

**User Guidelines for**  
*Post Ethical Approval Submission*  
*- Amendment*

National Medical Research Register v2.0

National Institutes of Health (NIH)

Version 1.0 , March 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"><li>• Should logged in as Investigator or Clinical Research Associates (CRA)</li><li>• Should have completed the profile page</li><li>• Should have a submission submitted, registered successfully in NMRR issued NMRR ID)</li><li>• 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)</li></ul>
1.3	User has a role assigned in an approved submission either as: <ul style="list-style-type: none"><li>• Principal / Coordinating Investigator (PI)</li><li>• Main Corresponding Person (Main CP)</li><li>• Backup Corresponding Person (Backup CP)</li></ul>

## Information/ Documents Required

### **Declaration on type of Amendment (to select the**

1. Substantial changes
2. Non-substantial changes

### **Amendment Summary Detail**

1. Submission Amendment (based on selection on type of amendment)
2. List of Updated Documents

### **Study Information Updates** (based on selection on type of amendment)

1. General Information
2. Study Type Information
3. Study Information
4. Disease and/or Research Area
5. Investigational Products
6. Inclusion / Exclusion Criteria
7. Study Timeline
8. Subject (Sample Size) Description

9. Sites Description
10. Current Study Recruitment Status / Study Status
11. Outcome Measures
12. Biospecimen Collection / Archiving
13. Ethical Application Status
14. Study URL

**Study Site Updates** (based on selection on type of amendment)

**Investigator & Sponsor Updates** (based on selection on type of amendment)

1. Study Team
2. Contact for Public Queries
3. Corresponding Person
4. SAE Corresponding Person
5. PD Corresponding Person
6. Sponsor
7. Contract Research Organization - CRO

**Document Updates** (based on selection on type of amendment)

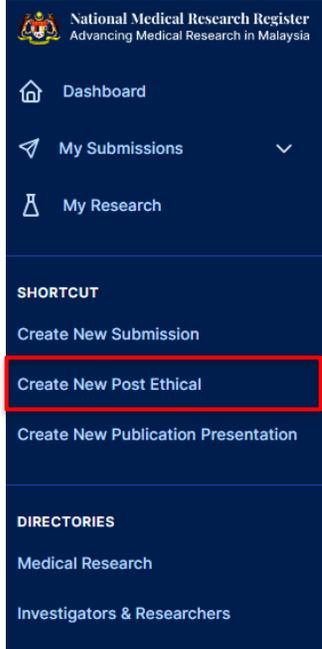
**Amendment Documents**

1. Cover Letter
2. Supporting Documents (user will be able to upload multiple documents in this part)

# User Guidelines for Submission

## 1.0 - New Amendment Submission

### 1.1 – Creating an Amendment 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 &amp; user has been assigned with a role either as:</p> <ul style="list-style-type: none"> <li>• Principal / Coordinating Investigator (PI)</li> <li>• Main Corresponding Person (Main CP)</li> <li>• Backup Corresponding Person (Backup CP)</li> </ul>

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 “Amendment.”

### New Post Ethical Approval

Keyword

Select Post Ethical Approval Type

- 
- 
- 
- 
- 
- 
- 
-

Show 10 entries

#	NMRR ID	TITLE	RESEARCH SCOPE	RESEARCH TYPE	STATUS	ACTION
1	NMRR-10-2160-28521	Therapeutic Drug Monitoring of Intraperitoneal Anticancer Agents and Neurotoxicity in Peritoneal Dialysis Patients with Peritoneal and Their Effect on Residual Renal Function.	Clinical		Full Board	
2	NMRR-17-2077-27438	The Role of Intraperitoneal Augmentation in Peritoneal Dialysis Related Fungal Peritonitis: Ten year Review from a Malaysian Center.	Clinical	Observational	Approval granted via Expedited Review by MREC Chairperson/ Deputy Chairperson	
3	NMRR-20-2160-27762	A comparison between the effect of various catheters on peritoneal dialysis in patients with peritoneal dialysis: an in vitro and in vivo experimental study.	Clinical	Interventional	Approval granted via MREC Full Board	

Once Amendment is selected, list of submission accessible for Amendment 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-10-2160-28521	Therapeutic Drug Monitoring of Intraperitoneal Anticancer Agents and Neurotoxicity in Peritoneal Dialysis Patients with Peritoneal and Their Effect on Residual Renal Function.	Clinical	Interventional	Approval granted via MREC Full Board	
2	NMRR-17-2077-27438	The Role of Intraperitoneal Augmentation in Peritoneal Dialysis Related Fungal Peritonitis: Ten year Review from a Malaysian Center.	Clinical	Observational	Approval granted via Expedited Review by MREC Chairperson/ Deputy Chairperson	

4. Click on the  icon to create a New Amendment 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 2100-2021	Therapeutic Drug Monitoring of Intraperitoneal Anticancer Agents and Neurokinin in Peritoneal Ovarian Patients with Peritoneal Disease: Patients with Peritoneal and Their Effect on Renal Renal Function.	Clinical	Interventional	Approval granted via MREC Full Board	

**\*\*Only one submission of Amendment is allowed at one time.**

**Subsequent Amendment Submission of the same NMRR ID can only be created** once the previous Amendment ID (if any) has received the final decision by MREC (either Approved, Disapproved or Exempted)

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

### Amendment Submission

Therapeutic Drug Monitoring of Intraperitoneal Anticancer Agents and Neurokinin in Peritoneal Ovarian Patients with Peritoneal and Their Effect on Renal Renal Function.

NMRR ID NMRR ID 2100-2021 Protocol ID -  Last updated on Sep 23, 2021

Status Approval granted via MREC Full Board

Amendment Status Pending Submission

An Amendment Submission 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 Type of Amendment ” . Select the type of changes that user want to apply and made on the amendment submisison . There are 2 main type of changes available with each of the type has their own individual listing. Once the type of changes has been selected ,click  to save the information .

Declaration Type of Amendment

Substantial Changes

- Major changes to the design or methodology of the study, or to background information affecting its scientific value
- Changes to the Research Objective & Outcome Measure
- Changes to the procedures undertaken by participants
- Any change relating to the safety or physical or mental integrity of participants, or to the risk/benefit assessment for the study
- Changes to the inclusion/ exclusion criteria
- Significant changes to study documentation such as participant information sheets/ informed consent forms, questionnaires, advertisement, letters of invitation, letters to GPs or other clinicians, information sheets for relatives or careers.

- 
- Changes to the sponsor/funding arrangements or Contract Research Organization (CRO)
  - Changes to the documentation used by the research team for recording study data;
  - Changes to the logistical arrangements for storing or transporting samples
  - Extension of the study beyond the period specified
  - Changes to the presentation of previously approved wording such as an approved advertisement being used in a different format
  - Changes to contact details for the sponsor(s), sponsor's legal representative or Contract Research Organization (CRO)
  - Changes to contact details for principal investigator, study team or other project staff
  - Any other non-substantial amendment (Please specify)



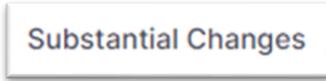
A popup up will appear indicating the Declaration Type of Amendment Information has been succesfully saved.



