User Acceptance Testing

MREC Secretariat

National Medical Research Register v2.0
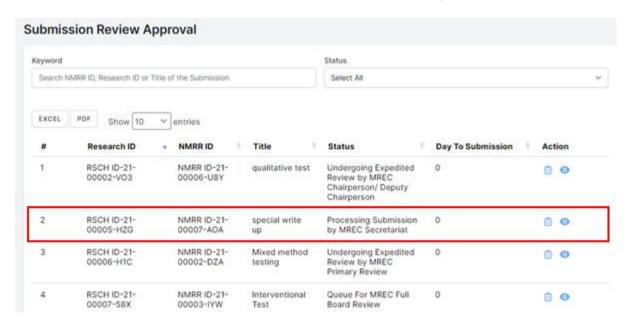July 30, 2021

National Institutes of Health (NIH)

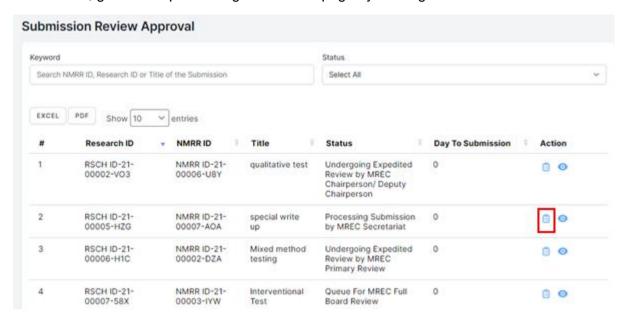# 1.0 - Flow for Review and Approval

1.1 - Screening & Reviewer Assignment

1. Go to the url https://nmrr.gov.my
2. Login as necessary individuals with an assigned role as MREC Secretariat and go to the Approval page located at the left side.
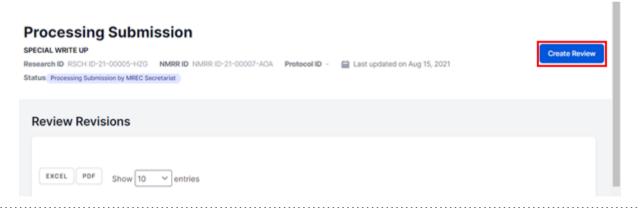

3. Secretariat should be able see all submissions under the assigned secretariat.
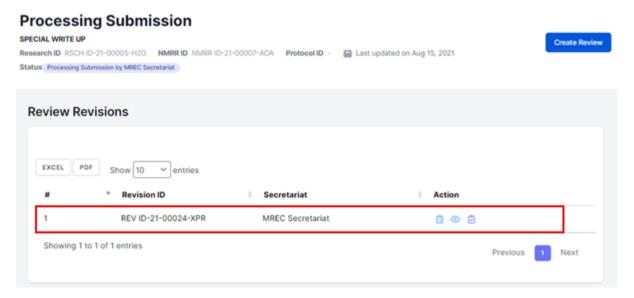
4. Click on the view data (eye icon) to go into that submission details. To process the submission, go into the processing submission page by clicking the sheet icon

5. Click on the "Create Review" button at the top to create a new review sheet and a review revision should be created as below. History detail also can be seen at the bottom part of the page. For processing of the submitted revision, the previous Review Revision will be available to be viewed. (Secretariat needs to create a new Review Revision template each time for a new revision submission)

6. Click on the view data (eye icon) to go into that submission details. To access the
    screening checklist & risk assessment form, click on the screening checklist icon

7. Click on the status drop down to change status of the checklist item
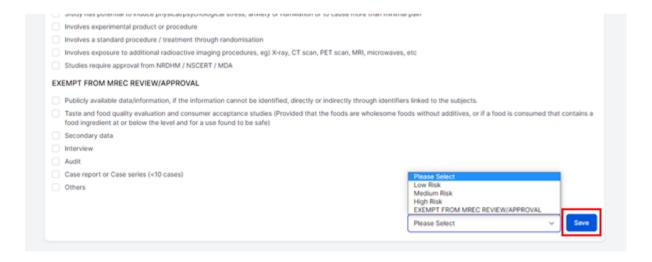
8. Click on the comment icon to do a comment

9. If revision is required, the decision can be accessed by clicking the decision icon located on the top right of the "Screening Checklist Details" .

