User Guidelines for

Post Ethical Approval Submission

- Global SUSAR

National Medical Research Register v2.0

National Institutes of Health (NIH)

Table of Contents

Prerequisite For Submission

No	Criteria
1.1	User has the access to NMRR Version 2.0 (nmrr.gov.my) via a stable internet connection
1.2	Prerequisite: ● 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 with a NMRR ID) with "Interventional" Research Type ● Submission has received Initial Ethical Approval from MREC (Approval granted via MREC Full Board)
1.3	User has a role assigned in an approved submission either as: • Principal / Coordinating Investigator (PI) • Main Corresponding Person (Main CP) • Backup Corresponding Person (Backup CP) • Global SUSAR Coordinator

Information/ Documents Required

General Global SUSAR Reporting Information
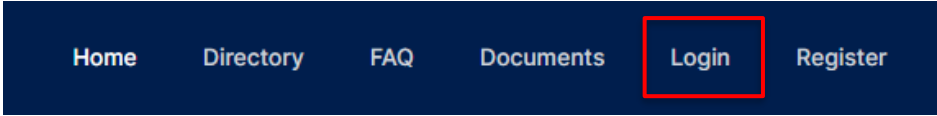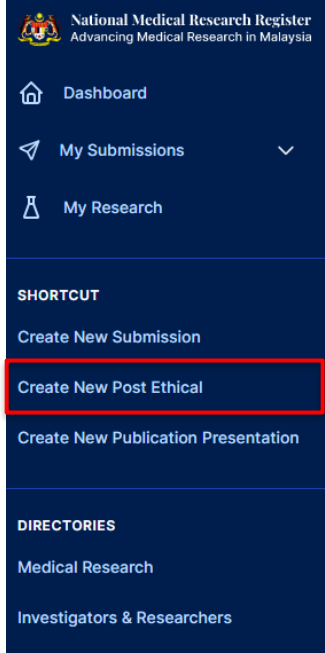1. Global SUSAR Reporting Title
2. Narrative of Global SUSAR Reported

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

User Guidelines for Submission

1.0 - New Global SUSAR Reporting Submission

1.1 – Creating a New Global SUSAR Reporting Submission

No	Step-by-step instructions	Remark
1.	Log in as Investigator or CRA in NMRR	
2.	Scroll over the main menu located on the side of the display page, go to shortcut, and select Create New Post Ethical	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: • Principal / Coordinating Investigator (PI) • Main Corresponding Person (Main CP) • Backup Corresponding Person (Backup CP) • Global SUSAR Coordinator

| 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 "Global SUSAR" |

Once Global SUSAR is selected, list of submission accessible for Global SUSAR Submission will be displayed

4.	Click on the 📋 icon to create a new Global SUSAR Submission

Keyword

Search NMRR ID, Research ID or Title of the Submission

Select Post Ethical Approval Type

Global SUSAR

Show 10 ✔ entries

#	NMRR ID	TITLE	RESEARCH SCOPE	RESEARCH TYPE	STATUS	ACTION
1	NMRR ID-22-01776-BGJ	Testing Submission	Clinical	Interventional	Approval granted via Expedited Review by MREC Primary Reviewers	📋

