User Guidelines for
Post Ethical Approval Submission

- Protocol Deviation

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 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) • Protocol Deviation Coordinator (PD Coordinator) • Protocol Deviation Corresponding Person (PD CP) - based on site/s assignment

Information/ Documents Required

General Protocol Deviation Reporting Information
1. Site Conducted - if multiple sites are assigned to Protocol Deviation Corresponding Person (PD CP)
2. Reporting Investigator

Protocol Deviation Reporting Details Information
1. Date of Awareness
2. Subject ID List
    a. Subject ID
    b. Date of PD Occurrence
    c. Date of Recruitment
    d. Total Days (PD Occurrence to Awareness) – auto calculated
    e. Gender
    f. No of PD ID Reported on subject – auto calculated
3. Type of Protocol Deviation
4. Narrative of Protocol Deviation/ Protocol Violation Report
5. PD/PV Incident Repetition - Has this type of protocol deviation/ violation (or similar deviations) previously occurred in this study or this study site?
    a. If Yes - has it been reported to MREC?
    b. Deviation/ Violation List
        i. Subject ID
        ii. Date of Deviation/Violation
        iii. Description
6. Means of Awareness - How was the deviation picked up/ made aware (eg. Noted by Study Monitor etc.)
7. Subejct Safety Involvement - Does the Investigator feel that this Protocol Deviation (PD) Reporting / Protocol Violation (PV) affects the safety of the subject?
8. Study Integrity Involvement - Does the Investigator feel that this Protocol Deviation (PD) Reporting / Protocol Violation (PV) affects the integrity (i.e scientific validity and ethics) of the study data?
9. Event Anticipation - Was the event unanticipated?
10. Modification of Data Safety Monitoring - Is a modification required to the data safety monitoring plan?
11. Corrective Action Taken
12. Preventive action Taken
13. Incident Resolution - Has this event been resolved?
    a. If No, Explain why?

Protocol Changes and/ or Actions Taken

1. Amendment Requirement to Research Document - Should there be an amendment to the research protocol / consent form or other documents as a consequence of this event?
    a. If Yes, Amendment Date
    b. Amendment Description
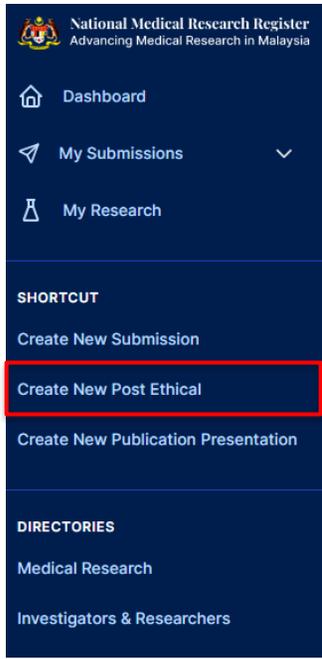2. Action Taken by Site
3. Notes/ Remarks to MREC

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

User Guidelines for Submission

1.0 - New Protocol Deviation Submission

1.1 – Creating a new Protocol Deviation Report 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) • Protocol Deviation Coordinator (PD Coordinator) • Protocol Deviation Corresponding Person (PD 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 "Protocol Deviation"
	Once Protocol Deviation (PD) is selected, list of submission accessible for Protocol Deviation Submission will be displayed

4.	Click on the 📋 icon to create a new Protocol Deviation Submission	
	New Post Ethical Approval Keyword Select Post Ethical Approval Type [Search NMRR ID, Research ID or Title of the Submission] [Protocol Deviation ▾] Show [10 ▾] entries <table><tr><th>#</th><th>NMRR ID</th><th>TITLE</th><th>RESEARCH SCOPE</th><th>RESEARCH TYPE</th><th>STATUS</th><th>ACTION</th></tr><tr><td>1</td><td></td><td></td><td>Clinical</td><td>Interventional</td><td>Approval granted via MREC Full Board</td><td>📋</td></tr><tr><td>2</td><td></td><td></td><td>Clinical</td><td>Interventional</td><td>Approval granted via MREC Full Board</td><td>📋</td></tr></table>	
5.	A page will be displayed with the General information of the Submission is shown over the top part of the display page **Protocol Deviation Reporting** ██ **NMRR ID** ███████████ **Protocol ID** - 📅 Last updated on Oct 21, 2022 **Status** [Approval granted via MREC Full Board] **Post Ethical Submission Status** [Pending Submission]	

6.	Scoll down the page to the "General Protocol Deviation Reporting Information".	**"Site Conducted"** will be auto-selected depending on the site assigned to user in the Protocol Deviation Corresponding Person assignment during NMRR Registration Submission.

General Protocol Deviation Study Information

Study Status
Not Yet Recruiting

Site Conducted
Hospital Selayang

Reporting Investigator *

NAME OF INVESTIGATOR	ROLE OF INVESTIGATOR	STATE CONDUCTED
LAU SIEW WIN	Principal / Coordinating Investigator	Selangor Darul Ehsan
Lee Pei Yee	Co / Sub Investigator at the site	Selangor Darul Ehsan
Bee Boon Cheak	Co / Sub Investigator at the site	Selangor Darul Ehsan
MUHAMMAD ZULHAFIZ BIN ZULKIFLI	Co / Sub Investigator at the site	Selangor Darul Ehsan

"Site Conducted" column right-side note:

** **Incase of a user is assigned with 2 or more sites, user is required to select the site intended for the reporting.**

Insert the information on the "Reporting Investigator" by selecting a name from the list displayed. Click [Save] to save the information .

Reporting Investigator *

Please Select...

Please Select...
LAU SIEW WIN
Lee Pei Yee
Bee Boon Cheak
MUHAMMAD ZULHAFIZ BIN ZULKIFLI
WONG HIN SENG

	Co / Sub Investigator at the site
	Co / Sub Investigator at the site
	Co / Sub Investigator at the site
	Co / Sub Investigator at the site

[Save]

A popup up will appear indicating the "General Protocol Deviation Reporting Information" has been succesfully saved

> ✓ General Protocol Deviation Study Information Saved.

A Protocol Deviation Post Ethical ID will be generated and Protocol Deviation Status will be displayed as "Case Open". This information can be seen over the top part of the display page

Protocol Deviation Submission

A RANDOMISED CONTROLLED TRIAL ON TUBERCULOSIS VERSUS STANDARD OF CARE IN PERITONEAL DIALYSIS RELATED PERITONITIS.