10. If Screening is complete, secretariat can proceed with the risk assessment located right after the screening checklist

Risk Assessment

Involve HUMAN SUBJECTS? YES, if satisfy ANY of the following criteria:

☐ Data Obtained Through Intervention or Interaction with a living individual
☐ Investigator has access to Identifiable Private Information from living individual

Is it a RESEARCH? YES, if satisfy ALL of the following criteria:

☐ It is a Systematic Investigation
☐ Current design produces generalizable knowledge

LOW RISK = (more than one may be chosen)

☐ Retrospective
☐ Medical records
☐ Secondary data
☐ Interview
☐ Questionnaire / Survey
☐ Focus group discussion
☐ Observational

11. Click Save for the Overall Risk Assessment at the bottom of the page

☐ Study has potential to induce physical/psychological stress, anxiety or humiliation or to cause more than minimal pain
☐ Involves experimental product or procedure
☐ Involves a standard procedure / treatment through randomisation
☐ Involves exposure to additional radioactive imaging procedures, eg) X-ray, CT scan, PET scan, MRI, microwaves, etc
☐ Studies require approval from NRDHM / NSCERT / MDA

EXEMPT FROM MREC REVIEW/APPROVAL

☐ Publicly available data/information, if the information cannot be identified, directly or indirectly through identifiers linked to the subjects.
☐ Taste and food quality evaluation and consumer acceptance studies (Provided that the foods are wholesome foods without additives, or if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe)
☐ Secondary data
☐ Interview
☐ Audit
☐ Case report or Case series (<10 cases)
☐ Others

Please Select
Low Risk
Medium Risk
High Risk
EXEMPT FROM MREC REVIEW/APPROVAL

Please Select ⌄   **Save**

12. Once done with the Overall risk Assessment, The Review Checklist Completion page will be then accessible. Secretariat will then click the paper icon to go into the" Review Checklist Completion", Click on "Assign Reviewer "to assign study reviewers

Processing Submission

SPECIAL WRITE UP

Research ID RSCH ID-21-00005-HZG   NMRR ID NMRR ID-21-00007-AOA   Protocol ID -   📅 Last updated on Aug 15, 2021

Status Processing Submission by MREC Secretariat

Create Review

Review Revisions

EXCEL	PDF	Show	10 ▼	entries

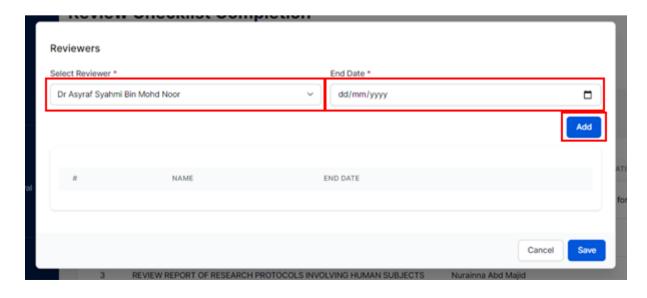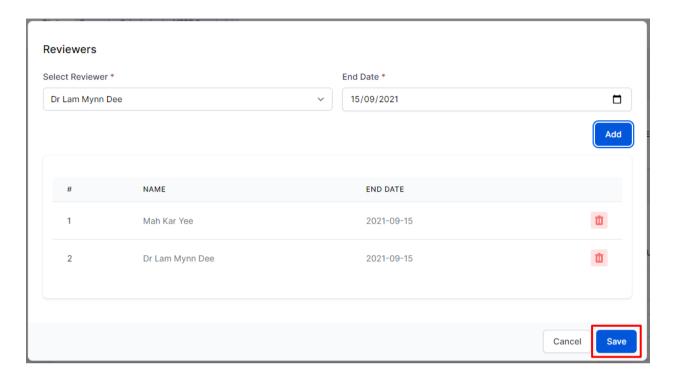| # ▲	Revision ID	Secretariat	Action
1	REV ID-21-00024-XPR	MREC Secretariat	📋 👁 ☑