Showing 1 to 1 of 1 entries

Previous 1 Next

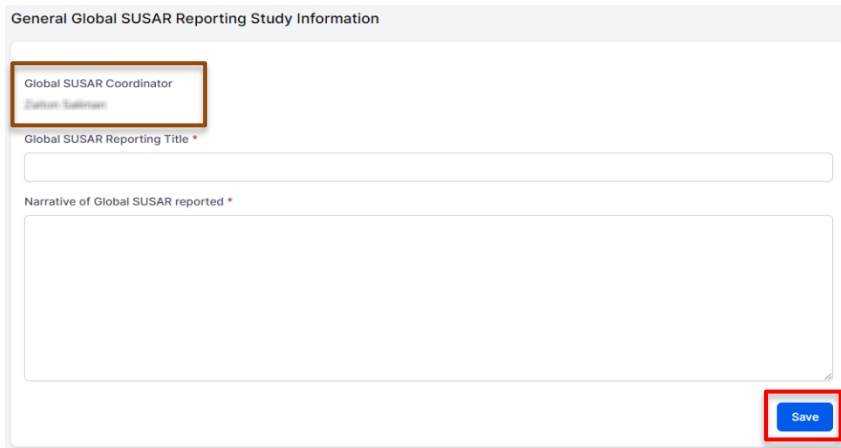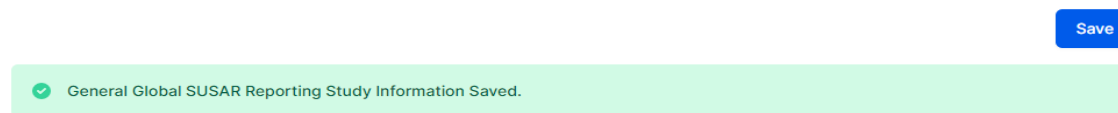| 5.	A page will be displayed with the General information of the Submission is shown over the top part of the display page

Submission

TESTING SUBMISSION

NMRR ID NMRR ID-22-01776-BGJ   **Protocol ID** V1, 24/08/2022   📅 Last updated on Aug 24, 2022

Status Approval granted via Expedited Review by MREC Primary Reviewers

6.	Scoll down the page to the "General Global SUSAR Reporting Information".Insert information on the "Global SUSAR Reporting Title" &" Narative of Global SUSAR Reported". Click [Save] to save the information .	**Global SUSAR Coordinator** name will be displayed in the General Global SUSAR Reporting Information

General Global SUSAR Reporting Study Information

Global SUSAR Coordinator
Zaitun Salman

Global SUSAR Reporting Title *

Narrative of Global SUSAR reported *

[Save]

A popup up will appear indicating the "General Global SUSAR Reporting Information" has been succesfully saved

[Save]

✓ General Global SUSAR Reporting Study Information Saved.

A Global SUSAR Post Ethical ID will be generated and Global SUSAR Status will be displayed as "Pending Submission". This information can be seen over the top part of the display page under the General Information of the Submission

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

Global SUSAR Submission

TESTING SUBMISSION

NMRR ID NMRR ID-22-01776-BGJ   **Protocol ID** V1, 24/08/2022   📅 Last updated on Aug 24, 2022

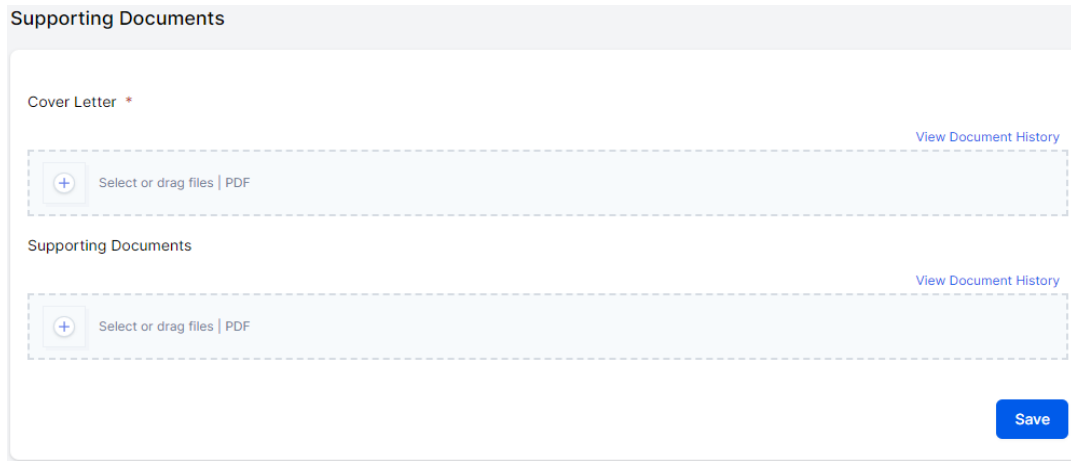**Status**   Approval granted via Expedited Review by MREC Primary Reviewers

