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

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	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 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)
	Proof of Concept / Theoretical 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 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 9. Investigator Documents (uploaded from Investigator & Sponsor section)
	Registry/ Biobanking/Clinical Database	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 9. Investigator Documents (uploaded from Investigator & Sponsor section)
	Clinical Audit/ Quality Assurance/ Quality Control	1. Research Documents* 2. Patient/Participant Information Sheet 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 (uploaded from Investigator & Sponsor section)
	Systematic Review/ Scoping review/ Rapid-review/ Meta-analysis/ Meta-synthesis	1. Research Documents* 2. Project Gantt Chart* 3. Reason Not to Provide Document 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)

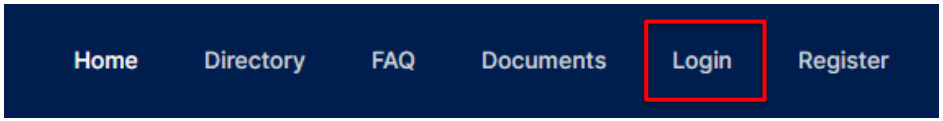
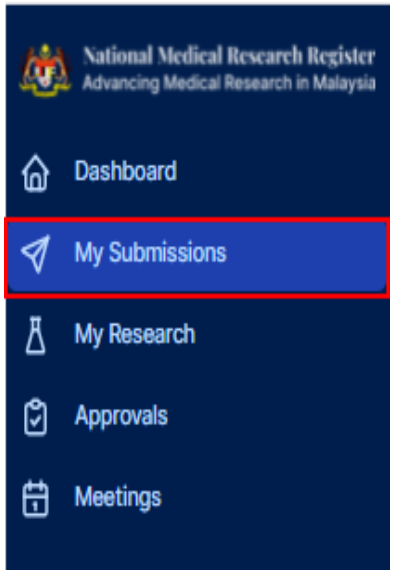
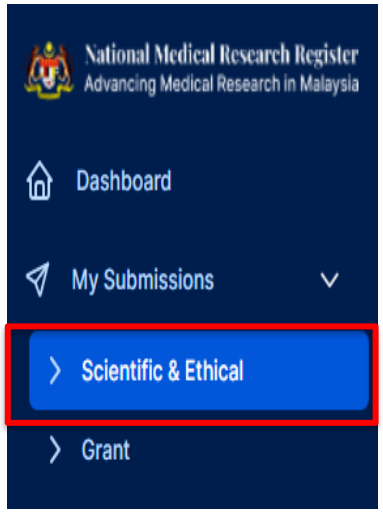
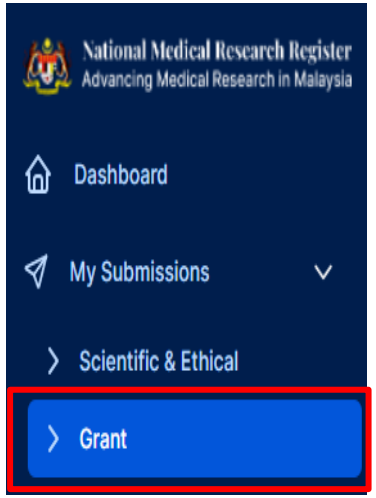
- **MOH Research Grant (MRG) Application**

