User Guidelines for

Post Ethical Approval Submission

- Amendment

National Medical Research Register v2.0

National Institutes of Health (NIH)

Version 1.0 , March 2023

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Prerequisite For Submission

ID	Criteria
1.1	User has the access to NMRR Version 2.0 (nmrr.gov.my) via a stable internet connection
1.2	 Prerequisite: 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 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

Declaration on type of Amendment (to select the

- 1. Substantial changes
- 2. Non-substantial changes

Amendment Summary Detail

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

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

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

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

<u>Study Site Updates (based on selection on type of amendment)</u>

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

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

Document Updates (based on selection on type of amendment)

Amendment Documents

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

User Guidelines for Submission

1.0 - New Amendment Submission

1.1 – Creating an Amendment Submission

No	Step-by-step instructions	Remark
1.	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 Mutical Research Register My Submissions Create New Submission Create New Post Ethical Create New Post Ethical 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)

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Keyword				Select Post Ethical Approval Type		
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				Select All Amendment Acknowledgement of Receipt (AC	R)	
Show 10 #	✓ entries NMRR ID	TITLE	RESEARCH SCO	Closure \ Termination Global SUSAR F Protocol Deviation Ethical Approval Renewal		
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Click on the 📋 icon to create a N	ew Amendment Submission	**Only one submission of Amendment is allowed at one time.
New Post Ethical Approval		Subsequent Amendment Submission of
Keyword	Select Post Ethical Approval Type	the same NMRR ID can only be created
Search NMRR ID, Research ID or Title of the Submission	Amendment	has received the final decision by MREC (either Approved, Disapproved or Exampted)
Show 10 v entries		Exempled)
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Declaration Type of Amendment	Substantial Changes
Substantial Changes	
 Major changes to the design or methodology of the study, or to background information affecting its scientific value 	11 selections of
Changes to the Research Objective & Outcome Measure	Non-Substantial Changes
Changes to the procedures undertaken by participants	
Any change relating to the safety or physical or mental integrity of participants, or to the risk/benefit assessment for the study	
Changes to the inclusion/ exclusion criteria	Refer to point no 7 & no 8 for the
Significant changes to study documentation such as participant information sheets/ informed consent forms, questionnaires, advertisement, letters of invitation, letters to GPs or other clinicians, information sheets for relatives or careers.	selection list
Changes to the sponsor/funding arrangements or Contract Research Organization (CRO)	
Changes to the documentation used by the research team for recording study data;	
Changes to the logistical arrangements for storing or transporting samples	
Extension of the study beyond the period specified	
Changes to the presentation of previously approved wording such as an approved advertisement being used in a different format	
Changes to contact details for the sponsor(s), sponsor's legal representative or Contract Research Organization (CRO)	
Changes to contact details for principal investigator, study team or other project staff	
Any other non-substantial amendment (Please specify)	
Save	
A popup up will appear indicating the Declaration Type of Amendment Information has been succesfully saved.	
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Sav	re

