

User Guidelines for
Post Ethical Approval Submission
- Closure & Termination Notification

National Medical Research Register v2.0

National Institutes of Health (NIH)

Version 1.0, May 2023

Table of Contents

Prerequisite For Submission	1
Information/ Documents Required	1
User Guidelines for Submission.....	2
1.0 - New Closure / Termination Submission.....	2
1.1 – Creating a Closure / Termination Submission	2
2.0 – Existing Closure/Termination Submission	16
2.1 – Viewing an Existing Closure/Termination Submission	16
2.2 – Editing of Closure/Termination Submission with status “Revision Required”	21
2.3 – Editing/ Deletion of Closure/Termination Submission with status “Pending Submission”	30

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 of Study Information

- Study Terminate
 - Date of Termination
 - Reason for Termination
 - Status of Recruited Subject
 - Number of recruited subjects up to date
- Study Complete
 - Date of Completion
 - Final number of recruitment/data collection
 - Brief Summary of Study Result
 - Publication Status

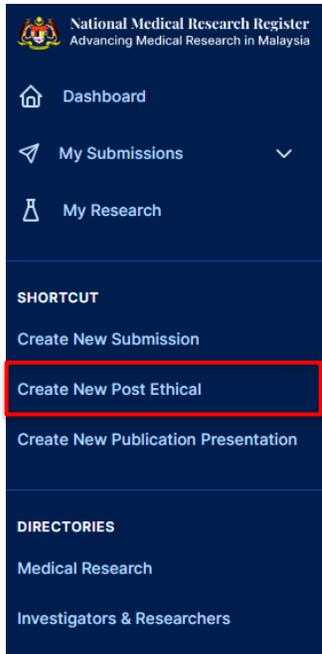
Supporting Documents

1. Cover Letter
2. Borang Pemberitahuan Tamat Projek MRG (only for Closure Submission)
3. Final Report (only for Closure Submission)
4. Supporting Documents (user will be able to upload multiple documents in this part)

User Guidelines for Submission

1.0 - New Closure / Termination Submission

1.1 – Creating a Closure / Termination 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 “Closure / Termination”

New Post Ethical Approval

Keyword

Show entries

Select Post Ethical Approval Type

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

#	NMRR ID	TITLE	RESEARCH SCOPE	RESEARCH TYPE	STATUS	ACTION
1	NMRR-10-2180-28521	Therapeutic Drug Monitoring of Intraperitoneal Antineoplastic and Hormonal Therapy in Peritoneal Ovarian Patients with Peritoneal and Their Effect on Recidual Recal Function.	Clinical		Full Board	
2	NMRR-17-2071-27438	The Role of Intraperitoneal Remiprantin in Peritoneal Ovarian Related Tumor Peritoneal 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 antineoplastic agents on ovarian cancer in Malaysia: a retrospective study.	Clinical	Interventional	Approval granted via MREC Full Board	

Once Closure / Termination is selected, list of submission accessible for Closure / Termination Submission will be displayed

New Post Ethical Approval

Keyword

Select Post Ethical Approval Type

Closure \ Termination

Show entries

#	NMRR ID	TITLE	RESEARCH SCOPE	RESEARCH TYPE	STATUS	ACTION
1	NMRR-08-402-1588	Agreement versus non-pharmacologic intervention in Peritoneal Ovarian Cancer Patients Who Have Failed or are Unavailable for Therapy of Intraperitoneal Treatment	Clinical	Interventional	Approval granted via MREC Full Board	
2	NMRR-08-223-2882	A Multicenter Randomized Double Blind Active Controlled Study to Evaluate the Efficacy and Safety of Abiraterone Compared to Placebo 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 Closure / Termination Submission

New Post Ethical Approval

Keyword Select Post Ethical Approval Type

Show entries

#	NMRR ID	TITLE	RESEARCH SCOPE	RESEARCH TYPE	STATUS	ACTION
1	NMRR ID 400-1000	Approval versus Best Practice: How Best to Provide Stroke in Home (Random Patients Who Have Fallen or are Unstable for Reasons of Inappropriate Treatment)	Clinical	Interventional	Approval granted via MREC Full Board	
2	NMRR ID 200-1000	A Multicentre Randomised Double-Blind Active-Controlled Study to Evaluate the Durability of the Efficacy and Safety of Abigabatil Compared to Gabapentin When Used in Combination with Tricyclic Antidepressants Type II Diabetes	Clinical	Interventional	Approval granted via MREC Full Board	

****Only one submission of either Closure or Termination is allowed for one NMRR ID.**

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

Submission

AN OPEN LABEL EXTENSION STUDY TO EVALUATE THE LONG TERM SAFETY, TOLERABILITY, AND EFFICACY OF PEGASIVIR AND CONCOMITANT COMBINATION THERAPY IN PATIENTS WITH HEPATITIS B CHRONIC HEPATITIS B VIRUS

