

User Guidelines for
Post Ethical Approval Submission
- Renewal

National Medical Research Register v2.0

National Institutes of Health (NIH)

Version 1.0 , May 2023

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Prerequisite For Submission

ID	Criteria
1.1	User has the access to NMRR Version 2.0 (nmrr.gov.my) via a stable internet connection
1.2	Prerequisite: <ul style="list-style-type: none"> ● Should logged in as Investigator or Clinical Research Associates (CRA) ● Should have completed the profile page ● Should have a submission submitted, registered successfully in NMRR issued NMRR ID) ● Submission has received Initial Ethical Approval from MREC (Approval granted via Expedited Review by MREC Chairperson/ Deputy Chairperson or Approval granted via Expedited Review by MREC Primary Reviewers or Approval granted via MREC Full Board)
1.3	User has a role assigned in an approved submission either as: <ul style="list-style-type: none"> ● Principal / Coordinating Investigator (PI) ● Main Corresponding Person (Main CP) ● Backup Corresponding Person (Backup CP)

Information/ Documents Required

Declaration on Study Information

1. Study Status
2. Summary of Study Subjects In MREC Approved Sites
 - a. Expected number of subjects/participants approved by MREC.
 - b. Total number subjects enrolled since study was initiated.
 - c. Reason of enrollment no. up to date is below or above the expected.
3. Summary of study data/biological specimens /archive samples
 - a. Expected number of study data/biological specimens /archive samples approved by MREC.
 - b. Total number of study data/biological specimens /archive samples collected since study was initiated.
 - c. Reason of collection no. up to date is below or above the expected.
 - d. Has Any Subject Withdrawn/ Terminated from This Study (MREC Approved Site Only) Since the Last MREC Ethical Approval Renewal?
 - i. Subject Withdrawn/ Terminated from This Study (MREC Approved Site Only) – if the selection on “3d” is Yes
 - e. Has there been new/ additional investigational new drug/ device registration

associated with this study since the last MREC initial approval/ Ethical Approval Renewal?

- f. Has any information appeared in the literature, or evolved from this or similar research that might affect MREC's evaluation of the risks / benefits on human subjects involved in this study since the last MREC initial approval/ Ethical Approval Renewal? (Eg: Investigator Brochure, Data Safety Monitoring Board Report, etc)
- g. Has any investigator developed equity or consultative relationship with a source related to this study which might be considered a conflict of interest since the last MREC initial approval/ Ethical Approval Renewal?
- h. Has the study trial insurance been updated since the last MREC initial approval/ Ethical Approval Renewal?

Declaration on Study Amendment Information

1. List of amendment that has been approved since initial approval/last Ethical Approval Renewal
2. Is there any amendment that has been made to the study without MREC approval? *

Declaration of Protocol Deviation/Violation (PD/PV)

1. List of PD/PV submitted to MREC for the NMRR ID since initial approval up to date of the submission of Ethical Approval Renewal with status decision.
2. Acknowledgement by CP

Declaration of Serious Adverse Event (SAE) Reporting & SUSAR

1. List of SAE submitted to MREC for the NMRR ID since initial approval up to date of the submission of Ethical Approval Renewal with status decision.
2. List of Global SUSAR submitted to MREC for the NMRR ID since initial approval up to date of the submission of Ethical Approval Renewal with status decision.
3. Are there any outstanding actions that the Data Safety Monitoring Board, or another EC has requested you take with regard to any problems or adverse events?
4. Acknowledgement by CP

Declaration of Information

1. Is this annual Ethical Approval Renewal application being submitted past the expiration date of MREC ethical approval? *Corresponding Person

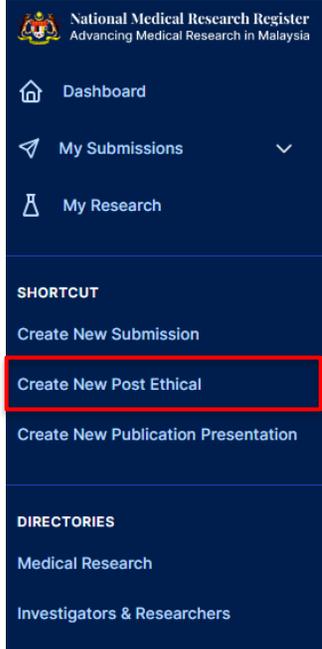
Amendment Documents

1. Cover Letter
2. Supporting Documents

User Guidelines for Submission

1.0 - New Ethical Renewal Submission

1.1 – Creating an Ethical Renewal Submission

No	Step-by-step instructions	Remark
1.	<p>Log in as Investigator or CRA in NMRR</p> 	
2.	<p>Scroll over the main menu located on the side of the display page, go to shortcut, and select Create New Post Ethical</p> 	<p>Shortcut access “Create New Post Ethical” is only available when user has a submission that has received an Initial Ethical Approval from MREC & user has been assigned with a role either as:</p> <ul style="list-style-type: none"> • Principal / Coordinating Investigator (PI) • Main Corresponding Person (Main CP) • Backup Corresponding Person (Backup CP)

3. A list of all submission that has received MREC initial Ethical Approval will be shown on display. Go to “Select Post Ethical Approval Type” and choose “Ethical Approval Renewal.”

New Post Ethical Approval

Keyword

Select Post Ethical Approval Type

- Select All
- Amendment
- Acknowledgement of Receipt (AOR)
- Closure \ Termination
- Global SUSAR
- Protocol Deviation
- Ethical Approval Renewal**
- Serious Adverse Event (SAE)

Show 10 entries

#	NMRR ID	TITLE	RESEARCH SCOPE	RESEARCH TYPE	STATUS	ACTION
1	NMRR-10-2180-28521	Therapeutic Drug Monitoring of Intraperitoneal Anticancer Agents and Neurokinin in Peritoneal Disease Patients with Peritonitis and Their Effect on Recidual Bursal Function.	Clinical		Full Board	
2	NMRR-17-2071-27438	The Role of Intraperitoneal Resiquimod in Peritoneal Disease Related Tumor Peritonitis: Ten-year Review from a Malaysian Center.	Clinical	Observational	Approval granted via Expedited Review by MREC Chairperson/ Deputy Chairperson	
3	NMRR-20-2186-27762	A comparison between the effect of various antidiabetic agents versus insulin in diabetic patients with Type 2 Diabetes Mellitus in a cross-sectional study.	Clinical	Interventional	Approval granted via MREC Full Board	

Once Ethical Approval Renewal is selected, list of submission accessible for Renewal Submission will be displayed.