 Declaration Type of Amendment Information Saved.

Declaration Type of Amendment consists of :

14 selections of



11 selections of



Refer to **point no 7 & no 8** for the selection list

Once “Declaration Type of Amendment ” is saved, an Amendment Post Ethical ID will be generated.

### Amendment Submission

THE PHARMACEUTICAL DRUG MONITORING OF INTERPERSONAL ANXIETY DISORDERS AND WORKING IN PERSONAL ANALYSIS PATIENTS WITH PERSONALITY AND THEIR EFFECT ON RESPIRATORY RENAL FUNCTION

NMRR ID **NMRR ID-2100-2021** Protocol ID - Last updated on Sep 23, 2021

Status **Approval granted via MREC Full Board**

Amendment Post Ethical ID **AMDT ID-23-00042-ERD**

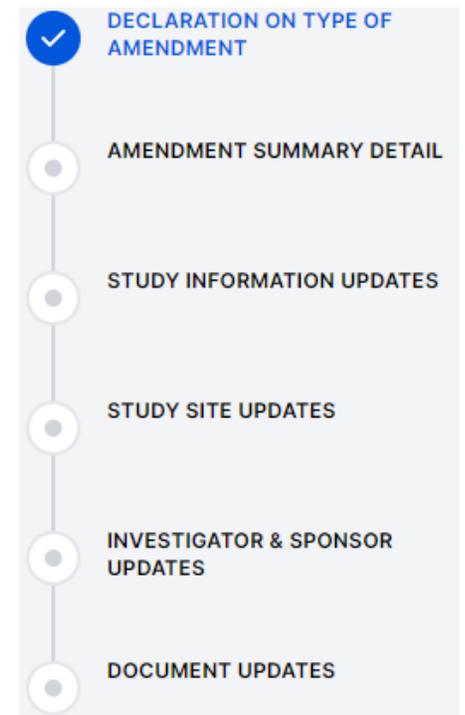
Amendment Status **Pending Submission**

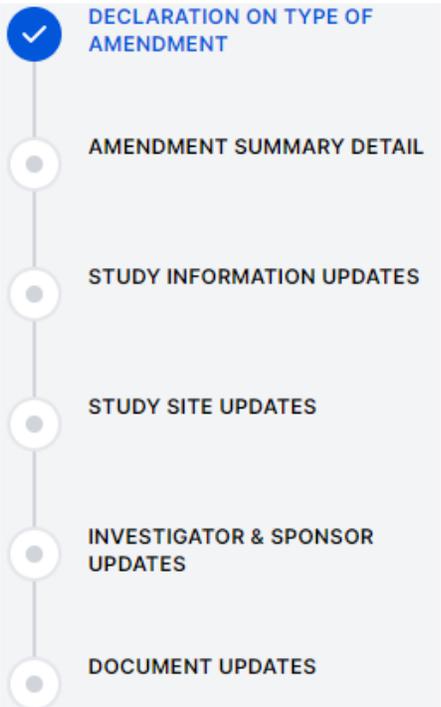
**Amendment Post Ethical ID** will be the reference number for the Amendment Submission from this point onwards. Once an Amendment Post Ethical ID is generated, Amendment submission has now been created successfully and is available to be accessed from “My Submission” menu. **Amendment Post Ethical ID**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

7. Substantial change will lead to specific section and subsection to open. The list is as of the following:

- Major changes to the design or methodology of the study, or to background information affecting its scientific value → **all section will be open**
- Changes to the Research Objective & Outcome Measure → **study information section updates [subsection study information & outcome measure] and document updates section**
- Changes to the procedures undertaken by participants → **all section will be open**
- Any change relating to the safety or physical or mental integrity of participants, or to the risk/benefit assessment for the study → **study information section updates [subsection investigational product, exclusion & inclusion criteria] and document updates section**
- Changes to the inclusion/ exclusion criteria → **study information section updates [subsection exclusion & inclusion criteria] and document updates section**
- Significant changes to study documentation such as participant information sheets/ informed consent forms, questionnaires, advertisement, letters of invitation, letters to GPs or other clinicians, information sheets for relatives or careers. → **document updates section**
- A change of sponsor(s) or sponsor’s legal representative → **Investigator & sponsor section updates [subsection sponsor & contract research organisation] and document updates section**
- Appointment of a new principal investigator → **Investigator & sponsor section updates [subsection Study Team , Public Query, Corresponding Person ] and document updates section**
- Addition of new trial/study site → **study information section updates [subsection Sites Description] , study site section updates and document updates section**
- A change to the insurance or indemnity arrangements for the study → **document**

Based on the selection of the changes, specific part & section of NMRR data submission will be open