Global SUSAR Post Ethical ID   SSR ID-22-00009-GTS
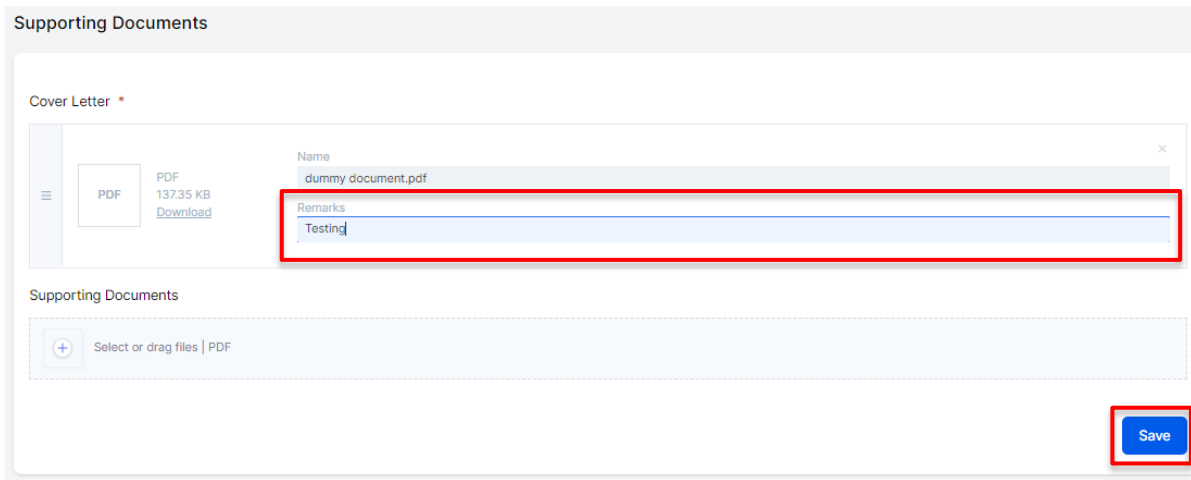
Global SUSAR Status   Pending Submission

7.	Continue to scroll down on the page. "Supporting Documents" part will be availble for user to upload the relevant documents.	
		**Only PDF format file is allowed to be uploaded in this section
	User can upload the "Cover Letter to MREC" and other "Supporting Document" by either clicking on the ⊕ icon to acces the document file or draging the document into the box available.Once it has been uploaded, user can insert a remark to the uploaded document (if any). Document name can also be changed if needed. Once all documents have been uploaded, Click Save to complete and save the uploaded documents.	**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**

	A popup up will appear indicating the "Supporting Documents" has been succesfully saved Save ✓ Supporting Documents Information Saved.	
8.	Next, user needs to acknowledge the submission made at the "Submission Acknowledgement". Tick on the box ☐ "I acknowledge that I have read, and do hereby accept the terms and conditions contained in NMRR terms and condition document." Submission Acknowledgement ☐ I acknowledge that I have read, and do hereby accept the terms and conditions contained in NMRR terms and condition document. Submit Decision History | #	APPROVER NAME	DECISION	DECISION DATE	APPROVAL AUTHORITY | Once submission has been acknowlegded, user can submit the Global SUSAR Reporting Submission by clicking the Submit button. Submission Acknowledgement ☑ I acknowledge that I have read, and do hereby accept the terms and conditions contained in NMRR terms and condition document. Submit Decision History | #	DECISION	DECISION DATE	APPROVAL AUTHORITY		****Please ensure all the information has been filled up and all the documents required has been uploaded and saved.**

Once the new Global SUSAR Reporting Submission has been successfully submitted, user will be brought to the Global SUSAR Reporting listing page.