New Post Ethical Approval

Keyword

Select Post Ethical Approval Type

Show 10 entries

#	NMRR ID	TITLE	RESEARCH SCOPE	RESEARCH TYPE	STATUS	ACTION
1	NMRR-08-425-1086	Amputation Versus Acetylsalicylic Acid (ASA) to Prevent Stroke in Stroke/Paralysis Patients Who Have Failed or are Unavailable for Venous Thrombolysis Treatment	Clinical	Interventional	Approval granted via MREC Full Board	
2	NMRR-09-223-1080	A Multicenter, Randomized, Double-Blind, Active-Controlled Study to Evaluate the Durability of the Efficacy and Safety of Rosiglitazone Compared to Glimepiride When Used in Combination with Metformin in Subjects with Type 2 Diabetes	Clinical	Interventional	Approval granted via MREC Full Board	

4. Click on the  icon to create a New Ethical Renewal Submission

New Post Ethical Approval

Keyword Select Post Ethical Approval Type Ethical Approval Renewal

Show 10 entries

#	NMRR ID	TITLE	RESEARCH SCOPE	RESEARCH TYPE	STATUS	ACTION
1	NMRR ID 433-1000	Aspirin Versus Acetylsalicylic Acid (ASA) to Prevent Stroke in Atrial Fibrillation Patients Who Have Failed or are Unsuitable for Vitamin K Antagonist Treatment	Clinical	Interventional	Approval granted via MREC Full Board	
2	NMRR ID 210-1000	A Multicenter, Randomized, Double-Blind, Active-Controlled Study to Evaluate the Efficacy and Safety of Abigatinib Compared to Placebo When Used in Combination with Metformin in Subjects with Type 2 Diabetes	Clinical	Interventional	Approval granted via MREC Full Board	

****Only one submission of Ethical Renewal per NMRR ID is allowed at one time.**

5. A page will be displayed with the General information of the Submission is shown over the top part of the display page.

Ethical Approval Renewal Submission

ASPIRIN VERSUS ACETYSALICYLIC ACID (ASA) TO PREVENT STROKE IN ATRIAL FIBILLATION PATIENTS WHO HAVE FAILED OR ARE UNSUITABLE FOR VITAMIN K ANTAGONIST TREATMENT

NMRR ID NMRR ID 433-1000 Protocol ID CV180006  Last updated on Sep 24, 2021

Status Approval granted via MREC Full Board

Ethical Approval Renewal Status Pending Submission

An Ethical Approval Renewal Status will be displayed as **“Pending Submission”**. This information can be seen over the top part of the display page

6.

Scroll down the page to the “Declaration of Study Information ” .Insert information on regarding the study status and summary of study subject in MREC approved site followed by information on the summary of study data/biological specimens/ archieve samples and other relevant changes. Then click  to save the information .

①

Declaration on Study Information

Study Status *

Not Yet Recruiting

Summary of Study Subjects In MREC Approved Sites

Expected number of subjects/participants approved by MREC

6

Total number subjects enrolled since study was initiated

Reason of enrollment no up to date is below or above the expected

.....

Study Status *

Not Yet Recruiting

Not Yet Recruiting

Recruiting /Active Enrolment

Study Suspended/Withhold

Active, not recruiting /Closed Enrolment

Completed follow up

②

Summary of study data/biological specimens /archive samples

Expected number of study data/biological specimens /archive samples approved by MREC

24

Total number of study data/biological specimens /archive samples collected since study was initiated

Reason of collection no up to date is below or above the expected

③

Has Any Subject Withdrawn/ Terminated from This Study (MREC Approved Site Only) Since the Last MREC ethical Ethical Approval Renewal? *

Yes

No

Not applicable

Has there been any change in the subject population, recruitment or selection criteria since the last MREC initial approval/ Ethical Approval Renewal? *

Yes

No

④

Has there been new/ additional investigational new drug/ device registration associated with this study since the last MREC initial approval/ Ethical Approval Renewal? *

Yes

No

Has any information appeared in the literature, or evolved from this or similar research that might affect MREC's evaluation of the risks / benefits on human subjects involved in this study since the last MREC initial approval/ Ethical Approval Renewal? (Eg: Investigator Brochure, Data Safety Monitoring Board Report, etc) *

Yes

No

Not applicable

Has any investigator developed equity or consultative relationship with a source related to this study which might be considered a conflict of interest since the last MREC initial approval/ Ethical Approval Renewal? *

Yes

No

Has the study trial insurance been updated since the last MREC initial approval/ Ethical Approval Renewal? *

Yes

No

Not applicable

Save

A popup will appear indicating the Declaration of Study Information has been successfully saved.

Save

✔ Declaration on Study Information Information Saved.

Once “Declaration of Study Information” is saved, an Ethical Approval Renewal Post Ethical ID will be generated.

Ethical Approval Renewal Submission

AN OPEN LABEL, EXTENSION STUDY TO EVALUATE THE LONG TERM SAFETY, TOLERABILITY, AND EFFICACY OF PROLINE AND CORTICOSTEROID COMBINATION THERAPY IN PATIENTS WITH PRAECOXIDEMIA, ACUTE CHRONIC HEPATITIS C

NMRR ID [NMRR ID-23-00005-ESG](#) Protocol ID [R3310 \(Phase 2\)](#) Last updated on Dec 02, 2022

Status: Approval granted via MREC Full Board

Ethical Approval Renewal Post Ethical ID [RNW ID-23-00005-ESG](#)

Ethical Approval Renewal Status: Pending Submission

Ethical Approval Renewal Post Ethical ID will be the reference number for the Ethical Renewal Submission from this point onwards. Once an Amendment Ethical Approval Renewal Post Ethical ID is generated, Ethical Renewal submission has now been created successfully and is available to be accessed from “My Submission” menu. **Ethical Approval Renewal Post Ethical ID** later in the submission will also be referred to as **Ethical Renewal Submission ID**

7. Scroll down to “Declaration on Study Amendment Information” section

Declaration on Study Amendment Information

List of amendment that has been approved since initial approval/last Ethical Approval Renewal

AMENDMENT ID	DECISION DATE	DECISION
No records available		

Is there any amendment that has been made to the study without MREC approval? *

Yes No

[Save](#)

.....