Showing 1 to 1 of 1 entries

Previous **1** Next

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Review Checklist Completion

INTERVENTIONAL TEST

Research ID RSCH ID-21-00007-58X   NMRR ID NMRR ID-21-00003-IYW   Protocol ID -   📅 Last updated on Aug 15, 2021

Status Queue For MREC Full Board Review

Reviewers   **Assign Reviewer**

#	CHECKLIST	NAME	RECOMMENDATION

13. Select name of reviewer and end date of the reviewing process, click add to insert the name of reviewers

Reviewers

Select Reviewer *   End Date *

Dr Asyraf Syahmi Bin Mohd Noor   ▼   dd/mm/yyyy   📅

                                                                                                Add

#	NAME	END DATE

                                                                        Cancel   **Save**

3   REVIEW REPORT OF RESEARCH PROTOCOLS INVOLVING HUMAN SUBJECTS   Nurainna Abd Majid

14. Multiple Reviewers can be added during the assignment. To confirm the reviewers and to send email notification to the reviewer, click the "Save" button.,

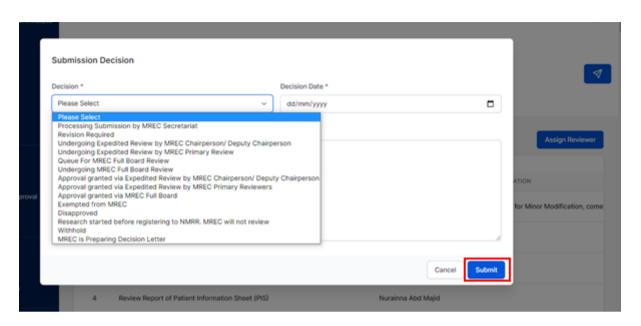

15. Once the reviewer names are saved, a list will be displayed on the "Review Checklist Completion" page. Secretariat can then change the decision by clicking the decision icon on the top right of the.

16. Select the decision with the decision date, then click the "submit" button to finalise the decision.

End of Flow

End of Flow

1.2 Compilation of Comments and Checking of Review & Response
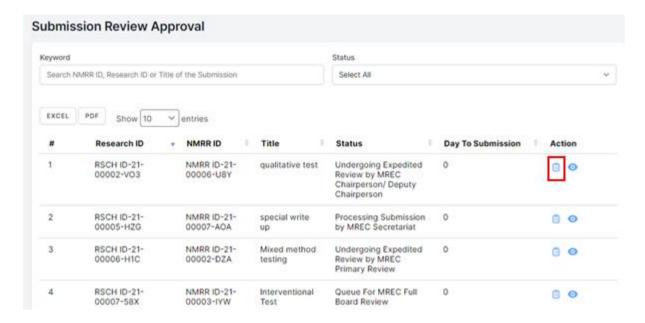
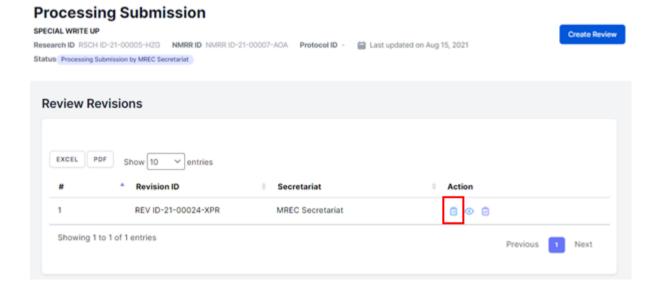1. Go to the Approval page located at the left side

