User Guidelines for

Post Ethical Approval Submission

- AOR

National Medical Research Register v2.0

National Institutes of Health (NIH)

Version 1.0 , January 2023

Table of Contents

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: ● 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: • Principal / Coordinating Investigator (PI) • Main Corresponding Person (Main CP) • Backup Corresponding Person (Backup CP)

Information/ Documents Required

General Acknowledgement of Receipt (AOR) Information
1. Study Site involvement - are all study site invoved?
2. Type of Acknowledgement of Receipt (AOR)
3. Description of Acknowledgement of Receipt (AOR)

Acknowledgement of Receipt (AOR) 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 Acknowledgement of Receipt (AOR) Submission

1.1 – Creating a New Acknowledgement of Receipt (AOR) Submission

No	Step-by-step instructions	Remark
1.	Log in as Investigator or CRA in NMRR Home Directory FAQ Documents **Login** Register	
2.	Scroll over the main menu located on the side of the display page, go to shortcut, and select Create New Post Ethical National Medical Research Register Advancing Medical Research in Malaysia Dashboard My Submissions My Research SHORTCUT Create New Submission Create New Post Ethical Create New Publication Presentation DIRECTORIES Medical Research Investigators & Researchers	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)
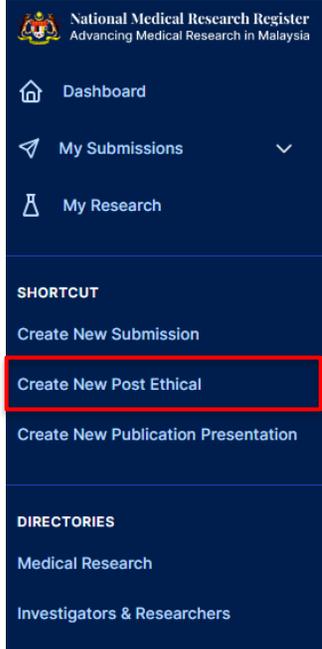
3.	A list of all submission that has received MREC initial Ethical Approval will be shown on display. Go to "Select Post Ethical Approval Type" and choose "AOR"

Once AOR is selected, list of submission accessible for Acknowledgement of Receipt (AOR) Submission will be displayed

4.	Click on the 📋 icon to create a New Acknowledgement of Receipt (AOR) Submission **New Post Ethical Approval** Keyword	Select Post Ethical Approval Type Search NMRR ID, Research ID or Title of the Submission	AOR Show 10 entries 	#	NMRR ID	TITLE	RESEARCH SCOPE	RESEARCH TYPE	STATUS	ACTION	 	1			Clinical	Interventional	Approval granted via MREC Full Board	📋	
5.	A page will be displayed with the General information of the Submission is shown over the top part of the display page. **AOR 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 Sep 23, 2021 **Status**	Approval granted via MREC Full Board

6.	Scoll down the page to the "General Acknowledgement of Receipt (AOR) Information" .Insert information on the "Study Site involvement ", "Type of Acknowledgement of Receipt (AOR)" & " Description of Acknowledgement of Receipt (AOR)". Click [Save] to save the information .	Refer to **step No. 7** if "Study Site Involvement" is **not involving all sites** and for the detail of **Type of Acknowledgement of Receipt**
	Acknowledgement of Receipt Are all study sites involved * ◉ Yes ○ No Type of Acknowledgement of Receipt * Please Select... ⌄ Description of AOR * Description in writing [ ] [Save] A popup up will appear indicating the Acknowledgement of Receipt (AOR) Information has been succesfully saved. [Save] ✓ Acknowledgement of Receipt Information Saved. An AOR Post Ethical ID will be generated and AOR Submission Status will be displayed as "Pending Submission". This information can be seen over the top part of the display page **AOR 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 Sep 23, 2021 Status Approval granted via MREC Full Board AOR Post Ethical ID AOR ID-23-00017-L5U AOR Status Pending Submission	
		AOR Post Ethical ID will be the reference number for the Acknowledgement of Receipt (AOR) Submission from this point onwards. Once an AOR Post Ethical ID is generated, Acknowledgement of Receipt (AOR) submission has now been created successfully and is available to be accessed from "My Submission" menu. **AOR Post Ethical ID** later in the submission will also be referred to as **Acknowledgement of Receipt (AOR) Submission ID**
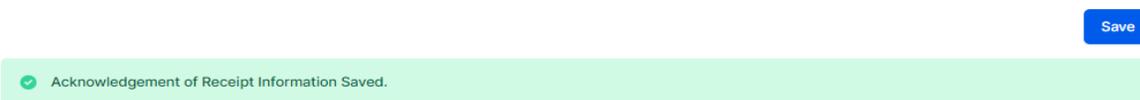
7.	a) If "Study Site involment" selection is "No" , user is required to select which sites are involved in this Acknowledgement of Receipt (AOR) Submission. In order **to select more than one site**, user is required **to press and hold CTRL button** on keyboard while selecting the site involved.	
	Acknowledgement of Receipt Are all study sites involved * ◯ Yes ⦿ No Site Reporting * Please Select... Sarawak General Hospital Raja Permaisuri Bainun Hospital Kuala Lumpur Hospital Hospital Tengku Ampuan Afzan (Htaa) *Press and hold CTRL to choose more than one.* e.g. For selection of Sarawak General Hospital & Hospital Kuala Lumpur **PRESS & HOLD THE** CTRL **BUTTON !!. Then click Sarawak General Hospital & Kuala Lumpur Hospital one after another .** Site Reporting * Please Select... Sarawak General Hospital Raja Permaisuri Bainun Hospital Kuala Lumpur Hospital Hospital Tengku Ampuan Afzan (Htaa) *Press and hold CTRL to choose more than one.* b) Select one of the relevant type of Acknowledgement of Receipt (AOR) user would like to submit to MREC Type of Acknowledgement of Receipt * Please Select... ⌄ Please Select... Research Documents Progress Report Site Closure Interim report DSMB report Clinical Study Report (CSR) Other	

