone \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Fax \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  E-mail \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Contact person name \_\_\_\_\_\_\_\_\_  Contact person phone\_\_\_\_\_\_\_\_  Contact person e-mail \_\_\_\_\_\_\_\_\_\_\_\_ |
| **Clinical Research Organization, if different from Applicant** | Name \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  NRA’s license (if applicable) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Address\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Phone\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Fax\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  E- mail\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Contact person name \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Contact person phone \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Contact person e-mail \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
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| **PART 4: CLINICAL STUDY** | |
| **Study Title** |  |
| **Protocol Number** |  |
| **Version Number** |  |
| **Name of Lead Investigator** |  |
| **Contact Details of Lead Investigator** |  |
| **Study Investigation Medical Device** |  |
| **Is the device registered**  **By SAHPRA?** | Yes, where applicable:  SAHPRA  registration No: \_\_\_\_\_\_\_  No, but registered in:  Australia  Canada  Japan  USA  EU  Other, please specify:  ……………………………..…  Not registered anywhere |
| **Risk Classification of Medical Device**  **(South African)** |  |
| **Device Category** | Active implantable devices  Anaesthetic and respiratory devices  Dental devices  Electromechanical medical devices  Hospital hardware  Non-active implantable devices  Ophthalmic and optical devices  Reusable devices  Single use devices  Assistive products for persons with disability  Diagnostic and therapeutic radiating devices  Complementary therapy devices  Biologically derived devices  Healthcare facility products and Adaptations  Laboratory equipment  Other: ………………………………. |
| **Is the device an**  **implantable?** | No  Yes, brief description: ……..  …………………………………………  Is the device intended to remain permanently in patient:  No  Yes |
| **Whether the device**  **intended to be used for**  **cosmetic rather than**  **medical purposes** | No  Yes, Select  A non-corrective contact lens  An implant for augmentation, fixation, or sculpting of body parts  A facial or other skin fill  Equipment for liposuction  Surgical laser equipment |
| **Does the device**  **incorporate, as an**  **integral part or**  **substance, a medicinal**  **product in achieving its**  **primary intended**  **action?** | No  Yes  Brand name of drug:  …………………………… |
| **Does the device**  **incorporate a substance**  **of animal origin?** | No  Yes  Type of tissue, cell, or substance: ………………………………… |
| **Does the device**  **incorporate human**  **tissue, cell, or**  **substance?** | No  Yes  Type of tissue, cell, or substance:  ………………………………… |
| **Does the device**  **incorporate cells or**  **substance of microbial**  **origin?** | No  Yes  Type of microorganism:  ………………………………… |
| **The intended purpose of the investigational device** |  |

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| **PART 5: TRIALIST AND SITE INFORMATION** | |
| **Number of study centres in the South Africa** |  |
| **Details of selection of sites** | Site 1:  Name \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Address\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Phone\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  E-mail \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Name of principal investigator  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  EC name \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  EC address\_\_\_\_\_\_\_\_\_\_\_\_\_\_  EC phone\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  EC E-mail\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Protocol number approved by EC \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Site 2:  Name \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Address\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Phone\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  E-mail \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Name of principal investigator  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  EC name \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  EC address\_\_\_\_\_\_\_\_\_\_\_\_\_\_  EC phone\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  EC E-mail\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Protocol number approved by EC \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Site 3:  Name \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Address\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Phone\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  E-mail \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Name of principal investigator  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  EC name \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  EC address\_\_\_\_\_\_\_\_\_\_\_\_\_\_  EC phone\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  EC E-mail\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Protocol number approved by EC \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **Other countries where this clinical investigation is carried out** |  |
| **Ethics Committees which will be involved in approving the evaluation** |  |

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| **PART 6: INFORMATION SUMMARY CONTAINED IN CLINICAL INVESTIGATION PLAN/ CLINICAL TRIAL/**  **CLINICAL PERFORMANCE ASSESSMENT FOR MEDICAL DEVICE PROTOCOL** | |
| **Quantity of the investigational medical device (IMD) units required** |  |
| **Information in respect of design , manufacture and expected performance of the IMD** |  |
| **Details of device**  **(Full name, closed/ open system/ POCT, registration status in other countries, package inserts, sample collection, etc.), supported by relevant documents** |  |
| **Properties of device**  **(Scope, performance, operational characteristics,** |  |
| **Details of comparator technology**  **(Full name, closed/ open system/ POCT, registration status in other countries, package inserts, sample collection, etc.), supported by relevant documents** |  |
| **Type of Design** | Open-label non-randomized clinical investigation  Randomization, Randomized  controlled clinical investigation Parallel group: ………………………  Cross over: ………………………  Blinding  Single blinded  Double blinded  Other  Comparator used  Placebo  Comparator device, identify: |
| **Does this study**  **includes vulnerable**  **subjects?** | No  Yes |
| **Size of the sample**  **population** | Planned total number of subjects involved in the clinical investigation …………………….  Planned number of subjects involved in South Africa ……… |