NMRR ID Protocol ID  Last updated on Dec 02, 2022

Status Approval granted via MREC Full Board

6. Select a type of study status user would like to submit .This can be either “ Study Terminate” or “Study Complete”.

MREC First Approval Date
01/12/2022

MREC Latest Approval/Ethical Approval Renewal Date
01/12/2022

Study Status *

Study Terminate Study Complete

Save

7. **Study Termination Notification**

If user selects “Study Terminate” , information regarding the termination notification (date and the reason of termination is required to be inserted as follows

Study Status *

Study Terminate Study Complete

Date of Termination

mm/dd/yyyy

Reason of Termination

Study Status *

Study Terminate

Study Complete

Date of Termination

05/07/2023

Reason of Termination

lack of recruitment

User is then required to insert information regarding the status of the recruited subject and the latest number of the recruitment up to date . Click [Save](#) to save the information.

Status for Recruited Subject

|

No of Recruited subject Up to Date

[Save](#)

Status for Recruited Subject

continue until EOT

No of Recruited subject Up to Date

2

Save

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

Save

✔ Declaration on Study Information Saved.

For Closure Notification

If user selects "Study Complete", information regarding the closure notification (date and the final number of subject recruitment /data collection is required to be inserted as follows

Study Status *

Study Terminate Study Complete

Date of Closure
mm/dd/yyyy

Final no of subject recruitment / data collection

Study Status *

Study Terminate

Study Complete

Date of Closure

05/05/2023

Final no of subject recruitment / data collection

50

User is the required to insert information on the summary of the results briefly and the publication status . Click **Save** to save the information.

Brief Summary of the Results

Information for this section will be made for public viewing

Publication

No

On Process

Yes

Save

Brief Summary of the Results

Information for this section will be made for public viewing

testing submission closure... as per the document attached

Publication

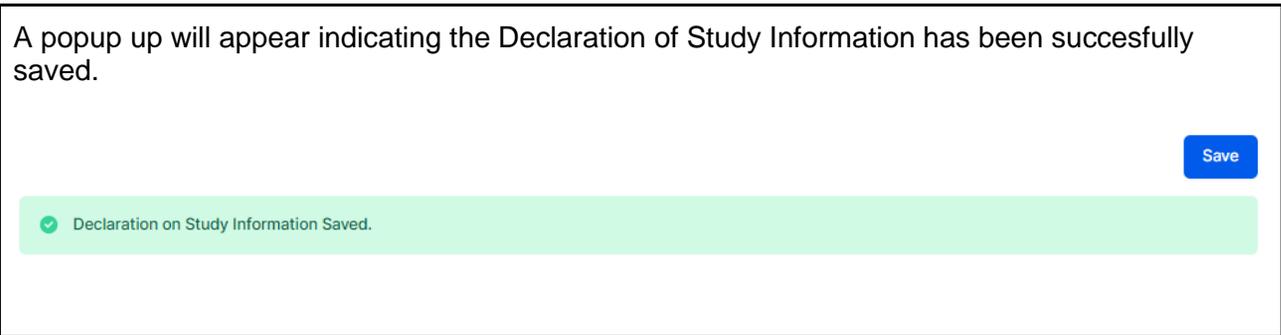
No

On Process

Yes

Save

If the selection is "Yes" for publication status, refer step No.9

	<p>A popup up will appear indicating the Declaration of Study Information has been successfully saved.</p> 	
<p>8.</p>	<p>Once Declaration on Study Information is saved, the General information of the Submission will be updated and is shown over the top part of the display page.</p> <p>Closure \ Termination Submission</p> <p>AN OPEN LABEL EXTENSION STUDY TO EVALUATE THE LONG TERM SAFETY, TOLERABILITY, AND EFFICACY OF PEGASIS AND COMBINATION THERAPY IN PATIENTS WITH INTERMEDIATE AND TERTIARY HERPES ZOSTER</p> <p>NMRR ID NMR18-000000-0000 Protocol ID P18052-IFY Last updated on Dec 02, 2022</p> <p>Status Approval granted via MREC Full Board</p> <p>Closure \ Termination Post Ethical ID CLS ID-23-18052-IFY</p> <p>Closure \ Termination Status Pending Submission</p>	<p>Closure / Termination Post Ethical ID will be the reference number for the Closure / Termination Notification Submission from this point onwards. Once a Closure / Termination Post Ethical ID is generated, Closure / Termination Notification submission has now been created successfully and is available to be accessed from “My Submission” menu. Closure / Termination Post Ethical ID later in the submission will also be referred to as Closure / Termination Submission ID</p> <p>A Closure / Termination Submission Status will be displayed as “Pending Submission”. This information can be seen over the top part of the display page</p>

9. In submission of "Closure Notification", if publication has been selected as "Yes", user is required to insert information regarding the publication that has been submitted and published. Click **Add** to add the information on the publication.

