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

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Prerequisite For Submission

ID	Criteria
1.1	User has the access to NMRR Version 2.0 (nmrr.gov.my) via a stable internet connection
1.2	 Prerequisite: 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
- 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 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 Create New Post Ethical My Submissions Create New Submission 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) Protocol Deviation Coordinator (PD Coordinator) Protocol Deviation Corresponding Person (PD CP)

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Click on the 📋 icon to create a new Protocol Deviation Submission 4. **New Post Ethical Approval** Select Post Ethical Approval Type Keyword Search NMRR ID, Research ID or Title of the Submission Protocol Deviation \sim ✓ entries Show 10 TITLE NMRR ID RESEARCH SCOPE RESEARCH TYPE STATUS ACTION # 1 HARAPPER TO The quantity (trong / deviation tog) of Clinical Interventional Approval granted via 8 27480 (285527) and approximate the manager and the MREC Full Board annel Alena centralite de l'Agolicanese Traductor Parlaments and Parliaments and That Office or Meddlad Statut Putricities. 2 Address of the Approval granted via T. CONTRACTOR CONTRACTOR (The Clinical Interventional Ē 1984 177 161 stream of solicitum contemples MREC Full Board alterative interaction and the alterand in the second second 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** A MANAGAMENT CONTROLOUD THAN, ON TAUNOLOUTTY & 21,000 LOOK VENULS STANDARD OF CARE MORE THANKS, DALAND RELEASE PERFORMANC NMRR ID Protocol ID - 🚔 Last updated on Oct 21, 2022 Status Approval granted via MREC Full Board Post Ethical Submission Status Pending Submission

Study Status Not Yet Recruiting		
Site Conducted		
Hospital Selayang		
Reporting Investigator *		
LINE BEALWAR		
NAME OF INVESTIGATOR	ROLE OF INVESTIGATOR	STATE CONDUCTED
LAU SEW WHI	Principal / Coordinating Investigator	Selangor Darul Ehsan
Less Fail Yes	Co / Sub Investigator at the site	Selangor Darul Ehsan
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"Site Conducted" will be autoselected depending on the site assigned to user in the Protocol Deviation Corresponding Person assignment during NMRR Registration Submission.

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

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NMRR ID Here II - Protocol ID - 🗎 Last updated on Oct 21, 2022

Status Approval granted via MREC Full Board

Protocol Deviation Status Case Open

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

"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

Cor Rej Ins lisť	ntinue to scroll down or porting Details Informat ert the following informa ' and "Type of PD" .	n the page. User is the ion" part of the submis ation regardinng the "[n required to sison. Date of Aware	fill up th ness" c	ne "Proto of the PE	ocol Devia) , "Subejc	tion t ID	"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
Prot Pro	tocol Deviation Detail Information							submission of the entire Protocol Deviation Post Ethical ID to MREC)
Da	te of Awareness (Days to awareness : 0) *							
	mm/dd/yyyy	-						
Su	bject ID List						Add	** User can add multiple subjects
	NO. SUBJECT ID	DATE OF PD OCCURRENCE	DATE OF RECRUITMENT	TOTAL DAYS	GENDER	NO OF PD ID REPORTED		Protocol Deviation that happened in different dates. However, the
		No records found.						date of the awareness of the
•							× ·	same for all the incidents.
Ту	pe of PD (Based on group of Selection)							
	Please Select						~	
Clic	NO. SUBJECT ID	nation regarding the s		ed in the	e PD.	NO OF PD	Add	User is required to click Add for every addition of subject into the list (one click per subject entry)
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		No records found.						
4							* +	
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Subjec	ct ID List							
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Next , user is required to fill u (PD) / Protocol Violation (PV) Awareness".	ip information regarding the "Narrative of Protocol Deviation) Report ", "PD/PV Incident Repeatition" & "Means of	
Narrative of Protocol Deviation (PD) Reporting / Protoco Provide actual detailed description of protocol deviation/ violation subject visit details, description of PD. Please refrain from using m	sl Violation (PV) * 1 event including but not limited to date of event, Ion standard abbreviations	
Has this type of protocol deviation/ violation (or similar	deviations) previously occurred in this study or this study site?	
O Yes	• No	
How was the deviation picked up/ made aware (eg. Note	ed by Study Monitor etc.)	"Incident Repeatition " is selected as "Yes"
Follows by information regard ' Event Anticipation" & "Modif	Jing "Subejct Safety Involvement" , "Study Integrity Involvemen fication of Data Safety Monitoring".	nt",
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User is then required to fill up the Corrective A awareness of the incident.	Action & Preventive action taken following the	
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 fr	iture	
The last question of the "Protocol Deviation De information regarding the "Incident Resolution	etail Information" requires user to choose ". User need to click swe to complete and save	Refer to step No. 8 (b) if the
the information filled.		"Incident Resolution – has this event been resolved " is selected as "No"
Has this event been resolved?		
O Yes	O No	
On Going		
	Save	
l		
A popup up will appear indicating the "Protoco	I Deviation Reporting Details Information" has	
	Save	
Protocol Deviation Detail Information Saved.		