NMRR ID [redacted]   **Protocol ID** -   🗓 Last updated on Oct 21, 2022

Status Approval granted via MREC Full Board

Protocol Deviation Post Ethical ID   PD ID-23-00021-TXZ
Protocol Deviation Status   Case Open

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

"Protocol Deviation Status" refers to the **status of Protocol Deviation Post Ethical ID** in general. "Case Open" means the reporting case is now open for submission. User may send updates/follow up if needed/ required

7.	Continue to scroll down on the page. User is then required to fill up the "Protocol Deviation Reporting Details Information" part of the submisison. Insert the following information regardinng the "Date of Awareness" of the PD , "Subejct ID list" and "Type of PD" . **Add**	**"Days to awareness"** refers to days from the date of PD report submitted to MREC to the date of awareness of the PD (it will be auto calculated and updated by the system following the submission of the entire Protocol Deviation Post Ethical ID to MREC)

Protocol Deviation Detail Information

Protocol Deviation Report Type
Initial Report

Date of Awareness (Days to awareness : 0) *

mm/dd/yyyy

Subject ID List   **Add**

NO.	SUBJECT ID	DATE OF PD OCCURRENCE	DATE OF RECRUITMENT	TOTAL DAYS	GENDER	NO OF PD ID REPORTED
		No records found.				

Type of PD (Based on group of Selection)

Please Select...

** User can add multiple subjects involved in a same type of Protocol Deviation that happened in different dates. However, the date of the awareness of the Protocol Deviation must be the same for all the incidents.

Click **Add** to add the information regarding the subject involved in the PD.

User is required to click **Add** for every addition of subject into the list (one click per subject entry)

Subject ID List   **Add**

NO.	SUBJECT ID	DATE OF PD OCCURRENCE	DATE OF RECRUITMENT	TOTAL DAYS	GENDER	NO OF PD ID REPORTED
		No records found.				

Once **Add** is clicked, user is required to fill up the following information regarding subejct involvement and then click **Save** to save the information.

Subject ID List

Subject Id

[   ]

Date of PD Occurrence

[mm/dd/yyyy   📅]

Subject Recruitment Date

[mm/dd/yyyy   📅]

Gender

| ○ Male | ○ Female |

Cancel   **Save**

Subject ID List   **Add**

NO.	SUBJECT ID	DATE OF PD OCCURRENCE	DATE OF RECRUITMENT	TOTAL DAYS	GENDER	NO OF PD ID REPORTED		
1	Subejct 1	17/11/2022	01/09/2022	28	Male	0	✏️	🗑️

the following action icons are accessible to user in the Subject ID Listing:
- Icon ✏️ is used for editing the information
- Icon 🗑️ is used for deletion of the information

"Total Days" refers to total days from the date of PD occurrence to the date of awareness

10

Next , user is required to fill up information regarding the " Narrative of Protocol Deviation (PD) / Protocol Violation (PV) Report " , "PD/PV Incident Repeatition" & "Means of Awareness".

Narrative of Protocol Deviation (PD) Reporting / Protocol Violation (PV) *
Provide actual detailed description of protocol deviation/ violation event including but not limited to date of event, subject visit details, description of PD. Please refrain from using non standard abbreviations

Has this type of protocol deviation/ violation (or similar deviations) previously occurred in this study or this study site?

○ Yes   ● No

How was the deviation picked up/ made aware (eg. Noted by Study Monitor etc.)

Refer to **step No. 8 (a)** if the "PD/PV "Incident Repeatition " is selected as **"Yes"**

Follows by information regarding "Subejct Safety Involvement" , "Study Integrity Involvement", " Event Anticipation" & "Modification of Data Safety Monitoring".

Does the Investigator feel that this Protocol Deviation (PD) Reporting / Protocol Violation (PV) affects the safety of the subject?

○ Yes   ● No

○ Unknown

Does the Investigator feel that this Protocol Deviation (PD) Reporting / Protocol Violation (PV) affects the integrity (i.e scientific validity and ethics) of the study data?

○ Yes   ● No

○ Unknown

Was the event unanticipated?

○ Yes   ● No

Is a modification required to the data safety monitoring plan?

○ Yes   ● No

User is then required to fill up the Corrective Action & Preventive action taken following the awareness of the incident.

Corrective action done for this event? Please explain:
(If any training is done, please upload supporting document in section VII such as training log, etc.)

Preventive action done for this event?
Please explain the preventive action plan that you have put in to prevent the event from recurring in future

The last question of the "Protocol Deviation Detail Information" requires user to choose information regarding the "Incident Resolution". User need to click [Save] to complete and save the information filled.

Has this event been resolved?

○ Yes   ○ No

● On Going

[Save]

Refer to **step No. 8 (b)** if the "Incident Resolution – has this event been resolved " is selected as **"No"**

A popup up will appear indicating the "Protocol Deviation Reporting Details Information" has been succesfully saved

[Save]

✓ Protocol Deviation Detail Information Saved.

	A change to Protocol Deviation Post Ethical ID (PD Case) will happen (ID is then assigned with a Report Type) and Report Submisison Status will be generated and displayed as "Pending Submisison". This information can be seen over the top part of the display page	**"Protocol Deviation Post Ethical ID – Report Type"** will be the reference for the Protocol Deviation Reporting Submission from this point onwards. **Protocol Deviation Post Ethical ID – Report Type later in the submission will also be referred to as Protocol Deviation Report (PD Report)**
	Protocol Deviation Submission NMRR ID Protocol ID - 🗓 Last updated on Oct 21, 2022 Status Approval granted via MREC Full Board Protocol Deviation Post Ethical ID PD ID-23-00021-TXZ : Initial Report Protocol Deviation Status Case Open Report Submission Status Pending Submission	**"Report Submission Status"** refers to the **current status of PD Report** while **"Protocol Deviation ID Status"** refer to **status of Protocol Deviation Post Ethical ID or PD Case** in general (can be either **Case Open or Case Closed or Case Reopen**)
8.	a) In case user selects the **"PD/PV Incident Repetition - Has this type of protocol deviation/ violation (or similar deviations) previously occurred in this study or this study site?"** as **"Yes"** : User is required to filled up the following additional information regarding the repetitve incident that happened . Required information is about "Previous MREC Reports" and "Protocol Deviation/Protocol Violation List" of the previousIy occurred incident. Has this type of protocol deviation/ violation (or similar deviations) previously occurred in this study or this study site? ⦿ Yes ○ No If yes, has it been reported to MREC? ○ Yes ⦿ No Deviation / Violation List Add NO. SUBJECT DATE OF DEVIATION / VIOLATION DESCRIPTION No records found.	

