**Instructions:**

Please note that this application form is intended as a reference to assist the CRM Importers / Local Manufacturers to prepare for the online submission of Application for Clinical Research Material Notification via PRISM.

Unless otherwise stated, this application form is not intended for offline submission. All submissions must be made via PRISM.

In order to proceed with PRISM submission, please ensure that your company has a CRIS account set up with the Health Sciences Authority. Please refer to our webpage on [Client Registration and Identification Service (CRIS)](https://www.hsa.gov.sg/e-services/cris) for more details.

**Note:**

Please complete this notification only if therapeutic products / medical devices / medicinal products are to be imported, or supplied by a local manufacturer, for the purposes of an IRB-approved clinical research.

**Legend:**

Fields marked with an asterisk (\*) are mandatory.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

|  |  |
| --- | --- |
| APPLICATION TYPE | |
| This is a: \* | Please specify CRM No.: Click here to enter text. |

|  |  |  |
| --- | --- | --- |
| **SECTION 1: INTRODUCTION** | | |
| 1.1 | Please select: \* |  |
| 1.2 | Please select the type of CRM to be imported or supplied: \* |  |
| **Particulars of Importer / Local Manufacturer** | | |
| 1.3 | UEN: \* | Click here to enter text. |
| 1.4 | Company Name: \* | Click here to enter text. |
| 1.5 | Company Address: \* | Click here to enter text. |
| Postal Code: Click here to enter text. |
| **1.6 Contact Particulars** | | |
| 1.6.1 | Salutation: | Choose an item. |
| 1.6.2 | Company Representative: \* | Click here to enter text. |
| 1.6.3 | NRIC: \* | Click here to enter text. |
| 1.6.4 | Designation: \* | Click here to enter text. |
| 1.6.5 | Telephone No.: \* | Click here to enter text. |
| 1.6.6 | Fax No.: | Click here to enter text. |
| 1.6.7 | Handphone: | Click here to enter text. |
| 1.6.8 | Email: \* | Click here to enter text. |
| **SECTION 2: PARTICULARS OF CLINICAL RESEARCH** | | |
| 2.1.1 | CRM is intended for: \* |  |
| 2.1.2 | For CRM intended for multiple studies with multiple sponsors, has any of the sponsors been identified? \* |  |
| If the research sponsor(s) for the study(ies) has not been identified, please ensure that the research sponsor(s), once identified subsequently, is made aware of their legal obligations under the Health Products (Clinical Research Material) Regulations, the Health Products (Medical Devices) Regulations, or the Medicines (Medicinal Products as Clinical Research Material) Regulations, as applicable. | | |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| 2.2  Name of Research Sponsor: \* | 2.3  Name of Research Sponsor Representative: \* | 2.4  NRIC of Research Sponsor Representative: | 2.5  Email of Research Sponsor Representative: \* | 2.6 Title of Clinical Research: \* | 2.7 Research reference or protocol number: \* | 2.8/2.9  Research Site(s) and Principal Investigator(s): \* |
| Click here to enter text. | Click here to enter text. | NA | Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. |
| Click here to enter text. | Click here to enter text. | NA | Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. |
| Click here to enter text. | Click here to enter text. | NA | Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. |
| Click here to enter text. | Click here to enter text. | NA | Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. |
| Click here to enter text. | Click here to enter text. | NA | Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. |