Global SUSAR Reporting

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

EXCEL   PDF   Show 10 entries

#	NMRR ID	TITLE	STATUS	GLOBAL SUSAR REPORTING ID	NO OF GLOBAL SUSAR REPORTING REPORTED	DATE OF SUBMISSION	ACTION
1							
2	NMRR ID-22-01776-BGJ	Testing Submission	Processing Submission by MREC Secretariat	SSR ID-22-00009-GTS Follow Up 1	1	25/08/2022	

Showing 1 to 2 of 2 entries

Previous 1 Next

When viewing the data of Global SUSAR Reporting Submission, the General information of the Submission will be shown on the top of the display page

Global SUSAR Submission

TESTING SUBMISSION

NMRR ID NMRR ID-22-01776-BGJ   Protocol ID V1, 24/08/2022   📅 Last updated on Aug 24, 2022

Status Approval granted via Expedited Review by MREC Primary Reviewers

Global SUSAR Post EthicalID SSR ID-22-00009-GTS

Global SUSAR Status Processing Submission by MREC Secretariat
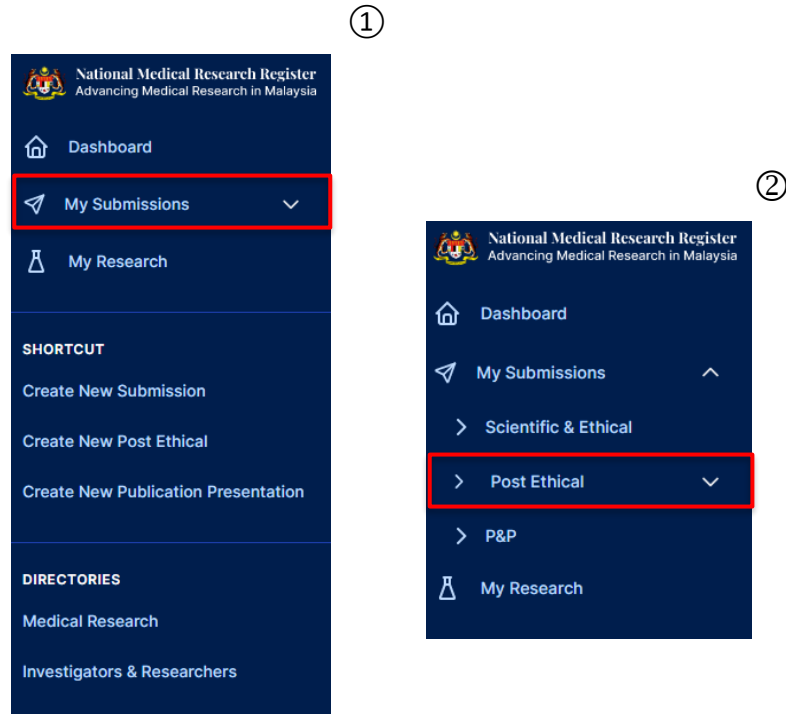
In Global SUSAR Reporting listing, the following action icons are accessible to user :

- Show 👁 icon - to view the data of Global SUSAR Reporting Submission
- Initial Submission 📋 icon - to show the initial registration data of NMRR ID Submission

The status of a successful new submission of Global SUSAR Reporting will change from "**Pending Submission**" to "**Processing Submission by MREC Secretariat** "

2.0 – Existing Global SUSAR Reporting Submission

2.1 – Viewing an Existing Global SUSAR Reporting Submission

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

2.	Click on Global SUSAR to access the existing Global SUSAR Reporting Submission listing.	
		Please note that one NMRR ID might have a multiple Global SUSAR Reporting Submission. Therefore, Global SUSAR Reporting Submission will be referred according to the **Global SUSAR Post Ethical ID** or **Global SUSAR Reporting ID**
	A list of all existing Global SUSAR Reporting Submission will be displayed. 	In Global SUSAR Reporting listing, the following action icons are accessible to user : - Show ⊙ icon - to view the data of Global SUSAR Reporting Submission - Initial Submission ⊡ icon to show the initial registration data of NMRR ID Submission - Edit ✎ icon - to edit the Global SUSAR Reporting Submission (icon available only for Global SUSAR Reporting Submission with status "Pending Submission" and "Request for More Information/ Revision Required" - Bin 🗑 icon - to delete Global SUSAR Reporting Submission (icon available only in Global SUSAR Submission with status "Pending Submission"

3.	To view submission, click on the 👁 icon at the intended Global SUSAR Reporting Submission	This can only be accessible by user that has been assigned with a role either as:

Global SUSAR Reporting

Keyword

| Search NMRR ID, Research ID or Title of the Submission |

Status

| Select All ⌄ |

EXCEL   PDF   Show | 10 ⌄ | entries

#	NMRR ID ▼	TITLE ⇳	STATUS ⇳	GLOBAL SUSAR REPORTING ID ⇳	NO OF GLOBAL SUSAR REPORTING REPORTED	DATE OF SUBMISSION ⇳	ACTION
1	NMRR-ID-1234-5525	A Randomized Double-Blind Placebo-Controlled Phase 3 Study to Investigate the Efficacy and Safety of Progesterone in Patients with Severe Traumatic Brain Injury	Revision Submitted To MREC Secretariat	SSR ID-23-00011-AJB	1	07/01/2023	👁 📋

User will be able to view the data & documents uploaded of Global SUSAR Reporting Submission

General Global SUSAR Reporting Study Information

Global SUSAR Reporting Coordinator
Zaiton Salleh

Global SUSAR Reporting ID
SSR ID-23-00011-AJB

Global SUSAR Reporting Title
testing

Narrative of Global SUSAR reported
testing

Supporting Documents

Cover Letter *

View Document History

Right column text:

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)
- Global SUSAR Coordinator

These roles can view and edit each other submission

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User also will be able to see the Decision History of the Global SUSAR Reporting Submission. The decision history is available at the bottom of the data submission page.
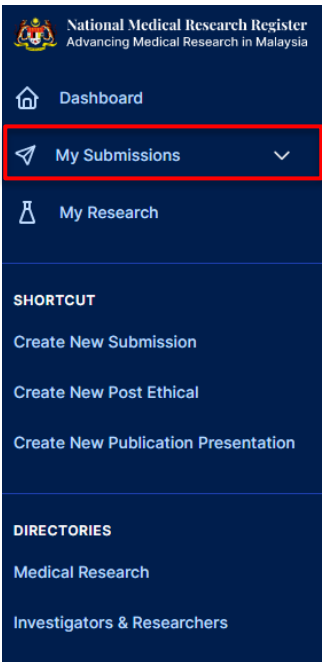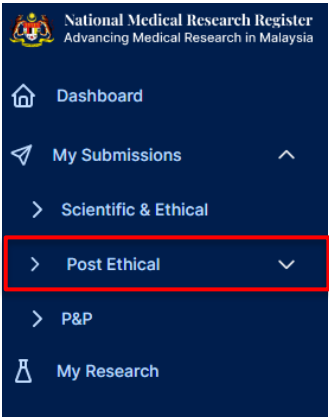
Decision History

#	DECISION	DECISION DATE	APPROVAL AUTHORITY
1	Initial Submission	25-08-2022 12:20:17	Investigator

User also will be able to download 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	07/01/2023 05:21:01	Investigator	
2	Request for more information / Revision required	07/01/2023 00:00:00	MREC Secretariat	
3	Revision Submitted To MREC Secretariat	07/01/2023 22:06:36	Investigator	
4	Submission Notified	02/01/2023 00:00:00	MREC Secretariat	⤓

2.2 – Editing of Global SUSAR Reporting Submission with status "Request for More Information/ Revision Required "

No	Step-by-step instructions	Remark
1.	In the case where Global SUSAR Reporting Submission is assigned with status "Request for More Information/Revision Required". Scroll over the main menu located on the side of display page, go to "My Submission". Then Click on the "Post Ethical" ① ②	User will be notified via email if a particularGlobal SUSAR Reporting Submission requires revision or more information.

2.	Click on Global SUSAR to access the existing Global SUSAR Reporting Submission listing.	
	A list of all existing Global SUSAR Reporting Submission will be displayed.	
		The status of a Global SUSAR Reporting Submission that requires revision or more information will be **"Request for more information / Revision Required"**
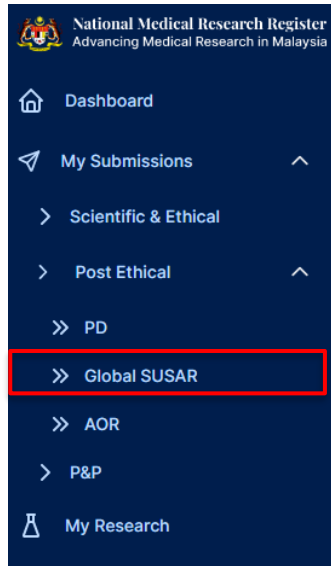
3.	To edit submission, click on the ✏ icon at the intended Global SUSAR Reporting Submission	This can only be accessible by user that has been assigned with a role either as:
	Global SUSAR Reporting	• Principal / Coordinating Investigator (PI)
	Keyword	Status	• Main Corresponding Person (Main CP)
	Search NMRR ID, Research ID or Title of the Submission	Select All ▾	• Backup Corresponding Person (Backup CP)
	EXCEL PDF Show 10 ▾ entries		• Global SUSAR Coordinator
			These roles can view and edit each other submission