2. Secretariat should be able see all submissions under the assigned secretariat
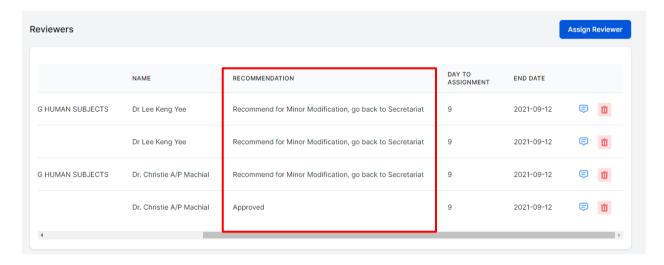
3. Click on the view data (eye icon) to go into the submission details. To access the checklist and decision selection, click the Review Checklist Completion page (paper icon)

4. Click the paper icon to go into the" Review Checklist Completion"

5. On reviewer listing, click on the Reviewer comment icon to view individual reviewers' comment (this will appear once the reviewer has reviewed the submission and make a recommendation- individual comment.) Recommendation made by each reviewer will be displayed individually.

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Reviewer's Comment

Reviewer's Checklist Details

INTERVENTIONAL STUDY CLINICAL TRIAL TESTING

Research ID RSCH ID-21-00002-X4B **NMRR ID** NMRR ID-21-00001-JWB **Protocol ID** - 📑 Last updated on Aug 29, 2021

Status Queue For MREC Full Board Review

REVIEW REPORT OF RESEARCH PROTOCOLS INVOLVING HUMAN SUBJECTS

◉ All(55) ○ Yes(0) ○ No(0) ○ Not Relevant(0) ○ Complete(53) ○ Not Complete(2)

DATA	STATUS	COMMENTS
1. General Information		
1.1 Is study title appropriate?	Complete	💬
1.2 Is there a protocol identifying number and date?	Complete	💬
1.3 Is the name and address of sponsor stated?	Complete	💬

6. Once reviewers have completed the review, compilation can be done by Secretariat. Secretariat first need to finalise the status of each item by clicking on the status drop-down to change the status of the checklist item

9. Then the compilation is performed by clicking on the comment icon as shown.

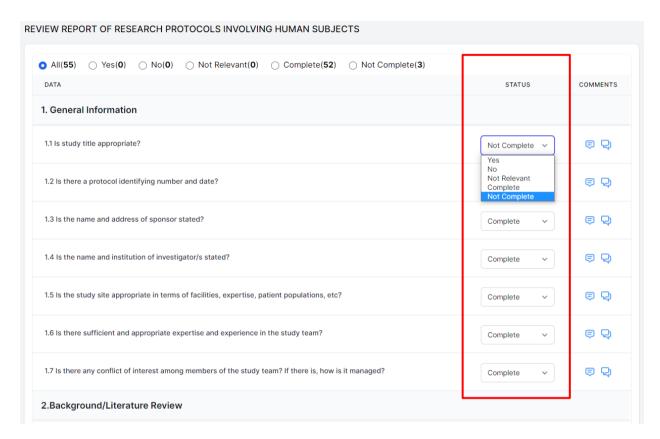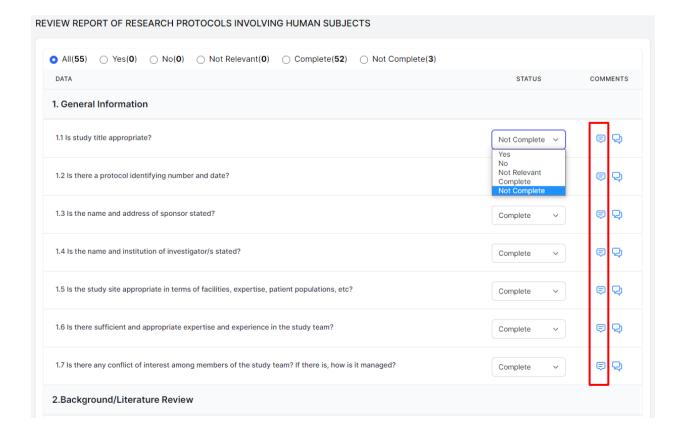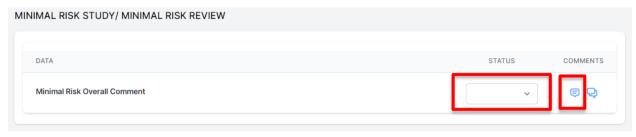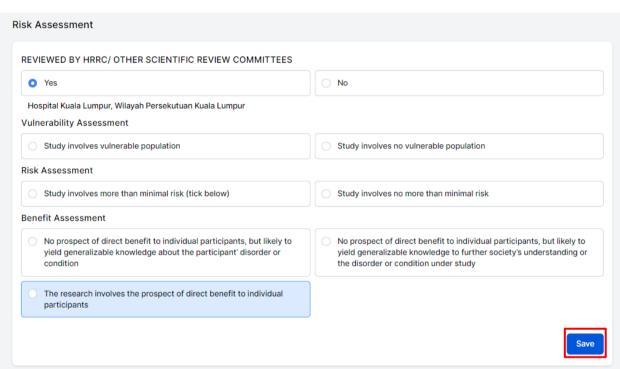..