To insert the information regarding the "Protocol Deviation/Protocol Violation List" , click on the [Add] button , then insert the following information required .

Deviation / Violation List   [Add]

NO.	SUBJECT	DATE OF DEVIATION / VIOLATION	DESCRIPTION
		No records found.	

Insert the required information and once the information has been filled, click [Save] button to save the information.

Deviation / Violation List

Subject Id

Date of Deviation / Violation

mm/dd/yyyy

Description

Cancel   Save

	b) Incase user selects the **"Protocol Deviation Detail Information – Has this event been resolved?"** as **"No"** User is required to fill additional information regarding the reason of the incident is not yet resolved Has this event been resolved? ○ Yes ⦿ No ○ On Going Please explain why [text box]	
9.	Next , user is required to fill up "Protocol Changes and/ or Actions Taken". Information regarding the "Amendment Requirement to Research Document" & "Action Taken by Site". Protocol Changes and/or Actions Taken Should there be an amendment to the research protocol / consent form or other documents as a consequence of this event? ○ Yes ⦿ No Actions taken Please Select... ⌄ Notes / Remarks to MREC [text box] Save	Refer to **step No. 10** if "Amendment Requirement to Research Document" is selected as **"Yes"**

Select the action taken from the listing displayed and user can insert some notes / remarks to MREC (if any). To complete and save the "Protocol Changes and/ or Actions Taken" information, user is required to click the Save button.

Actions taken

Please Select...

Please Select...
Research activity and subject's follow up continues as scheduled, CAPA has been done to the Protocol Deviation (PD) Reporting / Protocol Violation (PV).
Subject has been withdrawn from further study participation. Research activity continues as scheduled.
Research activity for all subjects have been stopped temporarily
Research activity for all subjects have been stopped permanently
Approved study data analysis plan modified
Others

Save

A popup up will appear indicating the "Protocol Deviation Reporting Details Information" has been succesfully saved

Save

✓ Protocol Changes and/or Actions Taken Information Saved.

10.	In case user selects **"Amendment Requirement to Research Document - Should there be an amendment to the research protocol / consent form or other documents as a consequence of this event? "** as **"Yes"** User is required to fill up additional information regarding the changes or amendment done following the awareness of the incident – "Amendment Date" and "Amendment Description". Should there be an amendment to the research protocol / consent form or other documents as a consequence of this event? ⦿ Yes　　　　　　　　　　　　　◯ No Date Amendment Submitted mm/dd/yyyy Short Description of the Amendment	
11.	Continue to scroll down on the page. "Protocol Deviation Support Documents" part will be availble for user to upload the relevent documents. Protocol Deviation Supporting Documents Cover Letter * ⬇ Download Cover Letter Template View Document History ⊕ Select or drag files │ PDF Other Supporting Documents View Document History ⊕ Select or drag files │ PDF Save	**"Protocol Deviation Cover Letter to MREC Template"** can be downloaded for user to use as reference.

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

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

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

Protocol Deviation Supporting Documents

Cover Letter *

↓ Download Cover Letter Template

View Document History

Name
dummy document.pdf

≡ | PDF | PDF 24.98 KB Download

Version *
testing

Version Date *
01/04/2023

Other Supporting Documents

View Document History

⊕ Select or drag files | PDF

Save

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

Save

✓ Supporting Documents Information Saved.

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 acknowleqdes, user can submit the entire Protocol Deviation 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]

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

Decision History

#	DECISION	DECISION DATE	APPROVAL AUTHORITY

In viewing data of Protocol Deviation Reporting Submission, the General information of the Submission will be shown over the top part of the display page

Protocol Deviation Submission

NMRR ID   Protocol ID -   📅 Last updated on Oct 21, 2022

Status   Approval granted via MREC Full Board

Protocol Deviation Post Ethical ID   PD ID-23-00026-KTC : Initial Report

Protocol Deviation Status   Case Open   Report Submission Status   Processing Submission by MREC Secretariat

The status of new successful submission of a **PD Report** will change from **"Pending Submission"** to **"Processing Submission by MREC Secretariat"**

Once a new Protocol Deviation Reporting Submission has been successfully submitted, user will be brought to the Protocol Deviation Case lisitng

Protocol Deviation Case

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

Status
[Undergoing Review by PDSC ⌄]

EXCEL PDF   Show [10 ⌄] entries

#	NMRR ID	TITLE	PD CASE ID	NO OF PD CASE REPORTED	MREC DECISION	CASE STATUS	ACTION
1			PD ID-23-00026-KTC	2	Undergoing Review by PDSC	Case Open	👁 📋 📋

Showing 1 to 1 of 1 entries

Previous **1** Next

To see the details listing of the Protocol Deviation Post Ethical ID – Report Type (PD Report) , click on PD Report Listing 📋 icon .

Protocol Deviation Case

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

Status
[⌄]

EXCEL PDF   Show [10 ⌄] entries

#	NMRR ID	TITLE	PD CASE ID	NO OF PD CASE REPORTED	MREC DECISION	CASE STATUS	ACTION
1			PD ID-23-00026-KTC	2	Undergoing Review by PDSC	Case Open	👁 📋 **📋**

Showing 1 to 1 of 1 entries

Previous **1** Next

In Protocol Deviation Case listing, **No of Protocol Deviation Case Reported** indicates the number of **Protocol Deviation Post Ethical ID – Report Type (PD Report) that has been successfully created** by the Protocol Deviation Corresponding Person (PD CP) (e.g. **2** means there are two PD Reports that have been created:
 Protocol Deviation Post Ethical ID – Initial Report & Protocol Deviation Post Ethical ID – Follow up Report 1

MREC Decision indicates **the latest decision assigned by MREC Secretariat** to either one of the PD Report submitted to MREC for processing.

In Protocol Deviation Case listing the following action icons are accessible to user:

- Show 👁 icon - to view of the General Protocol Deviation Submission of **Protocol Deviation Post Ethical ID (PD Case)**
- Initial Submission 📋 icon - to show the initial registration data of NMRR ID Submission
- PD Report Listing 📋 icon - to view the detail listing of **Protocol Deviation Post Ethical ID – Report Type (PD Report)**

Once clicked ,it will bring user to the Protocol Deviation Report listing where the detail listing of the **"Protocol Deviation Post Ethical ID – Report Type"** or **PD Report** will be displayed. together with the Current status of the submission.

