

**Health Sciences Authority**

11 Biopolis Way #11-03 Helios  
Singapore 138667  
Tel: 65 6866 3400 Fax: 65 6478 9027  
Website: www.hsa.gov.sg



HPRG CTB Ref: 25:40

16 March 2015

To: Applicants / Sponsors of Clinical Trials

**NOTIFICATION OF SERIOUS BREACHES OF THE SINGAPORE GUIDELINE FOR GOOD CLINICAL PRACTICE, TRIAL PROTOCOL OR CLINICAL TRIAL REGULATIONS**

The Clinical Trials Branch, Health Sciences Authority (HSA) would like to inform all applicants / sponsors of clinical trials on the following updates, with immediate effect:

1 Not every deviation from the Singapore Guideline for Good Clinical Practice (SGGCP), trial protocol or clinical trial regulations should be notified to HSA.

2. Serious breach\*\* of the SGGCP, trial protocol or clinical trial regulations should be notified to HSA within 7 calendar days of the sponsor becoming aware of the serious breach.

*\*\*A serious breach is a deviation which is likely to affect to a significant degree:*

- a) *The safety or physical or mental integrity of any subjects in a clinical trial; or*
- b) *The scientific value of the clinical trial.*

3. The Guideline on Notification of Serious Breaches can be downloaded at our HSA website. Please refer to the Guideline for detailed information on the notification process and requirements.

4. If you need further information or any clarification, please contact us at 68663446 for assistance or email your enquiries to Ms Sumitra Sachidanandan (GCP Inspection Consultant, Clinical Trial Branch) at [sumitra\\_sachidanandan@hsa.gov.sg](mailto:sumitra_sachidanandan@hsa.gov.sg) or Ms Poh Cuiqin (GCP Compliance Inspector, Clinical Trial Branch) at [poh\\_cuiqin@hsa.gov.sg](mailto:poh_cuiqin@hsa.gov.sg).

Thank you.

Yours sincerely,

A handwritten signature in black ink, appearing to read 'Foo Yang Tong', is written over a light blue horizontal line.

Foo Yang Tong  
Director  
Clinical Trials Branch  
Health Products Regulation Group  
Health Sciences Authority