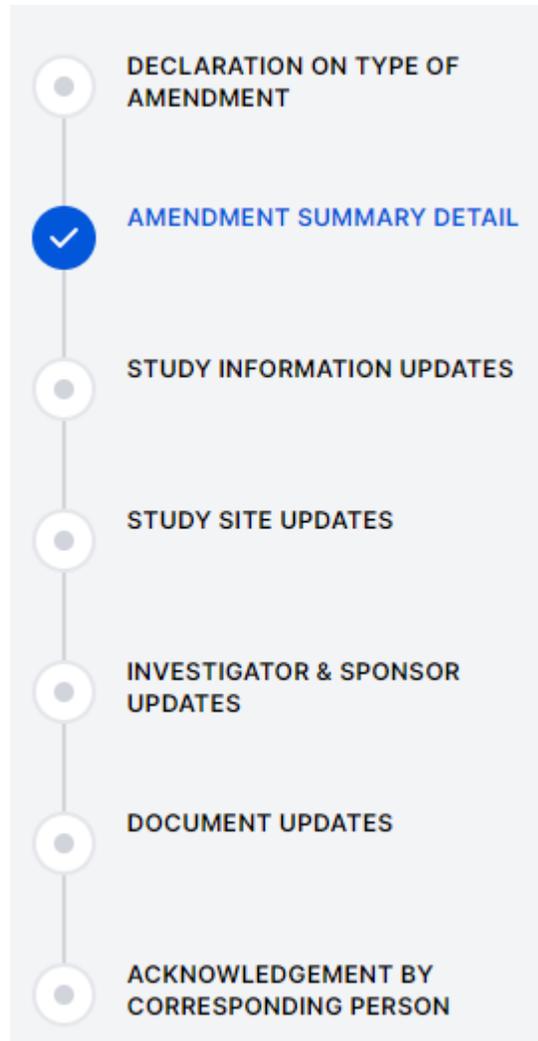


	<p><b>updates section</b></p> <ul style="list-style-type: none"> <li>• A change to the payments, benefits or incentives to be received by participants or researchers in connections with taking part in the study, or any other change giving rise to a possible conflict of interest on the part of any investigator/ collaborator → <b>document updates section</b></li> <li>• A change to the definition of the end of the study → <b>study information section updates [subsection study information &amp; outcome measure] and document updates section</b></li> <li>• Change in subject recruitment number → <b>study information section updates [subsection subsection subject (sample size) description] and document updates section</b></li> <li>• Any other significant change to the protocol or the terms of the MREC application → <b>all section will be open</b></li> </ul>	
<p>8.</p>	<p>Non- substantial change will lead to specific section and subsection to open. The list is as of the following:</p> <ul style="list-style-type: none"> <li>• Minor changes to the protocol or other study documentation, (e.g. correcting errors, updating contact points, minor clarifications) → <b>all section will be open</b></li> <li>• Minor Updates to the study documents (eg: investigator’s brochure / Summary of product report, participant information sheets/ informed consent forms, questionnaires, advertisement, letters of invitation) → <b>document updates section</b></li> <li>• Changes to the research team /Addition of sub-Investigators (other than appointment of new principal investigator) + document update section → <b>Investigator &amp; sponsor section updates [subsection Study Team , Public Query, Corresponding Person ] and document updates section</b></li> <li>• Changes in funding arrangements + document update section → <b>Investigator &amp; sponsor section updates [subsection sponsor &amp; contract research organisation] and document updates section</b></li> <li>• Changes in the documentation used by the research team for recording study data → <b>document updates section</b></li> <li>• Changes in the logistical arrangements for storing or transporting samples+ document update section</li> <li>• Extension of the study beyond the period specified → <b>all section will be open</b></li> <li>• Changes to the presentation of previously approved wording such as an approved advertisement being used in a different format. → <b>document updates section</b></li> <li>• Changes to contact details for the sponsor(s) or sponsor’s legal representative,+ document update section → <b>Investigator &amp; sponsor section updates [subsection sponsor &amp; contract research organisation] and document updates section</b></li> <li>• Changes to contact details for principal investigator, study team or other project staff+ document update section → <b>Investigator &amp; sponsor section updates [subsection</b></li> </ul>	<p>Based on the selection of the changes, specific part &amp; section of NMRR data submission will be open</p> 

**Study Team , Public Query, Corresponding Person ] and document updates section**

- Any other non-substantial amendment → **all section will be open**

9. A section on details of the Amendment Submission is then will be available over the right side of the screen

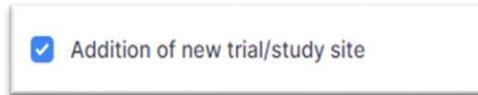


10. Insert the detail information of the amendment submission based on the selection on the “Declaration Type of Amendment” in the “Amendment Summary Detail”.



For Example if the selection in “Declaration Type of Amendment” are :

1) Addition of new trial/study site\*



2) Changes to the research team /Addition of sub-Investigators (other than appointment of new principal investigator) or changes to Corresponding Person (CP)/ Coordinator/ Contact for Public Queries\*



.....  
User is required to enter the detail in the box available under each selection

Addition of new trial/study site \*

Changes to the research team /Addition of sub-Investigators (other than appointment of new principal investigator) or changes to Corresponding Person (CP)/ Coordinator/ Contact for Public Queries \*

**11.** Once all details has been filled up ,insert the Information regarding the list of document updates

Changes to the research team /Addition of sub-Investigators (other than appointment of new principal investigator) or changes to Corresponding Person (CP)/ Coordinator/ Contact for Public Queries \*

addition of a Co- I for Hospital X site , Dr X

List of Document Updated \*

|

Save

12. Once the list of documents updates has been filled up , click  to save the information on the “Amendment Summary Detail” section

List of Document Updated \*

Cover Letter for Amendment Version x, dated dd/mm/yyyy  
Declaration of COI form Version x, dated dd/mm/yyyy  
Protocol Version x, dated dd/mm/yyyy

Investigator Document  
- CV , Dr x



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



 Amendment Summary Detail Information Saved.

13

Based on selection at “Declaration Type of Amendment ”, go to the specific section containing the submisison information .

For Example if the selection in “Declaration Type of Amendment” are :

3) Addition of new trial/study site\*

Addition of new trial/study site

4) Changes to the research team /Addition of sub-Investigators (other than appointment of new principal investigator) or changes to Corresponding Person (CP)/ Coordinator/ Contact for Public Queries\*

Changes to the research team /Addition of sub-Investigators (other than appointment of new principal investigator) or changes to Corresponding Person (CP)/ Coordinator/ Contact for Public Queries

①

“Addition of new trial/study site “ will require information updates regarding “Site Description” in Study Information Updates” Section and “Study Sites Update”

1)

STUDY INFORMATION UPDATES

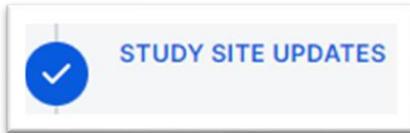
Click  to save the updates information updates

Sites Description Sites Description Changes

Number of sites in Malaysia \*

Refer to **point no 7 & no 8** for the selection list and the section relevant to the selection that will be opened.

2)



Click **Add** to update the site

Study Site Updates  
Study Site Study Site Changes

List of Study Site **Add**

#	NAME (LOCAL)	NAME (ENGLISH)	
1		HOSPITAL SELAYANG	 

Search for the site and click **Save** to save the update information

Amendment Status Pending Submission

Study Site

Establishment +

  
  
  
  
Cancel **Save**

### Study Site Updates

#### Study Site

[Study Site Changes](#)

List of Study Site

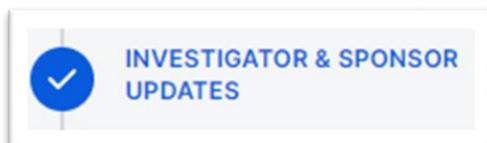
Add

#	NAME (LOCAL)	NAME (ENGLISH)		
1		HOSPITAL SELAYANG		
2	KAJANG HOSPITAL	Hospital Kajang		

✔ Study Sites Information's Saved.

②

“Changes to the research team /Addition of sub-Investigators (other than appointment of new principal investigator) or changes to Corresponding Person (CP)/ Coordinator/ Contact for Public Queries” will require information updates regarding “Study Team” in the “Investigator & Sponsor Updates”



Click **Add** to update the study team members

### Investigator & Sponsor Updates

#### Study Team

[Study Team Changes](#)

List of Study Team

Add

NAME	STUDY SITE	ROLE		
LINA SIEM PINN	HOSPITAL SELAYANG	Principal / Coordinating Investigator		

Insert the information update on the study team, click  to save the updated information

**Study Team**

Name\*

Study Site\*

Investigator Role

Principal / Coordinating Investigator     Co / Sub Investigator at the site

Principal Investigator at the site     Expert Opinion

IA-HOD-IA 

File  
 No file chosen

CV

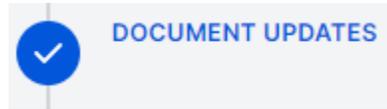
File \*  
 dummy document.pdf



Tan Yaka      Hospital Kajang      Co / Sub Investigator at the site     

 Study Team Information's Saved.