Publication

No On Process

Yes

Publication **Add**

NO.	PUBLICATION TITLE	PUBLICATION DATE	JOURNAL TITLE	JOURNAL CATEGORY	JOURNAL IMPACT FACTOR	JOURNAL TYPE	INDEXING SOURCE/PROVIDERS	IF DATABASE	AUTHORS
No records found.									

Save

Insert the information, then click **Save** to save the information.

Publication

Publication Title

Publication Date

mm/dd/yyyy

Journal Title

Journal Category

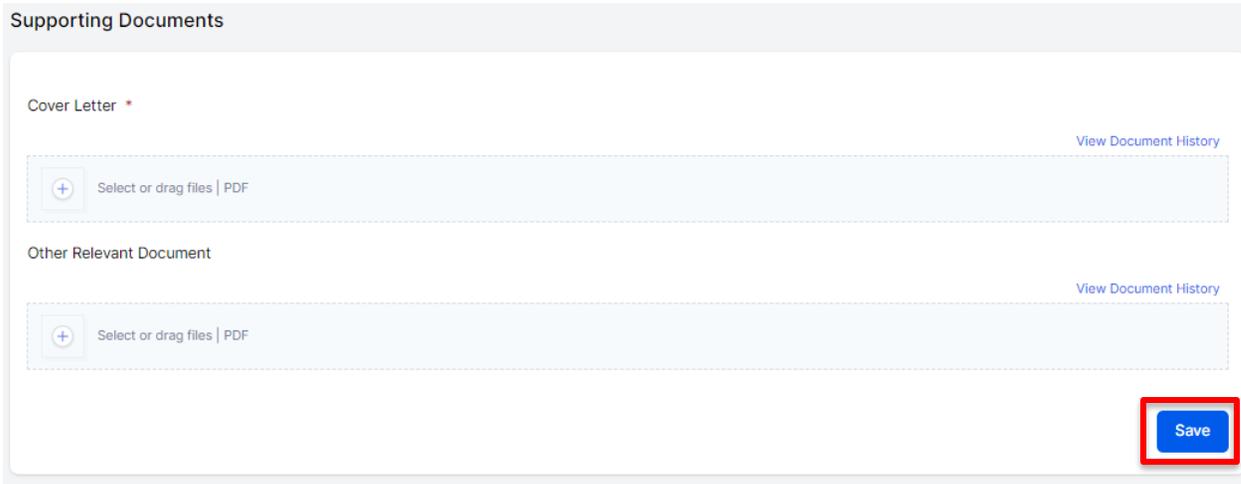
Please Select...

Journal Impact Factor

Cancel **Save**

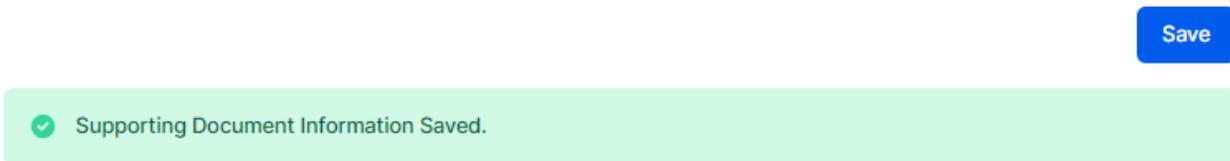
Declaration of publication is required in case user has come up with the publication and scientific dissemination of the research analysis and result. However, this part will still be editable updated later after the notification of the closure has been made.

10. Once all information are saved, continue to scroll down the page. “Supporting Documents” part will be available for user to upload the relevent supporting documents.



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.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  to complete and save the uploaded documents.

A popup up will appear indicating the “Supporting Documents” has been succesfully saved



****Only PDF format file is allowed to be uploaded in this section**

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

For Closure Notification

Addition to cover letter, user may also upload the Final Report and MRG Final Report Completion Notification in this section. Remark can be inserted upon uploading the document.

Borang Pemberitahuan Tamat Projek MRG (Required for MRG Completion Notification)

[View Document History](#)

 Select or drag files | PDF

Final Report

[View Document History](#)

 Select or drag files | PDF

Final Report

[View Document History](#)

		PDF	Name	<input type="text" value="dummy document.pdf"/>
		24.98 KB	Remarks	<input type="text"/>
		Download		

 Select or drag files | PDF

11. Next, user needs to acknowledge the submission made at the “Declaration on Study Information” section.

For Termination Notification

Tick on the box “ I declare that the information provided above is true & correct to the best of my understanding.”

Declaration on Study Information

I declare that the information provided above is true & correct to the best of my understanding

Submit

For Closure Notification

Tick on the box ‘ I declare that the information provided above is true & correct to the best of my understanding.’ with or without “Do you agree for the Study Document (Final Report & other Relevant Document) to be made accessible on the NMRR website for public viewing after it has been reviewed? (Please be noted that Clinical Trial Final Report usually is considered as private and confidential while the rest of research type is advisable to share the finding to the public)”

Declaration on Study Information

Do you agree for the Study Document (Final Report & other Relevant Document) to be made accessible on the NMRR website for public viewing after it has been reviewed?
(Please be noted that Clinical Trial Final Report usually is considered as private and confidential while the rest of research type is advisable to share the finding to the public)

I declare that the information provided above is true & correct to the best of my understanding

Submit

Please ensure all information has been filled up and all the documents required has been uploaded and saved

The later acknowledgement is done if user would like to share the finding and the final report with the public as the document will be made public and accessible upon user agreement.

