

15 August 2018

DSRB-150818: DSRB Announcement – Changes to Continuing Review Requirements for Studies at Data Analysis Stage

With effect from 15 August 2018, unless the DSRB determines otherwise, studies that have submitted a Study Status Report Form (SRF) whereby the study status is “Last Participant, Last Visit Over & Only Data Analysis Ongoing” will be exempted from continuing review once the SRF has been approved.

However, if amendments are made to the study which **changes the study status** such that it **no longer involves data analysis only** (e.g. collection of additional data), the Principal Investigator must submit a new SRF to update the DSRB of the new study immediately, and continuing review will be required.

Principal Investigators are still expected to report non-compliance, Unanticipated Problems Involving Risks to Subjects or Others (UPIRTSOs) and other important notifications to the DSRB. They must also submit a SRF to inform the DSRB when the study is considered completed or is terminated.

Please note that this change is only applicable for SRFs with the study status “Last Participant, Last Visit Over & Only Data Analysis Ongoing” that are approved **on/after 15 August 2018**. For studies with previously approved SRFs with the study status “Last Participant, Last Visit Over & Only Data Analysis Ongoing”, Principal Investigators may submit a new SRF to benefit from this exemption.

For more information, please contact the DSRB Secretariat at OHRPP@nhg.com.sg.