



## **NOTIFICATION OF UPDATED INVESTIGATOR BROCHURE**

1. This online Application form for Notification of Updated Investigator Brochure may take an average of 15 minutes to fill in. The time taken may vary depending on the number and file size of the attachments, configurations of your computer and network system, internet performance etc. The recommended computer and network configurations are at:

[http://www.hsa.gov.sg/publish/hsaportal/en/services/prism/sys\\_requirements.html](http://www.hsa.gov.sg/publish/hsaportal/en/services/prism/sys_requirements.html).

Please note that the time stated above excludes time taken for preparatory work in relation to filling the online form (e.g. scanning documents for file attachments).

2. You may need the following information/item(s) to fill the form:
  - Corresponding CTC Application no.
  - Updated Investigator's Brochure (IB)
  - Summary of Changes made to the Investigator's Brochure
  - List of Clinical Trial Reference nos. applicable to the updated IB
3. Please note that the applicant must be authorised via CRIS and is required to have a valid [CRIS](#) user rights to submit online applications on behalf of his/her company.
4. The applicant of the licence will require a Singpass for login to the PRISM system to retrieve the application form. A person who drafts an application on behalf of his/her company and is not a Singaporean Citizen, Permanent Resident or employment pass holder will need to apply for a HSA Pin to login to PRISM. The Singpass and HSA Pin login is necessary for authentication and authorization purposes.

For more information on Singpass, please visit <http://www.ecitizen.gov.sg/singpass/index.htm>.

For more information on HSA Pin, please visit [http://www.hsa.gov.sg/publish/hsaportal/en/services/hsa\\_pin.html](http://www.hsa.gov.sg/publish/hsaportal/en/services/hsa_pin.html).

### **Information Required To Complete The Application Form**

This online application form consists of 5 main sections:

1.	Particulars Of Clinical Trial Application
2.	Applicant Particulars
3.	Applications For Clinical Trials Involving The Same Study Drug
4.	Supporting Attachments
5.	Confirmation

#### **Part 1 – Particulars Of Clinical Trial Application**

- 1) Please enter the corresponding CTC application no and click “Retrieve”.
- 2) Details of the clinical trial will be auto-populated.

#### **Part 2 – Applicant Particulars**

The section requires the applicant to fill in the required information below:



- 1) Name, Designation, NRIC/FIN, Address (Postal Code, Level and Unit number), Contact Details (Telephone/Fax/Handphone and E-mail address)

### **Part 3 – Applications For Clinical Trials Involving The Same Study Drug**

The section requires the applicant to fill in the required information below:

- 1) The clinical trial reference nos. for which the safety information or updated IB is applicable.
- 2) Any supplementary information, if applicable.
- 3) To state if an updated IB is being submitted or safety information.
- 4) Version date and number of the updated IB

### **Part 4 – Supporting Attachments**

The applicant is required to provide the following supporting documents for the application:

- 1) Updated Investigator's Brochure
- 2) Summary of Changes made to the Investigator's Brochure
- 3) Other relevant supporting documents, if applicable

### **Part 5 –Confirmation**

Please confirm that the information you have entered is correct. Upon successful submission, please print the acknowledgement receipt stating that the application has been successfully submitted as well as the reference application number.