If previously submission had any amendment submission that has been approved by MREC, the list will be shown. User is required to acknowledge and declare if there are any amendment made without the MREC approval. Then click [Save](#) to save the information .

Declaration on Study Amendment Information

List of amendment that has been approved since initial approval/last Ethical Approval Renewal

AMENDMENT ID	DECISION DATE	DECISION
AMDT ID-23-00001-HI5	28/03/2023	Approval granted via Expedited Review by MREC Chairperson/ Deputy Chairperson

Is there any amendment that has been made to the study without MREC approval? *

Yes No

[Save](#)

.....

Is there any amendment that has been made to the study without MREC approval? *

Yes No

Save

If the answer is “Yes” , insert explanation regarding the amendment and why it was not notified.

Is there any amendment that has been made to the study without MREC approval? *

Yes No

Explain

[Empty text area for explanation]

Once the “Declaration on Study Amendment Information” is saved , a popup up will appear indicating the section has been succesfully saved.

Save

✔ Declaration on Study Amendment Information Information Saved.

8. Then, scroll down to the “Declaration of Protocol Deviation/Violation (PD/PV)” section. A list of all PD/PV submission and it’s current status will be displayed. User is required to acknowledge the listing and then click  to save the information .

Declaration of Protocol Deviation/Violation (PD/PV)

List of PD/PV submitted to MREC for the NMRR ID since initial approval up to date of the submission of Ethical Approval Renewal with status decision

PD ID	DECISION DATE	DECISION
No records available		

Acknowledgement by CP *

Yes No



Acknowledgement by CP *

Yes No

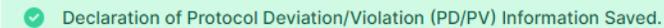


Once the “Declaration of Protocol Deviation/Violation (PD/PV)” is saved , a popup up will appear indicating the section has been succesfully saved.

Acknowledgement by CP *

Yes No



 Declaration of Protocol Deviation/Violation (PD/PV) Information Saved.

9. Then, scroll down to the “Declaration of Serious Adverse Event (SAE) Reporting & SUSAR” section. A list of all SAE, SUSAR & Global SUSAR submission and it’s current status will be displayed. User is required to acknowledge the listing and then click  to save the information .

Declaration of Serious Adverse Event (SAE) Reporting & SUSAR

List of SAE submitted to MREC for the NMRR ID since initial approval up to date of the submission of Ethical Approval Renewal with status decision

SAE ID	DECISION DATE	DECISION
No records available		

List of Global SUSAR submitted to MREC for the NMRR ID since initial approval up to date of the submission of Ethical Approval Renewal with status decision

GLOBAL SUSAR ID	DECISION DATE	DECISION
No records available		

Are there any outstanding actions that the Data Safety Monitoring Board, or another EC has requested you take with regard to any problems or adverse events? *

Yes No

Acknowledgement by CP *

Yes No



.....

User is also require to declare on any outstanding action by the Data Safety Monitoring Board (DSMB) or other Ethical Commiitee (EC) with regards on any adverse event that happened

Are there any outstanding actions that the Data Safety Monitoring Board, or another EC has requested you take with regard to any problems or adverse events? *

Yes No

Acknowledgement by CP *

Yes No



If the answer is "Yes", insert explanation regarding the action and DSMB or EC decision.

Are there any outstanding actions that the Data Safety Monitoring Board, or another EC has requested you take with regard to any problems or adverse events? *

Yes

No

Explain

Once the "Declaration of Serious Adverse Event (SAE) Reporting & SUSAR" is saved , a popup up will appear indicating the section has been succesfully saved.

Save

✔ Declaration of Serious Adverse Event (SAE) Reporting & SUSAR Information Saved.

10. Next, scroll down to the “Declaration of Information” section. If this submission is done past the expiry date (the selection is “Yes”), user is required to declare with regard to the research-related activities .Then click  to save the information .

Declaration of Information

Is this annual Ethical Approval Renewal application being submitted past the expiration date of MREC ethical approval? *

Yes

No



Is this annual Ethical Approval Renewal application being submitted past the expiration date of MREC ethical approval? *

Yes

No

If you are submitting this Ethical Approval Renewal after the expiration date of MREC ethical approval, were research-related activities conducted during the time MREC approval of this research was expired? *

Yes

No

If you are submitting this Ethical Approval Renewal after the expiration date of MREC ethical approval, were research-related activities conducted during the time MREC approval of this research was expired? *

