NHG RESEARCH EDUCATION

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Issue 27, July 2017

HBRA Update: Reporting of Expected Serious Adverse Events (SAE)

Background

The Human Biomedical Research Act (HBRA) requires that all expected and unexpected SAEs *(refer to the HBRA's Definition of SAE)* will need to be reported to the Research Institution. For NHG research studies, this means that there will be a new reporting requirement to DSRB.

Definition of SAE (HBRA Part 1 section 2)

SAE in relation to human biomedical research, means any untoward medical occurrence as a **result of any human biomedical research** which –

(i) Results in or contributes to death;
(ii) Is life-threatening;
(iii) Requires in-patient hospitalization or prolongation of existing hospitalization;
(iv) Results in or contributes to persistent or significant disability or incapacity;
(v) Results in or contributes to a congenital anomaly or birth defect; or
(vi) Results in such other events as may be prescribed.

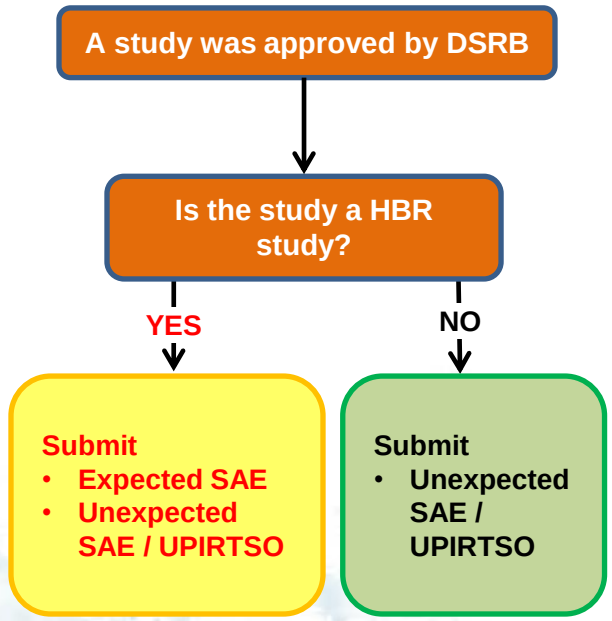
How will studies be impacted

From Quarter 4 of 2017 (Date TBC), apart from unexpected SAE submitted using the UPIRTSO form, expected SAEs will also need to be submitted. This new requirement will apply to all NHG Human Biomedical Research (HBR) studies reviewed by DSRB.

Submission Process

DSRB is currently working on the expected SAE form and channel of submission. More details will be furnished to the ground when the process is finalized. Please look out for our updates via ROAM and the NHG research website.

The following flow chart summarizes the SAE reporting requirements:



Contact Details

If you have any feedback or enquiries on expected SAE reporting, please contact us at researchquality@nhg.com.sg.

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