For Minimal Risk Study (Expedited Review by MREC Chairperson/ Deputy Chairperson/ Secretary). Assessment by MREC Chairperson/ Deputy Chairperson/ Secretary) need to be filled and saved by Secretariat as well.

MINIMAL RISK STUDY/ MINIMAL RISK REVIEW

DATA	STATUS	COMMENTS
Minimal Risk Overall Comment	⌄	💬 💬

Risk Assessment

REVIEWED BY HRRC/ OTHER SCIENTIFIC REVIEW COMMITTEES

⦿ Yes	○ No

Hospital Kuala Lumpur, Wilayah Persekutuan Kuala Lumpur

Vulnerability Assessment

○ Study involves vulnerable population	○ Study involves no vulnerable population

Risk Assessment

○ Study involves more than minimal risk (tick below)	○ Study involves no more than minimal risk

Benefit Assessment

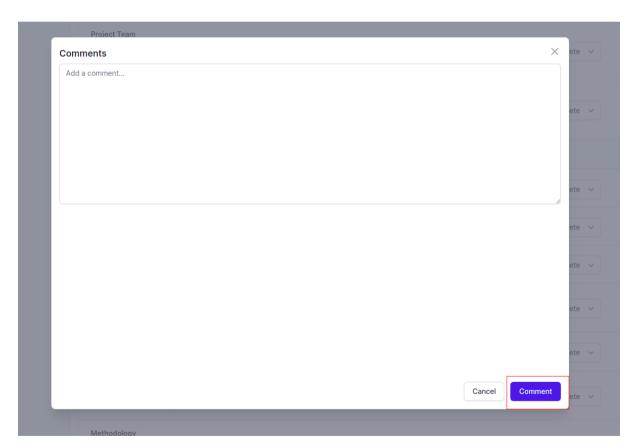| ○ No prospect of direct benefit to individual participants, but likely to yield generalizable knowledge about the participant' disorder or condition	○ No prospect of direct benefit to individual participants, but likely to yield generalizable knowledge to further society's understanding or the disorder or condition under study
○ The research involves the prospect of direct benefit to individual participants	

Save

10. This icon will show all the comments done by each individual reviewer inside the comment box. Secretariat will be able to edit the comments and finalise the comment given in the comments box. Additional sentences and comments can be inserted by the secretariat at this stage. Click the "comment button" to enter the final compilation comment (this is the comment investigator will be able to see during the revision)