Once submission has been acknowledged, user can submit the Closure/Termination Submission by clicking the  button.

- Do you agree for the Study Document (Final Report & other Relevant Document) to be made accessible on the NMRR website for public viewing after it has been reviewed? (Please be noted that Clinical Trial Final Report usually is considered as private and confidential while the rest of research type is advisable to share the finding to the public)
- I declare that the information provided above is true & correct to the best of my understanding



Once a new Termination or Closure submission has been successfully submitted, user will be brought the Closure/Termination Submission listing page.

Closure/Termination

Keyword Status

Show entries

#	NMRR ID	TITLE	POST ETHICAL ID	STATUS	DATE OF SUBMISSION	ACTION
1	NMRR ID-22-02493-GDM	An Open-Label Extension Study to Evaluate the Long-Term Safety, Tolerability, and Efficacy of Pozelimab and Cemdisiran Combination Therapy in Patients with Paroxysmal Nocturnal Hemoglobinuria	(T) CLS ID-23-18052-IFY	Processing Submission by MREC Secretariat	07/05/2023	 

The status of a successful new submission of Closure or Termination will change from “**Pending Submission**” to “**Processing Submission by MREC Secretariat**”

In Closure/Termination Submission Listing, the following action icons are accessible to user:

- Show  icon to view the data of Closure/Termination Submission
- Initial Submission  icon to show the initial registration data of NMRR ID Submission

In Post Ethical ID Column, the initial capital letter represents the submission type of a particular NMRR ID

- (T) = Termination
- (C) = Closure

When viewing the data of Closure/Termination submission, the General information of the Submission will be shown on the top part of the display page

Closure \ Termination Submission

AN OPEN LABEL, EXTENSION STUDY TO EVALUATE THE LONG-TERM SAFETY, TOLERABILITY, AND EFFICACY OF PEGOL-ADAM AND COMBINATION THERAPY IN PATIENTS WITH INTERMEDIATE AND TYPICAL HEMATOLOGICAL

NMRR ID [NMRR ID-23-18052-IFY](#) Protocol ID [20210-0141-0102](#) Last updated on Dec 02, 2022

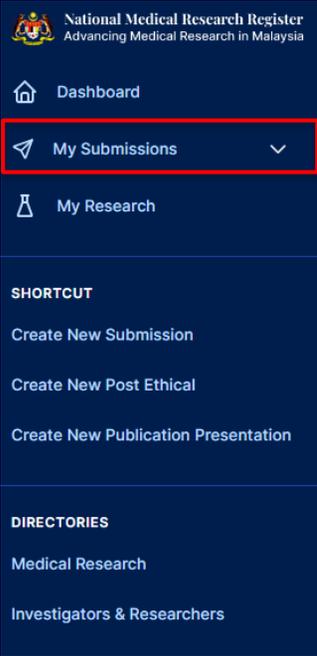
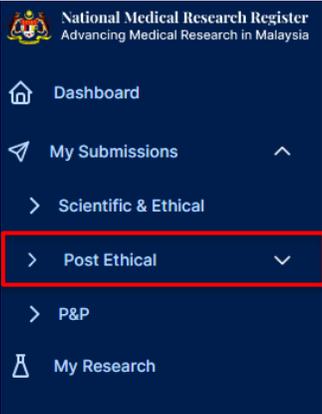
Status Approval granted via MREC Full Board

Closure \ Termination Post Ethical ID [CLS ID-23-18052-IFY](#)

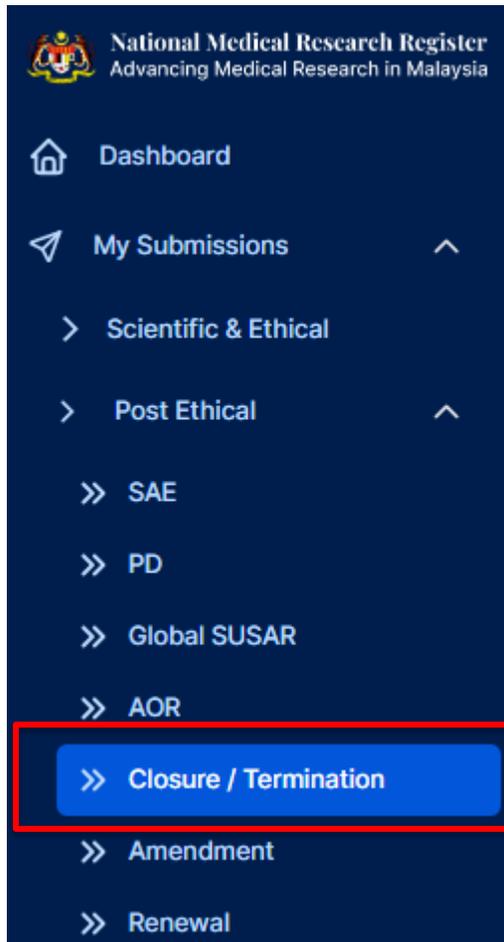
Closure \ Termination Status Processing Submission by MREC Secretariat

