User Guideline for

Investigator/Clinical Research Associate (CRA) – Revision & Deletion of Submission

National Medical Research Register v2.0

National Institutes of Health (NIH)

Version 1.0, November 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	 General Prerequisite: Should logged in as Investigator or Clinical Research Associates (CRA) Should have completed the profile page Submission with a Research ID (for research that hasn't been registered in NMRR) or Submission with an NMRR ID (for research that has successfully registered in NMRR and currently being processed at any level of processing (either by JPP-NIH or MREC or MRG)
	 Prerequisite for Revision Submission is assigned with status "Incomplete Submission/Revision Required" by NMRR Secretariat or with status "Revision Required" by either JPP-NIH or MREC or MRG
	 Prerequisite for Deletion Only for submission with Research ID (for research that hasn't been registered in NMRR) Submission with status "Pending Submission" or status "Incomplete Submission/Revision Required"
1.3	 User has a role assigned during submission of research registration either as: Principal Investigator (PI) Main Corresponding Person (Main CP) Backup Corresponding Person (Backup CP)

Information/ Documents Required

* Mandatory field/items/parameter/documents

** Kindly refer to the **Data Elements and Parameters for NMRR Submission** document for the definition and further explanation regarding each item and parameter required during a submission.

*** Depending on the query and comment given by the secretariat currently processing the submission

Research Registration Information

General Information

- 1. Submission Type*
- 2. Research Title*
- 3. Public Title*
- 4. Research Title Abbreviation*
- 5. Protocol ID
- 6. Research Scope*
- 7. Research Type*

Study Information

- 1. Research Type Information* (based on Research Type selected)
- 2. Study Information*
- 3. Disease and/or Research Area*
- 4. Investigational Products* (only for Interventional Research Type)
- 5. Inclusion / Exclusion Criteria*
- 6. Study Timeline*
- 7. Subject (Sample Size) Description*
- 8. Sites Description*
- 9. Current Study Recruitment Status / Study Status
- 10. Outcome Measures*
- 11. Biospecimen Collection / Archiving* (only for Interventional & Registry/ Biobanking/ Clinical Database Research Type)
- 12. Ethical Application Status*
- 13. Study URL*

Study Site

1. Study Site Listing*

Investigator & Sponsor Updates

- 1. Study Team*
- 2. Contact for Public Queries* (only for Interventional Research Type)
- 3. Corresponding Person*

- 4. SAE Corresponding Person (only for Interventional & Observational Research Type)
- 5. PD Corresponding Person (only for Interventional & Observational Research Type)
- 6. Sponsor*
- 7. Contract Research Organisation CRO*

Submission Purposes

- 1. Purpose of Submission Listing*
 - a. Research Registration (auto selected on initial creation of research submission)
 - b. Scientific Review & Ethical Approval
 - c. Grant (MRG) Submission
- 2. Notification of Research to Other Authority

• MREC Ethical Approval

Scientific Review & Ethical Approval (If Scientific Review & Ethical Approval

Submission is selected)

- 1. Research Documents
 - a. Cover Letter to MREC
 - b. Declaration of Conflict of Interest (COI form)
 - c. Study Protocol
 - d. Study Protocol Checklist (only for Interventional Research Type)
- 2. Patient/Participant Information Sheet
 - a. Patient Information Sheet (PIS) & Informed Consent Form (ICF)
 - b. Patient Information Sheet (PIS) & Informed Consent Form (ICF) checklist (only for Interventional Research Type)
 - c. Information Sheet & Assent Form for Minors, 7-12 years
 - d. Information Sheet & Assent Form for Minors, 13 to less than 18 years
 - e. Optional Patient Information Sheet (PIS) & Informed Consent Form (ICF) for genetic, pharmacodynamic / pharmacogenomic / other studies (only for Interventional Research Type)
 - f. Optional Patient Information Sheet (PIS) & Informed Consent Form (ICF) for future research other studies (only for Interventional Research Type)
 - g. Pregnant Partner Information Sheet & Informed Consent Form (only for Interventional Research Type)
 - i. Checklist for Research on Stem Cell & Cell Based Therapy, National Stem Cell Research and Ethics Subcommittee (NSCERT) (only for Interventional Research Type)
 - h. Checklist for First Research Protocol (only for Interventional Research Type)
- 3. Clinical Form Report / Data Collection Form
- 4. Questionnaire
- 5. Interview Guideline (only for Qualitative & Mixed Method Research Type)
- 6. Project Gantt Chart