14 Once all amendment information has been added ,click at “Document Updates” Section to upload amended documents



Select the required document type

Document Updates

Document Type \*

Please Select...

Select Document Type

Click [Select Document Type](#) to see the previously uploaded document

Please Select...

- Protocol Review Checklist
- Research Protocol
- Research Protocol Review Checklist
- Adult/Parental Participant Information Sheet (PIS) & Informed Consent Form (ICF) ( interventional/ minimal risk)
- Patient Information Sheet (PIS) & Informed Consent Form (ICF)
- Patient Information Sheet (PIS) & Informed Consent Form (ICF) Review Checklist
- Information Sheet & Assent Form, 7-12 years
- Information Sheet & Assent Form, 13 to less than 18 years
- Optional Patient Information Sheet (PIS) & Informed Consent Form (ICF) for genetic, pharmacodynamic / pharmacogenomic / other studies
- Optional Patient Information Sheet (PIS) & Informed Consent Form (ICF) for future research other studies
- Pregnant Partner Information Sheet & Informed Consent Form
- Checklist for Research on Stem Cell & Cell Based Therapy, National Stem Cell Research and Ethics Subcommittee(NSCERT)
- Checklist for First Research Protocol / Archive Biospecimen
- Clinical Form Report / Data Collection Form
- Questionnaire
- Interview Guideline
- Project Gantt Chart
- Investigational Brochure
- Advertisement

Please Select...

Select Document Type

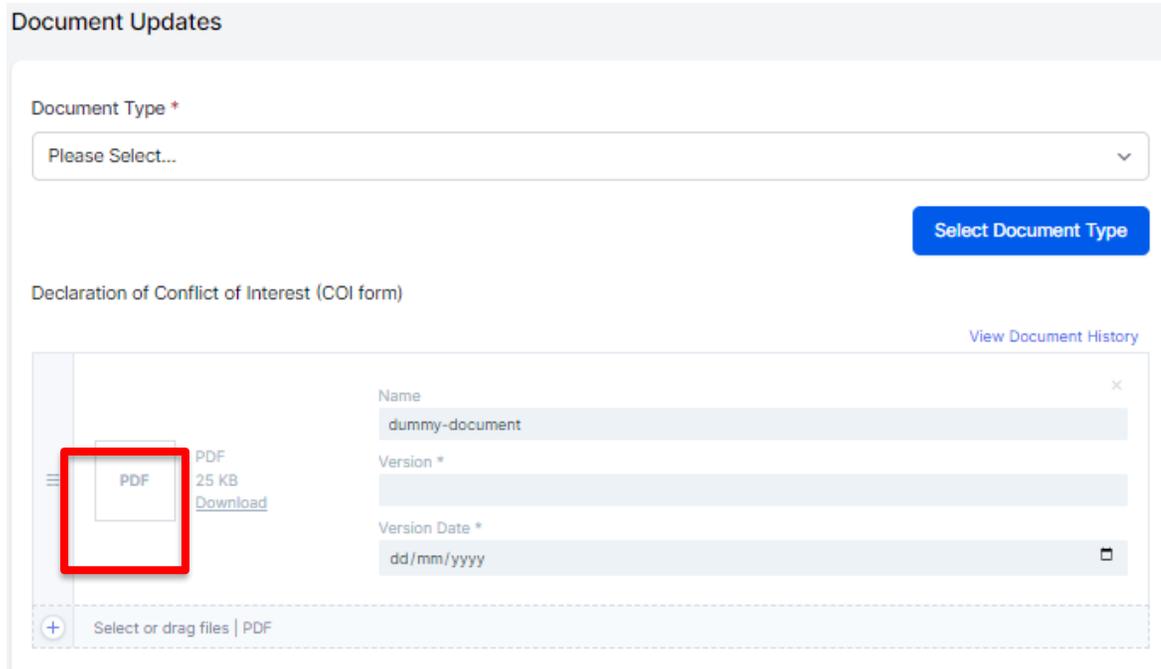
AMENDMENT SUMMARY DETAIL

STUDY INFORMATION

**\*\*Multiple documents can be selected one after another for the update purposes.**

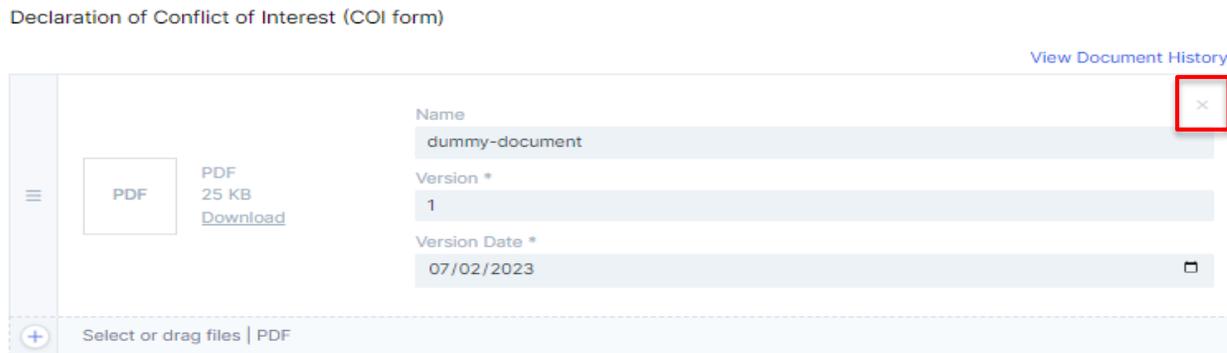
15 To update and replace the amended document:

- 1) Click on the pdf icon  when hovering over the PDF icon to select the new document or drag the document over the old file – this will replace the old document with the new one.

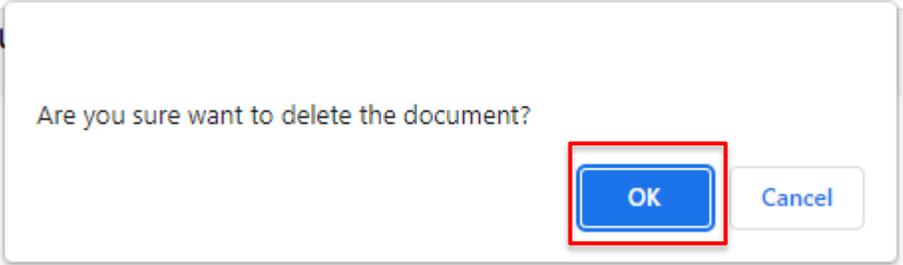


or

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



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



Click on the  icon to acces the document file or drag the document over the box available. Once a document has been uploaded, user can insert the updated version and version date to the file uploaded (if any) . File name can also be changed if needed.