7.	Once "Acknowledgement of Receipt Information" saved, continue to scroll down the page. "Supporting Documents" part will be availble for user to upload the relevent documents.	****Only PDF format file is allowed to be uploaded in this section**

Supporting Documents

Cover Letter *

View Document History

(+) Select or drag files | PDF

Supporting Documents

View Document History

(+) Select or drag files | PDF

Save

User can upload the "Cover Letter to MREC" and other "Supporting Document" by either click on the (+) icon to acces the document file or by draging the document over the box available. Once it has been uploaded, user can insert a remark 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.

Supporting Documents

Cover Letter *

≡	PDF	PDF 137.35 KB Download	Name dummy document.pdf
			Remarks Testing

Supporting Documents

(+) Select or drag files | PDF

Save

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

	A popup up will appear indicating the "Supporting Documents" has been succesfully saved	
	[Save] ✅ Acknowledgement of Receipt Supporting Document Information Saved.	
8.	Next, user needs 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 acknowlegded, user can submit the Acknowledgement of Receipt (AOR) 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 a new Acknowledgement of Receipt (AOR) submission has been successfully submitted, user will be brought the Acknowledgement of Receipt (AOR) Submission listing page.

Acknowledgement of Receipt

Keyword

Status

Select All

EXCEL   PDF   Show 10 ⌄ entries

#	NMRR ID	TITLE	STATUS	ACKNOWLEDGEMENT OF RECEIPT ID	NO OF AOR SUBMITTED	DATE OF SUBMISSION	ACTION
1			Pending Submission	AOR ID-23-00022-4J1	2		👁 ✏ 🗑 📋
2			Processing Submission by MREC Secretariat	AOR ID-23-00017-L5U	2	08/01/2023	👁 📋

Showing 1 to 2 of 2 entries

Previous **1** Next

When viewing the data of Acknowledgement of Receipt (AOR) Submission, the General information of the Submission will be shown on the top part of the display page

AOR Submission

NMRR ID ▓▓▓▓   Protocol ID ▓▓▓▓   📅 Last updated on Sep 23, 2021

Status Approval granted via MREC Full Board

AOR Post Ethical ID AOR ID-23-00017-L5U

AOR Status Processing Submission by MREC Secretariat

In AOR 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

The status of a successful new submission of Acknowledgement of Receipt (AOR) will change from "**Pending Submission**" to " **Processing Submission by MREC Secretariat** "

2.0 – Existing Acknowledgement of Receipt (AOR) Submission

2.1 – Viewing an Existing Acknowledgement of Receipt (AOR) 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 AOR to access the existing Acknowledgement of Receipt (AOR) Submission listing.	
		Please note that one NMRR ID might have a multiple Acknowledgement of Receipt (AOR) submission. Therefore, AOR submission will be referred according to the **AOR Post Ethical ID** or **Acknowledgement of Receipt (AOR) ID.**
	A list of all existing Acknowledgement of Receipt (AOR) Submission will be displayed.	**No of AOR Submitted** indicates the number of AOR Post Ethical ID that has been successfully submitted by PI/ Main or Backup CP.
		In Acknowledgement of Receipt (AOR) Submission Listing, In AOR 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 - Edit ✏ icon - to edit the AOR submission (icon available only for AOR Submission with status "Pending Submission" and "Request for More Information/ Revision Required" - Bin 🗑 icon - to delete AOR submission (icon accessible only in AOR Submission with status "Pending Submission"