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **SECTION 3: PARTICULARS OF CLINICAL RESEARCH MATERIALS (CRM)** | | | | | | | | |
| **3.1 Therapeutic Product / Medicinal Product / Cell, Tissue and Gene Therapy Product** | | | | | | | | |
| 3.1.1  Active Ingredient / Generic Name / Any code designation: \* | 3.1.2  Brand/Trade Name, if any: | 3.1.3  Does this product contain a psychotropic substance or a controlled drug? \* | 3.1.4  Dosage Form: \* | 3.1.5  Route of Administration: \* | 3.1.6  Strength: \* | 3.1.7  Registration / Marketing Status: \* | 3.1.8  Estimated Total Quantity: \* | 3.1.9 Remarks: |
| Click here to enter text. | Click here to enter text. | Choose an item. | Choose an item. | Choose an item. | Click here to enter text. | Choose an item. | Click here to enter text. | Click here to enter text. |
| Click here to enter text. | Click here to enter text. | Choose an item. | Choose an item. | Choose an item. | Click here to enter text. | Choose an item. | Click here to enter text. | Click here to enter text. |
| Click here to enter text. | Click here to enter text. | Choose an item. | Choose an item. | Choose an item. | Click here to enter text. | Choose an item. | Click here to enter text. | Click here to enter text. |
| Click here to enter text. | Click here to enter text. | Choose an item. | Choose an item. | Choose an item. | Click here to enter text. | Choose an item. | Click here to enter text. | Click here to enter text. |
| Click here to enter text. | Click here to enter text. | Choose an item. | Choose an item. | Choose an item. | Click here to enter text. | Choose an item. | Click here to enter text. | Click here to enter text. |
| Click here to enter text. | Click here to enter text. | Choose an item. | Choose an item. | Choose an item. | Click here to enter text. | Choose an item. | Click here to enter text. | Click here to enter text. |
| Notes  For 3.1.1, please use the active ingredient / generic name stated in the Product Label or Investigator Brochure.  For 3.1.3, please note that a separate approval is required for the import of each consignment of therapeutic/medicinal product containing a psychotropic substance or a controlled drug. Please refer to [Controlled drugs and psychotropic substances](https://www.hsa.gov.sg/controlled-drugs-psychotropic-substances) for more information. | | | | | | | | |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **3.2 Medical Device for Investigational Purpose** | | | | | | | | | | | | | | |
| 3.2.1  Device Name: \* | 3.2.2  Type of Medical Device: \* | 3.2.3  Identifier (e.g. Model No.): \* | | 3.2.4  Description & Intended Purpose: \* | | 3.2.5  Risk Class: \* | 3.2.6  Product Owner: \* | | 3.2.7  Address of Product Owner: \* | 3.2.8  Registration / Marketing Status: \* | | | 3.2.9  Estimated Total Quantity: \* | 3.2.10  Remarks: |
| Click here to enter text. | Choose an item. | Click here to enter text. | | Click here to enter text. | | Choose an item. | Click here to enter text. | | Click here to enter text. | Choose an item. | | | Click here to enter text. | Click here to enter text. |
| Click here to enter text. | Choose an item. | Click here to enter text. | | Click here to enter text. | | Choose an item. | Click here to enter text. | | Click here to enter text. | Choose an item. | | | Click here to enter text. | Click here to enter text. |
| Click here to enter text. | Choose an item. | Click here to enter text. | | Click here to enter text. | | Choose an item. | Click here to enter text. | | Click here to enter text. | Choose an item. | | | Click here to enter text. | Click here to enter text. |
| Click here to enter text. | Choose an item. | Click here to enter text. | | Click here to enter text. | | Choose an item. | Click here to enter text. | | Click here to enter text. | Choose an item. | | | Click here to enter text. | Click here to enter text. |
| Click here to enter text. | Choose an item. | Click here to enter text. | | Click here to enter text. | | Choose an item. | Click here to enter text. | | Click here to enter text. | Choose an item. | | | Click here to enter text. | Click here to enter text. |
| Click here to enter text. | Choose an item. | Click here to enter text. | | Click here to enter text. | | Choose an item. | Click here to enter text. | | Click here to enter text. | Choose an item. | | | Click here to enter text. | Click here to enter text. |
| Click here to enter text. | Choose an item. | Click here to enter text. | | Click here to enter text. | | Choose an item. | Click here to enter text. | | Click here to enter text. | Choose an item. | | | Click here to enter text. | Click here to enter text. |
| **3.3 Medical Device for Non-Investigational Purpose** | | | | | | | | | | | | | | |
| 3.3.1  Device Name: \* | | | 3.3.2  Identifier (e.g. Model No.): \* | | 3.3.3  Product Owner: \* | | | 3.3.4  Address of Product Owner: \* | | | 3.3.5  Estimated Total Quantity: \* | 3.3.6  Remarks: | | |
| Click here to enter text. | | | Click here to enter text. | | Click here to enter text. | | | Click here to enter text. | | | Click here to enter text. | Click here to enter text. | | |
| Click here to enter text. | | | Click here to enter text. | | Click here to enter text. | | | Click here to enter text. | | | Click here to enter text. | Click here to enter text. | | |
| Click here to enter text. | | | Click here to enter text. | | Click here to enter text. | | | Click here to enter text. | | | Click here to enter text. | Click here to enter text. | | |
| Click here to enter text. | | | Click here to enter text. | | Click here to enter text. | | | Click here to enter text. | | | Click here to enter text. | Click here to enter text. | | |
| Click here to enter text. | | | Click here to enter text. | | Click here to enter text. | | | Click here to enter text. | | | Click here to enter text. | Click here to enter text. | | |
| Click here to enter text. | | | Click here to enter text. | | Click here to enter text. | | | Click here to enter text. | | | Click here to enter text. | Click here to enter text. | | |
| Click here to enter text. | | | Click here to enter text. | | Click here to enter text. | | | Click here to enter text. | | | Click here to enter text. | Click here to enter text. | | |