	A change to Protocol Deviation Post Ethical ID with a Report Type) and Report Submisison S "Pending Submisison". This information can be	(PD Case) will happen (ID is then assigned tatus will be generated and displayed as 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
	NMRR ID Protocol ID -	ntenis ernentenne er Lenti in men finnen in hav ven del ven finnen men finnen finnen in del ven del ven del ven	- Report Type later in the submission will also be referred to as Protocol Deviation Report (PD Report)
			"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 R deviation/ violation (or similar deviations) p study site?" as "Yes": User is required to filled up the following addition that becaused a page information is about 	epetition - Has this type of protocol previously occurred in this study or this onal information regarding the repetitive incident	
	Deviation/Protocol Violation List" of the previou	Ilsy occurred incident.	
	Yes	No	
	If yes, has it been reported to MREC?	• No	
	Deviation / Violation List	Add	
	No record	s found.	
		•	

vistion / Violation List		
viation / violation List		
NO. SUBJECT	DATE OF DEVIATION / VIOLATION DESCRIPTION	
	No records found.	
	• • •	
sert the required informat	tion and once the information has been filled, click see button to	
ve the information.		
Deviation / Violation List		
Subject Id		
Date of Deviation / Violation		
mm/dd/yyyy		
Description		
	li l	
	Cancel	

User is required to fill ac	ditional information reg	garding the reason of th	e incident is not yet	
Has this event been resolved?				
Yes		O No		
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Please explain why				
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Next , user is required to regarding the "Amendmo	o fill up "Protocol Chan ent Requirement to Re	ges and/ or Actions Tal search Document" & "A	en". Information	Refer to step No. 10 if "Amendm Requirement to Research Docur
Next , user is required to regarding the "Amendmo	o fill up "Protocol Chan ent Requirement to Re	ges and/ or Actions Tal search Document" & "A	en". Information ction Taken by Site".	Refer to step No. 10 if "Amendm Requirement to Research Docur is selected as "Yes "
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tions taken					
Please Select				~	
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2.0 – Existing Protocol Deviation Reporting Submission

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

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Protocol Deviation Submission

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

		ROLE OF INVESTIGATOR	STATE CONDUCT	ED
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Initial Submission