3.	To view submission, Click on the 👁 icon at the intended Acknowledgement of Receipt (AOR) Submission	This can only be accessible by user that has been assigned with a role either as:

To view submission, Click on the 👁 icon at the intended Acknowledgement of Receipt (AOR) Submission

Acknowledgement of Receipt

Keyword
1384

Status
Select All

EXCEL   PDF   Show 10 entries

#	NMRR ID	TITLE	STATUS	ACKNOWLEDGEMENT OF RECEIPT ID	NO OF AOR SUBMITTED	DATE OF SUBMISSION	ACTION
1			Pending Submission	AOR ID-23-00022-4J1	2		👁 ✏ 🗑 📋
2			Processing Submission by MREC Secretariat	AOR ID-23-00017-L5U	2	08/01/2023	👁 📋

Showing 1 to 2 of 2 entries

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User will be able to view the data & documents uploaded for the Acknowledgement of Receipt (AOR) Submission.

Acknowledgement of Receipt

Acknowledgement of Receipt ID
AOR ID-23-00029-FVG

Are all study sites involved
Yes

Sites
Hospital Selayang

Type of Acknowledgement of Receipt
Research Documents

Description of AOR
testing

Acknowledgement of Receipt Supporting Documents

Cover Letter *

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 see the Decision History of the Acknowledgement of Receipt (AOR) 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 the attachment file if MREC Secretariat has uploaded it for user's attention or reference (if any). To download, click on the ⬇ icon next to the approval authority list.

Decision History

#	DECISION	DECISION DATE	APPROVAL AUTHORITY	
1	Initial Submission	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 Acknowledgement of Receipt (AOR) Submission with status "Request for More Information/ Revision Required"

No	Step-by-step instructions	Remark
1.	In the case where Acknowledgement of Receipt (AOR) 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"	User will be notified via email if a particular Acknowledgement of Receipt (AOR) Submission requires revision or more information.
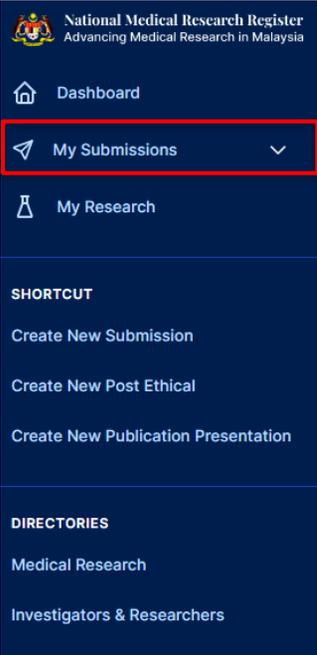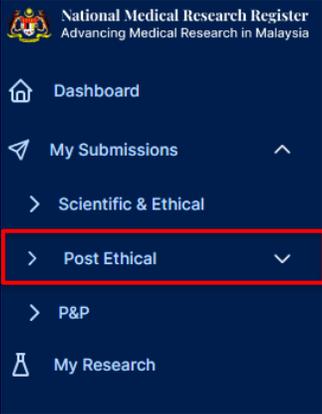
2.	Click on AOR to access the existing Acknowledgement of Receipt (AOR) Submission listing.	
	A list of all existing Acknowledgement of Receipt (AOR) Submission will be displayed.	
		The status of an Acknowledgement of Receipt (AOR) Submission that requires revision or more information will have the status **"Request for more information / Revision Required"**

3.	To edit submission, Click on the ✎ icon at the intended Acknowledgement of Receipt (AOR) Submission	This can only be accessible by user that has been assigned with a role either as:

To edit submission, Click on the ✎ icon at the intended Acknowledgement of Receipt (AOR) Submission
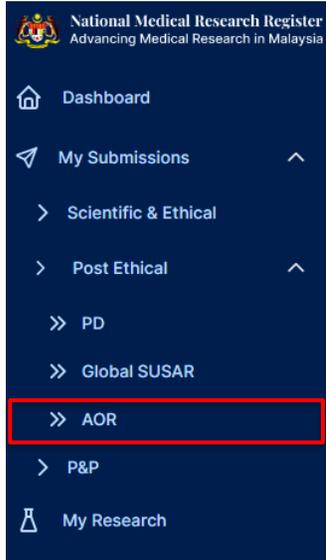
Acknowledgement of Receipt

