

User Guideline

MREC Reviewer

National Medical Research Register v2.0

National Institutes of Health (NIH)

Version 1.0, April 2022

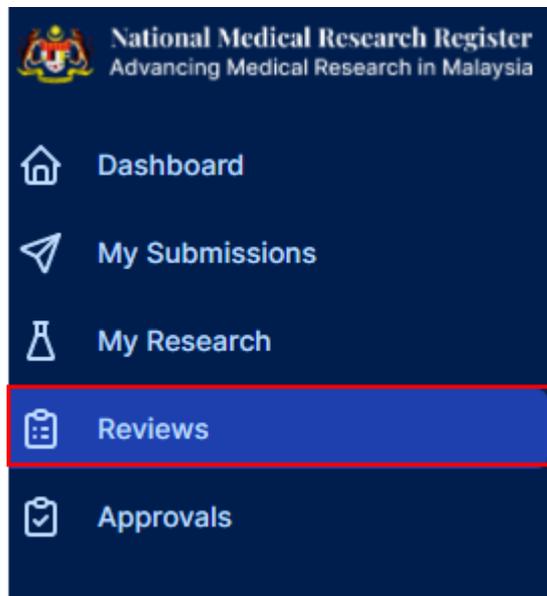
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1.0 – Flow & Function of MREC Reviewer

1.1 - As MREC Reviewer (Submission Review)

1. Go to the url <https://www.nmrr.com>
2. Login as a necessary individual with an assigned role as MREC Reviewer and the Reviewer page located at the left side.



3. Should be able see the submission under the assigned secretariat. (It should be stated as (Undergoing Expedited Review by MREC Chairperson/Deputy Chairperson, Undergoing Expedited Review by MREC Primary Reviewer, Queue for MREC Full Board Review)

Submission Review Approval

Keyword: Status:

Show entries

#	Research ID	NMRR ID	Title	Status	Day To Submission	Action
1	RSCH ID-21-00002-VO3	NMRR ID-21-00006-UBY	qualitative test	Undergoing Expedited Review by MREC Chairperson/ Deputy Chairperson	0	

- Click on the view data (eye icon) to go into that submission details and to review the submission, go into the Processing Submission page (paper icon)

Submission Review Approval

Keyword: Status:

EXCEL PDF Show 10 entries

#	Research ID	NMRR ID	Title	Status	Day To Submission	Action
1	RSCH ID-21-00002-VO3	NMRR ID-21-00006-UBY	qualitative test	Undergoing Expedited Review by MREC Chairperson/ Deputy Chairperson	0	 

- Click on the (eye icon) to go into the submission details and to access the checklist and recommendation selection, click the review checklist page (paper icon)

Review Revisions

EXCEL PDF Show 10 entries

#	Revision ID	Secretariat	Created Date	Action
1	REV ID-21-00022-MRH	MREC Secretariat	08-09-2021	  

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- Reviewer may choose the status of each item by clicking on the status dropdown

REVIEW REPORT OF RESEARCH PROTOCOLS INVOLVING HUMAN SUBJECTS

All(55) Yes(0) No(0) Not Relevant(0) Complete(55) Not Complete(0)

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	 
1.4 Is the name and institution of investigator/s stated?	Complete	 
1.5 Is the study site appropriate in terms of facilities, expertise, patient populations, etc?	Complete	 
1.6 Is there sufficient and appropriate expertise and experience in the study team?	Complete	 

7. If there is any query or revision required, click on the comment button to add a comment. Click the “comment button” to enter and save the comment intended for the investigator

REVIEW REPORT OF RESEARCH PROTOCOLS INVOLVING HUMAN SUBJECTS

All(55) Yes(0) No(0) Not Relevant(0) Complete(55) Not Complete(0)

DATA	STATUS	COMMENTS
1. General Information		
1.1 Is study title appropriate?	<input type="text" value="Complete"/>	 
1.2 Is there a protocol identifying number and date?	<input type="text" value="Complete"/> <input type="text" value="Yes"/> <input type="text" value="No"/> <input type="text" value="Not Relevant"/> <input type="text" value="Complete"/> <input type="text" value="Not Complete"/>	 
1.3 Is the name and address of sponsor stated?	<input type="text" value="Complete"/>	 
1.4 Is the name and institution of investigator/s stated?	<input type="text" value="Complete"/>	 
1.5 Is the study site appropriate in terms of facilities, expertise, patient populations, etc?	<input type="text" value="Complete"/>	 
1.6 Is there sufficient and appropriate expertise and experience in the study team?	<input type="text" value="Complete"/>	 