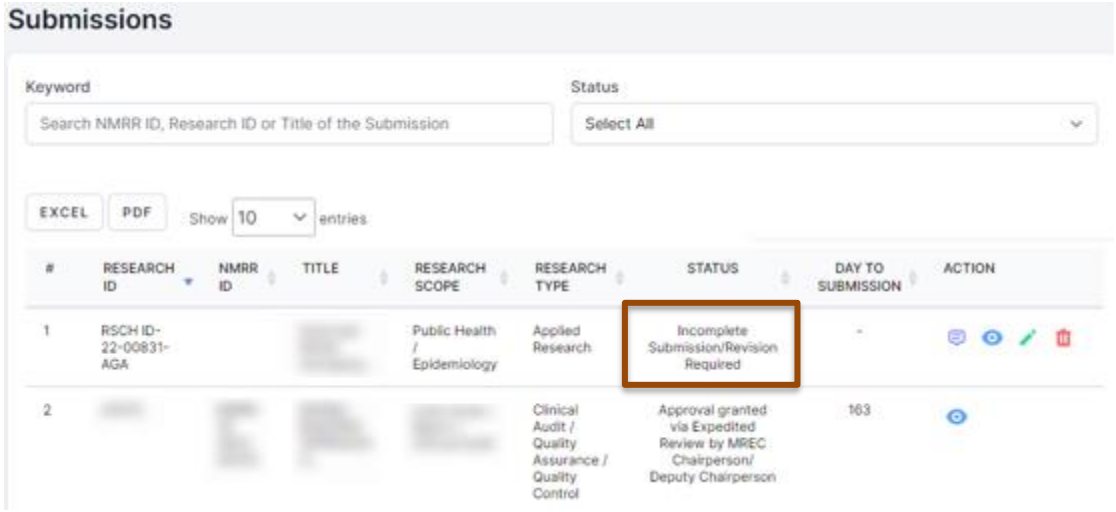
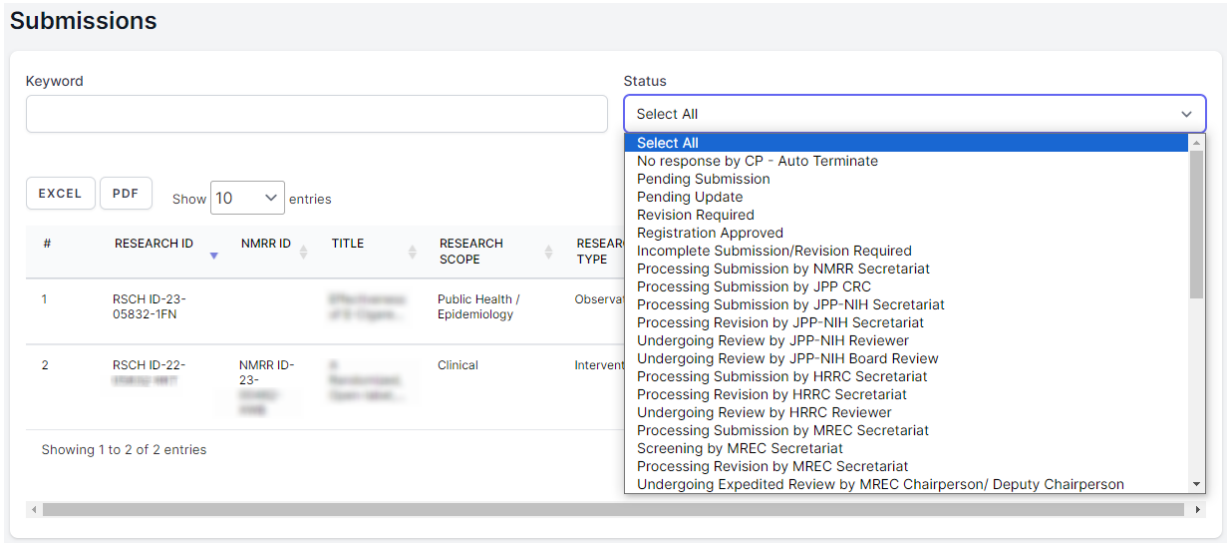
Grant (MRG) Submission (If Grant (MRG) Submission is selected)

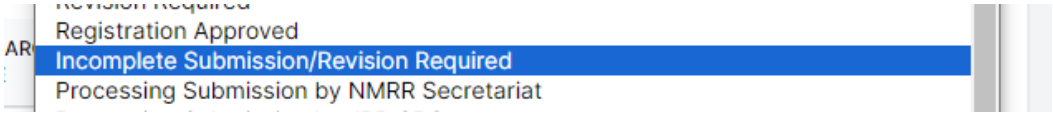
1. Costing Details
    a. By Years (Overall Total Costing – auto calculate)
        i. Cost Category
        ii. Details Justification
        iii. Amount per Category
        iv. Total per year

1.0 – Existing Research Submission (Revision & Incomplete Submission)

