**Instructions:**

Please note that this form is intended as a reference to assist the Sponsors to prepare for the online submission of Notification of Serious Breach / Urgent Safety Measure.

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@hsa)](http://www.hsa.gov.sg/content/hsa/en/Health_Products_Regulation/CRIS.html) for more details.

**Legend:**

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

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

|  |  |
| --- | --- |
| SECTION 1: PARTICULARS OF CLINICAL TRIAL | |
| HSA File Reference No.: \* | HPRG/CTB 78:10/Click here to enter text. |
| CTA/CTN/CTC Application No.: \* | Click here to enter text. |
| Title of Clinical Trial: \* | Click here to enter text. |
| Protocol No.: \* | Click here to enter text. |
| Local Sponsor: \* | Click here to enter text. |

|  |  |  |
| --- | --- | --- |
| SECTION 2: APPLICANT PARTICULARS | | |
| 2.1 | Name: \* | Click here to enter text. |
| 2.2 | NRIC/Foreign Identification No.: \* | Click here to enter text. |
| 2.3 | Designation: \* | Click here to enter text. |
| **Contact Details** | | |
| 2.4.1 | Tel: \* | Click here to enter text. |
| 2.4.2 | Fax: | Click here to enter text. |
| 2.4.3 | Handphone: | Click here to enter text. |
| 2.4.4 | Pager: | Click here to enter text. |
| 2.4.5 | Email: \* | Click here to enter text. |

|  |  |  |
| --- | --- | --- |
| SECTION 3: SERIOUS BREACH / URGENT SAFETY MEASURES DETAILS | | |
| 3.1 | Please select: \* | *(complete “Serious Breach” section)*    *(complete “Urgent Safety Measure” section)*  *Please complete the applicable sections below.* |
| Serious Breach | | |
| 3.2 | Date of occurrence of serious breach: \* | Click here to enter a date. |
| 3.3 | Date of awareness of serious breach: \* | Click here to enter a date. |
| 3.4 | Category: \* |  |
| 3.5 | Please indicate if the non-compliance was a serious breach to the following references: \* |  |
| 3.6 | Please indicate if the serious breach is of significant impact to the following: \* |  |
| 3.7 | Details of serious breach: \* | Click here to enter text. |
| 3.8 | Please elaborate how and why the serious breach occurred: \* | Click here to enter text. |
| 3.9 | Please elaborate on corrective and preventive actions implemented / to be implemented as a result of this serious breach: \* | Click here to enter text. |
| Urgent Safety Measures | | |
| 3.10 | Date of implementation of urgent safety measure: \* | Click here to enter a date. |
| 3.11 | Please describe urgent safety measure taken: \* | Click here to enter text. |
| 3.12 | Please elaborate how and why the urgent safety measures were taken: \* |  |

|  |  |
| --- | --- |
| SECTION 4: SUPPORTING DOCUMENTS | |
| 4.1 | Other Supporting Documents |

|  |  |  |
| --- | --- | --- |
| **DECLARATION** | | |
| We confirm that the information submitted in this application is true and accurate to the best of our knowledge and belief at the date of submission of this application. | |
| Signed on behalf of:    \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Name of Company  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Signature    \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Name    \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  NRIC No. / Foreign Identification No. | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Designation in Company    \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Date |