Protocol Deviation Report

Keyword

Search NMRR ID, Research ID or Title of the Submission

Status

Select All

EXCEL   PDF   Show 10 ∨ entries

| #	NMRR ID	TITLE	PD CASE ID	STATUS	PD CORRESPONDING PERSON	DATE OF SUBMISSION	ACTION
1	~~NMRR ID~~	~~A Randomized...~~	PD ID-23-00026-KTC Initial Report	Undergoing Review by PDSC	~~...~~	09/01/2023	👁 📋 ✎
2	~~NMRR ID~~	~~A Randomized...~~	PD ID-23-00026-KTC Follow-up Report 1	Pending Submission	~~...~~		👁 ✎ 🗑 📋

Showing 1 to 2 of 2 entries

Previous   1   Next

In Protocol Deviation Report listing, the following action icons are accessible to user

- Show 👁 icon - to view of the General Protocol Deviation Submission of **Protocol Deviation Post Ethical ID – Report Type (PD Report)**
- Initial Submission 📋 icon - to show the initial registration data of NMRR ID Submission
- Follow up Report ✎ icon - to add/send a new follow up PD Case (create a new PD Report)
- Edit 🖊 icon - to edit PD Reportıng submission (icon available only for PD Report Submission with status "Pending Submission")
- Bin 🗑 icon to PD Reporting submission (icon available only in PD Report Submission with status "Pending Submission')

21

2.0 – Existing Protocol Deviation Reporting Submission

2.1 – Viewing an existing Protocol Deviation Reporting Submission (PD Case & PD Report)

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	
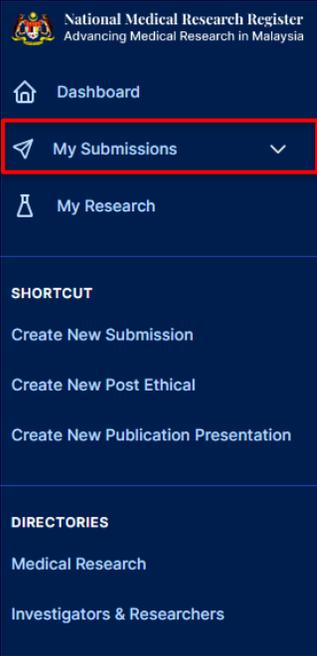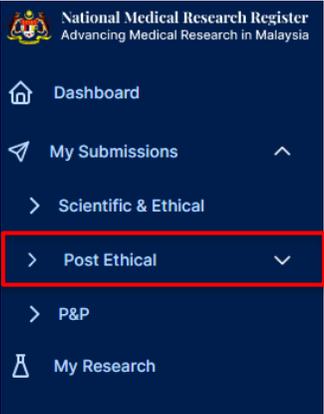
2.	Click on Protocol Deviation to access the existing Protocol Deviation Reporting Submission listing.

2. Click on Protocol Deviation to access the existing Protocol Deviation Reporting Submission listing.
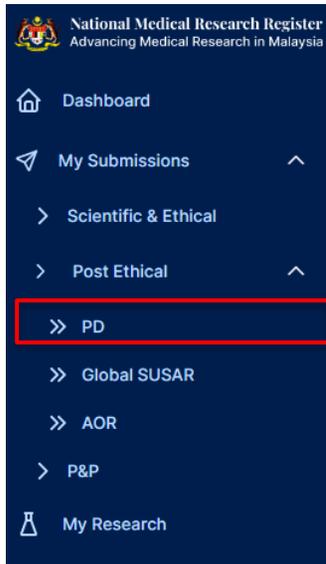
A list of all existing Protocol Deviation Post Ethical ID (Protocol Deviation Case) submission will be displayed.

Protocol Deviation Case

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

Status
Select All

EXCEL | PDF | Show 10 entries

#	NMRR ID	TITLE	PD CASE ID	NO OF PD CASE REPORTED	MREC DECISION	CASE STATUS	ACTION
1			PD ID-23-00026-KTC	2	Undergoing Review by PDSC	Case Open	
2			PD ID-23-00021-TXZ	1	Initial Submission	Case Open	

Showing 1 to 2 of 2 entries

Previous **1** Next

Please note that one NMRR ID might have a multiple Protocol Deviation Reporting Submission.Therefore, Protocol Deviation Reporting Submission will be referred according to the **Protocol Deviation Post Ethical ID** or **Protocol Deviation Case ID**

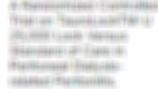In Protocol Deviation Case listing, the following action icons are accessible to user :

- Show 👁 icon - to view of the General Protocol Deviation Submission of **Protocol Deviation Post Ethical ID (PD Case)**
- Initial Submission 📋 icon - to show the initial registration data of NMRR ID Submission
- PD Report Listing 📋 icon - to view the detail listing of **Protocol Deviation Post Ethical ID – Report Type (PD Report)**

3.	To view a **PD Case**, click on the 👁 icon at the intended **Protocol Deviation Post Ethical ID (PD Case)**	This can only be accessible by user that has been assigned with a role either as:

Protocol Deviation Case

Keyword

Search NMRR ID, Research ID or Title of the Submission

Status

Select All

EXCEL   PDF   Show 10 entries

#	NMRR ID	TITLE	PD CASE ID	NO OF PD CASE REPORTED	MREC DECISION	CASE STATUS	ACTION
1			PD ID-23-00026-KTC	2	Undergoing Review by PDSC	Case Open	👁 📋 🗒
2			PD ID-23-00021-TXZ	1	Initial Submission	Case Open	👁 📋 🗒

Showing 1 to 2 of 2 entries

Previous **1** Next

Once clicked, user will be able to view the data of General Protocol Deviation Submission of the **Protocol Deviation Post Ethical ID (PD Case)**

General Protocol Deviation Study Information

Study Status
Not Yet Recruiting

Site Conducted
HOSPITAL SELAYANG

Reporting Investigator

Corresponding Person

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)
- Protocol Deviation Coordinator (PD Coordinator)
- Protocol Deviation Corresponding Person (PD CP)

With the top of the display page show general information of the NMRR ID with PD Case information

Protocol Deviation Submission

A [REDACTED] CONTROLLED TRIAL ON [REDACTED] VERSUS STANDARD OF CARE IN PERITONEAL DIALYSIS RELATED PERITONITIS.

