

15 Aug 2014

**DSRB-032014: Changes to the Informed Consent Form Requirements for Studies Involving Data Retention after Subject's Withdrawal**

**(A) Changes to the Informed Consent Form Requirements for**  
**i) Studies Involving Data Retention after Subject's Withdrawal**  
**ii) Additional clause for Personal Data Protection Notification**

According to the recent implementation of the Personal Data Protection Act, the NHG Domain Specific Review Board (DSRB) would like to inform investigators that subjects should be made aware during the informed consent process that any research data collected until the point of withdrawal will be kept for analysis by the study team.

This is to allow the preservation of the scientific, and therefore, ethical, integrity of the research and to ensure compliance with FDA (for FDA-regulated studies) and PDPA.

In order to avoid potential disputes between the subjects and the investigators regarding the data which have been collected before the subject's withdrawal, the DSRB has revised the Informed Consent Form requirements for studies involving data retention after subject's withdrawal.

In addition, the subjects should also be notified on the use of their personal data and also the relevant data protection policy that is in place.

Hence, with effect from **15 August 2014**:

1. It is recommended that studies that involve the collection of data will have to include a statement in the informed consent form to inform subjects that any data that have been collected until the point of withdrawal will be kept and analysed to enable a complete and comprehensive evaluation of the study. (Section 11 "Voluntary Participation")
2. The additional clause to inform subjects about the Personal Data Protection Notification should be included in the Informed Consent Form. (Section 13 "Confidentiality of Study and Medical Records" and "Consent Form" Portion)

Please refer to the updated DSRB Informed Consent Form Template (Document No. 207-001, Version 6, dated 15 Aug 14) which can be downloaded [here](#).