Declaration of Conflict of Interest (COI form)

[View Document History](#)



Declaration of Conflict of Interest (COI form)

[View Document History](#)

 PDF 25 KB <a href="#">Download</a>	Name	dummy document update.pdf
	Version *	2
	Version Date *	23/03/2023
	 Select or drag files   PDF	

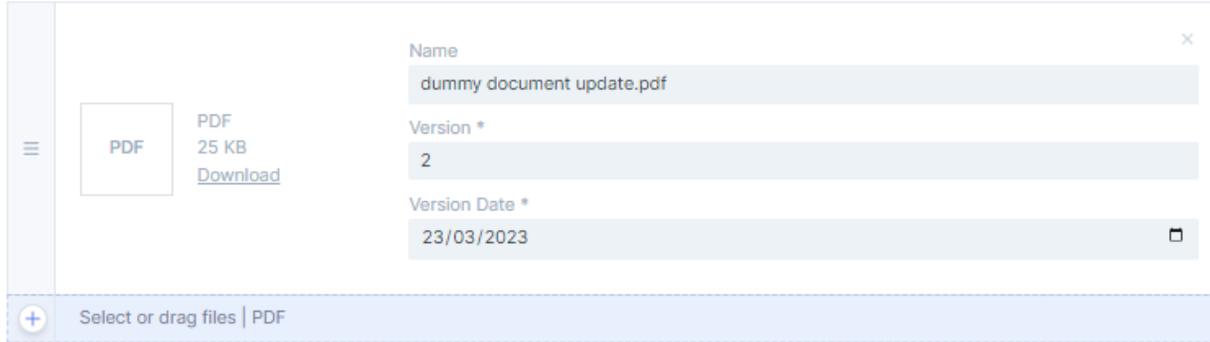
**\*\*Only PDF format file is allowed to be uploaded in this section**

**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**

Once all documents have been uploaded, Click [Save Document](#) to complete the steps and save the uploaded documents.

Declaration of Conflict of Interest (COI form)

[View Document History](#)



The document card displays the following information:

- Name:** dummy document update.pdf
- Version \*:** 2
- Version Date \*:** 23/03/2023

Additional details shown on the left side of the card include:

- File Type:** PDF
- Size:** 25 KB
- Action:** [Download](#)

At the bottom of the card, there is a button labeled "Select or drag files | PDF" with a plus icon.

[Save Document](#)

[Save Document](#)

✓ Amendment Documents Has Been Saved.

16. Once all document updates are saved, continue to scroll down the page. "Amendment Documents" part will be available for user to upload the relevant supporting documents.

Amendment Documents

Cover Letter \*

[View Document History](#)

+ Select or drag files | PDF

Other Supporting Documents

[View Document History](#)

+ Select or drag files | PDF

Save

User can upload the "Cover Letter" and "Other Supporting Document" by either click on the icon + to access 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 [Save](#) to complete and save the uploaded documents.

Cover Letter \*

[View Document History](#)

PDF 25 KB [Download](#)

Name  
dummy-document.pdf

Version \*  
1

Version Date \*  
21/03/2023

Other Supporting Documents

[View Document History](#)

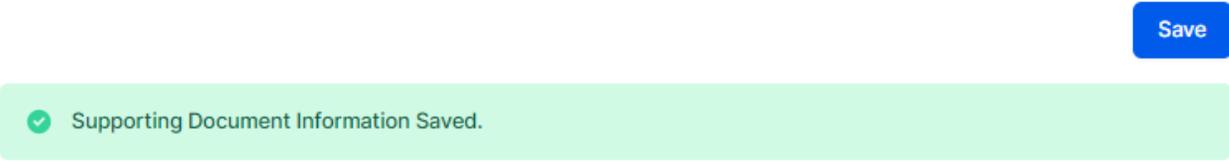
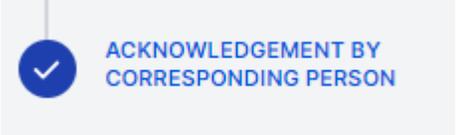
+ Select or drag files | PDF

+ Select or drag files | PDF

Save

**\*\*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**

	<p>A popup up will appear indicating the “Supporting Documents” has been succesfully saved</p> 	
<p>17.</p>	<p>Next, user needs to acknowledge the submisison made at the “Acknowledgement by Corresponding Person ” section.</p>  <p>Tick on the box <input type="checkbox"/> “Yes, I declare that the information provided above is true &amp; 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 amended i formation will results in submission will not be processed further and disapproval by MREC.”</p> 	<p><b>Please ensure all the amended information has been filled up and all the documents required has been uploaded and saved</b></p>

Once submission has been acknowledged, user can submit the Amendment Submission by clicking the  button.

### Submission Acknowledgement By Corresponding Person

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 amended information will result in submission will not be processed further and disapproval by MREC



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

### Amendment

Keyword  Status

Show  entries

#	NMRR ID	AMENDMENT ID	TITLE	STATUS	DATE OF SUBMISSION	ACTION
1	NMRR ID-23-1088	AMDT ID-23-00002-2DG	Approval Versus Analyticals And (23) To Present Drugs In Oral Pediatric Patients Who Have Failed or are Unavailable for Various & Alternative Treatment	Processing Submission by MREC Secretariat	21/03/2023	 

Showing 1 to 1 of 1 entries

Previous  Next

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

In Amendment 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

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

## Amendment Submission

APPROVAL VERSUS ACETYLCHOLINE ACID (AChA) TO PREVENT STROKE IN AT-RISK POPULATION PATIENTS WHO HAVE FAILED OR ARE UNELIGIBLE FOR STROKE-SPECIFIC TREATMENT

NMRR ID [NMRR-00-000-1000](#) Protocol ID [CAT00000](#)  Last updated on Sep 23, 2021