Global SUSAR Reporting

Keyword
Search NMRR ID, Research ID or Title of the Submission

Status
Select All

EXCEL   PDF   Show 10 entries

#	NMRR ID	TITLE	STATUS	GLOBAL SUSAR REPORTING ID	NO OF GLOBAL SUSAR REPORTING REPORTED	DATE OF SUBMISSION	ACTION
1			Request for more information / Revision required	SSR ID-23-00011-AJB	1	07/01/2023	👁 ✏ 📋
2			Pending Submission	SSR ID-23-00013-BJT	1		👁 ✏ 🗑 📋

Showing 1 to 2 of 2 entries   Previous **1** Next

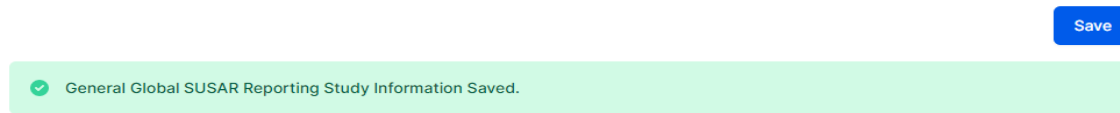| 4.	Insert new information required as per email by MREC . Click [Save] to save the information.	

General Global SUSAR Reporting Study Information

Global SUSAR Coordinator

Global SUSAR Reporting Title *

Testing Submissions

Narrative of Global SUSAR reported *

Testing Submissions Narrative

[Save]

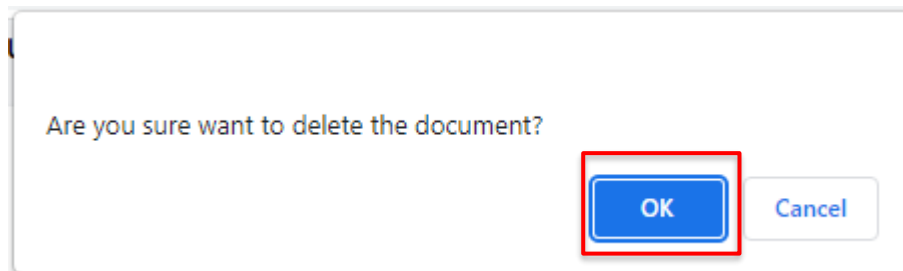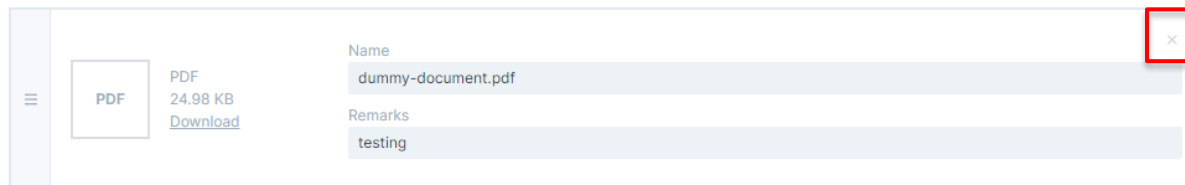|		A popup up will appear indicating the General Global SUSAR Reporting Information has been succesfully saved
		Save
		✓ General Global SUSAR Reporting Study Information Saved.
5.		To update and replace document in the "Supporting Documents" ,
		1) Click on the pdf icon [⏎] to select the new document or drag the document over the old file – this will replace the old document with the new one. Then click on the **Save** 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
		☰ PDF	PDF 24.98 KB Download	Name dummy-document.pdf Remarks testing	×
		Are you sure want to delete the document?
		OK Cancel