NMRR ID [REDACTED]   Protocol ID -   📅 Last updated on Oct 21, 2022

Status `Approval granted via MREC Full Board`

Protocol Deviation Post Ethical ID   `PD ID-23-00021-TXZ`

Protocol Deviation Status   `Case Open`

Following the general information, user will be able to see the list of Investigators assigned to the site involved & List of Protocol Deviation Reporting

NAME OF INVESTIGATOR	ROLE OF INVESTIGATOR	STATE CONDUCTED
[REDACTED]	Principal / Coordinating Investigator	Selangor Darul Ehsan
[REDACTED]	Co / Sub Investigator at the site	Selangor Darul Ehsan
[REDACTED]	Co / Sub Investigator at the site	Selangor Darul Ehsan
[REDACTED]	Co / Sub Investigator at the site	Selangor Darul Ehsan
[REDACTED]	Co / Sub Investigator at the site	Selangor Darul Ehsan

List Of Protocol Deviation Reporting

NO.	INITIAL / FOLLOW UP REPORT	REPORTING INVESTIGATOR	MREC REPORT DECISION	
1	Initial Report	[REDACTED]	Undergoing Review by PDSC	👁
2	Follow-up Report 1	[REDACTED]	Pending Submission	👁

User may view the data of the **Protocol Deviation Post Ethical ID -Report Type (PD Report)** by clicking the 👁 icon inside the list of PD Reporting available

Other than that, user also will be able to see the Decision History of the PD Case that has been submitted. The decision History is available at the bottom of the data submission page.

Decision History

#	DECISION	DECISION DATE	APPROVAL AUTHORITY
1	Initial Submission	09/01/2023 11:06:09	Investigator

4.	To view **PD Case** data, other than the one mentioned previously.From the Protocol Deviation Case lisitng page, click on the PD Report listing 📋 icon.	**PD Case** versus **PD Report?**

To view **PD Case** data, other than the one mentioned previously.From the Protocol Deviation Case lisitng page, click on the PD Report listing 📋 icon.

Protocol Deviation Case

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

Status
> Select All

EXCEL PDF Show 10 ∨ entries

#	NMRR ID	TITLE	PD CASE ID	NO OF PD CASE REPORTED	MREC DECISION	CASE STATUS	ACTION
1			PD ID-23-00026-KTC	2	Undergoing Review by PDSC	Case Open	👁 📋 📋
2			PD ID-23-00021-TXZ	1	Initial Submission	Case Open	👁 📋 📋

Showing 1 to 2 of 2 entries

Previous **1** Next

Protocol Deviation Report listing will be then displayed. To view PD Report, click on the 👁 icon of the intended **Protocol Deviation Post Ethical ID – Report Type (PD Report)**.

Protocol Deviation Report

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

Status
> Select All

EXCEL PDF Show 10 ∨ entries

#	NMRR ID	TITLE	PD CASE ID	STATUS	PD CORRESPONDING PERSON	DATE OF SUBMISSION	ACTION
1			PD ID-23-00026-KTC Initial Report	Undergoing Review by PDSC		09/01/2023	👁 📋 ✎
2			PD ID-23-00026-KTC Follow-up Report 1	Pending Submission			👁 ✎ 🗑 📋

Showing 1 to 2 of 2 entries

Previous **1** Next

PD Case versus **PD Report?**

1. **PD Case** is a reference term used referring to a particular group report. It contains **only Protocol Deviation Post Ethical ID (e.g. ID 001)**

   PD Report is the details report sequence of the Protocol Deviation Post Ethical ID. It represented by the **report type at the end** of the **Protocol Deviation Post Ethical ID**
   (e.g. ID 001 – initial report,
        ID 001 – follow up report 1,
        ID 001 – follow up report 2,
        and so on….)

2. **PD Case listing** shows information as a group report which **latest MREC Decision made on either one of the submissions** is displayed

   PD Report listing show information of **each sequence report as individual status of the current MREC Decision**

3. Comparing Data in between reports **only available in PD Report** view 👁 icon

Display page will then show the general information of the Submisison with PD Report information **(Protocol Deviation Report Type and Report Submission Status)** and user will be able to see the General Protocol Deviation Reporting Submission (the same as in the PD Case view).

Protocol Deviation Submission

NMRR ID ~~blurred~~   Protocol ID -   📅 Last updated on Oct 21, 2022

Status `Approval granted via MREC Full Board`

Protocol Deviation Post Ethical ID `PD ID-23-00021-TXZ : Initial Report`

Protocol Deviation Status `Case Open`   Report Submission Status `Pending Submission`

In viewing the **PD Report**, user is able to view the entire submisssion data : "Protocol Deviation Detail Information" , "Protocol Changes and/or Actions Taken" and "Protocol Deviation Supporting Documents". User is also able to view the Decision History of individual PD Report.

Decision History

#	DECISION	DECISION DATE	APPROVAL AUTHORITY
1	Initial Submission	09/01/2023 11:06:09	Investigator
2	Undergoing Review by PDSC	11/01/2023 00:37:34	MREC Secretariat
3	Completed Review by PDSC	11/01/2023 16:18:25	MREC Protocol Deviation Subcommittee
4	Completed Review by Chairperson/ Deputy Chairperson/Secretary	11/01/2023 16:27:19	MREC Chairperson

User also will be able to download attachment file if MREC Secretariat has uploaded any documents 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	09/01/2023 11:06:09	Investigator	
2	Undergoing Review by PDSC	11/01/2023 00:37:34	MREC Secretariat	
3	Completed Review by PDSC	11/01/2023 16:18:25	MREC Protocol Deviation Subcommittee	
4	Completed Review by Chairperson/ Deputy Chairperson/Secretary	11/01/2023 16:27:19	MREC Chairperson	
5	Request for more information	12/01/2023 00:00:00	MREC Secretariat	⬇

In PD Report General Protocol Deviation Reporting Submission, user will be able to compare in between different PD Report submitted. To compare, click on the compare ![icon] icon in the List of the Protocol Deviation Reporting under the General Protocol Deviation Reporting Information of the PD Report

As reference, the blue colour highlight indicates that user is currently at the Follow up Report-1. By clicking ![icon] icon on the initial report. – it will **compare in between these 2 PD Reports**

Once clicked, information between these two PD Reports submissions will be displayed side by side

The blue-coloured information represents the set of data from the Initial Report as shown at the "Compare Report" header located at the top of the display page