- 7. Investigational Brochure (only for Interventional Research Type)
- 8. Advertisement (only for Interventional Research Type)
- 9. Patient Diary (only for Interventional Research Type)
- 10. Insurance Indemnity
- 11. Memorandum of Understanding / Research Agreement / Clinical Trial Agreement (CTA)
- 12. Letter from Other Ethical Committee/ Approval Committee
 - a. Other Ethical Committee
 - b. Other Approval Body (NSCERT, NRDHM, MDA, First-In Human Committee)
- 13. Other Related Documents
- 14. Reason Not to Provide Document
- 15. Investigator Documents

Type of Document required for different research type

**Different research type may also require certain documents to be uploaded and submitted to MREC (even it is not marked as mandatory document in NMRR).

No	Research Type	Document Required (* mandatory for submission)
1.	Interventional	1. Research Documents*
		2. Patient/Participant Information Sheet*
		3. Clinical Form Report / Data Collection Form*
		4. Questionnaire
		5. Interview Guideline
		6. Project Gantt Chart*
		7. Investigational Brochure
		8. Advertisement
		9. Patient Diary
		10. Insurance Indemnity
		11. Memorandum of Understanding / Research
		Agreement / Clinical Trial Agreement (CTA)
		12. Letter from Other Ethical Committee/ Approval
		Committee
		13. Other Related Documents
		14. Reason Not to Provide Document
		15. Investigator Documents (uploaded from Investigator
		& Sponsor section)
	Observational	1. Research Documents*
		2. Patient/Participant Information Sheet
		3. Clinical Form Report / Data Collection Form
		4. Questionnaire
		5. Project Gantt Chart*
		6. Insurance Indemnity
		7. Memorandum of Understanding / Research
		Agreement / Clinical Trial Agreement (CTA)
		8. Letter from Other Ethical Committee/ Approval
		Committee

	9. Other Related Documents
	10. Reason Not to Provide Document
	11. Investigator Documents (uploaded from Investigator
	& Sponsor section)
Qualitative Research	1. Research Documents*
	2. Patient/Participant Information Sheet*
	3. Clinical Form Report / Data Collection Form
	4. Questionnaire
	5. Interview Guideline*
	6. Project Gantt Chart*
	7. Insurance Indemnity
	8. Memorandum of Understanding / Research
	Agreement / Clinical Trial Agreement (CTA)
	9. Letter from Other Ethical Committee/ Approval
	Committee
	10. Other Related Documents
	11. Reason Not to Provide Document
	12. Investigator Documents (uploaded from Investigator
	& Sponsor section)
 Mixed Method	1. Research Documents*
Research	2. Patient/Participant Information Sheet*
	3. Clinical Form Report / Data Collection Form*
	4. Questionnaire
	5. Interview Guideline*
	6. Project Gantt Chart*
	7. Insurance Indemnity
	8. Memorandum of Understanding / Research
	Agreement / Clinical Trial Agreement (CTA)
	9. Letter from Other Ethical Committee/ Approval
	Committee
	10. Other Related Documents
	11. Reason Not to Provide Document
	12. Investigator Documents (uploaded from Investigator
	& Sponsor section)
Proof of Concept /	1. Research Documents*
Theoretical Research	2. Patient/Participant Information Sheet
	3. Clinical Form Report / Data Collection Form
	Project Gantt Chart*
	5. Memorandum of Understanding / Research
	Agreement / Clinical Trial Agreement (CTA)
	6. Letter from Other Ethical Committee/ Approval
	Committee
	7. Other Related Documents
	8. Reason Not to Provide Document
	9. Investigator Documents (uploaded from Investigator
	& Sponsor section)