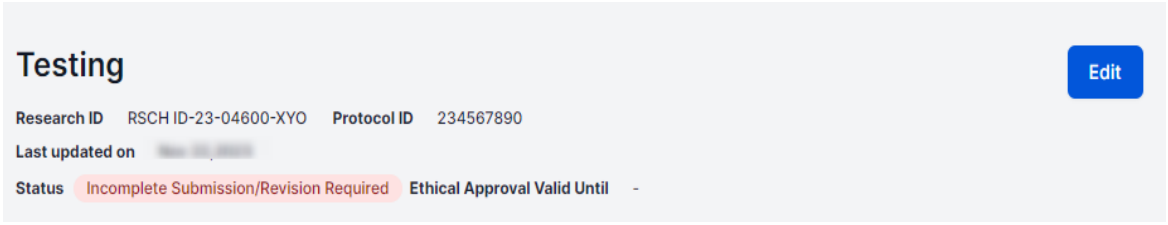
1.1 – Editing of Research Submission with status either as “Incomplete Submission/Revision Required” or “Revision Required”

No	Step-by-step instructions	Remark
1.	Log in as Investigator or CRA in NMRR. Click on the Login menu. 	
2.	In the case where a Research Submission is assigned with status either as “Incomplete Submission/Revision Required”. “Revision Required”. Scroll over the main menu located on the side of display page, go to “My Submission”. Then click on the “Scientific & Ethical” (if the revision is during the registration of NMRR or under review by either JPP-NIH or MREC) or “Grant” (if the revision is during the grant review.) ①   or ② 	User (PI, Main CP & Backup CP) will be notified via email if a particular Research Submission requires revision at any level of the research processing,

3	A list of all existing Research Submission will be displayed  …… User also may use the filter function to filter “Revision Required” study  ……	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 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

	 **Or** 	Submission/Revision Required” - Bin icon - to delete Research Submission (icon accessible only in Scientific & Ethical Menu with Research status “Pending Submission” or “Incomplete Submission/Revision Required” at NMRR Registration level

4. When viewing the data of Research Submission (click on the), user will be able to view the General information of the Submission over the top of the display page with research status as “Revision Required”



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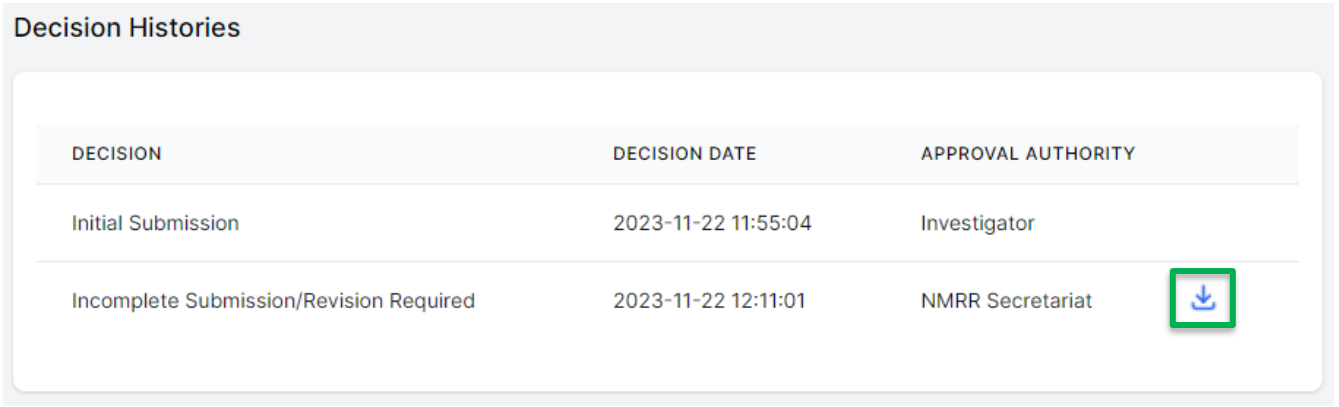
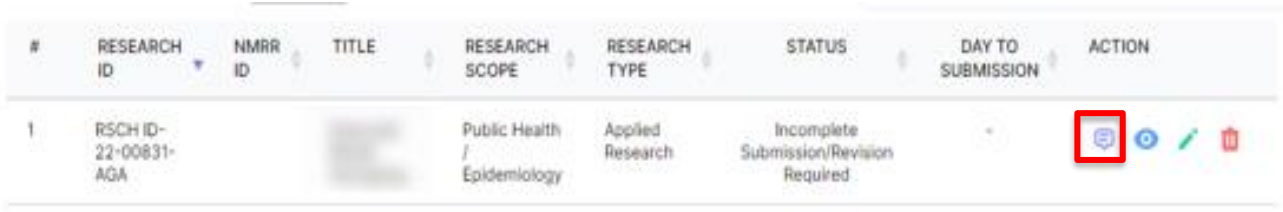
User will be able to see the decision history of the submission at the end of the General Information as well. The submission history is displayed in historical order