2.2 – Submission of Follow up Protocol Deviation Reporting (Subsequent PD Report)

No	Step-by-step instructions	Remark
1.	In the case where user wants to submit a follow up report of **the Protocol Deviation Post Ethical ID (PD Case)**. Scroll over the main menu located on the side of display page, go to "My Submission". Then Click on the "Post Ethical" ① ②	**Submission of Follow Up Protocol Deviation Reporting can be done at any time following a complete submission of a Protocol Deviation ID – Initial Report.** MREC may also request user/site for a Follow Up PD Reporting Submission with decision status **"Request for More Information"** or **"Follow Up Submission Required"**
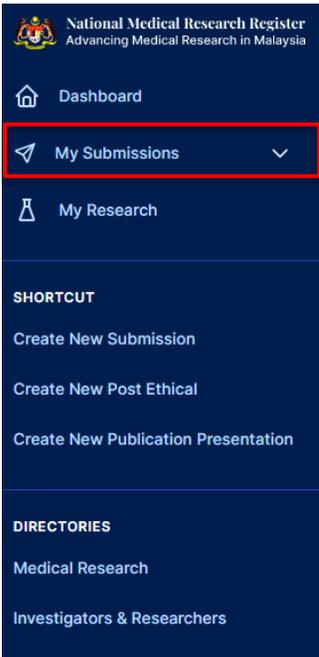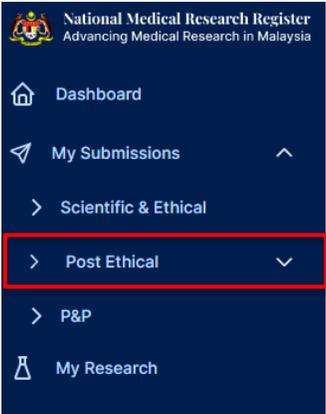
2.	Click on Protocol Deviation to access the existing Protocol Deviation Reporting Submission listing.	Please note that one NMRR ID might have a multiple **Protocol Deviation Reporting Submission**. Therefore, Protocol Deviation Reporting Submission will be referred according to the **Protocol Deviation Post Ethical ID** or **Protocol Deviation Case ID**

A list of all existing Protocol Deviation Post Ethical ID (Protocol Deviation Case) submission will be displayed.

In Protocol Deviation Case Listing, the following action icons are accessible to user:

- Show 👁 icon - to view of the General Protocol Deviation Submission of **Protocol Deviation Post Ethical ID (PD Case)**
- Initial Submission 📋 icon - to show the initial registration data of NMRR ID Submission
- PD Report Listing 📋 icon - to view the detail listing of **Protocol Deviation Post Ethical ID – Report Type (PD Report)**

3.	Click on the 📋 icon at the intended **Protocol Deviation Post Ethical ID (PD Case)** which requires the follow up submission	This can only be accessible by user that has been assigned with a role either as:

Protocol Deviation Case

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

Status
[Select All ▾]

[EXCEL] [PDF] Show [10 ▾] entries

#	NMRR ID ▾	TITLE	PD CASE ID	NO OF PD CASE REPORTED	MREC DECISION	CASE STATUS	ACTION
1	NMRR ID: 22-01760-WDF	A Randomised Controlled Trial on TeamLocalTW U 25,000 (Lock Versus Standard of Care in Peritoneal Dialysis related Peritonitis.	PD ID-23-00026-KTC	2	Request for more information	Case Open	👁 📋 📋

Then, Protocol Deviation Report List will be displayed. To create a follow up submission, click on the ✏ icon at the **intended PD Report**

Protocol Deviation Report

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

Status
[Select All ▾]

[EXCEL] [PDF] Show [10 ▾] entries

#	NMRR ID ▾	TITLE	PD CASE ID	STATUS	PD CORRESPONDING PERSON	DATE OF SUBMISSION	ACTION
1	NMRR ID: 22-01760-WDF	A Randomised Controlled Trial on TeamLocalTW U 25,000 (Lock Versus Standard of Care in Peritoneal Dialysis related Peritonitis.	PD ID-23-00026-KTC Initial Report	Request for more information	LAU SIEW YAN	09/01/2023	👁 📋 ✏

General Protocol Deviation Reporting Submission will be displayed with the List of Protocol Deviation Reporting as depicted below with the latest PD Report submission available is shown at the point of the follow up creation.

List Of Protocol Deviation Reporting

NO.	INITIAL / FOLLOW UP REPORT	REPORTING INVESTIGATOR	MREC REPORT DECISION	
1	Initial Report	Ola Lau Pai Yee	Request for more information	👁

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)
- Protocol Deviation Coordinator (PD Coordinator)
- Protocol Deviation Corresponding Person (PD CP)

	Continue by scrolling down the page to Protocol Deviation Detail Information. Information at the **Protocol Deviation Report Type** should display the next sequence PD Report following the latest PD Report available. **(e.g.: if latest available PD Report is PD ID 001- Initial Report,** the next PD Report supposed to be **PD ID 001- Follow up-1** and so on…) Protocol Deviation Detail Information Protocol Deviation Report Type Follow-up Report 1 Date of Awareness (Days to awareness : 7) * 04/01/2023 Subject ID List **Add** NO. SUBJECT ID DATE OF PD OCCURRENCE DATE OF RECRUITMENT TOTAL DAYS GENDER NO OF PD ID REPORTED 1 subject 1 01/01/2023 01/09/2022 3 Male 0	**It is advisable for user to always refer to the List of Protocol Deviation Reporting in the "General Protocol Deviation Reporting Information"**
4.	Insert relevant new information into the Protocol Deviaiton Detail information and click save **Save** to save the information added Has this event been resolved? ● Yes ○ No ○ On Going **Save** A popup up will appear indicating the " Protocol Deviation Detail Information" has been succesfully saved **Save** ✓ Protocol Deviation Detail Information Saved.	