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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
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IRR ID P Atus Approval granted via MREC Full Boa omparing Report: Follow-u	Reporting Com rotocol ID - Post Ethical ID PD rd Ip Report 1 (Pending Sul	parison ID-23-00026-KTC 🗎 omission) & Initial F	Last updated on Oct 21,	or more informa	ation)	The blue-coloured information represents the set of data from t Initial Report as shown at the "Compare Report" header locate
IRR ID P Atus Approval granted via MREC Full Box Domparing Report: Follow-u otocol Deviation Detail Information Protocol Deviation Report Type Follow-up Report 1	Reporting Com	parison ID-23-00026-KTC 🗎 omission) & Initial F	Last updated on Oct 21	or more informa	ation)	The blue-coloured information represents the set of data from t Initial Report as shown at the "Compare Report" header locate at the top of the display page
IRR ID P Atus Approval granted via MREC Full Boa Domparing Report: Follow-u otocol Deviation Detail Information Protocol Deviation Report Type Follow-up Report 1 Date of Awareness Date of Awareness Date of Awareness	Reporting Com	parison ID-23-00026-KTC É omission) & Initial F	Last updated on Oct 21	or more informa	ation)	The blue-coloured information represents the set of data from t Initial Report as shown at the "Compare Report" header locate at the top of the display page
IRR ID P Atus Approval granted via MREC Full Boa comparing Report: Follow-u rotocol Deviation Detail Information Protocol Deviation Report Type Follow-up Report 1 Date of Awareness 04/01/2023 Subject ID List	Reporting Com	parison ID-23-00026-KTC 🗎 omission) & Initial F Initial Report 04/01/2023	Last updated on Oct 21	or more informa	ation)	The blue-coloured information represents the set of data from t Initial Report as shown at the "Compare Report" header locate at the top of the display page
IRR ID P Attus Approval granted via MREC Full Box Omparing Report: Follow-u otocol Deviation Detail Information Protocol Deviation Report Type Follow-up Report 1 Date of Awareness 04/01/2023 Subject ID List N. SUBJECT ID	Reporting Com rotocol ID - Post Ethical ID PD rd Ip Report 1 (Pending Sul h	De23-00026-KTC Comission) & Initial F Comission) & Initial F Comission Cod/01/2023 RRENCE Cod Date of Recruitment	Last updated on Oct 21, Report (Request	NO OF PD ID REPORTED	ation)	The blue-coloured information represents the set of data from t Initial Report as shown at the "Compare Report" header locate at the top of the display page
IRR ID P Attus Approval granted via MREC Full Box Omparing Report: Follow-u otocool Deviation Detail Information Protocool Deviation Report Type Follow-up Report 1 Date of Awareness 04/01/2023 Subject ID List No. SUBJECT ID 1 subject 1	Reporting Com rotocol ID - Post Ethical ID PD rd Ip Report 1 (Pending Sul n DATE OF PD OCCU	De23-00026-KTC É Demission) & Initial F Initial Report 04/01/2023 RRENCE DATE OF RECRUITMENT 01/09/2022	Last updated on Oct 21 Report (Request	NO OF PD ID REPORTED	ation)	The blue-coloured information represents the set of data from t Initial Report as shown at the "Compare Report" header locate at the top of the display page

No	Step-by-step instructions	Remark
1.	In the case where user wants to submit a follow up report of the Protocol Deviation Pose Ethical ID (PD Case). Scroll over the main menu located on the side of display page, go "My Submission". Then Click on the "Post Ethical"	t b 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"

 Click on Protocol Deviational Medical Research Register Advancing Medical Research in Malaysian Advancing Medica	on to access the existing Protocol Deviation Reporting Submission	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 Proto will be displayed.	Col Deviation Post Ethical ID (Protocol Deviation Case) submission	 In Protocol Deviation Case Listing, the following action icons are accessible to user: Show o icon - to view of the General Protocol Deviation Submission of Protocol Deviation Post Ethical ID (PD Case) Initial Submission i icon - to show the initial registration data of NMRR ID Submission PD Report Listing i icon - to view the detail listing of Protocol Deviation Post Ethical ID – Report Type (PD Report)