User may also download the document supplemented by the secretariat if there is an icon *( ) available next to the decision status

5. To see the comment and query given to the submission, first click on the icon of the intended Research Submission.



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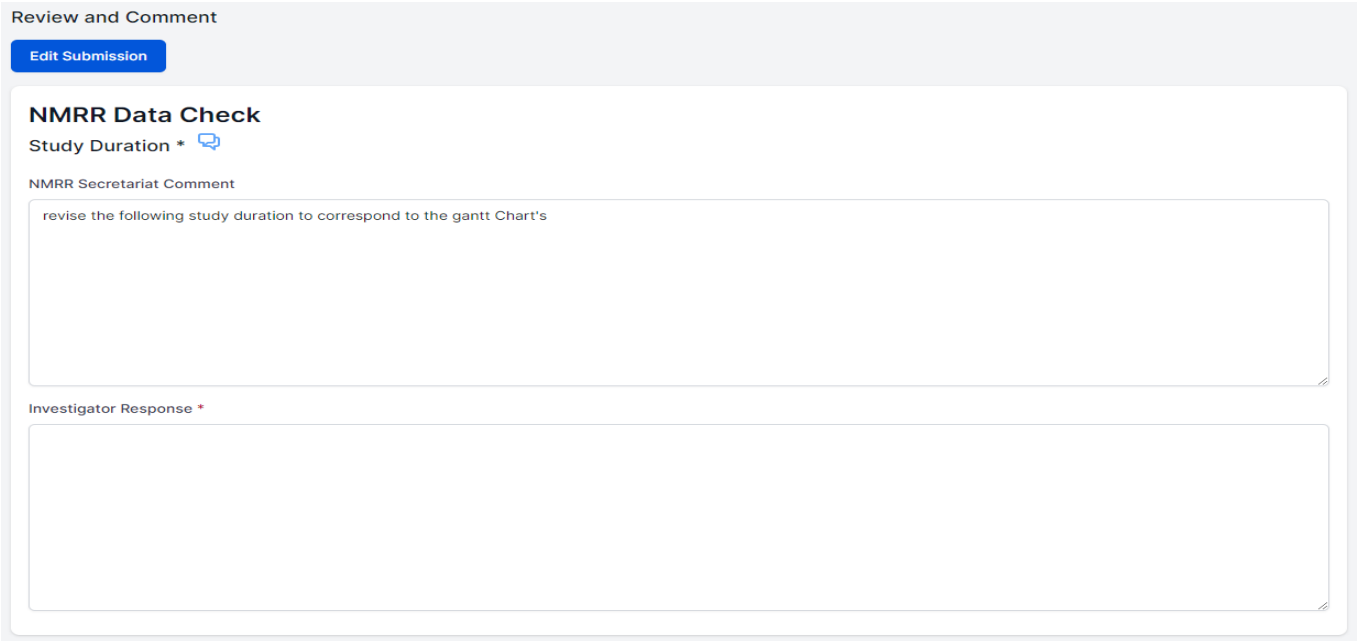
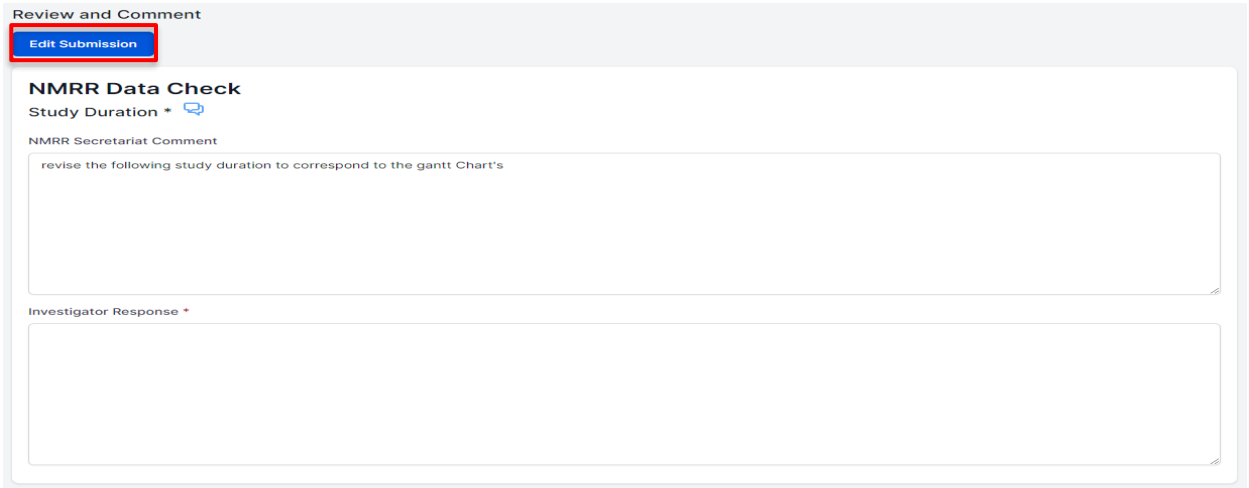
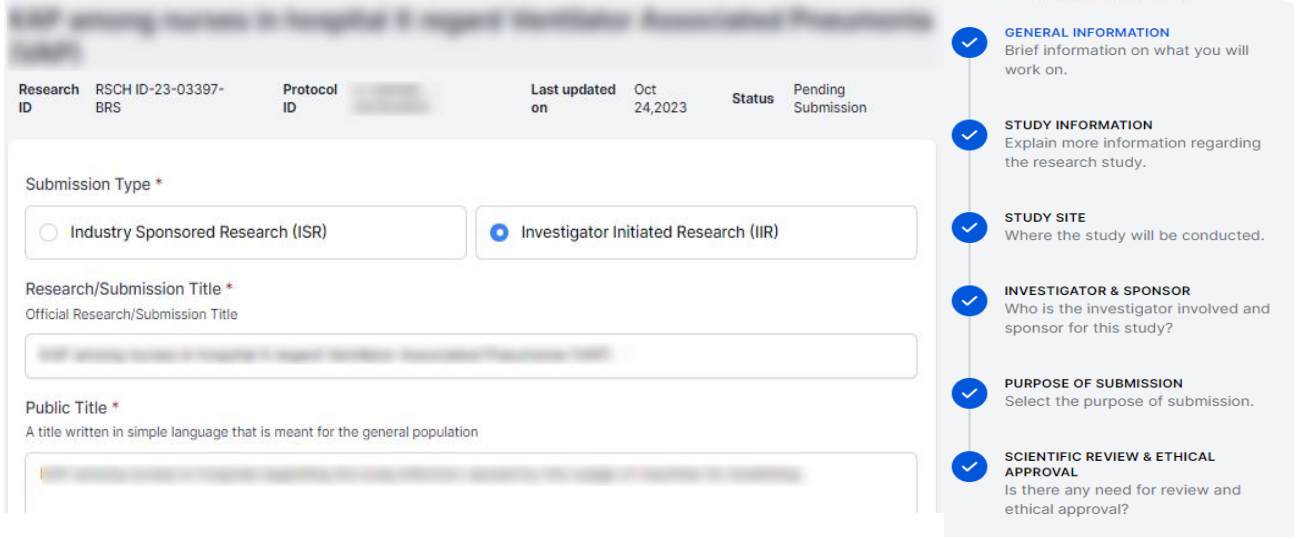
	A new page “Review and Comment will be shown displaying the list of queries and comment given by either secretariat or reviewers.  	User **is advised to read through the comment and query given and then proceed with the editing of the submission information and document** (do not response to the query inside the investigator response without the necessary editing and/or uploading the revised document first)
6.	Once all the comment and queries has been read through, to edit the submission, click on the Edit Submission located at the top right of display page .  	