32

5.	Once Protocol Deviation Detail Information is saved, the **Follow Up PD Report** has now been created successfully and its information will be displayed at the top of the display page together with the Report Submission Status **Protocol Deviation Submission** A RANDOMIZED CONTROLLED TRIAL ON TAUROLOCKTM-U 25,000 LOCK VERSUS STANDARD OF CARE IN PERITONEAL DIALYSIS-RELATED PERITONITIS. **NMRR ID** NMRR ID-22-01760-WDP **Protocol ID** - 📅 Last updated on Oct 21, 2022 **Status** Approval granted via MREC Full Board **Protocol Deviation Post Ethical ID** PD ID-23-00026-KTC : Follow-up Report 1 **Protocol Deviation Status** Case Open **Report Submission Status** Pending Submission The List of Protocol Deviation Reporting under the General Protocol Deviation Reporting information will have an additional listing added as follows : List Of Protocol Deviation Reporting 	NO.	INITIAL / FOLLOW UP REPORT	REPORTING INVESTIGATOR	MREC REPORT DECISION	
---	---	---	---	---
1	Initial Report	Cik Law Fai Yee	Request for more information	👁 📋 ✎
2	Follow-up Report 1	Cik Law Fai Yee	Pending Submission	👁 ✏ 🗑		The status of a newly created **Follow Up PD Report Submission** will be **"Pending Submisison"**
6.	User may then cotinue to update the information at the 'Protocol Changes and/or Actions Taken" section, followed by the "Protocol Deviation Supporting Documents" section . [Save] ✅ Protocol Changes and/or Actions Taken Information Saved. To update and replace document in the "Protocol Deviation Supporting Documents" - 1) Click on the ⊡ pdf icon to select new updated document or drag the document 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 document

User may look back at the previous uploaded document in the **"View Document History"** located at the top right of each document section once documents section is saved.

Then ,click on the ⊕ icon to acces the document file or drag the file over the box available.Once a document has been uploaded, user can update the version & version date to the document uploaded(if any) . File name can also be changed if needed. Once all documents have been uploaded, Click **Save** to complete the step and save the uplaoded 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

✓ Supporting Documents Information 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.	

| 7. | Once all the required follow up information and documents have been uploaded, user is required to acknowledge the submisison made at "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 acknowledged, user can submit the Follow up Protocol Deviation 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 | | | |

Once a Follow Up Protocol Deviation Reporting Submission has been successfully submitted, user will be broughtback to the Protocol Deviation Case listing

Protocol Deviation Case

Keyword

Search NMRR ID, Research ID or Title of the Submission

Status

Select All

EXCEL   PDF   Show 10 ∨ entries

#	NMRR ID ▼	TITLE	PD CASE ID	NO OF PD CASE REPORTED	MREC DECISION	CASE STATUS	ACTION
1	NMRR-ID-22-01760-WQF	A Randomized Controlled Trial on TauroLock(TM) U 25,000 Lock Versus Standard of Care in Perfoned Dialysis-related Peritonitis...	PD ID-23-00026-KTC	3	Undergoing Review by PDSC	Case Open	👁 📋 📋

Showing 1 to 1 of 1 entries

Previous **1** Next

The status of a successful follow up submission of Protocol Deviation Reporting will change from **"Pending Submission"** to either **"Undergoing Review by PDSC"** or **"Follow up Submitted to MREC Secretariat"**

No of PD Report Reported will also increase from the previous number of submissions

In Protocol Deviation Case Listing, the following action icons are accessible to user:

- Show 👁 icon - to view of the General Protocol Deviation Submission of **Protocol Deviation Post Ethical ID (PD Case)**
- Initial Submission 📋 icon - to show the initial registration data of NMRR ID Submission
- PD Report Listing 📋 icon - to view the detail listing of **Protocol Deviation Post Ethical ID – Report Type (PD Report)**

In viewing the Protocol Deviation Case, user will be able to see the PD Case Decision History as below:

Decision History

#	DECISION	DECISION DATE	APPROVAL AUTHORITY
1	Initial Submission	09/01/2023 03:21:48	Investigator
2	Follow Up Submitted To MREC Secretariat	11/01/2023 18:54:38	Investigator

While in viewing dof the Protocol Deviation Report for the follow-up , user will be able to just see the individual PD Report

Decision History

#	DECISION	DECISION DATE	APPROVAL AUTHORITY
1	Follow Up Submitted To MREC Secretariat	11/01/2023 18:54:38	Investigator

Decision history **PD Case** versus **PD Report**

1. **PD Case** shows only **history of submission of each PD Reports** – (initial status of each PD Reports under a same PD Case ID)

   PD Report shows **the history of processing decision status** of each individual PD Reports

2.3 – Editing/ Deletion of Protocol Deviation Reporting Submission with status "Pending Submission "

No	Step-by-step instructions	Remark
1.	In the case user have not managed to finish with submission and would like to come back to the existing Protocol Deviation Reporting Submission to edit or delete the 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	
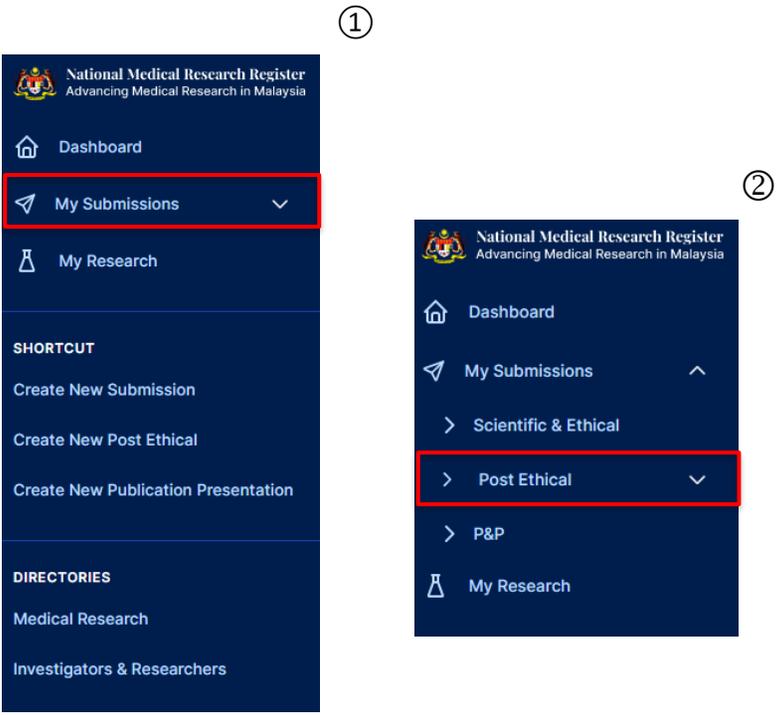
2.	Click on Protocol Deviation to go to the listing on the existing Protocol Deviation Reporting Submission. A list of all existing Protocol Deviation Post Ethical ID (Protocol Deviation Case) submission will be displayed. 	