Protoc	ol Deviation Case							either as:
FIOLOC	of Deviation Case							Principal / Coordinating Investigator (PI)
Keyword				Status				Main Corresponding Person (Main
Search	NMRR ID, Research ID or Title of th	e Submission		Select All			~	CP)
EXCEL	PDF Show 10 v entr	ēs						Backup Corresponding Person (Backup CP)
#	NMRR ID TITLE	DD C	ASE ID + NO OF REPOR	PD CASE				Protocol Deviation Coordinator
1	NAME OF A Resident OTTEL WORK States The Other State of The Other States and The Partnership	PD ID 00024	-23- 2 S-KTC	Requi	est for more Case Ope nation	n 🧿 🖞	Ê	 Protocol Deviation Corresponding Person (PD CP)
Protoc	ol Deviation Report							
Protoc Keyword	ol Deviation Report			Status				
Protoc Keyword Search	ol Deviation Report	e Submission		Status Select All			~	
Protoc Keyword Search EXCEL	OI Deviation Report	e Submission		Status Select All			~	
Protoc Keyword Search EXCEL #	OI Deviation Report	e Submission Is PD CASE ID	STATUS	Status Select All PD CORRESPONDING PERSON	DATE OF SUBMISSION	ACTION	~	
Protoc Keyword Search ExCEL #	ol Deviation Report	PD CASE ID PD CASE ID PD D23- 00026-KTC Initial Report	STATUS Request for more information	Status Select All PD CORRESPONDING PERSON	DATE OF SUBMISSION 09/01/2023	 ACTION O C C 	``]	
Protoc Keyword Search ExCEL # 1 Sener Deviat shown	ol Deviation Report	PD CASE ID PD CASE ID PD ID-23- 00026-KTC Initial Report Initial Report e follow up c	STATUS Request for more information g Submisss pw with the reation.	Status Select All PD CORRESPONDING PERSON	DATE OF SUBMISSION 09/01/2023 displayed with Report submis	 ▲ ACTION ▲ ACTION ■ I I I the List of I sion availa 	Protocol ble is	
Protoc Keyword Search Excel # 1 Sener Deviat shown List of Prof	ol Deviation Report	PD CASE ID PD CASE ID PD ID-23- 00026-KTC Initial Report depicted belo follow up c	STATUS Request for more information g Submiss pow with the reation.	Status Select All PD CORRESPONDING PERSON	DATE OF SUBMISSION 09/01/2023	 ACTION Image: Organization action 	Y Protocol ble is	

Protocol Deviation Detail Information							Reporting 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	/ 1	
4						•	
Incort rolevant new intern	aatian inta tha Drataac			intormo			
save to save the informati	ion added	Deviation	Detail	IIIIOIIIIa	alion and	CIICK Save	
Save to save the informati	ion added		Detail				
Save to save the informati Has this event been resolved? Yes On Going	ion added		Detail				
Save to save the informati Has this event been resolved? Yes On Going	ion added		i Detaii		ation and		
Save to save the informati Has this event been resolved? Yes On Going	ion added					Save	
Save to save the informati Has this event been resolved? Yes On Going	ion added					Save	
A popup up will appear ind	licating the " Protocol	○ No Deviation [Detail In	formati	on" has b	Save	
A popup up will appear ind	licating the " Protocol l	○ № Deviation [Detail In	formatio	on" has b	Save	
It is event been resolved? Yes On Going	licating the " Protocol	○ № Deviation [Detail In	formatio	on" has b	een Save	

5.	Once Protocol Deviation Detail Information is saved, the Follow Up PD Report created successfully and its information will be displayed at the top of the displayed together with the Report Submission Status	t has now been lay page The status of a newly creat Up PD Report Submission"	ated Follow on will be
	Protocol Deviation Submission A RANDOMIZED CONTROLLED TRIAL ON TAUROLOCKTM-U 25,000 LOCK VERSUS STANDARD OF CARE IN PERITONEAL DIALYSIS-RELA 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 I information will have an additional listing added as follows :	.ated peritonitis.	
	List Of Protocol Deviation Reporting	î.	
	NO. INITIAL / FOLLOW UP REPORT REPORTING INVESTIGATOR MREC REPORT DECISION		
	1 Initial Report Request for more information	● Ê, C	
	2 Follow-up Report 1 Pending Submission	⊙ / ₫	
6.	User may then cotinue to update the information at the 'Protocol Changes and/ Taken" section, followed by the "Protocol Deviation Supporting Documents" sec	/or Actions ction .	
	Protocol Changes and/or Actions Taken Information Saved.		
	 To update and replace document in the "Protocol Deviation Supporting Document) 1) Click on the pdf icon to select new updated document or drag the docu old file – this will replace the old documents with the new one. Then click of swe button to complete and save the new document. 	ents" - Iment over the on the	
	or		

ory" located at the document section s section is saved	Document History " locate top right of each document once documents section is	View Document History	ate	
section is saved	once documents section is	View Document History	<u>ite</u>	Letter *
				wnload Cover Letter T
		×	Name	
			durinity accument.par Version *	PDF
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		0	Version Date * 01/04/2023	
				Supporting Docume
		View Document History		
				Select or drag files
		Save		
		Cancel	e you sure want to delete the document:	
the file name ha	Please ensure the file na	he file over the box	n the 🕘 icon to acces the document file	Then .click
.pdf " at the end	the extension ".pdf " at t	te the version & version	ce a document has been uploaded, user	available.C
without the	its name. Files without th	changed if needed. Once	ocument uploaded(if any) . File name car	late to the
" may have the	extension ".pdf " may ha	step and save the	s have been uploaded, Click see to con	all docume
g able to be read	risk of not being able to		cuments.	iplaoded o
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	later	Save		