Yes

No

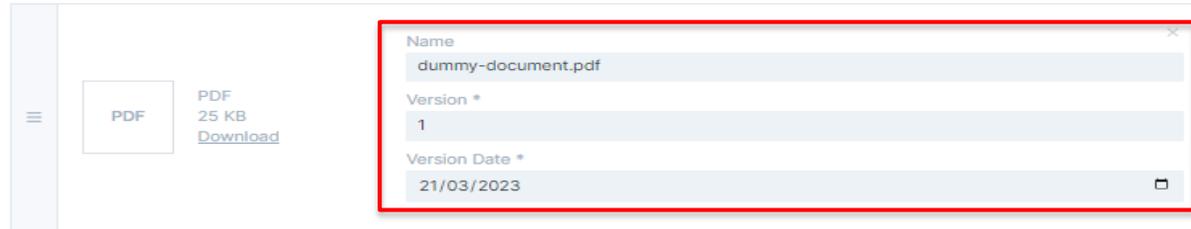
Explain

	<p>Is this annual Ethical Approval Renewal application being submitted past the expiration date of MREC ethical approval? *</p> <p> <input type="radio"/> Yes <input checked="" type="radio"/> No </p> <p style="text-align: right;">Save</p> <p>Once the “Declaration of Information” is saved , a popup up will appear indicating the section has been succesfully saved.</p> <p style="text-align: right;">Save</p> <p style="background-color: #e0ffe0; padding: 5px;">✔ Declaration of Information Saved.</p>	
<p>11.</p>	<p>Once all information has been added and saved, continue to scroll down the page. “Ethical Approval Renewal Documents” part will be availble for user to upload the relevent supporting documents.</p> <div style="border: 1px solid #ccc; padding: 10px; margin-bottom: 10px;"> <p>Ethical Approval Renewal Documents</p> <p>Cover Letter *</p> <p style="text-align: right;">View Document History</p> <div style="border: 1px dashed #ccc; padding: 5px; margin-bottom: 5px;"> + Select or drag files PDF </div> <p>Other Supporting Documents</p> <p style="text-align: right;">View Document History</p> <div style="border: 1px dashed #ccc; padding: 5px; margin-bottom: 5px;"> + Select or drag files PDF </div> <p style="text-align: right;">Save</p> </div> <p>User can upload the “Cover Letter ” and “ Other Supporting Document” by either click on the + icon to acces the document file or by dragging the document over the box available.</p>	<p>**Only PDF format file is allowed to be uploaded in this section</p>

Once it has been uploaded, user can insert a version and version date to the uploaded document (if any). File name can also be changed if needed. Once all documents have been uploaded, Click [Save](#) to complete and save the uploaded documents.

Cover Letter *

[View Document History](#)



The screenshot shows a document card for 'dummy-document.pdf' (25 KB) with a 'Download' link. A popup window is open over the card, containing the following fields:

Name	dummy-document.pdf
Version *	1
Version Date *	21/03/2023

Other Supporting Documents

[View Document History](#)



The screenshot shows a file upload area with a plus icon and the text "Select or drag files | PDF".

[Save](#)

A popup up will appear indicating the "Supporting Documents" has been successfully saved

[Save](#)

✔ Supporting Document Information Saved.

Please ensure the file name has extension ".pdf" at the end of its name. Files without the extension ".pdf" may have the risk of not being able to be read later

8.

Next, user needs to acknowledge the submission made at the “Acknowledgement by Corresponding Person ” section.

Acknowledgement by Corresponding Person

I declare that the information provided above is true & correct to the best of my understanding (CP will need to click this choice and an email to PI will be sent to notify the PI regarding this submission) Failure to declare all ethical approval renewal information will results in submission will not be processed further and disapproval by MREC

Submit

Tick on the box “Yes, I declare that the information provided above is true & correct to the best of my understanding (CP will need to click this choice and an email to PI will be sent to notify the PI regarding this submission) Failure to declare all ethical approval renewal information will results in submission will not be processed further and disapproval by MREC.”

Acknowledgement by Corresponding Person

I declare that the information provided above is true & correct to the best of my understanding (CP will need to click this choice and an email to PI will be sent to notify the PI regarding this submission) Failure to declare all ethical approval renewal information will results in submission will not be processed further and disapproval by MREC

Submit

Once submission has been acknowledged, user can submit the Ethical Approval Renewal Submission by clicking the  button.

Acknowledgement by Corresponding Person

I declare that the information provided above is true & correct to the best of my understanding (CP will need to click this choice and an email to PI will be sent to notify the PI regarding this submission) Failure to declare all ethical approval renewal information will results in submission will not be processed further and disapproval by MREC

Submit

Please ensure all the relevant ethical approval renewal information has been filled up and all the documents required has been uploaded and saved

Once a new Ethical Approval Renewal submission has been successfully submitted, user will be brought the Ethical Approval Renewal Submission listing page.

Ethical Approval Renewal

Keyword Status

EXCEL PDF Show 10 entries

#	NMRR ID	TITLE	ETHICAL RENEWAL ID	STATUS	DATE OF SUBMISSION	ACTION
1			RNW ID-23-00005-ESG	Processing Submission by MREC Secretariat	01/04/2023	

When viewing the data of Ethical Approval Renewal submission, the General information of the Submission will be shown on the top part of the display page.

Ethical Approval Renewal Submission

AN OPEN-LABEL, EXTENSION STUDY TO EVALUATE THE LONG-TERM SAFETY, TOLERABILITY AND EFFICACY OF PROCLINONE AND COMBINATION COGNITIVE THERAPY IN PATIENTS WITH PARADOXICAL, NON-TURNAL, HEMISPLASIA

NMRR ID Protocol ID Last updated on Dec 02, 2022

Status Approval granted via MREC Full Board

Ethical Approval Renewal Post Ethical ID RNW ID-23-00005-ESG

Ethical Approval Renewal Status Processing Submission by MREC Secretariat

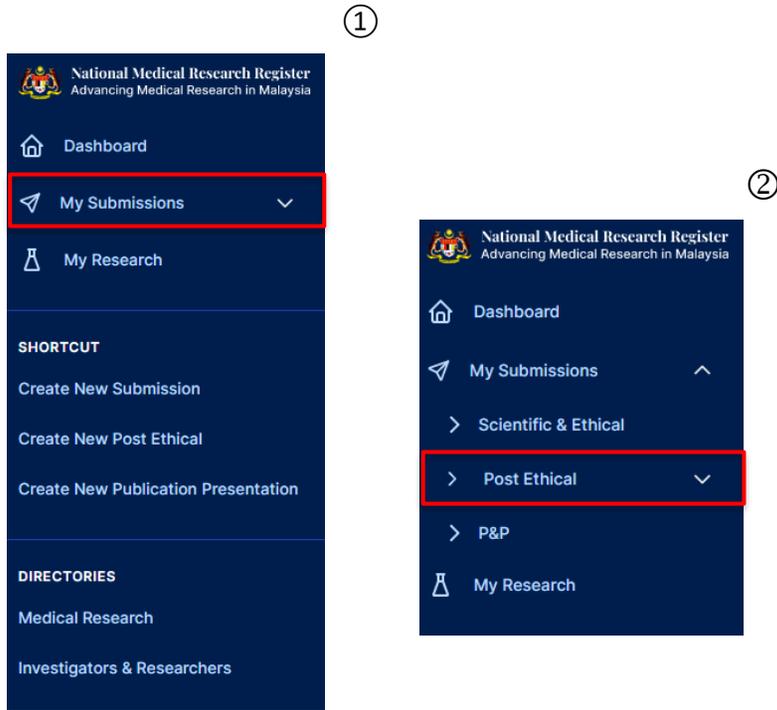
The status of a successful new submission of Ethical Approval Renewal will change from “**Pending Submission**” to “**Processing Submission by MREC Secretariat**”