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10. Compilation comments can also be seen by clicking chat icon (green box) next to comment icon (investigator response later will be displayed after the revision has been submitted by the investigator)
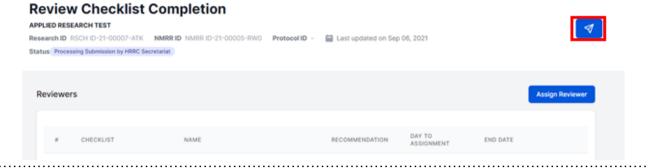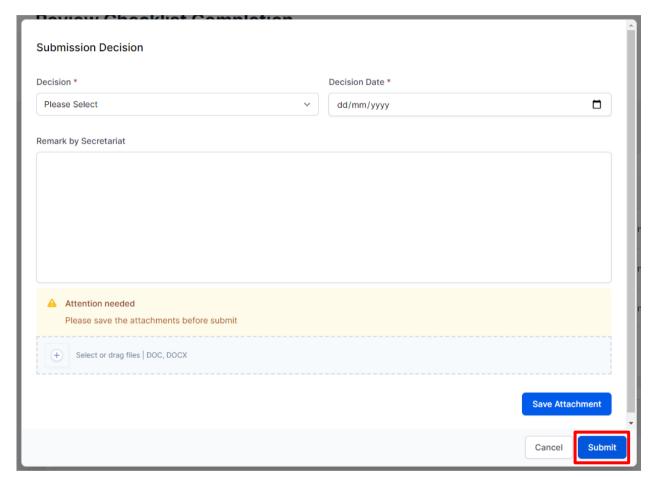

11. Click on the decision icon button on the top right to assign a decision. A selection of decisions should be listed according to the following: -
   - Processing Submission by MREC Secretariat
   - Revision Required (if revision is required, an end date can be inserted to give a timeline to the investigator)
   - Undergoing Expedited Review by MREC Chairperson/Deputy Chairperson
   - Undergoing Expedited Review by MREC Primary Reviewers
   - Queue For MREC Full Board Review
   - Undergoing MREC Full Board Review
   - Approval Granted via Expedited Review by MREC Chairperson/Deputy Chairperson
   - Approval Granted via MREC Chairperson/Deputy Chairperson
   - Approval Granted via MREC Full Board
   - Exempted from MREC Review
   - Disapproved
   - Research started before registering to NMRR. MREC will not review
   - Withhold
   - MREC is preparing decision Letter

Review Checklist Completion

APPLIED RESEARCH TEST

Research ID RSCH ID-21-00007-ATK   **NMRR ID** NMRR ID-21-00005-RW0   **Protocol ID** -   🗓 Last updated on Sep 06, 2021

Status Processing Submission by HRRC Secretariat

Reviewers

Assign Reviewer

#	CHECKLIST	NAME	RECOMMENDATION	DAY TO ASSIGNMENT	END DATE

Review Checklist Completion

Submission Decision

Decision *

Please Select ⌄

Decision Date *

dd/mm/yyyy 🗓

Remark by Secretariat

⚠ **Attention needed**

Please save the attachments before submit

⊕ Select or drag files | DOC, DOCX
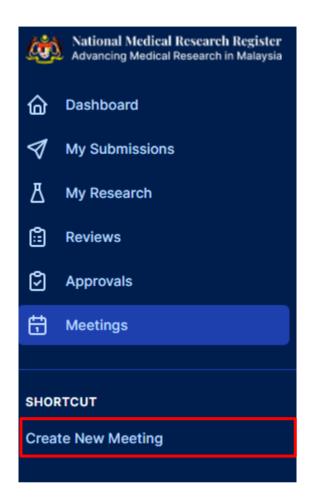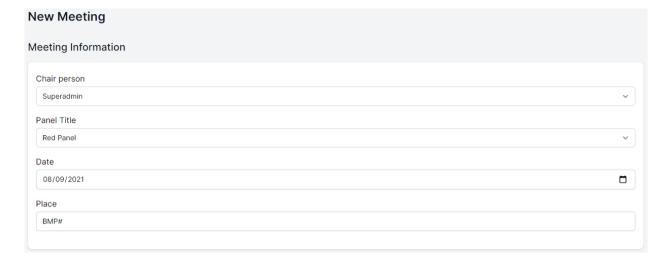
Save Attachment

