

Frequently Asked Questions (FAQs) Regarding DSRB Studies/Submissions During the ROAM System Shutdown

(A) For Department Representatives and Institution Representatives

(B) For Principal Investigators, Study Team Members and Study Administrators

(C) For Research Participants/Potential Research Participants

Please note that the DSRB continues to operate within its normal operating hours (Monday-Thursday: 830am-6pm, Friday: 830am-530pm), which will not be affected by the Shutdown Period.

If you have additional questions, you can contact the DSRB at OHRPP@nhg.com.sg.

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(A) For Department Representatives and Institution Representatives

1. Will I still be able to review and endorse the DSRB Applications in ROAM during the Shutdown Period?

Answer: No. All users will not be able to access the ROAM portal during the Shutdown Period therefore you will not be able to login to ROAM to review and endorse your department/institution staff's DSRB Applications.

2. Will my endorsement tasks be affected by the ROAM System Shutdown?

Answer: No. After the server upgrading is completed, all users will be able to login to ROAM again. All your endorsement tasks that were in your Homepage/Tasks before the Shutdown Period will still be available to you when you login.

3. I only have a limited number of days to review and endorse the DSRB Applications. What if I've not completed my review and the endorsement task expires during the Shutdown Period?

Answer: All Department Representative and Institution Representative endorsement tasks affected by the Shutdown Period will be given a one-time extension according to the missed days due to the Shutdown Period. **If you are midway through the review and completion of the checklist in ROAM, remember to save and check that it has been saved properly before the Shutdown Period.**

Example:

DR Endorsement Task Received Date	DR Endorsement Task Expiry/Transfer Date	No. of Missed Days Due to Shutdown Period	New DR Endorsement Task Expiry/Transfer Date (25 May + No. of Missed Days)
17 May	21 May	0	Not Affected
18 May	22 May	1	26 May
21 May	25 May	4	29 May

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4. I've posted questions to the study team for their clarifications on the DSRB Application. Will this be affected by the Shutdown Period?

Answer: No. After the server upgrading is completed, all users will be able to login to ROAM again and continue from the last saved status. The study team will be able to see your questions, respond to them and re-submit the DSRB Application for your review and endorsement.

(B) For Principal Investigators, Study Team Members and Study Administrators

1. Will I still be able to draft and submit the DSRB Applications in ROAM during the Shutdown Period?

Answer: No. All users will not be able to access the ROAM portal during the Shutdown Period therefore you will not be able to login to ROAM to draft and submit DSRB Applications, Amendments or Supp Forms (e.g. Study Status Report Form, Non-Compliance Report Form etc.). **If you are midway through drafting, remember to save and check that it has been saved properly before the Shutdown Period.** After the server upgrading is completed, you will be able to login to ROAM again to draft, to continue from the last saved status, and to submit them to DSRB.

However, DSRB will make provisions to review the following time-sensitive submissions/requests:

- a. if you have a time-sensitive COVID-19 related DSRB Application/Amendment that requires urgent review by DSRB, please refer to FAQ #3 below for more information;
- b. if you need to report an urgent Unanticipated Problem Involving Risks to Subject or Others (UPRTSO), please refer to FAQ #4 below for more information; and
- c. if you need to make an urgent, one-time request to enrol subjects in exceptional circumstances, please refer to FAQ #5 below for more information.

For other submissions, you can submit them when you are able to login to ROAM again.

If you require further advice/assistance, you can contact DSRB at OHRPP@nhg.com.sg.

2. Will my tasks to respond to Department Representative/Institution Representative/DSRB queries be affected by the ROAM System Shutdown?

Answer: No. After the server upgrading is completed, all users will be able to login to ROAM again. All your tasks that were in your Homepage/Tasks before the Shutdown Period will still be available to you when you login.

3. I've a time-sensitive COVID-19 related DSRB Application/Amendment that requires urgent review by DSRB. What should I do?

Answer: You can contact the DSRB at OHRPP@nhg.com.sg so that we can advise and assist you accordingly. Do ensure that you have a copy of essential documents like the Study Protocol and Informed Consent Form (Track Changes copies for Amendments) ready for DSRB review. As DSRB will also not be able to access the ROAM portal during the Shutdown Period, we therefore require a copy of the study documents to facilitate the review. Your submission will be forwarded to the relevant Domain for review. The DSRB Secretariat will contact you to inform you of the DSRB review outcome or request for more details or study documents.

Please note that you would still be required to submit a copy of the DSRB Application/Amendment in ROAM when you are able to login to ROAM again. This is required for complete and proper documentation of all study-related submissions.

4. I've an urgent reportable Unanticipated Problem Involving Risks to Subject or Others (UPRTSO) to submit to DSRB during the Shutdown Period. What should I do?

Answer: Principal Investigators are reminded to submit the UPIRTSO report promptly, within the applicable reporting timelines. A copy of the UPIRTSO reporting timelines is provided in the table below.

If there is a time-sensitive/urgent UPIRTSO report that must be submitted to DSRB during the Shutdown Period, you should download a softcopy of the UPIRTSO Form from *the links provided below** and complete the Form details. Next, you should submit the completed UPT Form with a copy of the current, DSRB-approved Study Protocol and Informed Consent Form to the DSRB at OHRPP@nhg.com.sg. As DSRB will also not be able to access the ROAM portal during the Shutdown Period, we therefore require a copy of the study documents to facilitate the review. Your submission will be forwarded to the relevant Domain for review. The DSRB Secretariat will contact you to inform you of the DSRB review outcome or request for more details or study documents.