In Ethical Approval Renewal Submission Listing, the following action icons are accessible to user:

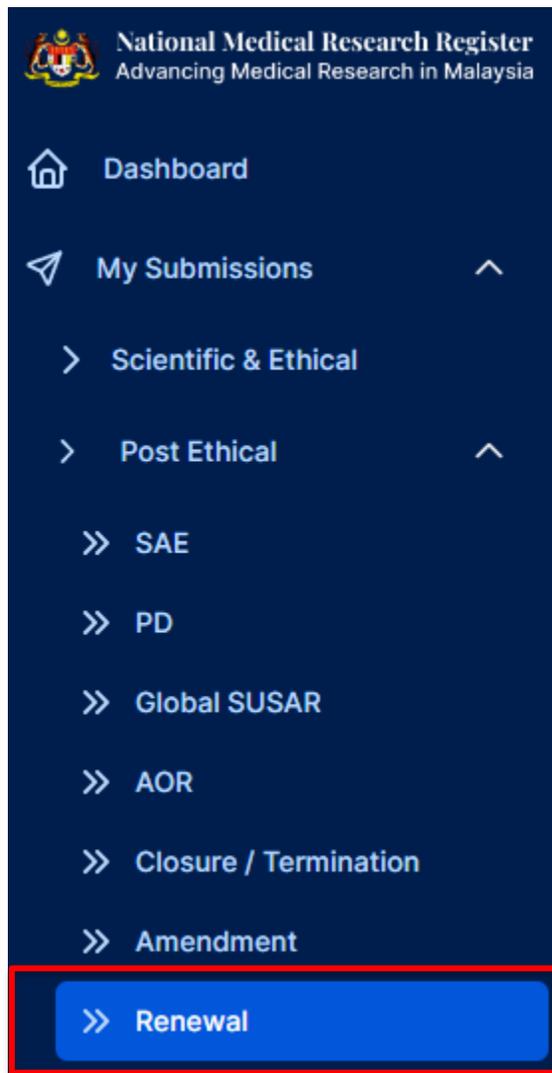
- Show icon to view the data of AOR Submission
- Initial Submission icon to show the initial registration data of NMRR ID Submission

2.0 – Existing Renewal Submission

2.1 – Viewing an Existing Renewal Submission

No	Step-by-step instructions	Remark
1.	<p data-bbox="201 370 1346 435">Scroll over the main menu located on the side of displayed page, go to “My Submission”. Then Click on the “Post Ethical”</p> <div data-bbox="205 472 982 1182"><p>The first screenshot shows the main menu of the National Medical Research Register. The 'My Submissions' option is highlighted with a red box and labeled with a circled '1'. The second screenshot shows the 'My Submissions' dropdown menu, with the 'Post Ethical' option highlighted by a red box and labeled with a circled '2'.</p></div>	

2. Click on Renewal to access the existing Ethical Approval Renewal Submission listing.



A list of all existing Ethical Approval Removal Submission will be displayed.

Ethical Approval Renewal

Key:----- Status

Search NMRR ID, Research ID or Title of the Submission Select All

EXCEL PDF Show 10 entries

#	NMRR ID	TITLE	ETHICAL RENEWAL ID	STATUS	DATE OF SUBMISSION	ACTION
1			RNW ID-23-00005-ESG	Processing Submission by MREC Secretariat	01/04/2023	 
2				Pending Submission		   

Showing 1 to 2 of 2 entries

Previous 1 Next

Please note that one NMRR ID might have a few Ethical Approval Removal Submission. Therefore, Ethical Approval Removal submission will be referred according to the **Ethical Approval Renewal Post Ethical ID** or **Ethical Renewal ID**.

Ethical Approval Renewal Submission of the same NMRR ID can only be created again once the previous Ethical Renewal ID (if any) has received the final decision by MREC

In Ethical Approval Removal Submission Listing, the following action icons are accessible to user

- Show  icon - to view the data of Ethical Approval Removal Submission
- Initial Submission  icon - to show the initial registration data of NMRR ID Submission
- Edit  icon - to edit the A Ethical Approval Removal Submission (icon available only for Ethical Approval Removal Submission with status "Pending Submission" and "Revision Required")
- Bin  icon - to delete Ethical Approval Removal Submission (icon accessible only in Amendment Submission with status "Pending Submission")

3. To view submission, Click on the  icon at the intended Ethical Approval Removal Submission

Ethical Approval Renewal

Keyword Status

EXCEL PDF Show 10 entries

#	NMRR ID	TITLE	ETHICAL RENEWAL ID	STATUS	DATE OF SUBMISSION	ACTION
1			RNW ID-23-00005-ESG	Processing Submission by MREC Secretariat	01/04/2023	 
2				Pending Submission		   

Showing 1 to 2 of 2 entries Previous 1 Next

User will be able to view the data & documents uploaded for the Ethical Approval Removal Submission. User also will be able to see the Decision History of the Amendment Submission. The decision history is available at the bottom of the data submission page.