7. User will be brough to a new tab with the general information of the submission data displayed in the *editing view*.



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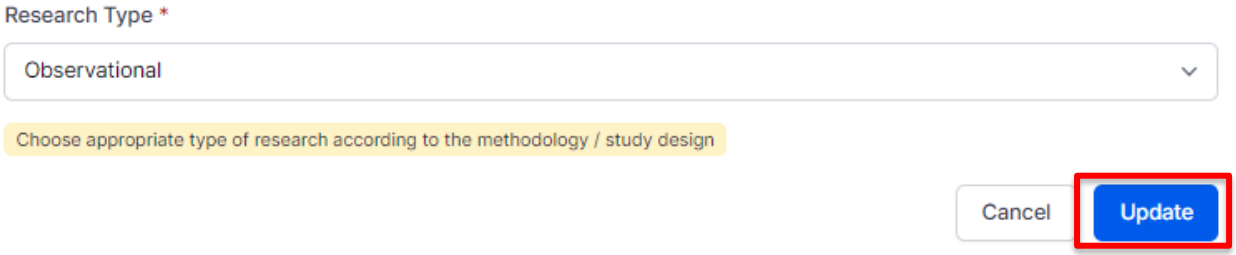
At the end of the page displayed, 2 option buttons are available. If user has made any editing or changes to the general information section, click Update . If not, select the other part from the section listing to add the information and continue with the editing of the submission.