Comments

no complete

8. For minimal risk study (Undergoing Expedited Review by MREC Chairperson/Deputy Chairperson) the reviewer will insert the assessment by filling up the form and click save. If there is any query or revision required, click on the comment button at the “minimal risk overall comment”. Click the “comment button” to enter and save the comment intended for the investigator

MINIMAL RISK STUDY/ MINIMAL RISK REVIEW

DATA	STATUS	COMMENTS
Minimal Risk Overall Comment	<input type="text"/>	<input type="button" value="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

9. For other type of review, compilation comments can be seen by clicking the compilation & response icon (green box) next to the comment icon (investigator response later will be displayed after the revision has been submitted by the investigator). The compilation is used during the revision reassignment by the reviewer. Reviewers will be able to see the compilation of comment and investigator answers as below

Justification	
1) (Is the rationale/justification for the study clearly stated in the context of present knowledge?)	Not Complete <input type="button" value="v"/>  
2) (Does the project address important/relevant scientific/public health issues?)	Not Complete <input type="button" value="v"/>  
3) (Will the proposed research contribute new knowledge in the subject area?)	Not Complete <input type="button" value="v"/>  
Objectives (Are the objectives and/or hypothesis clearly stated and realistic (Specific, Measurable, Achievable, Resourced within the project and Time bound))	Not Complete <input type="button" value="v"/>  
Expected Outcome and Output (What are the intended outputs and outcomes?)	Not Complete <input type="button" value="v"/>  
Stakeholder	

Comments ✕

“Compilation comment made by secretariat”
.....

“Investigator answers to the query”
.....

10. Grouping of status can be used as a guide to reviewers to see which item are complete, not complete and etc.

REVIEW REPORT OF RESEARCH PROTOCOLS INVOLVING HUMAN SUBJECTS

All(55) Yes(0) No(0) Not Relevant(0) Complete(55) Not Complete(0)

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	 
1.4 Is the name and institution of investigator/s stated?	Complete	 
1.5 Is the study site appropriate in terms of facilities, expertise, patient populations, etc?	Complete	 
1.6 Is there sufficient and appropriate expertise and experience in the study team?	Complete	 

11. Once the review is complete, the reviewer will then select the recommendation at the end of the checklist. Click the submit button to notify the Secretariat regarding the completion and the recommendation made. (Applicable for all type of review; minimal risk, medium and high-risk study)

Reviewer Feedback & Recommendation

Feedback

Submission Recommendation

Unable to review 

12. Once the submit button is clicked, all the status and the recommendation will not be able to be changed.

Miscellaneous

13.1 Is the grammar and language acceptable? Complete  

13.2 Additional Document & Comment from Reviewers Complete  

Reviewer Feedback & Recommendation

Feedback

Submission Recommendation

Revision Required, Go back to Secretariat ▼

13. Once all required review is completed, the list of review will be disappeared from the submission review dashboard

Submission Review

Keyword Status Select All ▼

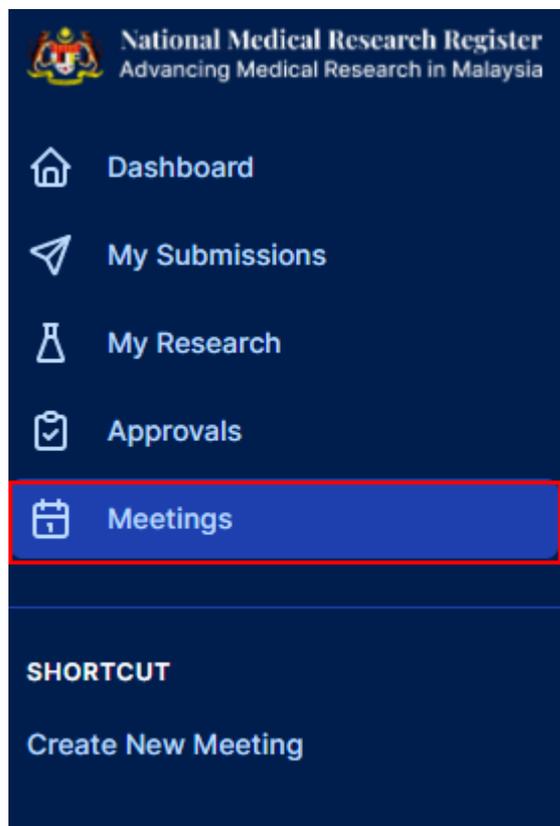
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#	Research ID	NMRR ID	Title	Status	Day To Submission	Action
No data available in table						