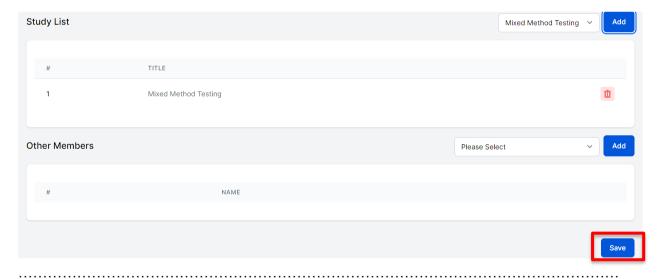**Cancel**   **Submit**

End of Flow

1.3- JPP NIH Meeting Setup

1. Go to the url https://nmrr.gov.my
2. Login as necessary individual with assigned role as MREC Secretariat .
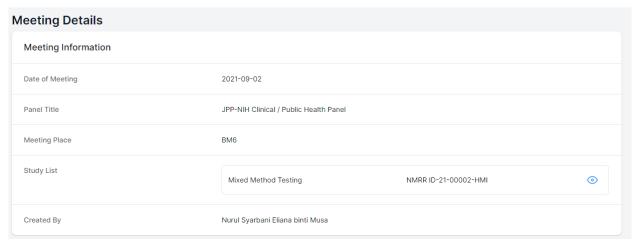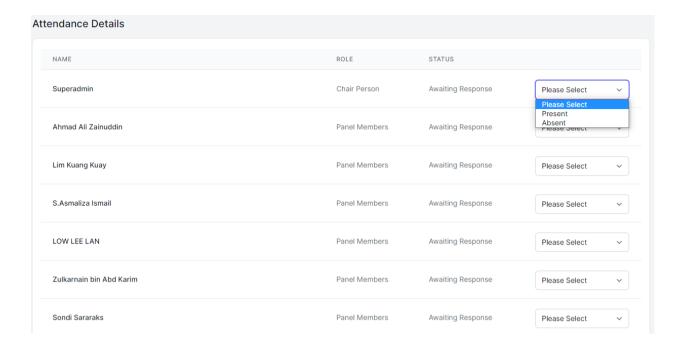3. Click on the create meeting on the left of the page

4. Fill in the title, panel and other necessary information. The chairperson should be selected from either MREC Chairperson or Deputy Chairperson. Panel Title should be selected either Blue Panel, Red Panel of Conjoint Panel. Selection of the panel title will lead to panel member list to be shown automatically and secretariat and choose to add additional members from outside of the panel if necessary.

New Meeting

Meeting Information

Chair person

| Superadmin | ⌄ |

Panel Title

| Red Panel | ⌄ |

Date

| 08/09/2021 | 📅 |

Place

| BMP# |

5. The study list will appear from the list of studies assigned with "Queue for MREC Full Board Meeting". Once the information has been completed, click on the save/create button. A meeting file should be created with a list of attendance for the upcoming meeting. An email will be sent to all attendees for confirmation.

Study List   [Mixed Method Testing ⌄] [Add]

#	TITLE	
1	Mixed Method Testing	🗑

Other Members   [Please Select ⌄] [Add]

#	NAME

[Save]

. . . .