Only if there are changes/ editing in the general information section!!

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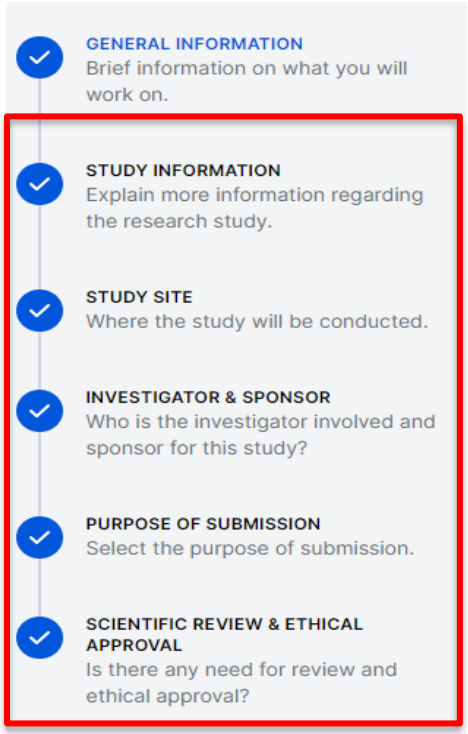
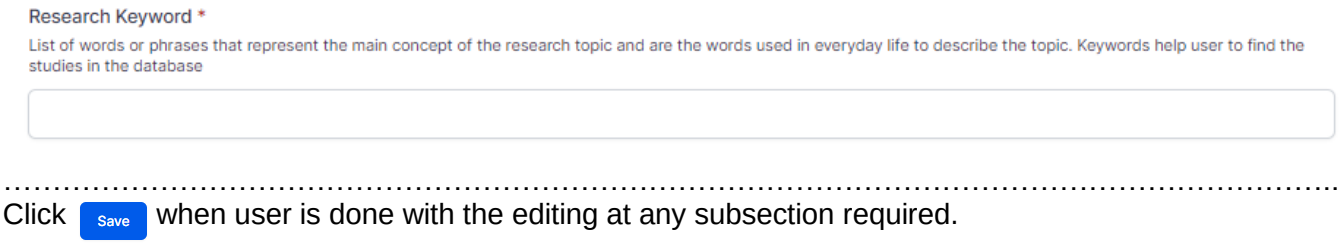


Do the revision or editing in each section accordingly Complete each section in a sequence order.

8. Mandatory fields is marked with *. User is then required to complete the necessary revision based on the query or comment given in the comment section.