Decision History

#	DECISION	DECISION DATE	APPROVAL AUTHORITY
1	Initial Submission	01/04/2023 23:06:28	Investigator

This can only be accessible by user that has been assigned with a role either as:

- Principal / Coordinating Investigator (PI)
- Main Corresponding Person (Main CP)
- Backup Corresponding Person (Backup CP)

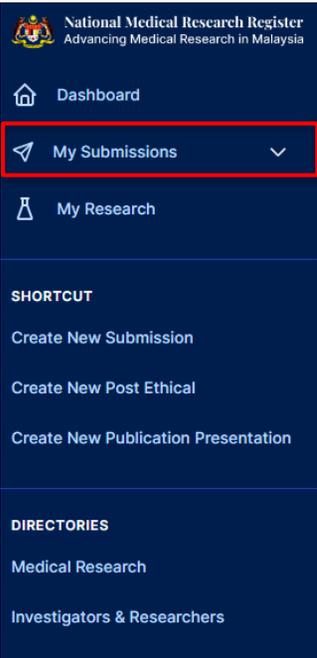
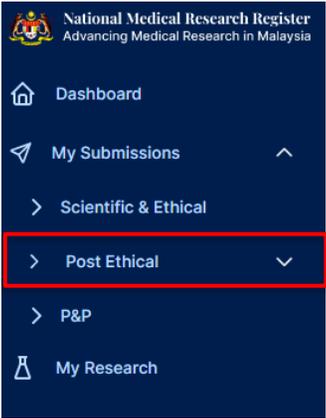
These roles can view and edit each other submission

User also will be able to download the attachment file if MREC Secretariat has uploaded it for user's attention or reference (if any). To download, click on the  icon next to the approval authority list.

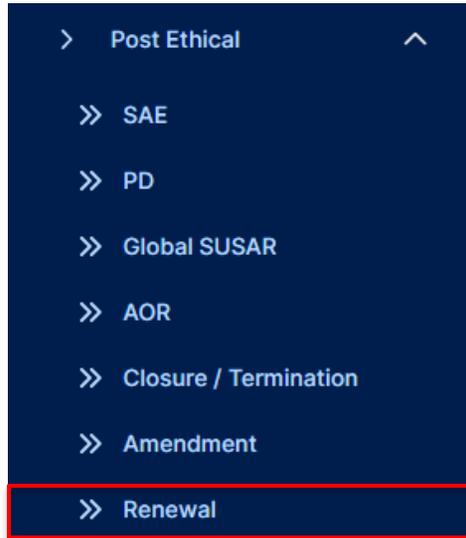
Decision History

#	DECISION	DECISION DATE	APPROVAL AUTHORITY
1	Initial Submission	01/04/2023 23:06:28	Investigator
2	Undergoing Expedited Review by MREC Chairperson/ Deputy Chairperson	02/04/2023 23:39:36	MREC Secretariat
3	Revision Required	02/04/2023 23:41:10	MREC Secretariat
4	Revision Submitted To MREC Secretariat	02/04/2023 23:45:35	Investigator
5	Approval granted via Expedited Review by MREC Chairperson/ Deputy Chairperson	02/04/2023 23:48:07	MREC Secretariat 

2.2 – Editing of Amendment Submission with status “Revision Required”

No	Step-by-step instructions	Remark
1.	<p>In the case where Ethical Approval Renewal Submission is assigned with status “Revision Required”. Scroll over the main menu located on the side of display page, go to “My Submission”. Then Click on the “Post Ethical”</p> <div style="display: flex; justify-content: space-around; align-items: center;"> <div style="text-align: center;"> <p>①</p>  </div> <div style="text-align: center;"> <p>②</p>  </div> </div>	<p>User will be notified via email if a particular Ethical Approval Renewal Submission requires revision.</p>

2. Click on Renewal to access the existing Ethical Approval Renewal Submission listing.



A list of all existing Ethical Approval Renewal Submission will be displayed.

Ethical Approval Renewal

Keyword Status

Show entries

#	NMRR ID	TITLE	ETHICAL RENEWAL ID	STATUS	DATE OF SUBMISSION	ACTION
1			RNW ID-23-00005-ESG	Revision Required	01/04/2023	

The status of an Ethical Approval Renewal Submission that requires revision or more information will have the status **“Revision Required”**

User also may use the filter function to filter “Revision Required” study

Ethical Approval Renewal

Keyword

Search NMRR ID, Research ID or Title of the Submission

Status

Select All

EXCEL

PDF

Show 10 entries

Status

Select All

Select All

No response by CP - Auto Terminate

Processing Submission by MREC Secretariat

Revision Required

Undergoing Expedited Review by MREC Chairperson/ Deputy Chairperson

Undergoing Expedited Review by MREC Primary Review

Queue For MREC Full Board Review

Undergoing MREC Full Board Review

Approval granted via Expedited Review by MREC Chairperson/ Deputy Chairperson

Approval granted via Expedited Review by MREC Primary Reviewers

Approval granted via MREC Full Board

Disapproved

Withhold

MREC is Preparing Decision Letter

Exempted from MREC

Revision Submitted To MREC Secretariat

3. To edit and revise the submission, first click on the  icon at the intended Ethical Approval Renewal Submission.

Ethical Approval Renewal

Keyword Status

Show entries

#	NMRR ID	TITLE	ETHICAL RENEWAL ID	STATUS	DATE OF SUBMISSION	ACTION
1			RNW ID-23-00005-ESG	Revision Required	01/04/2023	   

This can only be accessible by user that has been assigned with a role either as:

- Principal / Coordinating Investigator (PI)
- Main Corresponding Person (Main CP)
- Backup Corresponding Person (Backup CP)

These roles can view and edit each other submission

Investigator will be able to see all the query/ comments made by the secretariat & reviewers

Other Relevant Comment

Secretariat *2 minutes ago*

rectify and explain on the number of recruitment exceeding the number approved by MREC

Response

When viewing the data of Ethical Approval Renewal Submission (click on the ) user will be able to view the General information of the Submission over the top of the display page with amendment status as “Revision Required”

Ethical Approval Renewal Submission

AN OPEN LABEL EXTENSION STUDY TO EVALUATE THE LONG TERM SAFETY, TOLERABILITY, AND EFFICACY OF PEGOLADOLIMON AND COMBINATION CONJUGATION THERAPY IN PATIENTS WITH PROSTATECTOMY AND ADJUVANT ANDROGEN DEPRIVATION

NMRR ID  Protocol ID  Last updated on Dec 02, 2022

Status 

Ethical Approval Renewal Post Ethical ID 

Ethical Approval Renewal Status 

4. To edit the revise submission, click on the  located at the top of display page .

Other Relevant Comment



Secretariat

2 minutes ago

rectify and explain on the number of recruitment exceeding the number approved by MREC