Keyword

Status

Select All

EXCEL   PDF   Show 10 ⌄ entries

#	NMRR ID ▼	TITLE ⇅	STATUS ⇅	ACKNOWLEDGEMENT OF RECEIPT ID ⇅	NO OF AOR SUBMITTED ⇅	DATE OF SUBMISSION ⇅	ACTION
1			Request for more information / Revision required	AOR ID-23-00017-L5U	2	08/01/2023	👁 ✎ 📋
2			Pending Submission	AOR ID-23-00022-4J1	2		👁 ✎ 🗑 📋

Showing 1 to 2 of 2 entries

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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.	Insert new information required as per email by MREC . Click [Save] to save the revision.
	Acknowledgement of Receipt
	Are all study sites involved *
	◉ Yes ○ No
	Type of Acknowledgement of Receipt *
	Please Select... ⌄
	Description of AOR *
	Description in writing
	[Save]
	A popup up will appear indicating the Acknowledgement of Receipt (AOR) Information has been succesfully saved
	[Save]
	✓ Acknowledgement of Receipt Information Saved.

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 [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 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 [Save] to complete the steps 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**
	Save	
	✓ Supporting Documents Information Saved.	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
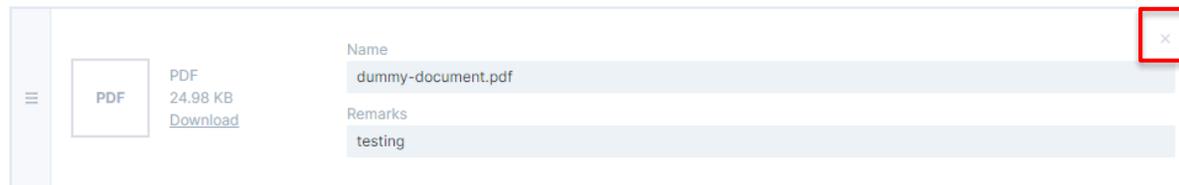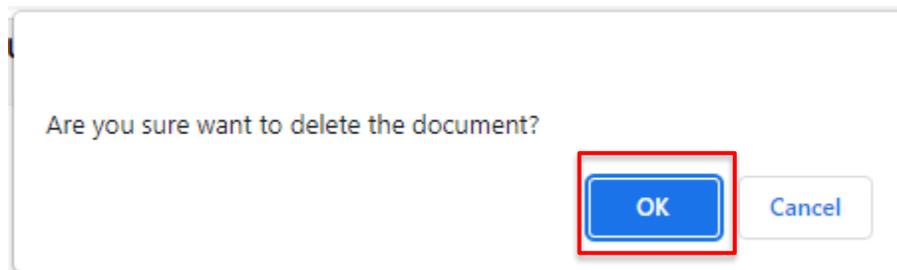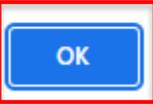
6.	To view back the previously uploaded document, Click on the "View Document History" located at the top right of each document section. Document will be shown in chronological order. User also will able to download the previously uploaded document (if needed) by clicking the ⬇ Download icon next to the document title. **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 Acknowledgement of Receipt (AOR) 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.
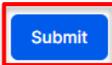
Submit

Decision History

#	DECISION	DECISION DATE	APPROVAL AUTHORITY

Once Acknowledgement of Receipt (AOR) revision submission has been successfully submitted, user will be brought back to the Acknowledgement of Receipt (AOR) Submission listing.

Acknowledgement of Receipt

Keyword	Status
1004	Select All

EXCEL PDF Show 10 entries

#	NMRR ID	TITLE	STATUS	ACKNOWLEDGEMENT OF RECEIPT ID	NO OF AOR SUBMITTED	DATE OF SUBMISSION	ACTION
1			Revision Submitted To MREC Secretariat	AOR ID-23-00017-L5U	2	08/01/2023	👁 📋
2			Pending Submission	AOR ID-23-00022-4J1	2		👁 ✏ 🗑 📋

Showing 1 to 2 of 2 entries

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The status of a successful revision submission of Acknowledgement of Receipt (AOR) will change from **"Request for more information / Revision Required"** to **"Revision Submitted to MREC Secretariat"**