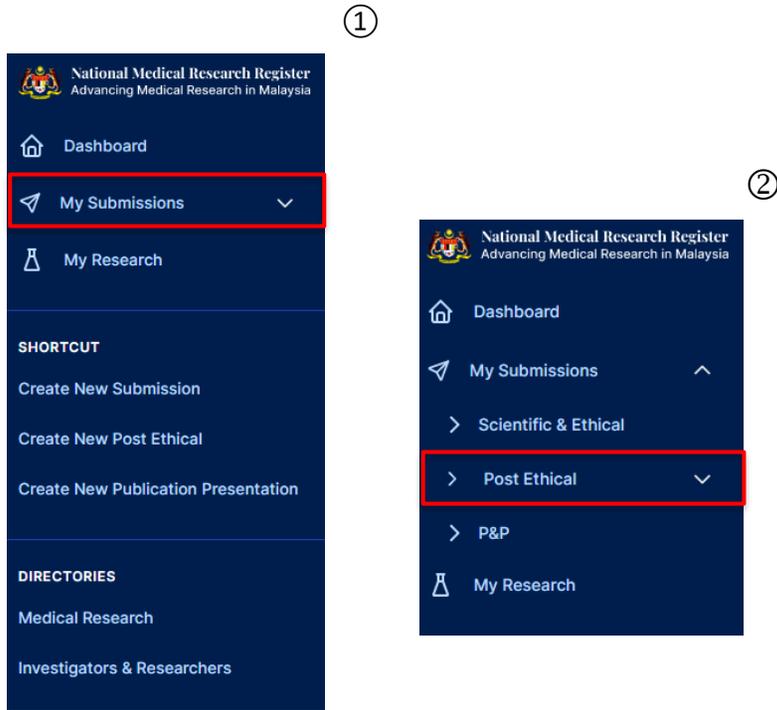
Status Approval granted via MREC Full Board

Amendment Post Ethical ID [AMDT ID-23-00002-2DG](#)

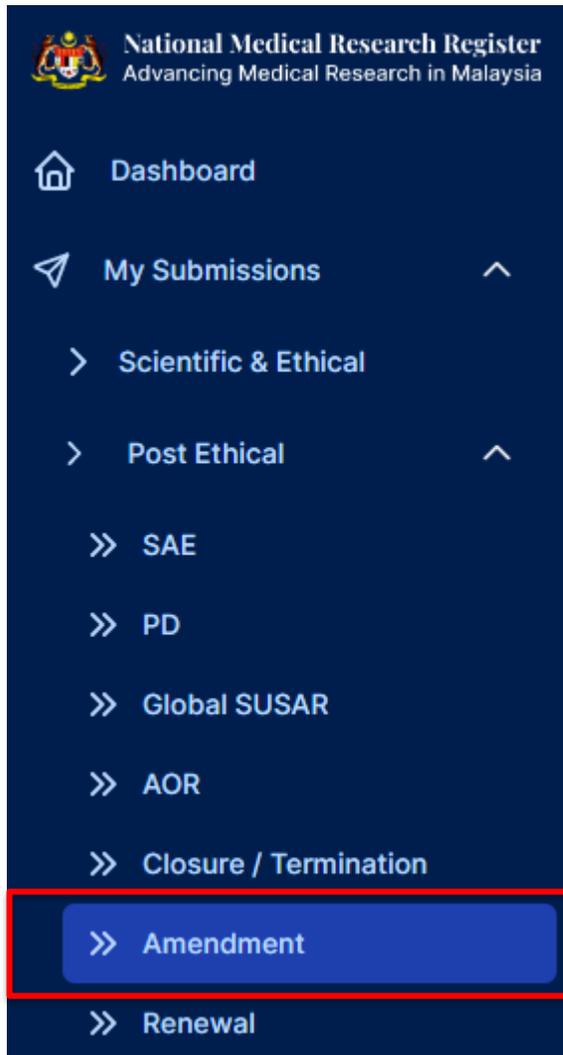
Amendment Status Processing Submission by MREC Secretariat

## 2.0 – Existing Amendment Submission

### 2.1 – Viewing an Existing Amendment 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 image shows two screenshots of the National Medical Research Register dashboard. The first screenshot, labeled with a circled '1', shows the main menu with 'My Submissions' highlighted by a red box. The second screenshot, labeled with a circled '2', shows the 'My Submissions' dropdown menu with 'Post Ethical' highlighted by a red box.</p></div>	

2. Click on Amendment to access the existing Amendment Submission listing.



A list of all existing Amendment Submission will be displayed.

### Amendment

Key, ... J      Status

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

EXCEL   PDF   Show 10 entries

#	NMRR ID	AMENDMENT ID	TITLE	STATUS	DATE OF SUBMISSION	ACTION
1	NMRR ID-23-00608-PLX	AMDT ID-23-00003-WQ3	Amendment testing submission	Pending Submission		   
2	NMRR ID-23-00608-PLX	AMDT ID-23-00002-2DG	Application Status Analytical/Toxicology Report Update to Present Stroke to Allerg Registration Patients Who have Failed or are Unavailable for Initiation of Outpatient Treatment	Processing Submission by MREC Secretariat	21/03/2023	 

Showing 1 to 2 of 2 entries

Previous 1 Next

Please note that one NMRR ID might have a multiple Amendment submission. Therefore, amendment submission will be referred according to the **Amendment Post Ethical ID** or **Amendment ID**.

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

In Amendment Submission Listing, the following action icons are accessible to user

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

3. To view submission, Click on the  icon at the intended Amendment Submission

### Amendment

Key ..... Status

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

EXCEL PDF Show 10 entries

#	NMRR ID	AMENDMENT ID	TITLE	STATUS	DATE OF SUBMISSION	ACTION
1	NMRR ID-23-00608-PLX	AMDT ID-23-00003-WQ3	Amendment testing submission	Pending Submission		   
2	<del>NMRR ID-23-00608-PLX</del>	AMDT ID-23-00002-2DG	Application Versus Anticipatory Social Order to Present Drugs to World Population Patients Who have Failed or are Unavailable for Various of Anticipatory Treatment	Processing Submission by MREC Secretariat	21/03/2023	 

Showing 1 to 2 of 2 entries

Previous 1 Next

User will be able to view the data & documents uploaded for the Amendment 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	21/03/2023 12:27:55	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 

4. To view the Amendment data submission and to compare with the previously approved information , click on the view changes (eg:  Sponsor Changes ) located at the top right corner of each subsection available .

Sponsor  Sponsor Changes

Sponsor

List of Sponsor

FUNDING SOURCE	PRIMARY SPONSOR	SECONDARY SPONSOR
Full Industry Sponsored	Regeneron Pharmaceuticals, Inc. (REGN)	Amgen (AMGN)

Information will be displayed as shown below. The previous data approved by MREC will be displayed in grey while the current ammended submisison will be displayed in red.

### Sponsor Changes

Submission's Sponsor

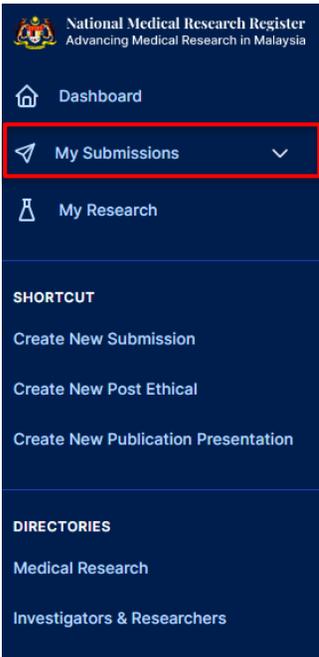
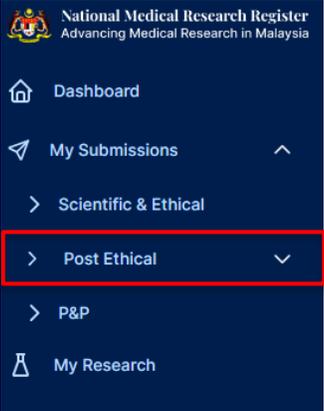
#	FUNDING SOURCE	PRIMARY SPONSOR	SECONDARY SPONSOR
1	Full Industry Sponsored	Regeneron Pharmaceuticals, Inc.	