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1.2 – Meeting Attendance

1. Go to the url <https://www.nmrr.com>
2. Login as individual (with assigned role as MREC Reviewer – either Red or Blue Panel)
3. Click on the “Meetings” icon menu selection over the left side of the display page



4. Select the intended upcoming meeting by clicking on the view (eye) icon present under “action” column

Meetings

Title: Place: Meeting Date:

Show entries

TITLE	PLACE	MEETING DATE	ACTION
Blue Panel	Bilik Mesyuarat Pintar 3, Level 4, Block D2, NIH Setia Alam	2021-10-26	
Red Panel	Bilik Mesyuarat Pintar 3, Level 4, Block D2, NIH Setia Alam	2021-10-12	

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- 5. Panels should be able to view the meeting details with all the study list attachment uploaded by Secretariat

Meeting Details

Meeting Information	
Date of Meeting	2021-10-12
Panel Title	Red Panel
Meeting Place	Bilik Mesyuarat Pintar 3, Level 4, Block D2, NIH Setia Alam
Study List	<p>A Phase 2/3, randomized, double-blind, placebo-controlled study to evaluate the efficacy and safety of orally administered SKF7™ (Standardized NMRR ID-21-01963-QGE extract of Labisia pumila) in the clinical improvement of category 3 COVID-19 patients.</p>  
Created By	Asyraf Syahmi Bin Mohd Noor

- 6. Individual attendees for specific panels and other additional people should be able to see their name listed in Attendance Details while selection is displayed to whether they will be “present” or “not able to present”

Meeting Details

Meeting Information	
Date of Meeting	2021-10-12
Panel Title	Red Panel
Meeting Place	Bilik Mesyuarat Pintar 3, Level 4, Block D2, NIH Setia Alam
Study List	<p>A Phase 2/3, randomized, double-blind, placebo-controlled study to evaluate the efficacy and safety of orally administered SKF7™ (Standardized NMRR ID-21-01963-QGE extract of Labisia pumila) in the clinical improvement of category 3 COVID-19 patients.</p>  
Created By	Asyraf Syahmi Bin Mohd Noor

Attendance Details

NAME	ROLE	STATUS
Dr Salina Binti Abdul Aziz	Chair Person	Awaiting Response



- By clicking the attendance selection, upcoming attendance confirmation will be updated to the Secretariat. If panel is unable to attend the upcoming meeting, reason can be stated to notify secretariat regarding the absence.

Attendance Details

NAME	ROLE	STATUS
Dr Salina Binti Abdul Aziz	Chair Person	Awaiting Response
Tuan Abdullah	Panel Members	Awaiting Response
Dr Sondri Sararaks	Panel Members	Awaiting Response

Not Able to Present

Reason

- Panel members will be able to see the list of studies that is going to be tabled during the upcoming meeting and documents uploaded (if any) during the meeting. To see the documents and review made by the reviewers assigned for the submission, click on the view (eye) icon while to insert comment related to the submission, click on the comment (paper) icon. All panels present during the meeting will be able to make comments to the study list by clicking on the comment icon in the study list (available only during the meeting day).

Meeting Details

Meeting Information

Date of Meeting: 2021-10-12

Panel Title: Red Panel

Meeting Place: Bilik Mesyuarat Pintar 3, Level 4, Block D2, NIH Setia Alam

Study List

A Phase 2/3, randomized, double-blind, placebo-controlled study to evaluate the efficacy and safety of orally administered SKF7™ (Standardized NMRR ID-21-01963-QGE extract of Labisia pumila) in the clinical improvement of category 3 COVID-19 patients.




Created By: Asyraf Syahmi Bin Mohd Noor