Response

Do the necessary changes as per required by the response in the comment section. User may click each of the section available to do the necessary revision. For each changes , click in the  to save the information changes

5. To update and replace document in the “Supporting Documents” ,

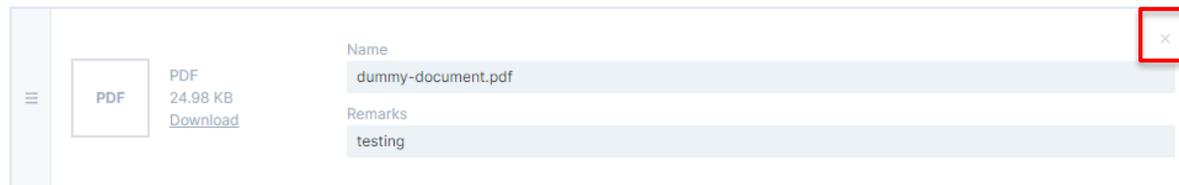
1) Click on the pdf icon  to select new document or drag the documents over the old file – this will replace the old documents with the new one. Then click  on the button to complete and save the new document

or

2) Click on the delete ‘x’ mark located at the right top corner of the document section. Select okay when popup appears asking user confirmation on the deletion of the current document

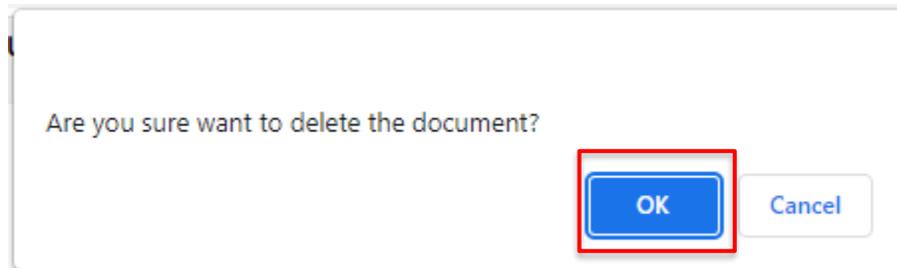
Cover Letter *

[View Document History](#)



Name
dummy-document.pdf
Remarks
testing

The screenshot shows a document list table. The first row contains the file name 'dummy-document.pdf'. The second row is for 'Remarks' and contains the text 'testing'. A red box highlights a small 'x' icon in the top right corner of the table area.



Are you sure want to delete the document?

The screenshot shows a confirmation dialog box with the text 'Are you sure want to delete the document?'. Below the text are two buttons: 'OK' and 'Cancel'. The 'OK' button is highlighted with a red box.

Click on the  icon to access the document file or drag the document over the box available. Once it has been uploaded, user can insert a remark to the documents uploaded (if any). File name can also be changed if needed. Once all documents have been uploaded, Click  to complete the steps and save the uploaded documents.



 Supporting Documents Information Saved.

Please ensure the file name has the extension “.pdf ” at the end of its name. Files without the extension “.pdf ” may have the risk of not being able to be read later

6. To view back the previously uploaded document, Click on the “View Document History” located at the top right of each document section. Document will be shown in chronological order. User also will able to download the previously uploaded document (if needed) by clicking the  [Download](#) icon next to the document title.

User may look back at the previous uploaded document in the “**View Document History**” located at the top right of each document section on the updated documents are saved

Supporting Documents

Cover Letter *

[View Document History](#)

	Name	
 PDF 35.67 KB Download	dummy documents updates.pdf	
	Remarks	
	updated document	

Documents

dummy-document.pdf

Uploaded 16 hours ago

 [Download](#)

CLOSE

7.

Once all revision is done and all document has been uploded, go back to the previous tab or comment page by click on the  . User is required to asnwer investigator's response in the response part of the comment page

Other Relevant Comment

[Edit Submission](#)

Secretariat

2 minutes ago

rectify and explain on the number of recruitment exceeding the number approved by MREC

Response

Secretariat

3 minutes ago

rectify and explain on the number of recruitment exceeding the number approved by MREC

Response

rectification done as per required

7. Once the revision is done and response has been answered in the response box, scroll down the page and user is required to acknowledge the submission made at the "Submission Acknowledgement". Tick on the box "Yes, I declare that the information provided above is true & correct to the best of my understanding (CP will need to click this choice and an email to PI will be sent to notify the PI regarding this submission) Failure to declare all ethical approval renewal information will result in submission will not be processed further and disapproval by MREC."

Acknowledgement by Corresponding Person

I declare that the information provided above is true & correct to the best of my understanding (CP will need to click this choice and an email to PI will be sent to notify the PI regarding this submission) Failure to declare all ethical approval renewal information will result in submission will not be processed further and disapproval by MREC

Submit

Once submission has been acknowledged, user can submit the Ethical Approval Renewal Submission revision by clicking the button.

Acknowledgement by Corresponding Person

I declare that the information provided above is true & correct to the best of my understanding (CP will need to click this choice and an email to PI will be sent to notify the PI regarding this submission) Failure to declare all ethical approval renewal information will result in submission will not be processed further and disapproval by MREC

Submit

Once Ethical Approval Renewal Submission revision submission has been successfully submitted, user will be brought back to the Ethical Approval Renewal Submission listing.