6.	To view back located at the order. User a clicking the	the previou top right of also will be a <u>Cownload</u>	sly uploaded docume each document sect ble to download the icon next to the doo	ent, Click on the " Vi tion. Document will b previously uploaded cument title.	ew Document I be shown in chro document (if ne	History" phological eeded) by	
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	<u> </u>	Letter Template			Viet	w Document History	
			Name			×	
		PDF	Version *				
	≡ PDF	25.01 KB <u>Download</u>	2				
			01/11/2023			Ö	
		Documents dummy-doc	s cument.pdf	Uploaded 16 hours ago	Jownload		
					CLOSE		

_							
	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 th 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.						
	Decision History						
	# APPROVER NAME DECISION DATE APPROVAL AUTHORITY						
	Reporting Submission by clicking the submit button.						
	Decision History						
	# DECISION DATE APPROVAL AUTHORITY						

ser will be broughtback to the P	otocol Deviation Case listing	submission of Protocol Deviation Reporting will change from "Pendin Submission" to either "Undergoin
Revword	Status	Review by PDSC" or "Follow up Submitted to MREC Secretariat"
Search NMRR ID, Research ID or Title of the Sub EXCEL PDF Show 10	nission Select All	No of PD Report Reported will also increase from the previous number submissions
# NMRR ID TITLE 1 Interest the second	PD CASE NO OF PD CASE MREC CASE ACTION PD ID-23- CNCC 3 Undergoing Review by PDSC Case Open Image: Ca	 In Protocol Deviation Case Listing, the following action icons are accessible to user: Show O icon - to view of the General Protocol Deviation Submission of Protocol Deviation Post Ethical ID (PD Case) Initial Submission O icon - to show the initial registration data of NMRR ID Submission PD Report Listing O Protocot Deviation Post Ethical ID – Report Type (PD Report)

ln viewiı as belov	ng the Protocol Deviation Case, u w:	user will be able to see th	ne PD Case Decision History	Decision history PD Case versus Report
Decision	History			1. PD Case shows only history of
#	DECISION	DECISION DATE	APPROVAL AUTHORITY	– (initial status of each PD Rep under a same PD Case ID)
1	Initial Submission	09/01/2023 03:21:48	Investigator	PD Report shows the history
2	Follow Up Submitted To MREC Secretariat	11/01/2023 18:54:38	Investigator	processing decision status of each individual PD Reports
See the Decision	individual PD Report		ap, user will be able to just	
#	DECISION	DECISION DATE	APPROVAL AUTHORITY	
1	Follow Up Submitted To MREC Secretariat	11/01/2023 18:54:38	Investigator	

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 the existing Protocol Deviation Reporting Submission to edit or delete the submover the main menu located on the side of display page, go to "My Submission on the "Post Ethical"	come back to hission, scroll ". Then Click
	Image: Provide a research in Multiput Imag	

2.	Click on Protocol Deviation to go to the listing on the existing Protocol Deviation Reporting	
	Submission. Mational Medical Research Register Advancing Medical Research in Malaysia	
	C Dashboard	
	V My Submissions	
	> Scientific & Ethical	
	> Post Ethical	
	» PD	
	» Global SUSAR	
	» AOR	
	∆ My Research	
	A list of all existing Protocol Deviation Post Ethical ID (Protocol Deviation Case) submission	
	will be displayed.	
	Protocol Deviation Case	
	Keyword Status	
	Search NMRR ID, Research ID or Title of the Submission Select All V	
	EXCEL PDF Show 10 ~ entries	
	# NMRR ID TITLE TITLE TITLE TITLE TITLE PD CASE ID PD CASE ID NO OF PD CASE REPORTED MREC DECISION CASE STATUS ACTION	
	1 PD ID-23- 00026-KTC 2 Request for more Case Open O C 🗎	