	Once "Declaration Type of Amendment " is saved, an Amendment Post Ethical ID will be generated. Amendment Submission NMR ID Protocol ID - Last updated on Sep 23, 2021 Status Approval granted via MREC Full Board Amendment Status Pending Submission	Amendment Post Ethical ID will be the reference number for the Amendment Submission from this point onwards. Once an Amendment Post Ethical ID is generated, Amendment submission has now been created successfully and is available to be accessed from "My Submission" menu. Amendment Post Ethical ID later in the submission will also be referred to as Amendment Submission ID
7.	 Substanstial change will lead to specific section and subsection to open. The list is as of the following: Major changes to the design or methodology of the study, or to background information affecting its scientific value → all section will be open Changes to the Research Objective & Outcome Measure → study information section updates [subsection study information & outcome measure] and document updates section Changes to the procedures undertaken by participants → all section will be open Any change relating to the safety or physical or mental integrity of participants, or to the risk/benefit assessment for the study → study information section updates [subsection investigational product, exclusion & inclusion criteria] and document updates section Changes to the inclusion/ exclusion criteria → study information section updates [subsection exclusion & inclusion criteria] and document updates section Significant changes to study documentation such as participant information sheets/ informed consent forms, questionnaires, advertisement, letters of invitation, letters to GPs or other clinicians, information sheets for relatives or careers. → document updates section A change of sponsor(s) or sponsor's legal representative → Investigator & sponsor section updates [subsection sponsor & contract research organisation] and document updates section Appointment of a new principal investigator → Investigator & sponsor section updates [subsection sponsor & contract research organisation] and document 	Based on the selection of the changes, specific part & section of NMRR data submission will be open DECLARATION ON TYPE OF AMENDMENT AMENDMENT AMENDMENT SUMMARY DETAIL STUDY INFORMATION UPDATES STUDY SITE UPDATES INVESTIGATOR & SPONSOR UPDATES DOCUMENT UPDATES
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 updates section A change to the payments, benefits or incentives to be received by participants or researchers in connections with taking part in the study, or any other change giving rise to a possible conflict of interest on the part of any investigator/ collaborator → document updates section A change to the definition of the end of the study → study information section updates section A change in subject recruitment number → study information section updates [subsection subject recruitment number → study information section updates section Change in subject recruitment number → study information section updates section Any other significant change to the protocol or the terms of the MREC application → all section will be open 	
 8. Non- substanstial change will lead to specific section and subsection to open. The list is as of the following: Minor changes to the protocol or other study documentation, (e.g. correcting errors, updating contact points, minor clarifications) → all section will be open Minor Updates to the study documents (eg: investigator's brochure / Summary of product report, participant information sheets/ informed consent forms, questionnaires, advertisement, letters of invitation) → document updates section Changes to the research team /Addition of sub-Investigators (other than appointment of new principal investigator) + document update section → Investigator & sponsor section updates [subsection Study Team , Public Query, Corresponding Person] and document updates section Changes in funding arrangements + document update section → Investigator & sponsor section updates [subsection sponsor & contract research organisation] and document updates section Changes in the documentation used by the research team for recording study data → document updates section Changes in the logistical arrangements for storing or transporting samples+ document update section Extension of the study beyond the period specified → all section will be open Changes to the presentation of previously approved wording such as an approved advertisement being used in a different format. → document updates section Changes to contact details for the sponsor(s) or sponsor's legal representative, + document update section and document updates section and document updates section Changes to contact details for the sponsor section updates section Changes to contact details for the sponsor section updates section Changes to contact details for the sponsor section updates section Changes to contact details for principal investigator, study team or other project staff+ 	Based on the selection of the changes, specific part & section of NMRR data submission will be open DECLARATION ON TYPE OF AMENDMENT AMENDMENT SUMMARY DETAIL O STUDY INFORMATION UPDATES STUDY SITE UPDATES INVESTIGATOR & SPONSOR UPDATES DOCUMENT UPDATES

	Study Team , Public section • Any other non-substa	Query, Corresponding Person] ntial amendment → all section wil	and document updates I be open	
9.	A section on details of the An the screen	nendment Submisison is then will b	e available over the right side of	
	•	DECLARATION ON TYPE OF AMENDMENT		
		AMENDMENT SUMMARY DETAIL		
	•	STUDY INFORMATION UPDATES		
	•	STUDY SITE UPDATES		
	•	INVESTIGATOR & SPONSOR UPDATES		
	•	DOCUMENT UPDATES		
	•	ACKNOWLEDGEMENT BY CORRESPONDING PERSON		

Insert the detail information of the amendment submission based on the selection on the "Declaration Type of Amendment" in the "Amendment Summary Detail".	
AMENDMENT SUMMARY DETAIL	
For Example if the selection in "Declaration Type of Amendment" are :	
1) Addition of new trial/study site*	
Addition of new trial/study site	
2) Changes to the research team /Addition of sub-Investigators (other than appointment of new principal investigator) or changes to Corresponding Person (CP)/ Coordinator/ Contact for Public Queries*	
Changes to the research team /Addition of sub-Investigators (other than appointment of new principal investigator) or changes to Corresponding Person (CP)/ Coordinator/ Contact for Public Queries	
User is required to enter the detail in the box available under each selection	
Addition of new trial/study site *	
Changes to the research team /Addition of sub-Investigators (other than appointment of new principal investigator) or changes to Corresponding Person (CP)/ Coordinator/ Contact for Public Queries *	