Amendment's Sponsor

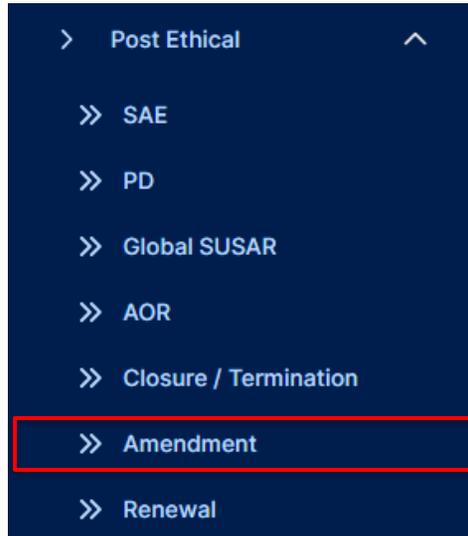
#	FUNDING SOURCE	PRIMARY SPONSOR	SECONDARY SPONSOR
1	Full Industry Sponsored	Regeneron Pharmaceuticals, Inc. STEPHEN 186-887-7182	PHOENIX-948,8728 / 206,848 Jennifer Chung MS 204-1-822-2182/2171

Close

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

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

2. Click on Amendment to access the existing Amendment Submission listing.



A list of all existing Amendment Submission will be displayed.

### Amendment

Keyword  Status

EXCEL PDF Show 10 entries

#	NMRR ID	AMENDMENT ID	TITLE	STATUS	DATE OF SUBMISSION	ACTION
1	NMRR ID-23-00608-PLX	AMDT ID-23-00003-WQ3	Amendment testing submission	Revision Required	22/03/2023	   
2	NMRR ID-23-00608-PLX	AMDT ID-23-00002-ZDG	Apixiban Versus Acetylsalicylic Acid (ASA) to Prevent Stroke in Atrial Fibrillation Patients Who have Failed or are Unavailable for Vitamin K Antagonist Treatment	Approval granted via Expedited Review by MREC Chairperson/ Deputy Chairperson	21/03/2023	 

Showing 1 to 2 of 2 entries

Previous **1** Next

The status of an Amendment 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

### Amendment

Keyword

Search NMRR ID, Research ID or Title of the Submission

Status

Select All

EXCEL

PDF

Show

10

entries

#

NMRR ID

AMENDMENT ID

TITLE

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 Amendment Submission.

### Amendment

Keyword  Status Revision Required

Show  entries

#	NMRR ID	AMENDMENT ID	TITLE	STATUS	DATE OF SUBMISSION	ACTION
1	NMRR ID-23-00608-PLX	AMDT ID-23-00003-WQ3	Amendment testing submission	Revision Required	22/03/2023	

Showing 1 to 1 of 1 entries

Previous 1 Next

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

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

When viewing the data of Amendment 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"

## Amendment Checklist Comments

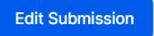
### AMENDMENT TESTING SUBMISSION

NMRR ID NMRR ID-23-00608-PLX Protocol ID -  Last updated on Mar 21, 2023

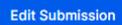
Status Approval granted via Expedited Review by MREC Chairperson/ Deputy Chairperson

Amendment Post Ethical ID AMDT ID-23-00003-WQ3

Amendment Status Revision Required

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

Other Relevant Comment



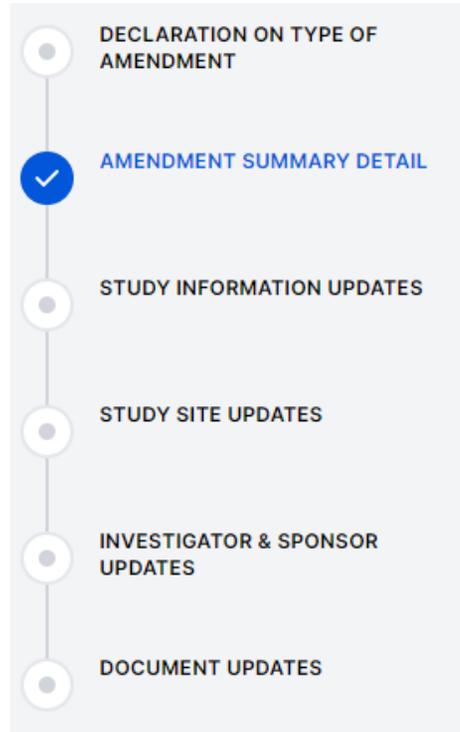
Secretariat

4 minutes ago

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

Response

A new tab will appear with the section of amendment submission appears over the right part of the display



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 [Save](#) to save the information changes

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

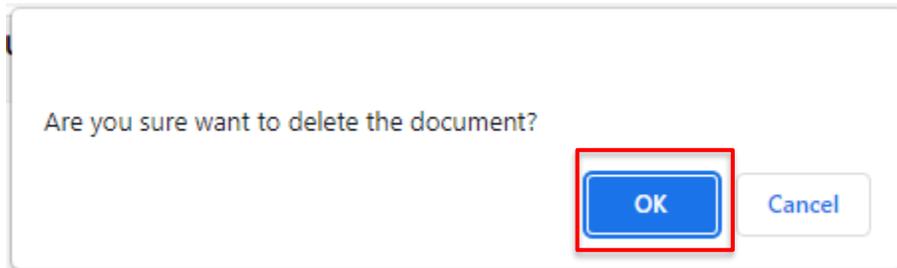
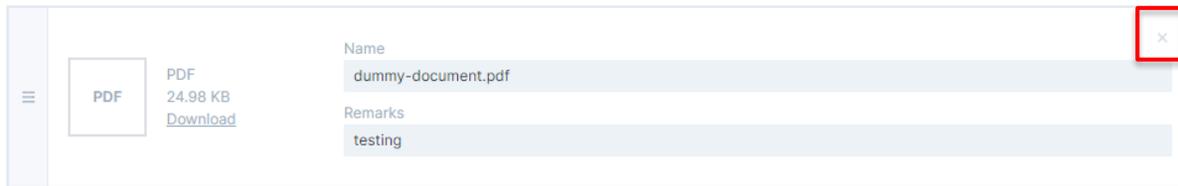
3) Click on the pdf icon  to select new document or drag the documents over the old file – this will replace the old documents with the new one. Then click  on the button to complete and save the new document

or

4) 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 <a href="#">Download</a>	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  "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 amended information will results in submission will not be processed further and disapproval by MREC."