2.0 – Existing Closure/Termination Submission

2.1 – Viewing an Existing Closure/Termination Submission

No	Step-by-step instructions	Remark
1.	<p>Scroll over the main menu located on the side of displayed page, go to “My Submission”. Then Click on the “Post Ethical”</p> <p>①</p>  <p>②</p> 	

2. Click on Amendment to access the existing Closure/Termination Submission listing.



A list of all existing Closure/Termination Submission will be displayed.

Closure/Termination

Key words: Status:

EXCEL PDF Show 10 entries

#	NMRR ID	TITLE	POST ETHICAL ID	STATUS	DATE OF SUBMISSION	ACTION
1	18053-PUU	Initial Submission for Closure/Termination of NMRR ID 18053-PUU	(T) CLS ID-23-18053-PUU	Pending Submission		   
2	18052-IFY	Initial Submission for Closure/Termination of NMRR ID 18052-IFY	(T) CLS ID-23-18052-IFY	Processing Submission by MREC Secretariat	07/05/2023	 

Please note that one NMRR ID should only have either Closure or Termination Submission. In each submission only one Post Ethical ID will be issued and this will be referred to as the **Closure/Termination Post Ethical ID**

In Closure/Termination Submission Listing, the following action icons are accessible to user

- Show  icon - to view the data of Closure/Termination Submission
- Initial Submission  icon - to show the initial registration data of NMRR ID Submission
- Edit  icon - to edit the Closure/Termination Submission (icon available only for Closure/Termination Notification Submission with status "Pending Submission" and "Revision Required")
- Bin  icon - to delete Closure/Termination Submission (icon accessible only in Closure/Termination Submission with status "Pending Submission")

3. To view submission, Click on the  icon at the intended Closure or Termination Submission

Closure/Termination

Keyword Status

EXCEL PDF Show 10 entries

#	NMRR ID	TITLE	POST ETHICAL ID	STATUS	DATE OF SUBMISSION	ACTION
1	HEALTH ID-23-18053-PUU	# Double Blind Randomized Active Controlled Phase 3 Study to Compare Safety of 177 Lu-PSMA and Approved Radioactive Ligand Treatment for Metastatic or Recurrent Non-Squamous Non-Small Cell Lung Cancer	(T) CLS ID-23-18053-PUU	Pending Submission		   
2	HEALTH ID-23-18052-IFY	An Open Label Extension Study to Evaluate the Long Term Safety, Tolerability and Efficacy of Intravenous and Intrathecal Combination Therapy in Patients with Recurrent Metastatic Hemangiomas	(T) CLS ID-23-18052-IFY	Processing Submission by MREC Secretariat	07/05/2023	 

User will be able to view the data & documents uploaded for the Closure/Termination Submission .User also will be able to see the Decision History of the Closure or Termination Submission. The decision history is available at the bottom of the data submission page.

Decision History

#	DECISION	DECISION DATE	APPROVAL AUTHORITY
1	Initial Submission	07/05/2023 22:12:00	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)

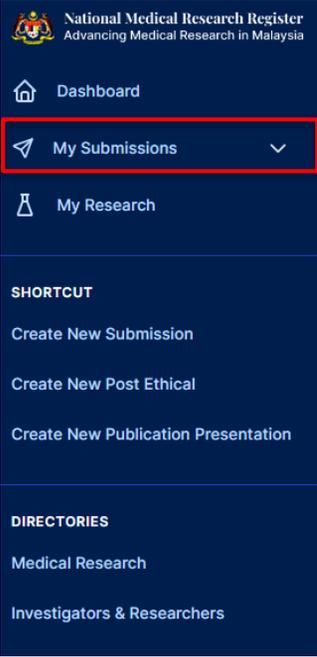
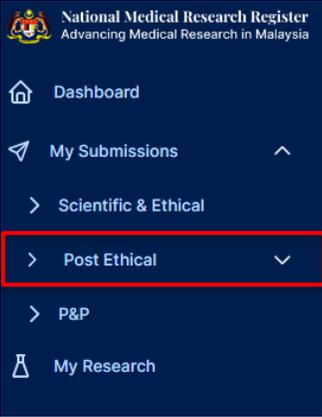
These roles can view and edit each other submission

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.