Protocol Deviation C	ase						
Keyword			Status				
Search NMRR ID, Research ID or	Title of the Submission		Select All			~	
EXCEL PDF Show 10	✓ entries						
# NMRR ID	TITLE DCAS	SE ID 🔶 NO OF REPOR	PD CASE RTED MREC DECISIO	N 🔶 CASE STATUS			
1 NAME () () (1750-MDP	PD ID-2 00026-	23- 2 -KTC	Request for mo information	re Case Open	○ ○○□]	
Then, Protocol Dev	iation Report listir	ng will be	displayed. To ec	lit a submiss	ion, click o	n the 🧪	
· -	1	•			,		
con at the intende	d PD Report and f	follow the	step as mention	ed above in	1.1 "Crea	ting a	
icon at the intende new Protocol Dev	d PD Report and f viation Reporting	follow the ng Subn g (Subse	step as mention nission" or 2.2	ed above in 2 – "Submi	1.1 "Crea ssion of F	ting a Follow	
icon at the intender new Protocol Dev up Protocol Dev	d PD Report and f viation Reporting iation Reporting	follow the ng Subn g (Subse	step as mention nission" or 2.2 equent PD Rep	ed above in 2 – "Submi port)	1.1 "Crea ssion of F	ting a follow	
con at the intender new Protocol Dev up Protocol Dev Protocol Deviatio	d PD Report and f viation Reporting iation Reporting	follow the ng Subn g (Subse	step as mention nission" or 2.2 equent PD Rep	ed above in 2 – "Submi port)	1.1 "Crea ssion of F	ting a Follow	
con at the intender new Protocol Dev up Protocol Dev Protocol Deviatio	d PD Report and f viation Reporting iation Reporting n Report	follow the ng Subn g (Subse	step as mention nission" or 2.2 equent PD Rep	ed above in 2 – "Submi bort)	1.1 "Crea ssion of F	ting a Follow	
con at the intended new Protocol Dev up Protocol Dev Protocol Deviatio	d PD Report and f viation Reporting iation Reporting	follow the ng Subn g (Subse	step as mention nission" or 2.2 equent PD Rep	ed above in 2 – "Submi port)	1.1 "Crea ssion of F	ting a Follow	
icon at the intended new Protocol Dev up Protocol Dev Protocol Deviatio	d PD Report and f viation Reporting iation Reporting n Report	follow the ng Subn g (Subse	step as mention nission" or 2.2 equent PD Rep Status Select All	ed above in 2 – "Submi port)	1.1 "Crea ssion of F	ting a Follow	
Con at the intended new Protocol Deviation Protocol Deviation Keyword Search NMRR ID, Research	d PD Report and f viation Reporting iation Reporting n Report	follow the ng Subn g (Subse	step as mention nission" or 2.2 equent PD Rep Status Select All	ed above in 2 – "Submi port)	1.1 "Crea ssion of F	ting a Follow	
Con at the intended new Protocol Deviation Protocol Deviation Keyword Search NMRR ID, Research EXCEL PDF Show	D Report and f viation Reporting iation Reporting n Report	follow the ng Subn g (Subse	step as mention nission" or 2.2 equent PD Rep Status Select All	ed above in 2 – "Submi port)	1.1 "Crea ssion of F	ting a Follow	Editing of a submission is only
Protocol Deviation	A PD Report and f viation Reporting iation Reporting n Report n ID or Title of the Submission	follow the ng Subn g (Subse	step as mention nission" or 2.2 equent PD Rep Status Select All	DATE OF SUBMISSION	1.1 "Crea ssion of F	ting a Follow	Editing of a submission is only available for a PD Report with s
Protocol Deviation Keyword EXCEL PDF Show # NMRR ID, Research 1	A PD Report and f viation Reporting iation Reporting n Report 10 v entries 10 v PD CASE 10 PD ID- 23- 00026- KTC	follow the ng Subn g (Subse	step as mention nission" or 2.2 equent PD Rep Status Select All	DATE OF SUBMISSION	1.1 "Crea ssion of F	ting a Follow	Editing of a submission is only available for a PD Report with s "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 De completed the follow up and N Secretariat will close the Prot access the submission, scroll "My Submission". Then Click	viation Case is no longer required to be updated or has MREC Full Board is satisfied with the report provided, MREC ocol Deviation Case for filling and archiving. In order for to over the main menu located on the side of display page, go to on the "Post Ethical"	
	1		
	National Medical Research Register Advancing Medical Research in Malaysia		
	Dashboard	2	
	My Submissions	National Medical Research Register	
	▲ My Research	Dashboard	
	SHORTCUT	My Submissions	
	Create New Submission	> Scientific & Ethical	
	Create New Publication Presentation	> Post Ethical V	
		> P&P	
	DIRECTORIES Medical Research	人 My Research	
	Investigators & Researchers		