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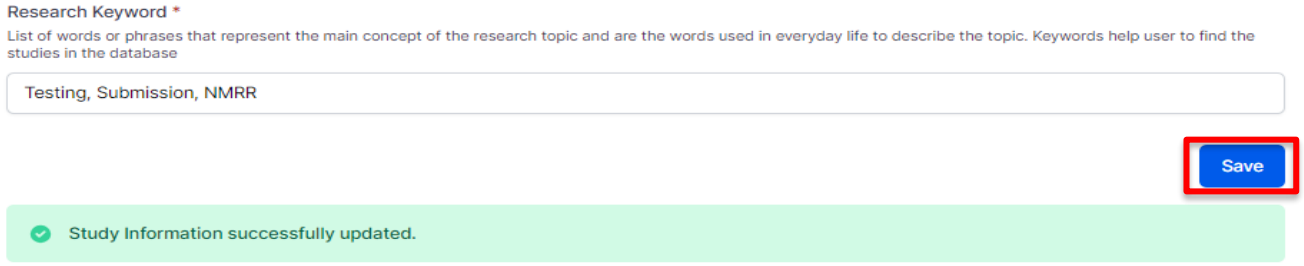
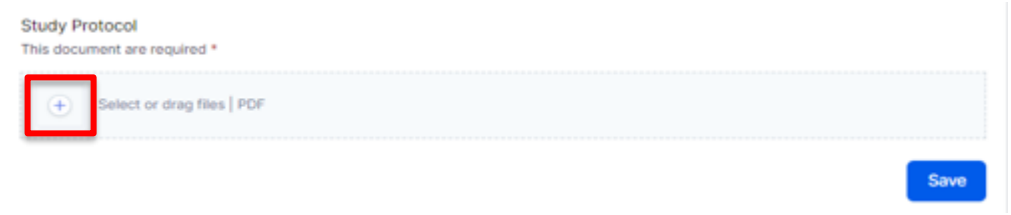
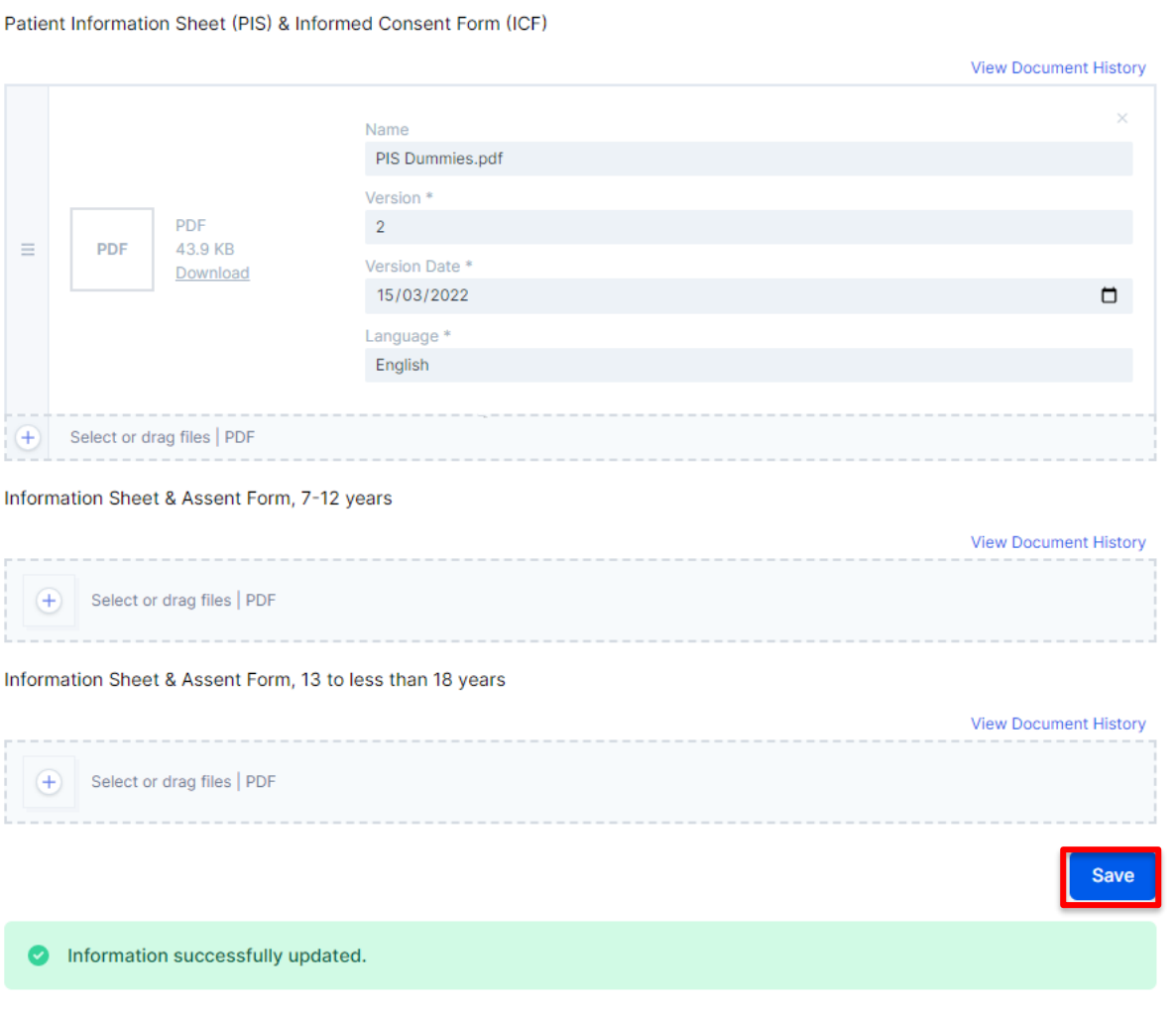
Click Save when user is done with the editing at any subsection required.