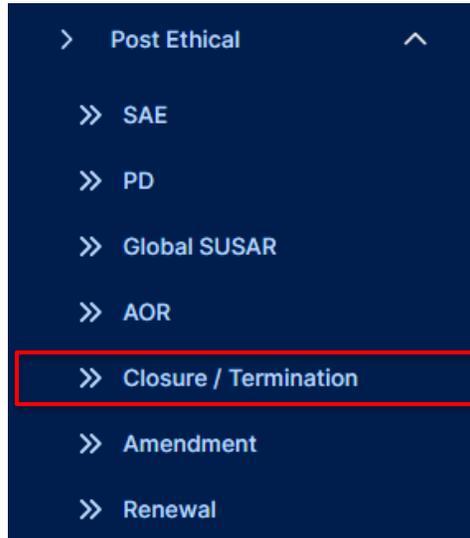
Decision History

	DECISION DATE	APPROVAL AUTHORITY
ion	21/03/2023 12:27:55	Investigator
:pedited Review by MREC Chairperson/ Deputy Chairperson	22/03/2023 00:00:00	MREC Secretariat
ted via Expedited Review by MREC Chairperson/ Deputy Chairperson	30/03/2023 00:00:00	MREC Secretariat 

2.2 – Editing of Closure/Termination Submission with status “Revision Required”

No	Step-by-step instructions	Remark
1.	<p>In the case where Closure or Termination 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 Closure/Termination Submission requires revision.</p>

2. Click on Closure/Termination to access the existing Closure/Termination Submission listing.



A list of all existing Closure/Termination Submission will be displayed.

Closure/Termination

Keyword Status

EXCEL PDF Show 10 entries

#	NMRR ID	TITLE	POST ETHICAL ID	STATUS	FILE STATUS	DATE OF SUBMISSION	ACTION
1	NMRR ID: 638-07285	...	(T) CLS ID-23-17944-TX8	Revision Required	-	10/05/2023	

The status of a Closure/Termination 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

Closure/Termination

Keyword

Status

EXCEL PDF Show 10 entries

#	NMRR ID	TITLE	POST ETHICAL ID	STATUS	FILE STATUS	DATE OF SUBMISSION	ACTION
---	---------	-------	-----------------	--------	-------------	--------------------	--------

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 Closure/Termination Submission.

Closure/Termination

Keyword Status

Show entries

#	NMRR ID	TITLE	POST ETHICAL ID	STATUS	FILE STATUS	DATE OF SUBMISSION	ACTION
1	NMRR ID- 17944-TX8	[REDACTED]	(T) CLS ID-23-17944-TX8	Revision Required	-	10/05/2023	   

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

Other Relevant Comment

Secretariat 4 minutes ago

Please upload the required document and revise the information in study site

Response

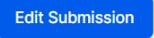
When viewing the data of Closure/Termination Submission (click on the ) , user will be able to view the General information of the Submission over the top of the display page with

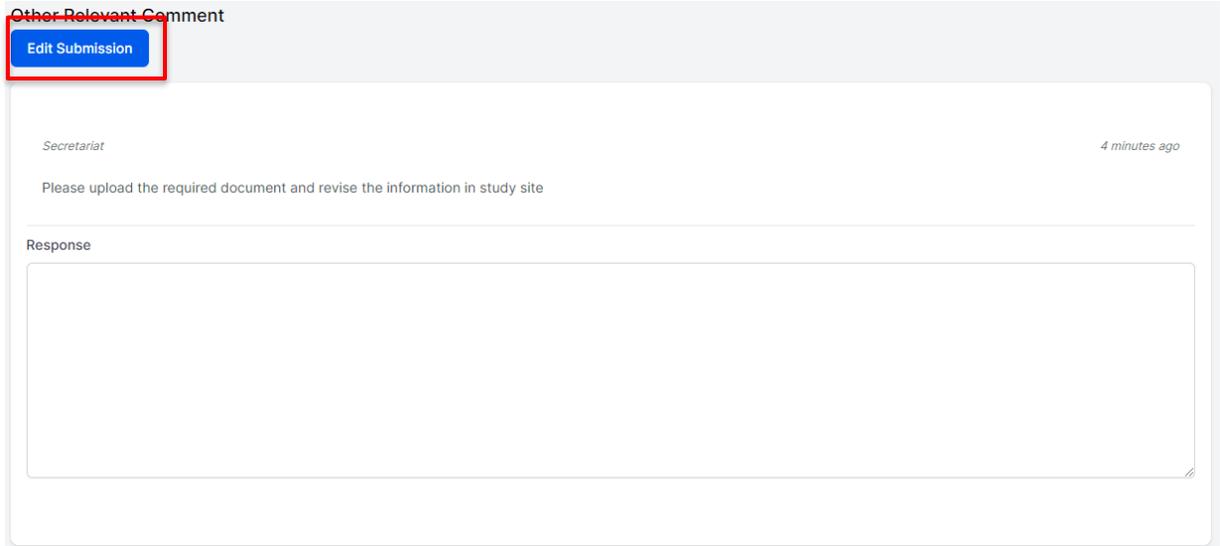
This can only be accessible by user that has been assigned with a role either as:

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

These roles can view and edit each other submission

amendment status as "Revision Required"

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



The screenshot shows a comment section titled "Other Relevant Comment". At the top left of this section is a blue button labeled "Edit Submission", which is highlighted with a red rectangular box. Below the button, the comment is attributed to "Secretariat" and dated "4 minutes ago". The text of the comment reads: "Please upload the required document and revise the information in study site". Below the comment is a "Response" section with a large, empty text input area.