Submission Acknowledgement By Corresponding Person

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 amended information will results in submission will not be processed further and disapproval by MREC

Submit

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

Submission Acknowledgement By Corresponding Person

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 amended information will results in submission will not be processed further and disapproval by MREC

Submit

Once Amendment Submission revision has been successfully submitted, user will be brought back to the Amendment Submission listing.

# Amendment Submission

## AMENDMENT TESTING SUBMISSION

NMRR ID NMRR ID-23-00608-PLX Protocol ID -  Last updated on Mar 21, 2023

Status Approval granted via Expedited Review by MREC Chairperson/ Deputy Chairperson

Amendment Post Ethical ID AMDT ID-23-00003-WQ3

**Amendment Status** Revision Submitted To MREC Secretariat

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

### Amendment

Keyword

Status

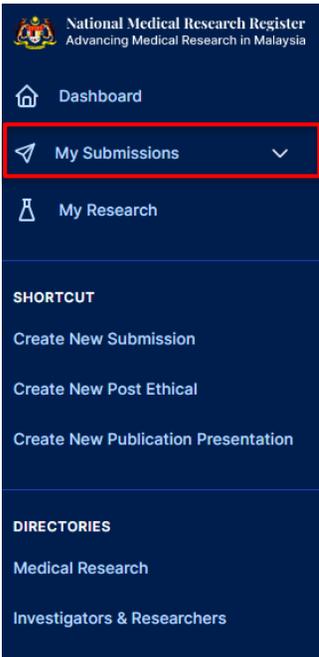
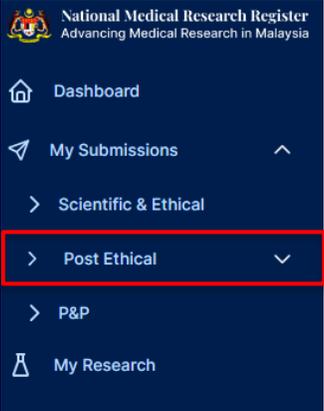
Show  entries

#	NMRR ID	AMENDMENT ID	TITLE	STATUS	DATE OF SUBMISSION	ACTION
1	NMRR ID-23-00608-PLX	AMDT ID-23-00003-WQ3	Amendment testing submission	Revision Submitted To MREC Secretariat	23/03/2023	 
2	NMRR-08-435-1590	AMDT ID-23-00002-2DG	Apixaban Versus Acetylsalicylic Acid (ASA) to Prevent Stroke in Atrial Fibrillation Patients Who have Failed or are Unsuitable for Vitamin K Antagonist Treatment	Approval granted via Expedited Review by MREC Chairperson/ Deputy Chairperson	21/03/2023	 

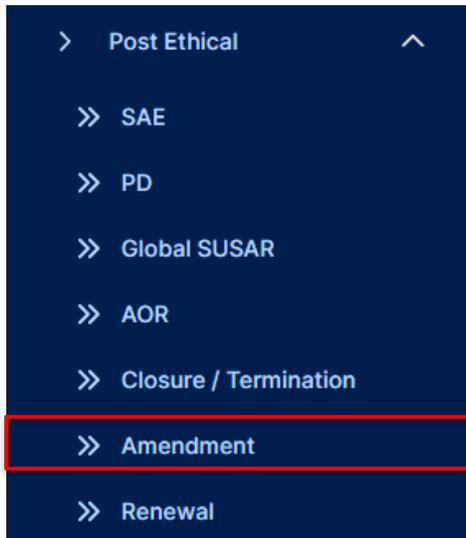
Showing 1 to 2 of 2 entries

Previous  Next

## 2.3 – Editing/ Deletion of Amendment 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 Amendment 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 Amendment to access the existing Amendment Submission listing.



A list of all existing Amendment Submission will be displayed.

**Amendment**

Keyword:  Status:

Show  entries

#	NMRR ID	AMENDMENT ID	TITLE	STATUS	DATE OF SUBMISSION	ACTION
1	NMRR ID-23-00608-PLX	AMDT ID-23-00005-6I7	Amendment testing submission	Pending Submission		
2	NMRR ID-23-00608-PLX	AMDT ID-23-00002-2DG	Amendment testing submission	Approval granted via Expedited Review by MREC Chairperson/ Deputy Chairperson	21/03/2023	
3	NMRR ID-23-00608-PLX	AMDT ID-23-00003-WQ3	Amendment testing submission	Revision Submitted To MREC Secretariat	22/03/2023	

Showing 1 to 3 of 3 entries

Previous  Next

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

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

### Amendment

Keyword  Status

Show  entries

#	NMRR ID	AMENDMENT ID	TITLE	STATUS	DATE OF SUBMISSION	ACTION
1		AMDT ID-23-00005-617		Pending Submission		 
2		AMDT ID-23-00002-2DG		Approval granted via Expedited Review by MREC Chairperson/ Deputy Chairperson	21/03/2023	 
3	NMRR ID-23-00608-PLX	AMDT ID-23-00003-WQ3	Amendment testing submission	Revision Submitted To MREC Secretariat	22/03/2023	 

Showing 1 to 3 of 3 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)

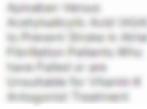
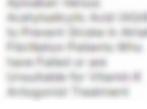
These roles can view and edit each other submission

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

#### Amendment

Keyword  Status

Show  entries

#	NMRR ID	AMENDMENT ID	TITLE	STATUS	DATE OF SUBMISSION	ACTION
1		AMDT ID-23-00005-617		Pending Submission		  
2		AMDT ID-23-00002-2DG		Approval granted via Expedited Review by MREC Chairperson/ Deputy Chairperson	21/03/2023	 
3	NMRR ID-23-00608-PLX	AMDT ID-23-00003-WQ3	Amendment testing submission	Revision Submitted To MREC Secretariat	22/03/2023	 

Showing 1 to 3 of 3 entries Previous **1** Next

Are you sure you want to remove this record?

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

Once it is clicked, the Amendment Submission will be deleted and removed from the Amendment Submission listing .

### Amendment

Keyword  Status

Show  entries

#	NMRR ID	AMENDMENT ID	TITLE	STATUS	DATE OF SUBMISSION	ACTION
1		AMDT ID-23-00002-2DG		Approval granted via Expedited Review by MREC Chairperson/ Deputy Chairperson	21/03/2023	
2		AMDT ID-23-00003-WQ3		Revision Submitted To MREC Secretariat	22/03/2023	

Showing 1 to 2 of 2 entries

Previous  Next

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-The End -

Prepared by: NMRR Secretariat

Flow checked & validated by: Asyraf Syahmi Bin Mohd Noor (date: 24/03/2023)