Meeting Details

Meeting Information

Date of Meeting	2021-09-02
Panel Title	JPP-NIH Clinical / Public Health Panel
Meeting Place	BM6
Study List	Mixed Method Testing NMRR ID-21-00002-HMI 👁
Created By	Nurul Syarbani Eliana binti Musa

Attendance Details

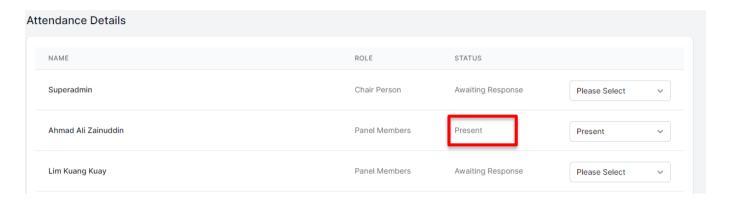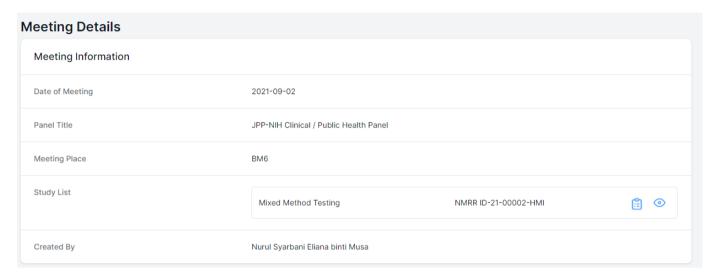| NAME	ROLE	STATUS	
Superadmin	Chair Person	Awaiting Response	Please Select ▾
			Please Select
			Present
			Absent
Ahmad Ali Zainuddin	Panel Members	Awaiting Response	Please Select ▾
Lim Kuang Kuay	Panel Members	Awaiting Response	Please Select ▾
S.Asmaliza Ismail	Panel Members	Awaiting Response	Please Select ▾
LOW LEE LAN	Panel Members	Awaiting Response	Please Select ▾
Zulkarnain bin Abd Karim	Panel Members	Awaiting Response	Please Select ▾
Sondi Sararaks	Panel Members	Awaiting Response	Please Select ▾

6. Secretariat may access the previous list and edit/ upload the meeting minute by clicking the meeting tab on the left side of the page
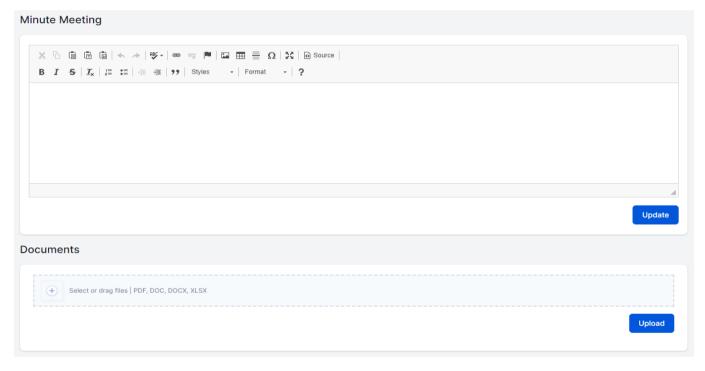
7. If Attendees/ Panel members answer the attendance confirmation, his or her status will be shown at the secretariat display (selection will be dimmed indicating the attendee's selection to the meeting)

Attendance Details

NAME	ROLE	STATUS	
Superadmin	Chair Person	Awaiting Response	Please Select ⌄
Ahmad Ali Zainuddin	Panel Members	Present	Present ⌄
Lim Kuang Kuay	Panel Members	Awaiting Response	Please Select ⌄

8. The Meeting minutes and appendix will be able to be generated by secretariat, downloaded (if necessary). Secretariat will be able to upload file too ifneeded. Attendees will be able to see the list of the study and all the appendix generated for a particular meeting minutes and will be able to give comments as well for the study list tabled during the meeting (which will be included during the completion process). The meeting minute and document also can be view by all the members attended the meeting

Meeting Details

Meeting Information

Date of Meeting	2021-09-02
Panel Title	JPP-NIH Clinical / Public Health Panel
Meeting Place	BM6
Study List	Mixed Method Testing NMRR ID-21-00002-HMI
Created By	Nurul Syarbani Eliana binti Musa

Minute Meeting

B I S I_x Styles Format ?

Update

Documents

(+) Select or drag files | PDF, DOC, DOCX, XLSX

Upload

End of Flow