Ethical Approval Renewal Submission

AN OPEN LABEL, EXTENSION STUDY TO EVALUATE THE LONG TERM SAFETY, TOLERABILITY AND EFFICACY OF PEGOLADOLIMAB AND CONCOMITANT COMBINATION THERAPY IN PATIENTS WITH METASTASIS, METASTASIS, METASTASIS

NMRR ID [NMRR ID-23-0005-ESG](#) Protocol ID [E0315 \(P4\) \(2022\)](#) Last updated on Dec 02, 2022

Status Approval granted via MREC Full Board

Ethical Approval Renewal Post Ethical ID [RNW ID-23-00005-ESG](#)

Ethical Approval Renewal Status Revision Submitted To MREC Secretariat

Ethical Approval Renewal

Keyword

Search NMRR ID, Research ID or Title of the Submission

Status

Select All

EXCEL

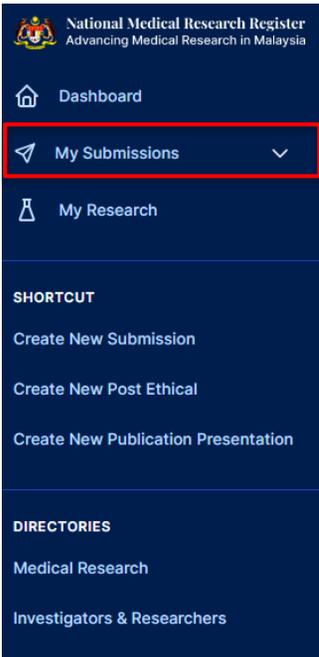
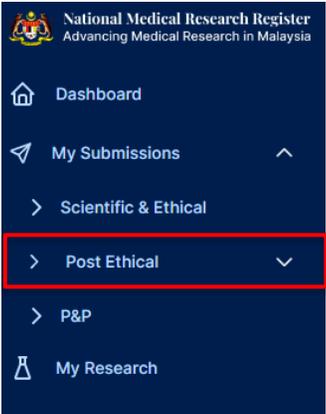
PDF

Show 10 entries

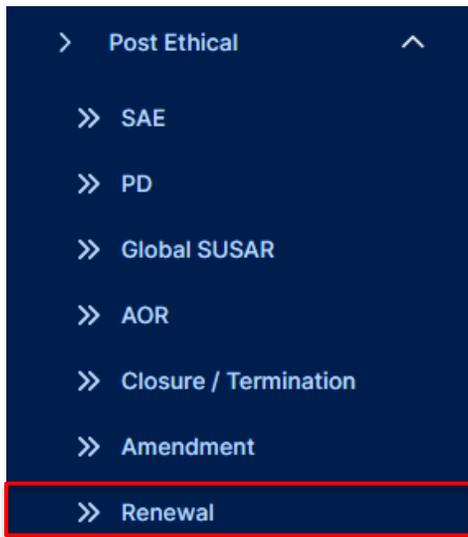
#	NMRR ID	TITLE	ETHICAL RENEWAL ID	STATUS	DATE OF SUBMISSION	ACTION
1			RNW ID-23-00005-ESG	Revision Submitted To MREC Secretariat	02/04/2023	 

The status of a successful revision submission of Ethical Approval Renewal t will change from **“Revision Required”** to **“Revision Submitted to MREC Secretariat”**

2.3 – Editing/ Deletion of Ethical Approval Renewal Submission with status “Pending Submission”

No	Step-by-step instructions	Remark
1.	<p>In the case where user have not managed to complete the submission and would like edit or delete the existing Ethical Approval Renewal Submission, scroll over the main menu located on the side of display page, go to “My Submission”. Then Click on the “Post Ethical”</p> <div style="display: flex; justify-content: space-around; align-items: center;"> <div style="text-align: center;"> <p>①</p>  </div> <div style="text-align: center;"> <p>②</p>  </div> </div>	

2. Click on Renewal to access the existing Ethical Approval Renewal Submission listing.



A list of all existing Ethical Approval Renewal Submission will be displayed.

Ethical Approval Renewal

Keyword Status

EXCEL PDF Show 10 entries

#	NMRR ID	TITLE	ETHICAL RENEWAL ID	STATUS	DATE OF SUBMISSION	ACTION
1		...	RNW ID-23-00005-ESG	Processing Submission by MREC Secretariat	01/04/2023	
2		...		Pending Submission		

Showing 1 to 2 of 2 entries

Previous 1 Next

The status of an Ethical Approval Renewal Submission that has not yet been sent will be **“Pending Submission”**

3. To edit submission, click on the  icon at the intended Ethical Approval Renewal Submission and follow the steps as mentioned above in 1.1 **“Creating a New Ethical Approval Renewal Submission”**

Ethical Approval Renewal

Keyword Status

Show entries

#	NMRR ID	TITLE	ETHICAL RENEWAL ID	STATUS	DATE OF SUBMISSION	ACTION
1		Dr. Dawn Label Extension Study to Evaluate the Long Term Safety, Tolerability, and Efficacy of Proton Pump Inhibitors and Combination Therapy in Patients with Helicobacter Pylori-Associated Gastrointestinal Hemorrhage	RNW ID-23-00005-ESG	Processing Submission by MREC Secretariat	01/04/2023	 
2				Pending Submission		   

Showing 1 to 2 of 2 entries Previous Next

This can only be accessible by user that has been assigned with a role either as:

- Principal / Coordinating Investigator (PI)
- Main Corresponding Person (Main CP)
- Backup Corresponding Person (Backup CP)

These roles can view and edit each other submission

4. To delete an Ethical Approval Renewal Submission, click on the delete  icon of the intended submission. Click  to confirm the deletion of the Ethical Approval Renewal Submission.

Ethical Approval Renewal

Keyword Status

Show entries

#	NMRR ID	TITLE	ETHICAL RENEWAL ID	STATUS	DATE OF SUBMISSION	ACTION
1			RNW ID-23-00005-ESG	Processing Submission by MREC Secretariat	01/04/2023	 
2				Pending Submission		  

Showing 1 to 2 of 2 entries Previous Next

Deletion of an Ethical Approval Renewal Submission will be only available for submission that has never been submitted to MREC Secretariat for processing.

Are you sure you want to remove this record?

Once it is clicked, the Ethical Approval Renewal Submission will be deleted and removed from the Ethical Approval Renewal Submission listing .

Ethical Approval Renewal

Keyword Status

Show entries

#	NMRR ID	TITLE	ETHICAL RENEWAL ID	STATUS	DATE OF SUBMISSION	ACTION
1			RNW ID-23-00005-ESG	Processing Submission by MREC Secretariat	01/04/2023	 

-The End -

Prepared by: NMRR Secretariat

Flow checked & validated by: Asyraf Syahmi Bin Mohd Noor (date: 08/05/2023)