|  |  |  |  |
| --- | --- | --- | --- |
| **SECTION 4: SUPPORTING DOCUMENTS** | | | |
| 4.1 | IRB Approval Letter | Institutional Review Board (IRB) Approval Letter for each local research site is required for non-regulated clinical research. |
| 4.2 | Listing of Components in a Medical Device System | *A medical device system comprises of components that are compatible and intended to be used in combination to complete a common intended purpose.*  For a medical device system, the applicant may list the name of the “system” as one item in the relevant section.  A separate document that lists the breakdown of the medical device system (including quantity) should be submitted for the purpose of good documentation, accountability and custom clearance. |
| 4.3 | Packing list for Study-Visits Specific Kits | A complete packing list of the items in each Study-Visits Specific Kit can be provided to facilitate the submission in Section 3: Medical Device for Non-Investigational Purpose.  Information required in Section 3 should be provided in the packing list (i.e. Device Name, Identifier, Name and Address of Product Owner and Quantity). Study protocol number should also be indicated on the packing list for reference. |
| 4.4 | GMP Certificate |  |
| 4.5 | Other Supporting Documents |  |

|  |
| --- |
| **All applicants under the Medicines Act (MA) / Health Products Act (HPA) / Poisons Act (PA) must comply where applicable, with the MA/HPA/PA and their corresponding regulations. Applicants must also comply with all other applicable laws and their regulations.** |
| **DECLARATION FOR IMPORTER / MANUFACTURER** | |
| 1. I, on behalf of my company, confirm that the information submitted in this application is true and accurate. 2. I, on behalf of my company, shall abide by the Medicines Act and the Medicines (Medicinal Products as Clinical Research Materials) Regulations, or the Health Products Act and the Health Products (Clinical Research Materials) Regulations and/or the Health Products (Medical Devices) Regulations, where applicable. 3. I, on behalf of my company, shall not supply the CRM stated in Section 3 of the notification other than for the purpose of a clinical research approved by an Institutional Review Board. 4. I, on behalf of my company, acknowledge that the CRM notification is valid for one year from date of notification, and shall ensure that the CRM stated in Section 3 are disposed of appropriately / exported out of Singapore within 6 months of the completion/termination of the clinical research. 5. I, on behalf of my company, acknowledge that the acknowledgement of this notification is not an endorsement of the safety, efficacy and quality of the products, which I am dealing in.   Signed on behalf of:    \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Name of Company  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Signature    \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Name    \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  NRIC No. / Foreign Identification No.    \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Designation in Company    \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Date |

|  |  |
| --- | --- |
| **DECLARATION FOR RESEARCH SPONSOR** | |
| 1. I, on behalf of my company, confirm that the information in Section 2 (relating to the clinical research) of this application is true and accurate. 2. I, on behalf of my company, shall abide by the Medicines Act and the Medicines (Medicinal Products as Clinical Research Materials) Regulations, or the Health Products Act and the Health Products (Clinical Research Materials) Regulations and/or the Health Products (Medical Devices) Regulations, where applicable. 3. I, on behalf of my company, shall ensure that the CRM stated in this notification is not used other than for the purpose of a clinical research that has been approved by an Institutional Review Board. 4. I, on behalf of my company, shall ensure that any unused CRM stated in Section 3 of the notification are disposed appropriately / exported out of Singapore within 6 months of the completion / termination of the clinical research, unless otherwise allowed by the Authority. 5. I, on behalf of my company, undertake to keep proper records of the receipt, supply and/or disposal or export of the CRM, where applicable, in accordance with prescribed requirements. 6. I, on behalf of my company, undertake to indemnify and hold the Health Sciences Authority harmless against all actions, claims or proceedings in respect of any loss, injury or death of any person whomsoever arising out of or in connection with the use of the CRM stated in Section 3 of the notification.   Signed on behalf of:    \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Name of Company  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Signature    \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Name    \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  NRIC No. / Foreign Identification No.    \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Designation in Company    \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Date |