Applied Research	1. Research Documents [*]
	2. Patient/Participant Information Sheet
	3. Clinical Form Report / Data Collection Form
	4. Project Gantt Chart*
	5. Memorandum of Understanding / Research
	Agreement / Clinical Trial Agreement (CTA)
	6. Letter from Other Ethical Committee/ Approval
	Committee
	7 Other Related Documents
	8 Reason Not to Provide Document
	0. Investigator Decuments (upleaded from Investigator
	& Sponsor section)
Registry/	1. Research Documents*
Biobanking/Clinical	2. Patient/Participant Information Sheet
Database	3. Clinical Form Report / Data Collection Form
	4 Project Gantt Chart*
	5 Memorandum of Understanding / Research
	Agreement / Clinical Trial Agreement (CTA)
	Agreement / Cinical That Agreement (CTA)
	6. Letter from Other Ethical Committee/ Approval
	Committee
	7. Other Related Documents
	8. Reason Not to Provide Document
	9. Investigator Documents (uploaded from Investigator
	& Sponsor section)
Clinical Audit/ Quality	1. Research Documents*
Assurance/ Quality	2. Patient/Participant Information Sheet
Control	3. Clinical Form Report / Data Collection Form
	4. Project Gantt Chart*
	5. Agreement / Clinical Trial Agreement (CTA)
	6. Letter from Other Ethical Committee/ Approval
	Committee
	7 Other Related Documents
	8 Reason Not to Provide Document
	9 Investigator Documents (unloaded from Investigator
	 Investigator Documents (uploaded norm investigator Sponsor coction)
Svotomotic Boviow/	A Sponsor section)
Systematic Review/	1. Research Documents
Scoping review/ Rapi	d- 2. Project Gantt Chart
review/ Meta-analysis	3. Reason Not to Provide Document
Meta-synthesis	4. Investigator Documents (uploaded from Investigator
	& Sponsor section)
Special Write Up	1. Research Documents*
	2. Project Gantt Chart
	3. Reason Not to Provide Document
	4. Investigator Documents (uploaded from Investigator
	& Sponsor section)

• MOH Research Grant (MRG) Application

Grant (MRG) Submission (If Grant (MRG) Submission is selected)

- 1. Costing Details
 - a. By Years (Overall Total Costing auto calculate)
 - i. Cost Category
 - ii. Details Justification
 - iii. Amount per Category
 - iv. Total per year

1.0 – Existing Research Submission (Revision & Incomplete Submission)

1.1 – Editing of Research Submission with status either as "Incomplete Submission/Revision Required" or "Revision Required"

	Step-by-step instructions		Remark
Log in as Investigator or CRA in NMI	RR. Click on the Login menu.		
Home Directory FAQ	Documents Login Register		
In the case where a Research Submi Required". "Revision Required". Sci Submission". Then click on the "Sci under review by either JPP-NIH or M	ssion is assigned with status either roll over the main menu located or entific & Ethical" (if the revision is IREC) or "Grant" (if the revision is c	as "Incomplete Submission/Revision the side of display page, go to "My during the registration of NMRR or during the grant review.)	
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The status of a Research Submission that requires revision or more information will have the status either:

- "Incomplete Submission/Revision Required": if the revision is from NMRR Secretariat
 "Revision Required":
- If the revision is from any other research processing levels (JPPNIH or MREC or MRG)

In Research Submission Listing, the following action icons are accessible to user

- Comment (=) icon to view the comment or query by reviewer/secretariat during revision required
- Show o icon to view the data of Research Submission
- Edit icon to edit the Research Submission (icon available only for Research Submission with status "Pending Submission" and "Revision Required" or "Incomplete



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12.	User is required to do the revision and editing in reference to the "Comment & Review" page. Once user has edited all the necessary revisions and uploaded all revised documents (please make sure all the updated information and documents is saved and all section is vicked), user is then required to go back at the "Comment & Review" tab to insert the comment respose to each of the query given.	Please note that at the revision stage, "Confirmation of Submission" section is not be available in the listing of the section. Submission of revision (with the acknowledgement of revision by user) will be available at the end of the Comment & Review page once user has answered all the query and comment given.
13.	In the Review & Comment Page, insert the response to each of the query or comment given by typing in the "Investigator Response" box.	

