

FAQs on the Enhancements to the DSRB Application Forms and Supplementary Forms

Q1: What is the purpose of these enhancements?

A1: Since 2016, there have been new local regulatory requirements that research institutions, researchers and institutional review boards have to comply with. This includes the requirements of the Human Biomedical Research Act (HBRA), Health Products (Clinical Trials) Regulations and Medicines (Clinical Trials) Regulations.

Some of these new requirements were not addressed adequately in the DSRB application form, resulting in additional rounds of queries between the DSRB, Principal Investigators (PIs) and study team. Furthermore, it was dependent on the DSRB staff, PIs and study team to manually identify the additional requirements for each application. This process is not efficient in the long run.

This round of enhancements will include new sections and revisions in the DSRB application forms to align with the local regulatory requirements, so that PIs and study teams can address them during the preparation of their DSRB application and expedite the review process.

Minor changes have also been made in the Non-Compliance/Study Deviation Report Form and Unanticipated Problems Involving Risks to Others (UPIRISO) Report Form so that Principal Investigators and study teams can provide clearer details about the non-compliance/study deviations or unanticipated problems to facilitate review and reporting.

Q2. What are the changes?

A2:

(i) Changes to the DSRB Application Forms

Both the DSRB Application Forms for Biomedical Research and Population Health Research have been updated. The key changes include:

- New section for PIs to indicate whether their studies fall under the purview of the HBRA
- Updated waiver of informed consent criteria according to the HBRA
- Updated section on Emergency Research for PIs according to the HBRA, Health Products (Clinical Trials) Regulations and Medicines (Clinical Trials) Regulations
- New question for PIs to indicate if a witness would be present during the consent process
- New questions and declaration for PIs who are conducting Restricted Research to ensure that they comply with consent requirements and restrictions on research involving oocytes and embryos (only in the Biomedical Research Application Form)

Please refer to the Guidebooks which can be downloaded [here](#) for the latest DSRB application form sections and questions (*available after 29 October 2018*).

(ii) Changes to the Non-Compliance/Study Deviation Report Form (Supplementary Form)
 There is a new question to indicate the study site where the non-compliance/study deviation occurred.

(iii) Changes to the Unanticipated Problems Involving Risks to Others (UPIRTSO) Report Form (Supplementary Form)
 There is a new question for unanticipated problems which are also Serious Adverse Events (SAEs) to indicate which criterion of an SAE it fulfils.

Q3: Will there be any impact to my DSRB Application Form/Study Amendment/Supplementary Form after the deployment?

Scenario	Task Owner	Impact
(A) I am still preparing my DSRB Application Form/Study Amendment/Supplementary Form and it is saved in the 'Draft' stage.	Principal Investigator	<p>After the deployment, when you next save/submit your DSRB Application Form/Study Amendment/Supplementary Form, you will be prompted to complete the new mandatory questions and revised sections with new branching logic.</p> <p>There will be no impact to the other answers that had been saved previously.</p>
(B) I have submitted my DSRB Application Form/Study Amendment and it is in the 'Department Representative/Institution Representative Queried' stage.	Principal Investigator	<p>After the deployment, when you next save/re-submit your DSRB Application Form/Study Amendment, you will be prompted to complete the new mandatory questions and revised sections with new branching logic.</p> <p>There will be no impact to the other answers that had been saved previously.</p>
(C) I have submitted my DSRB Application Form/Study Amendment/Supplementary Form and it is in the 'DSRB Queried' stage.	Principal Investigator	<p>After the deployment, when you next save/re-submit your DSRB Application Form/Study Amendment/Supplementary Form, you will be prompted to complete the new mandatory questions and revised sections with new branching logic.</p> <p>There will be no impact to the other answers that had been saved previously.</p>

Scenario	Task Owner	Impact
(D) I have submitted my DSRB Application Form/Study Amendment and it is pending Department Representative/Institution Representative endorsement.	Department Representative /Institution Representative	There is no impact to your DSRB Application Form/Study Amendment. No action is required by you at this stage. However, if there are queries posted by the Department Representative/Institution Representative/DSRB subsequently, then you will be prompted to complete the new mandatory questions and revised sections with new branching logic when you next save/re-submit your DSRB Application Form/Study Amendment.
(E) I have submitted/re-submitted my DSRB Application Form/Study Amendment/ Supplementary Form and it is pending DSRB review.	DSRB	There is no impact to your DSRB Application Form/Study Amendment. No action is required by you at this stage. However, if there are queries posted by the DSRB subsequently, then you will be prompted to complete the new mandatory questions and revised sections with new branching logic when you next save/re-submit your DSRB Application Form/Study Amendment.

Q4: If I've more questions who should I contact?

A4:

For enquiries related to the DSRB application form/supplementary forms, please contact the DSRB secretariat at OHRPP@nhg.com.sg or via their respective contacts. The DSRB secretariat's contact list can be found [here](#).

If you encounter any Technical difficulties with the ROAM system, please send an email to researchonline@nhg.com.sg with your **full name**, **NRIC/FIN** and a **description** of the problem together with **screen-capture of the error where possible**. Please provide your **DSRB Study Reference number** and **Study Title** where applicable. By providing detailed information about the error, we can better pin-point the problem and efficiently respond to you.