11.	Once all details has been filled up ,insert the Information regarding the list of document updates	
	Changes to the research team /Addition of sub-Investigators (other than appointment of new principal investigator) or changes to Corresponding Person (CP)/ Coordinator/ Contact for Public Queries *	
	addition of a Co- I for Hospital X site , Dr X	
	List of Document Updated *	
	Save	

2.	Once the list of documents updates has been filled up , click save to save the information on the "Amendment Summary Detail" section
	List of Document Updated *
	Cover Letter for Amendment Version x, dated dd/mm/yyyy Declaration of COI form Version x, dated dd/mm/yyyy Protocol Version x, dated dd/mm/yyyy
	- CV , Dr x
	Save
	A popup up will appear indicating the Declaration Type of Amendment Information has been
	successuity saved.
	Save
	Amendment Summary Detail Information Saved.

l	Based on selection at "Declaration Type of Amendment ", go to the submisison information .	ne specific section containing	Refer to point no 7 & no 8 for the selection list and the section relevant to
	For Example if the selection in "Declaration Type of Amendment"	are :	the selection that will be opened.
	Addition of new trial/study site*		
	Addition of new trial/study site		
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	Changes to the research team /Addition of sub-Investigators (other than appointment to Corresponding Person (CP)/ Coordinator/ Contact for Public Queries	of new principal investigator) or changes	
($\widehat{1}$		
	Addition of new trial/study site " will require information updates r Study Information Updates" Section and "Study Sites Update"	egarding "Site Description" in	
	1) STUDY INFORMATION UPDATES		
	Click Save to save the updates information updates		
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	Number of sites in Malaysia *		
		Save	

2) STUDY SITE UPDATES			
Click Add to update the site			
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Study Team				
Name*				
Tan Walka				
Study Site*				
Hospital Kajang			~ (4
Investigator Role				4
Principal / Coordinating Investigator		• Co / Sub Investigator at the site		
Principal Investigator at the site		Expert Opinion		٤
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			I I	
Tiam Wallow	Hospital Kajang	Co / Sub Investigator at the site	🖍 💼 📕	

14	Once all amendment information has been added ,click at "Document Updates" Section to upload amended documents	
	Select the required document type	
	Document Updates	
	Document Type *	
	Please Select ~	
	Select Document Type	
	Click Select Document Type to see the previously uploaded document	**Multiple documents can be selected
		one after another for the update
	Please Select Protocol Review Checklist	purposes.
	Research Protocol Research Protocol Review Checklist	
	Adult/Parental Participant Information Sheet (PIS) & Informed Consent Form (ICF) (interventional/minimal risk) Patient Information Sheet (PIS) & Informed Consent Form (ICF)	
	Patient Information Sheet (PIS) & Informed Consent Form (ICF) Review Checklist	
	Information Sheet & Assent Form, 7-12 years	
	Optional Patient Information Sheet (PIS) & Informed Consent Form (ICF) for genetic, pharmacodynamic / pharmacogenomic / other studies Optional Patient Information Sheet (PIS) & Informed Consent Form (ICF) for future research other studies	
	Pregnant Partner Information Sheet & Informed Consent Form Checklist for Research on Stem Cell & Cell Based Therapy, National Stem Cell Research and Ethics Subcommittee(NSCERT)	
	Checklist for First Research Protocol / Archive Biospecimen Clinical Form Report / Data Collection Form	
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	Please Select AMENDMENT SUMMARY DETAIL	
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2.0 – Existing Amendment Submission

2.1 – Viewing an Existing Amendment Submission



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Once submission has been acknowleged, user can submit the Amendment Submission revision by clicking the submit button.
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2.3 – Editing/ Deletion of Amendment Submission with status "Pending Submission"

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Prepared by: NMRR Secretariat

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