Review and Comment		
NMRR Data Chock Study Duration		
NMRR Secretariat Comment Revise the following study duration accordingly.		
Investigator Response *		
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 Comments revise the following study duration to correspond to the gantt Chart's Investigator answer Revise as requested. information has been changed to correspond to the Gantt's chart uploaded Revise the following study duration accordingly.	× 4 hours ago	The query and answe the previous revision be shown in historica order with the latest query/comment given displayed at the botto of the list
 Comments revise the following study duration to correspond to the gantt Chart's Investigator answer Revise as requested. information has been changed to correspond to the Gantt's chart uploaded Revise the following study duration accordingly.	× 4 hours ago 11 minutes ago	The query and answe the previous revision be shown in historica order with the latest query/comment giver displayed at the botto of the list

Revise as requested. Information had been changed to correspond to the Gantt's chart uploaded Confirmation of Submission I acknowledge that I have read, and do hereby accept the terms and conditions contained in NMRR terms and condition document. I indee the necessary changes and uploaded the revised documents in response to the secretariat's/reviewer's queries. I've also responded to all of the queries listed above. Confirmation of Submission Cick at the to acknowledge that the revision has been made acccordingly. Once both statement have been acknowledge , User can then finally submit the revision submission by click on the some Confirmation of Submission Confirmation of Submissi	vestigator Response *				
Confirmation of Submission I acknowledge that I have read, and do hereby accept the terms and conditions contained in NMRR terms and condition document. I made the necessary changes and uploaded the revised documents in response to the secretariat's/reviewer's queries. I've also responded to all of the queries listed above. I understand that failure to address the specified revisions will result in my submission will not be processed. Submit Click at the I to acknowledge that the revision has been made acccordingly. Once both statement have been acknowledge , User can then finally submit the revision submission by click on the Submit Confirmation of Submission confirmation of submission	Revise as requested. information has been changed to correspond to the Gantt's chart uploaded				
Confirmation of Submission I acknowledge that I have read, and do hereby accept the terms and conditions contained in NMRR terms and condition document. I understand that failure to address the specified revisions will result in my submission will not be processed. Submit Click at the to acknowledge that the revision has been made acccordingly. Once both statement have been acknowledge , User can then finally submit the revision submission by click on the submit Confirmation of Submission confirmation co					
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Submit	 acknowledge that I have read, and do hereby accept the terms and conditions contained in NMRR terms and condition document. I made the necessary changes and uploaded the revised documents in response to the secretariat's/reviewer's queries. I've also responded to all of the queries listed above. understand that failure to address the specified revisions will result in my submission will not be processed. 				
	Submit				

Submissions	The status of a
Keyword Status Search NMRR ID, Research ID or Title o Select All EXCEL PDF Show 10 entries # RESEARCH ID entries # RESEARCH ID entries 1 RSCH ID - 23- 04600-XYO Basic Science / Interventional Showing 1 to 1 of 1 entries Previous 1 Showing 1 to 1 of 1 entries Previous 1 When viewing the data of submission, the General information of the Submission will be shown on the top part of the display page with the status "Revision Submitted to NMRR Secretariat*"	subcession new submission of a Research Submission wi change from "Incomplete Submission/ Revision Required" or "Revision Required to "Revision Submitted to NMRR Secretariat*" *Depending on which secretariat or level of processing requested the revision (Either NMRR Secretariat, JPPNIH Secretariat, MREC Secretariat or MRG Secretariat)
Research ID RSCH ID-23-04600-XYO Protocol ID 234567890	the following action icon is accessible to user: - Show o icon to view the data of Submission

** The steps of revision submission will be the same across any level of processing (Research Registration by NMRR, Scientific Review & Ethical Approval by either JPP-NIH and MREC, and Grant Approval by MRG). Please refer to Flowchart for Research Submission/Scientific & Ethical Review Processing and Flowchart for MRG Review for more information on the processing of research submission in MOH.

2.0 – Existing Research Submission (Deletion of Submission)

2.1 – Deletion of Research Submission (only for submission with the status of "Pending Submission" or "Incomplete Submission/Revision Required")

No	Step-by-step instructions	Remark
1.	In the case where user have not managed to complete the submission and want to delete the existing Research Submission, scroll over the main menu located on the side of display page, go to "My Submission". Then Click on the "Scientific & Ethical"	
	 National Medical Research Register Advancing Medical Research in Malaysia National Medical Research Register Advancing Medical Research in Malaysia 	
	My Submissions	
	> Scientific & Ethical	
	> Post Ethical	
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Su	Ibmissions			
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3.0 – History of Updates

No.	Update Version	Date of Update	Description of Updates	Prepared by (Checked by)	Endorsement Signature
1.	Version 1.0	22 November 2023	Manual & guideline for revision and deletion of research submission (separation from the main Investigator and CRA Guideline		