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

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

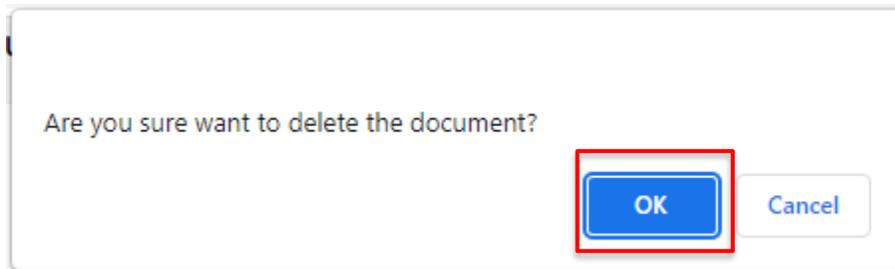
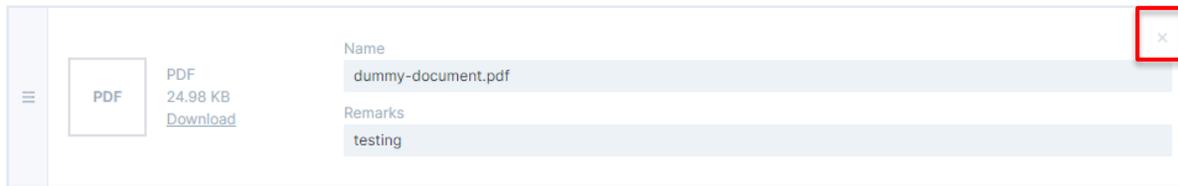
1) Click on the pdf icon  to select new document or drag the documents over the old file – this will replace the old documents with the new one. Then click  on the button to complete and save the new document

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](#)



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

4 minutes ago

Please upload the required document and revise the information in study site

Response

Response

revision is done as 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 "I declare that the information provided above is true & correct to the best of my understanding." **(for both Termination & Closure Notification)** and with or without "Do you agree for the Study Document (Final Report & other Relevant Document) to be made accessible on the NMRR website for public viewing after it has been reviewed? (Please be noted that Clinical Trial Final Report usually is considered as private and confidential while the rest of research type is advisable to share the finding to the public)" **(only for Closure Notification)**

Declaration on Study Information

declare that the information provided above is true & correct to the best of my understanding

Submit

Once submission has been acknowledged, user can submit the Closure/Termination Notification Submission revision by clicking the button.

Do you agree for the Study Document (Final Report & other Relevant Document) to be made accessible on the NMRR website for public viewing after it has been reviewed?
(Please be noted that Clinical Trial Final Report usually is considered as private and confidential while the rest of research type is advisable to share the finding to the public)

I declare that the information provided above is true & correct to the best of my understanding

Submit

Once Closure/Termination Notification Submission revision has been successfully submitted, user will be brought back to the Closure/Termination Submission listing.

Closure \ Termination Submission

A LONG-TERM OPEN LABEL, MULTICENTER, PHASE II STUDY TO ASSESS LONG-TERM CHANGES IN HEIGHT AND WEIGHT IN PATIENTS WITH MPFL WHO ARE RECEIVING ELAPRASE AND STARTED TREATMENT WITH ELAPRASE AT 18 YEARS OF AGE

NMRR ID [NMRR-15-030-25295](#) Protocol ID [SMP-CLA-071](#) Last updated on Sep 24, 2021

Status Approval granted via MREC Full Board

Closure \ Termination Post Ethical ID [CLS ID-23-17944-TX8](#)

Closure \ Termination Status Revision Submitted To MREC Secretariat

The status of a successful revision submission of Closure/Termination will change from **“Revision Required”** to **“Revision Submitted to MREC Secretariat”**

Closure/Termination

Keyword

Status

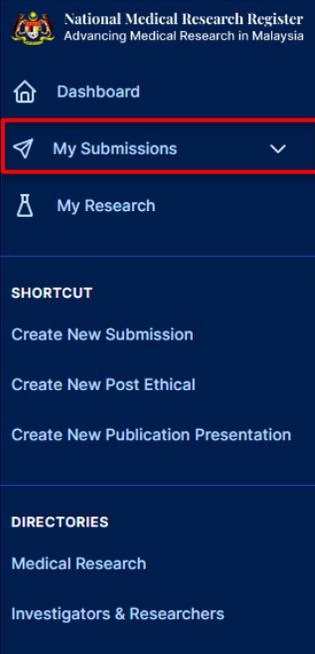
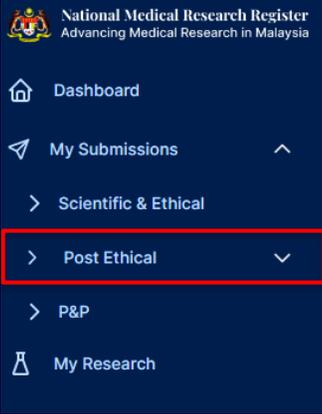
EXCEL