3.	Click on the 📋 icon at the intended **Protocol Deviation Post Ethical ID (PD Case)** which requires the editing.	

Protocol Deviation Case

Keyword

Search NMRR ID, Research ID or Title of the Submission

Status

Select All

EXCEL PDF Show 10 ∨ entries

#	NMRR ID ▼	TITLE	PD CASE ID	NO OF PD CASE REPORTED	MREC DECISION	CASE STATUS	ACTION
1			PD ID-23-00026-KTC	2	Request for more information	Case Open	👁 📋 📋

Then, Protocol Deviation Report listing will be displayed. To edit a submission, click on the ✏ icon at the intended **PD Report** and follow the step as mentioned above in **1.1 "Creating a new Protocol Deviation Reporting Submission" or 2.2 – "Submission of Follow up Protocol Deviation Reporting (Subsequent PD Report)**

Protocol Deviation Report

Keyword

Search NMRR ID, Research ID or Title of the Submission

Status

Select All

EXCEL PDF Show 10 ∨ entries

#	NMRR ID ▼	TITLE	PD CASE ID	STATUS	PD CORRESPONDING PERSON	DATE OF SUBMISSION	ACTION
1			PD ID-23-00026-KTC Follow-up Report 3	Pending Submission			👁 ✏ 🗑 📋

Editing of a submission is only available for a PD Report with status **"Pending Submission"**

41

|	
e	For Protocol Deviation Reporting Submisison deletion , click on the delete 🗑 icon at the intended **PD Report**

Protocol Deviation Report

Keyword

Search NMRR ID, Research ID or Title of the Submission

Status

Select All

EXCEL   PDF   Show 10 ∨ entries

#	NMRR ID ▼	TITLE	PD CASE ID	STATUS	PD CORRESPONDING PERSON	DATE OF SUBMISSION	ACTION
1			PD ID-23-00026-KTC Follow-up Report 3	Pending Submission			👁 ✏ 🗑 📋

Click **OK** to confirm the deletion of the intended PD Reporting Submission. Once it's clicked, the PD Report will be deleted and removed from the Protocol Deviation Report listing.
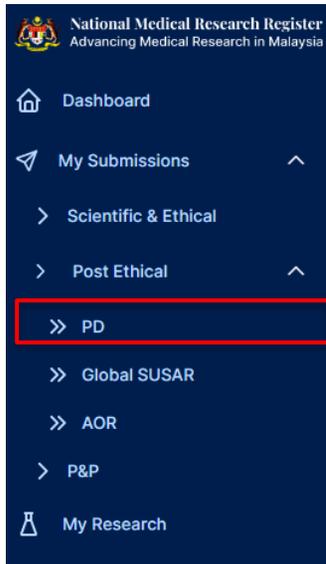
Are you sure you want to remove this record?

OK   Cancel

Deletion of a submission is only available for a PD Report with status **"Pending Submission"**
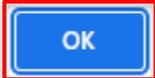
2.4 – Case Closed Protocol Deviation Post Ethical ID (PD Case)

No	Step-by-step instructions	Remark
1.	In case where a **Protocol Deviation Case** is no longer required to be updated or has completed the follow up and MREC Full Board is satisfied with the report provided, MREC Secretariat will close the **Protocol Deviation Case** for filling and archiving. In order for to access the 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	
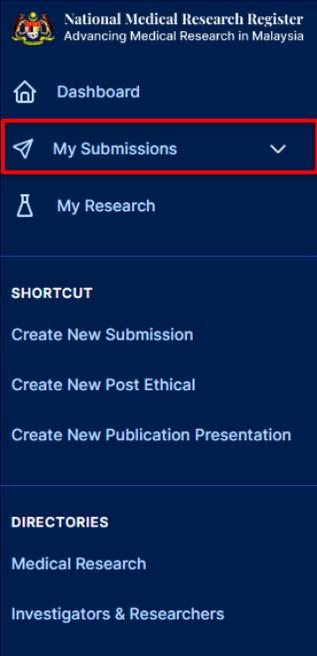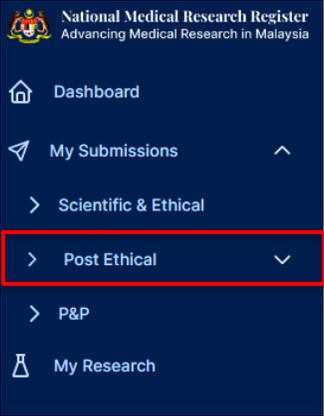
| 2. | Click on Protocol Deviation to access the existing Protocol Deviation Reporting Submission list. A list of all existing (Protocol Deviation Case) submission will be displayed. | - |

3.	For a PD Case that has been closed, the PD report list 📋 icon will not be available	User will not be able to access the PD Report list and follow up ✎ con. To **reopen a PD Case**, user is required to **contact MREC Secretariat** to make the request accordingly.

3. For a PD Case that has been closed, the PD report list 📋 icon will not be available

Protocol Deviation Case

Keyword

Search NMRR ID, Research ID or Title of the Submission

Status

Select All

EXCEL   PDF   Show 10 ⌄ entries

#	NMRR ID	TITLE	PD CASE ID	NO OF PD CASE REPORTED	MREC DECISION	CASE STATUS	ACTION
1			PD ID-23-00021-TXZ	2	Uphold MREC Full Board Decision with no further action	Case Closed	👁 📋

However, user will still be able to access each of the PD Report previously submitted by clicking on the 👁 icon at the closed PD Case

Protocol Deviation Case

Keyword

Search NMRR ID, Research ID or Title of the Submission

Status

Select All

EXCEL   PDF   Show 10 ⌄ entries

#	NMRR ID	TITLE	PD CASE ID	NO OF PD CASE REPORTED	MREC DECISION	CASE STATUS	ACTION
1			PD ID-23-00021-TXZ	2	Uphold MREC Full Board Decision with no further action	Case Closed	👁 📋

User will not be able to access the PD Report list and follow up ✎ con. To **reopen a PD Case**, user is required to **contact MREC Secretariat** to make the request accordingly.

4.	List of Protocol Deviation Report is available under the General Protocol Deviation Reporting Information. To view the PD report details , click on the ⊙ icon at the intended PD Report.	
	List Of Protocol Deviation Reporting	

NO.	INITIAL / FOLLOW UP REPORT	REPORTING INVESTIGATOR	MREC REPORT DECISION	
1	Initial Report		Request for more information	⊙
2	Follow-up Report 1		Uphold MREC Full Board Decision with no further action	⊙

-The End -