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| **PART 7: DECLARATION BY SPONSOR** | |
| I’m the sponsor defined in this application:  undertake that I comply with the Ethics Review Board requirements.  undertake that I will report to the Authority any Adverse device effect of which I become aware of an investigational medical; without delay but not later than <10> working days of occurrence.  undertake that I will provide the documents specified in sections 7 in the SAHPRA’S guidance entitled Guidelines on Clinical Investigations of Medical Devices.  undertake to notify Ethics Board and Principal investigators in case of withdrawal of SAHPRA’s approval, or part of it, within five working days of receiving the withdrawal notice.  undertake, under any request from the SAHPRA to respond by providing accurate, current, and complete information about any aspects of the study.  declare that SAHPRA has the right to inspect the study at any time without prior notification.  declare that all information provided in this application is true and complete.  declare that I will maintain if applicable a proper safe return or disposal of investigational devices. | |
| Signature of Sponsor |  |
| Name |  |
| Date |  |
| I, declare that I have reviewed the application and protocol and will ensure that if the above-said clinical trial/study/performance is approved, it will be conducted according to the submitted protocol and South African legal, ethical and regulatory requirements. | |
| Signature of National Principal Investigator |  |
| Name |  |
| Date |  |

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| **PART 8: DECLARATION BY APPLICANT/ NATIONAL PRINCIPAL INVESTIGATOR** | |
| Applicants should note that in terms of the provisions of the Medicines and Related Substances Act 101, 1965 (Act 101 of 1965), it is an offence to make false and misleading statements  I declare that all information contained in this application form, and in the documents attached, is true and correct at the date of signing. | |
| Signature of Authorised Person |  |
| Name |  |
| Date |  |
| I, declare that I have reviewed the application and protocol and will ensure that if the above-said clinical trial/study/performance is approved, it will be conducted according to the submitted protocol and South African legal, ethical and regulatory requirements. | |
| Signature of National Principal Investigator |  |
| Name |  |
| Date |  |

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| **PART 9: Disclosure of Principal Investigator Conflict of Interests** | | |
| Title of Clinical Investigation Plan | |  |
| Date received: | |  |
| Clinical Investigation Application Number: | |  |
| I disclose the following regarding the involvement in the investigation in the submitted  application:  any significant payments of other type made from the sponsor, including but not limited to a grant to fund ongoing research, compensation in the form of equipment, retainer or ongoing consultation, or honoraria;  any proprietary interest in the investigational product held by the clinical investigator;  any considerable equity interest (including but not limited to any ownership interest,  stock deal, or other financial interest) held by the clinical investigator in the sponsor of  the covered study. Details of the disclosable financial arrangements and interests are attached, along with a description of steps taken to minimize the potential bias of clinical study results by any of the disclosed arrangements or interests. | | |
| Signature of Authorised Person |  | |
| Name |  | |
| Date |  | |
| I, declare that I have reviewed the application and protocol and will ensure that if the above-said clinical trial/study/performance is approved, it will be conducted according to the submitted protocol and South African legal, ethical and regulatory requirements. | | |
| Signature of National Principal Investigator |  | |
| Name |  | |
| Date |  | |

**Note:** In case of Multicentre study, a separate form shall be filled for each Principal Investigator.

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| **PART 10: Change Form for Clinical Investigation of Medical Devices** | |
| Title of Clinical Investigation Plan |  |
| Date received: |  |
| Clinical Investigation Application Number: |  |
| 1. The document type where the change occur |  |
| 2. The original statement |  |
| 3. The changed statement |  |
| 4. Reason of change |  |

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| **PART 11: CHECKLIST -*Documents Submitted with Application*** | |
| Cover letter date | Yes No |
| Application form | Yes No |
| Checklist completed | Yes No |
| Protocol (version and date) | Yes No |
| Joint declaration by Sponsor/National PI | Yes No |
| CV and signed declaration by regional monitor (If applicable) | Yes No |
| Proof of application to register the trial on SANCTR | Yes No |
| Copy of letter submitted to Ethics Committee | Yes No |
| Proof of Payment | Yes No |
| Signed declaration | Yes No |