* DOWNLOAD UPIRTSO FORM (Temporary Use Only):	via Internet	via NHG Intranet
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Please note that you would still be required to submit a copy of the UPIRTSO report via the UPT Form in ROAM when you are able to login to ROAM again. This is required for complete and proper documentation of all study-related submissions.

UPIRTSO Reporting Timelines

Risk Profile of study	More Than Minimal Risk (Reviewed via Full Board)	No More Than Minimal Risk (Reviewed via Expedited / Exempt)	Regardless of Risk Profile	Regardless of Risk Profile
Event / Problem	*Local death	*Local death	Life-threatening problems not resulting in death	All other problems
Description of Event / Problem	Regardless of expectedness and causality	Must be related / possibly related to the study and regardless of expectedness	Unexpected and related / possibly related to the study	Unexpected and related / possibly related to the study
Timeline for Initial Report	Soonest possible but not later than 7 calendar days after first knowledge	Soonest possible but not later than 7 calendar days after first knowledge	Not later than 7 calendar days after first knowledge	Not later than 15 calendar days after first knowledge
Timeline for Follow-Up Report	Within 8 calendar days of initial report	Within 8 calendar days of initial report	Within 8 calendar days of initial report	-

*Local is defined as occurrence in institutions under the oversight of the NHG DSRB.

5. I've an urgent, one-time request to enrol "special" subjects during the Shutdown Period. What should I do?

Answer: An example of such "special" subjects are individuals who do not strictly meet the study's inclusion-exclusion criteria, but the investigators have determined that they could potentially benefit from the study intervention. DSRB approval is required before such exceptions can be allowed and Principal Investigators would normally have to submit the one-time request via the Other Study Notifications (OTH) Form in ROAM.

If you have such an urgent request during the Shutdown Period (e.g. the patient will be in the clinic/hospital on 24 May), you should send your request with a copy of the current, DSRB-approved Study Protocol and Informed Consent Form to the DSRB at OHRPP@nhg.com.sg. As DSRB will also not

be able to access the ROAM portal during the Shutdown Period, we therefore require a copy of the study documents to facilitate the review. Your submission will be forwarded to the relevant Domain for review. The DSRB Secretariat will contact you to inform you of the DSRB review outcome or request for more details or study documents.

Please note that you would still be required to submit a copy of the one-time request via the OTH Form in ROAM when you are able to login to ROAM again. This is required for complete and proper documentation of all study-related submissions.

6. My DSRB approval will expire during the Shutdown Period. Will my DSRB approval be extended?

Answer: Principal Investigators are reminded to submit the Study Status Report Form (SRF) in ROAM 4-6 weeks before the expiry date to allow sufficient time for DSRB review and renewal of DSRB approval.

For SRFs which have been submitted promptly, DSRB will review them before the Shutdown Period and renew the DSRB approval if there are no queries.

For SRFs which have not been submitted/have outstanding queries and the DSRB approval has expired, the study cannot continue beyond the expiry date until the DSRB approval is renewed. There will not be an extension of the DSRB approval. Principal Investigators and Study Teams should note that no research activities, including screening, enrolment, interventions, and interactions, and collection of identifiable data can occur during the lapse period, unless the DSRB or investigator determines that it is in the best interest for the subjects to continue their participation in the study. Please contact the DSRB at OHRPP@nhg.com.sg if you require further advice for this situation.

Please note that the system will not be able to send any email reminders or notifications of expiry that are due during the Shutdown Period. However, after the server upgrading is completed, the system will send out the auto-generated notification of expiry and the auto-generated Study Expiry letter will be available in the Study Summary page in ROAM under "Official DSRB Letters" for your documentation and filing.

7. I've an Exempt study that does not require renewal of DSRB approval. Will it be affected by the ROAM System Shutdown?

Answer: As Exempt studies do not require renewal of DSRB approval, there is no impact to the continuation of study activities and the "Expiry Date" displayed in ROAM (for completeness of the system data) will be auto-extended. However, the system will not be able to send any email reminders that are due during the Shutdown Period. If the study is completed, you are reminded to submit a completion report via the Study Status Report Form (SRF) in ROAM when you are able to login to ROAM again.

8. Can I still access the NHG Research website to refer to and download Guidance Documents, Templates etc. for my DSRB submissions during the Shutdown Period?

Answer: No. All users will not be able to access the NHG Research website (<https://www.research.nhg.com.sg/wps/wcm/connect/romp/nhgromp/home>) during the Shutdown Period. If you require any Guidance Documents, Templates etc., please download a copy on your own device before the Shutdown Period. After the server upgrading is completed, you will be able to access the NHG Research website again.

9. I need a copy of the Guidance Document/Template urgently for a time-sensitive submission, but I can't download them during the Shutdown Period. What should I do?

Answer: You can contact the DSRB at OHRPP@nhg.com.sg and we will advise and assist you accordingly.



(C) For Research Participants/Potential Research Participants

1. I would like to find out more about participating in research or my rights as a research subject, but I can't access the NHG Research website as mentioned in the Informed Consent Form which the study team had passed to me. What should I do?

Answer: Due to the server upgrading, all users will not be able to access the NHG Research website (<https://www.research.nhg.com.sg/wps/wcm/connect/romp/nhgromp/home>) during the Shutdown Period. After the server upgrading is completed, you will be able to access the NHG Research website again.

In the meantime, you can contact the DSRB at OHRPP@nhg.com.sg or the DSRB Hotline 6471 3266 and we will advise and assist you accordingly.