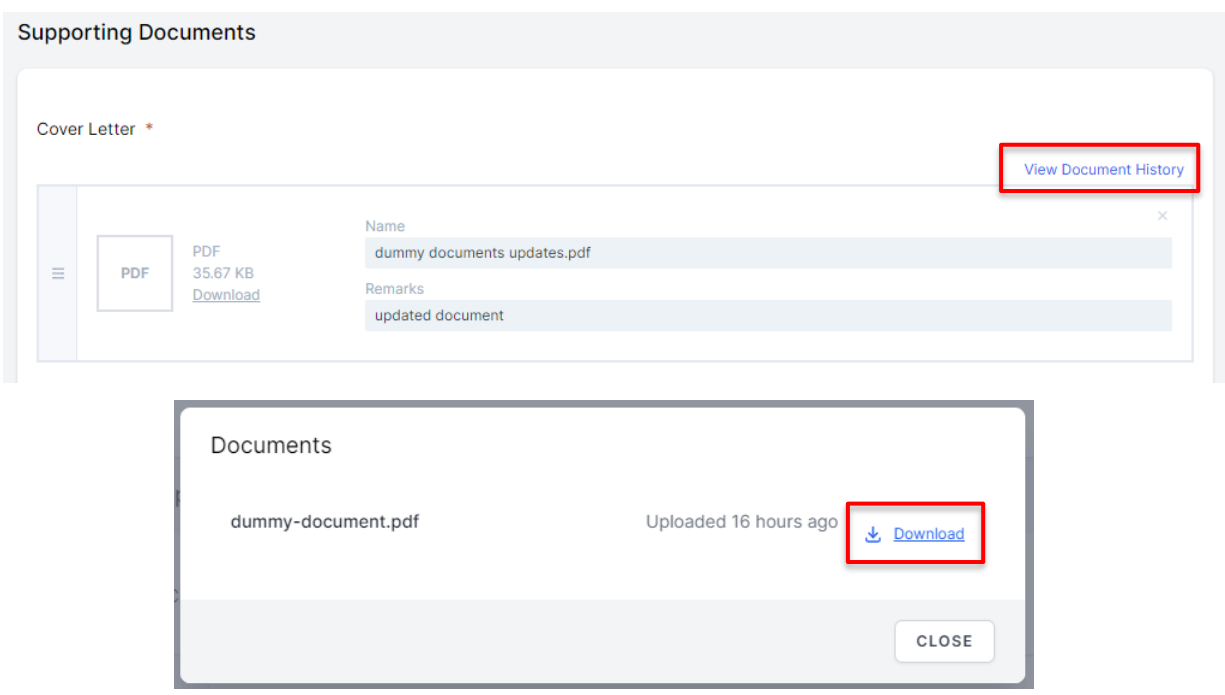|		Click on the ⊕ icon to acces the document file or drag the document over the box available.Once a document has been uploaded, user can insert a remark to the file uploaded (if any) . File name can also be changed if needed. Once all documents have been uploaded, Click **Save** to complete the steps and save the uploaded documents. **Save** ✓ 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** User may look back at the previous uploaded document in the "**View Document History"** located at the top right of each document section after the updated documents are saved
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 be able to download the previously uploaded document (if needed) by clicking the ↓ Download icon next to the document title. **Supporting Documents** Cover Letter * View Document History Name dummy documents updates.pdf ≡ PDF PDF 35.67 KB Download × Remarks updated document Documents dummy-document.pdf Uploaded 16 hours ago ↓ Download CLOSE	

7.	Once all the required revision and documents have been uploaded, user is required to acknowledge the submisison made at the "Submisison Acknowledgement. Tick on the box ☐ "I acknowledge that I have read, and do hereby accept the terms and conditions contained in NMRR terms and condition document."	

Submission Acknowledgement

☐ I acknowledge that I have read, and do hereby accept the terms and conditions contained in NMRR terms and condition document.

Submit

Decision History

#	APPROVER NAME	DECISION	DECISION DATE	APPROVAL AUTHORITY

Once submission has been acknowleged, user can submit the Global SUSAR Reporting submission revision by clicking the Submit button.