Natio	ional Medical Resear ancing Medical Researc	rch Register ch in Malaysia							
🔓 Dash	hboard								
🔊 My Si	ubmissions	^							
> Scie	entific & Ethical								
> Pos	st Ethical	^							
» PD	D								
» Glo	lobal SUSAR								
» A0	OR								
> P&P)								
<u>Д</u> му р	Research								
<u>А</u> му R	Research all existing	(Protocol D	eviation C	ase) submi	ssion will be di	splayed.			
My R list of rotoco	all existing	(Protocol De n Case	eviation C	ase) submis	ssion will be di	splayed.			
My R list of rotoco Keyword Search t	all existing ol Deviatio	(Protocol De on Case	eviation C	ase) submis Status Status	ssion will be di	splayed.		~	
My R list of rotoco Search 1 EXCEL	All existing ol Deviation NMRR ID, Research PDF Show	(Protocol Do on Case	Submission	Status Status NO OF PD CASE REPORTED	ssion will be di	splayed.	ACTION	~	
My R list of rotoco Search 1 EXCEL # 1	All existing ol Deviation NMRR ID, Research PDF Show NMRR ID	(Protocol De on Case th ID or Title of the S (10 ~ entries TITLE	PD CASE PD ID-23- 00021-TXZ	ASE) Submis	ssion will be di	Splayed.	ACTION © [©]	~	

				Status					
Search N	MRR ID, Researc	ch ID or Title of the S	Submission	Selec	t All			~	User will not be able to access PD Report list and follow up
EXCEL # 1	PDF Show	v 10 v entries		NO OF PD CASE REPORTED	MREC DECISION DECISION Decision	CASE STATUS Case Closed		1	To reopen a PD Case , user is required to contact MREC Secretariat to make the reque accordingly.
	1100	Distant Carls Martines			further action				
lowever licking c Protocc	, user will in the o	still be able t icon at the c on Case	to access e losed PD C	each of the Case	PD Report pr	eviously st	ubmitted by		
lowever licking c Protocc	, user will on the o I Deviatio	still be able icon at the c on Case	to access e losed PD C	each of the Case	PD Report pr	eviously st	ubmitted by		
lowever licking c Protocc Keyword Search N	, user will on the o I Deviatic	still be able i icon at the c on Case	to access e losed PD C	each of the Case Status Selec	PD Report pr	eviously su	ubmitted by	~	
lowever licking c Protocc Keyword Search N Excel	, user will on the ol Deviatic MRR ID, Researd PDF Show	still be able icon at the c on Case	to access e losed PD C	Status No of PD CASE	PD Report pr	eviously su		~	

. Li: In	st of Pr formati	rotocol Deviation F ion. To view the P	Report is available D report details , c	e under the General Protocol Deviation I click on the <a>o icon at the intended PD	Reporting Report.
	NO.	INITIAL / FOLLOW UP REPORT	REPORTING INVESTIGATOR	MREC REPORT DECISION	
	1	Initial Report	Dr Wong Hin Sang	Request for more information	0
	2	Follow-up Report 1	Dr Wong Him Sang	Uphold MREC Full Board Decision with no further action	o
	•				•

-The End -

Prepared by: NMRR Secretariat

Checked & validated by: Asyraf Syahmi Bin Mohd Noor (date : 10/01/2023)