PDF

Show entries

#	NMRR ID	TITLE	POST ETHICAL ID	STATUS	FILE STATUS	DATE OF SUBMISSION	ACTION
1	NMRR-15-030-25295	A LONG-TERM OPEN LABEL, MULTICENTER, PHASE II STUDY TO ASSESS LONG-TERM CHANGES IN HEIGHT AND WEIGHT IN PATIENTS WITH MPFL WHO ARE RECEIVING ELAPRASE AND STARTED TREATMENT WITH ELAPRASE AT 18 YEARS OF AGE	(T) CLS ID-23-17944-TX8	Revision Submitted To MREC Secretariat	-	10/05/2023	  

2.3 – Editing/ Deletion of Closure/Termination 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 Closure/Termination 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 Closure/Termination to access the existing Closure/Termination Submission listing.	

- > Post Ethical ^
- >> SAE
- >> PD
- >> Global SUSAR
- >> AOR
- >> Closure / Termination
- >> Amendment
- >> Renewal

A list of all existing Closure/Termination Submission will be displayed.

The status of a Closure/Termination Submission that has not yet sent will be **“Pending Submission”**

Closure/Termination

Keyword Status Select All

EXCEL PDF Show 10 entries

#	NMRR ID	TITLE	POST ETHICAL ID	STATUS	DATE OF SUBMISSION	ACTION
1	18053-PUU	41 Closure/ Termination Submission for (T) CLS ID-23-18053-PUU	(T) CLS ID-23-18053-PUU	Pending Submission		
2	18052-IFY	41 Closure/ Termination Submission for (T) CLS ID-23-18052-IFY	(T) CLS ID-23-18052-IFY	Processing Submission by MREC Secretariat	07/05/2023	

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

Closure/Termination

Keyword Status

EXCEL PDF Show 10 entries

#	NMRR ID	TITLE	POST ETHICAL ID	STATUS	DATE OF SUBMISSION	ACTION
1	18052-23-18052	A Phase IIa Randomized, Active- Controlled, Parallel, Group, Placebo- Controlled Study to Compare Efficacy and Safety of (T) 18052 and (S) 18052 Versus the Placebo in Treatment for Moderate to Severe Non-Smoking Non- Small Cell Lung Cancer	(T) CLS ID-23- 18052-PUU	Pending Submission		  
2	18052-23-18052	An Open Label Extension Study to Evaluate the Long Term Safety, Tolerability, and Efficacy of Placebo and Continued Treatment Therapy in Patients with Advanced Non-Small Cell Lung Cancer	(T) CLS ID-23- 18052-IFY	Processing Submission by MREC Secretariat	07/05/2023	 

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)

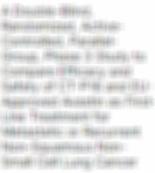
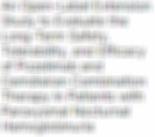
These roles can view and edit each other submission

4. To delete a Closure/Termination Submission, click on the delete  icon of the intended submission. Click  to confirm the deletion of the Closure/Termination

Closure/Termination

Keyword Status

Show entries

#	NMRR ID	TITLE	POST ETHICAL ID	STATUS	DATE OF SUBMISSION	ACTION
1			(T) CLS ID-23-18053-PUU	Pending Submission		  
2			(T) CLS ID-23-18052-IFY	Processing Submission by MREC Secretariat	07/05/2023	 

Are you sure you want to remove this record?

Deletion of a Closure/Termination Notification Submission will be only available for submission that has never been submitted to MREC Secretariat for processing.

Once it is clicked, the Closure/Termination Submission will be deleted and removed from the Closure/Termination Submission listing .

Closure/Termination

Keyword

Search NMRR ID, Research ID or Title of the Submission

Status

Select All

EXCEL

PDF

Show 10 entries

#	NMRR ID	TITLE	POST ETHICAL ID	STATUS	DATE OF SUBMISSION	ACTION
1	NMRR ID-23-18052-IFY	No Open Label Extension Study in Children for Long Term Safety, Tolerability, and Efficacy of Prednisolone and Corticosteroid Combination Therapy in Pediatric with Noncystic Fibrosis Management	(T) CLS ID-23-18052-IFY	Processing Submission by MREC Secretariat	07/05/2023	 

-The End -

Prepared by: NMRR Secretariat

Flow checked & validated by: Asyraf Syahmi Bin Mohd Noor (date: 10/05/2023)