AOR Submission

A RANDOMIZED, 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 Sep 23, 2021

Status Approval granted via MREC Full Board

AOR Post Ethical ID AOR ID-23-00017-L5U

AOR Status Revision Submitted To MREC Secretariat

2.3 – Editing/ Deletion of Acknowledgement of Receipt (AOR) 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 edit or delete the existing Acknowledgement of Receipt (AOR) Submission, scroll over the main menu located on the side of display page, go to "My Submission". Then Click on the "Post Ethical"	

2.	Click on AOR to access the existing Acknowledgement of Receipt (AOR) Submission listing.	

	National Medical Research Register
	Advancing Medical Research in Malaysia
	
	⌂ Dashboard
	
	◁ My Submissions ︿
	
	  › Scientific & Ethical
	
	  › Post Ethical ︿
	
	    » PD
	
	    » Global SUSAR
	
	    » AOR
	
	  › P&P
	
	⚗ My Research	
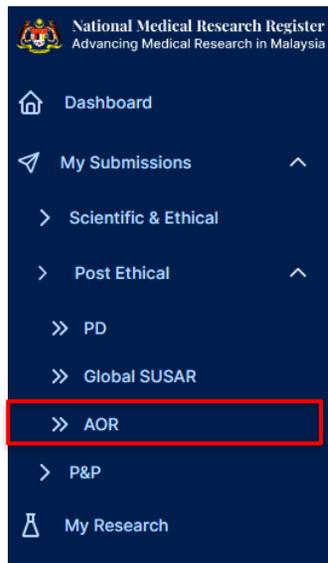
	A list of all existing Acknowledgement of Receipt (AOR) Submission will be displayed.	
	Acknowledgement of Receipt Keyword [ ] Status [Select All ∨] [EXCEL] [PDF] Show [10 ∨] entries | #	NMRR ID	TITLE	STATUS	ACKNOWLEDGEMENT OF RECEIPT ID	NO OF AOR SUBMITTED	DATE OF SUBMISSION	ACTION
---	---	---	---	---	---	---	---
1			Revision Submitted To MREC Secretariat	AOR ID-23-00017-L5U	2	08/01/2023	👁 📋
2			Pending Submission	AOR ID-23-00022-4J1	2		👁 ✏ 🗑 📋 | Showing 1 to 2 of 2 entries Previous [1] Next	The status of an Acknowledgement of Receipt (AOR) Submission that has not yet been sent will be **"Pending Submission"**

3.	To edit submission, click on the ✏ icon at the intended Acknowledgement of Receipt (AOR) Submission and follow the steps as mentioned above in 1.1 "**Creating a New Acknowledgement of Receipt (AOR) Submission**"	This can only be accessible by user that has been assigned with a role either as:

To edit submission, click on the ✏ icon at the intended Acknowledgement of Receipt (AOR) Submission and follow the steps as mentioned above in 1.1 "**Creating a New Acknowledgement of Receipt (AOR) Submission**"

Acknowledgement of Receipt

Keyword

Search NMRR ID, Research ID or Title of the Submission

Status

Select All

EXCEL   PDF   Show 10 entries

#	NMRR ID	TITLE	STATUS	ACKNOWLEDGEMENT OF RECEIPT ID	NO OF AOR SUBMITTED	DATE OF SUBMISSION	ACTION
1			Revision Submitted To MREC Secretariat	AOR ID-23-00017-L5U	2	08/01/2023	👁 📋
2			Pending Submission	AOR ID-23-00022-4J1	2		👁 ✏ 🗑 📋

Showing 1 to 2 of 2 entries

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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

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4.	To delete an Acknowledgement of Receipt (AOR) Submission, click on the delete 🗑 icon of the intended submission	
	Acknowledgement of Receipt Keyword Search NMRR ID, Research ID or Title of the Submission Status Pending Submission EXCEL PDF Show 10 entries | #	NMRR ID	TITLE	STATUS	ACKNOWLEDGEMENT OF RECEIPT ID	NO OF AOR SUBMITTED	DATE OF SUBMISSION	ACTION
1			Pending Submission	AOR ID-23-00022-4J1	2		👁 ✏ 🗑 📋 | Showing 1 to 1 of 1 entries Previous 1 Next Click [OK] to confirm the deletion of the Acknowledgement of Receipt (AOR) Submission. Once it is clicked, the Acknowledgement of Receipt (AOR) Submission will be deleted and removed from the Acknowledgement of Receipt (AOR) Submission listing. Are you sure you want to remove this record? [OK] [Cancel]	Deletion of an an Acknowledgement of Receipt (AOR) Submission will be only available for submission that has never been submitted to MREC Secretariat for processing.

-The End -

Prepared by: NMRR Secretariat

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