Submission Acknowledgement

☑ I acknowledge that I have read, and do hereby accept the terms and conditions contained in NMRR terms and condition document.

Submit

Decision History

#	DECISION	DECISION DATE	APPROVAL AUTHORITY

Once a Global SUSAR Reporting Submission revision has been successfully submitted, user will be brought back to the Global SUSAR Reporting listing .

Global SUSAR Reporting

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

EXCEL   PDF   Show 10 ⌄ entries

#	NMRR ID ▼	TITLE ⬍	STATUS ⬍	GLOBAL SUSAR REPORTING ID ⬍	NO OF GLOBAL SUSAR REPORTING REPORTED	DATE OF SUBMISSION ⬍	ACTION
1	▨▨▨▨	▨▨▨▨	Revision Submitted To MREC Secretariat	SSR ID-23-00011-AJB	1	07/01/2023	👁 📋

Global SUSAR Submission

A RANDOMISED, DOUBLE BLIND, PLACEBO CONTROLLED PHASE 3 STUDY TO INVESTIGATE THE EFFICACY AND SAFETY OF PROGESTERONE IN PATIENTS WITH SEVERE TRAUMATIC BRAIN INJURY

NMRR ID ▨▨▨▨   Protocol ID ▨▨▨▨   📅 Last updated on ▨▨▨▨

Status   Approval granted via MREC Full Board

Global SUSAR Post Ethical ID   SSR ID-23-00011-AJB

Global SUSAR Status   Revision Submitted To MREC Secretariat

The status of a successful revision submission of Global SUSAR Reporting will change from **"Request for more information / Revision Required"** to **"Revision Submitted to MREC Secretariat"**

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2.3 – Editing/ Deletion of Global SUSAR Reporting Submission with status "Pending Submission"

No	Step-by-step instructions	Remark
1.	In the case where user have not managed to complete the submission and would like to edit or delete the existing Global SUSAR Reporting Submission, scroll over the main menu located on the side of display page, go to "My Submission". Then Click on the "Post Ethical" ① ②	.

2.	Click on Global SUSAR to access the existing Global SUSAR Reporting Submission listing.	
	A list of all existing Global SUSAR Reporting Submission will be displayed.	
		The status of a Global SUSAR Reporting Submission that has not yet been sent will be **"Pending Submission."**

3.	To edit submission, click on the ✏️ icon at the intended Global SUSAR Reporting Submission and follow the steps as mentioned above in 1.1 "**Creating a New Global SUSAR Reporting Submission**"	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) • Global SUSAR Coordinator These roles can view and edit each other submission
4.	To delete a Global SUSAR Reporting Submisison, click on the delete 🗑️ icon of the intended submission	Deletion of a Global SUSAR Reporting Submission will only be available for submission that has never been submitted to MREC Secretariat for processing

Click [OK] to confirm the deletion of the Global SUSAR Reporting Submission. Once it is clicked, the Global SUSAR Reporting Submission will be deleted and removed from the Global SUSAR Reporting listing.

Are you sure you want to remove this record?

[OK] [Cancel]
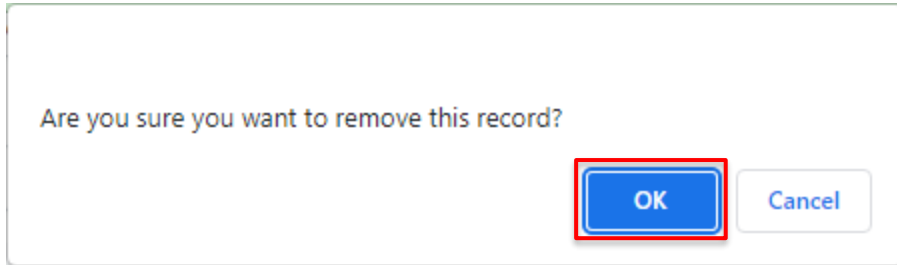
-The End -

Prepared by: NMRR Secretariat

Flow checked & validated by: Asyraf Syahmi Bin Mohd Noor (date : 09/01/2023)