9.	If there are any changes to the document and user is required to replace the file in the " Scientific Review & Ethical Approval " section, user first needs to delete the document on display by clicking the "x" button located at the top right of the document box.  	
10.	User then can upload/replace a new document by clicking on the  icon to acces the document file and then selects the required file or dragging the file document into the box. Then, insert the updated version and version date of the documents **(mandatory).**  .....  	****Only PDF format file is allowed to be uploaded in this section** **Please ensure the file name has extension ".pdf" at the end of its name. Files without the extension ".pdf" may have the risk of not being able to be read later**

Click Save for each of the subsection everytime the document has been completely uploaded and information has been filled up in each subsection



11. Document History is accessible to be viewed by clicking the “View Document History” located at the top right of each document box

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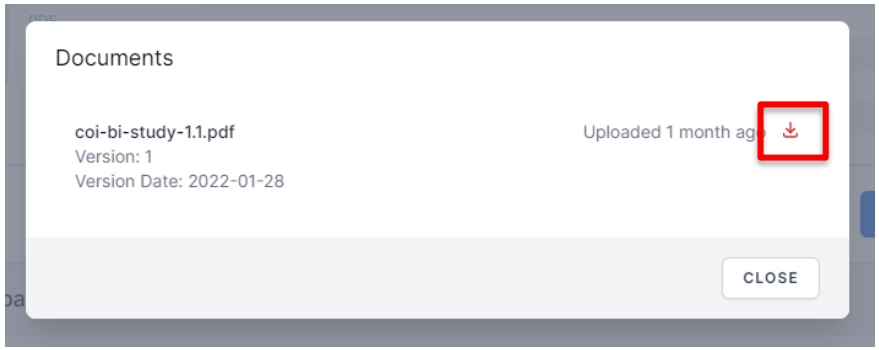
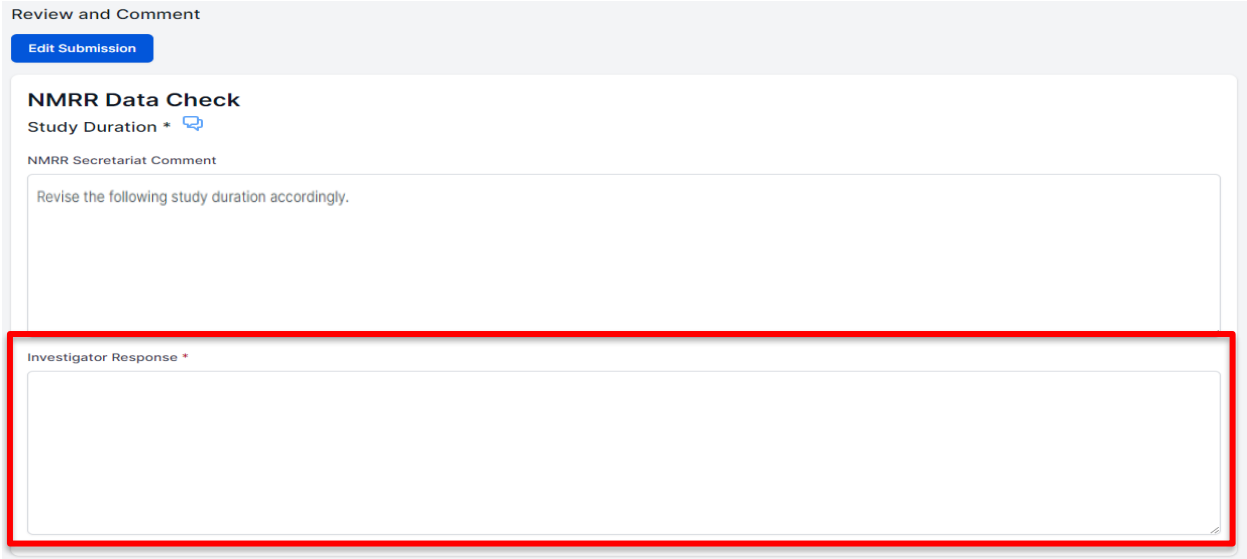
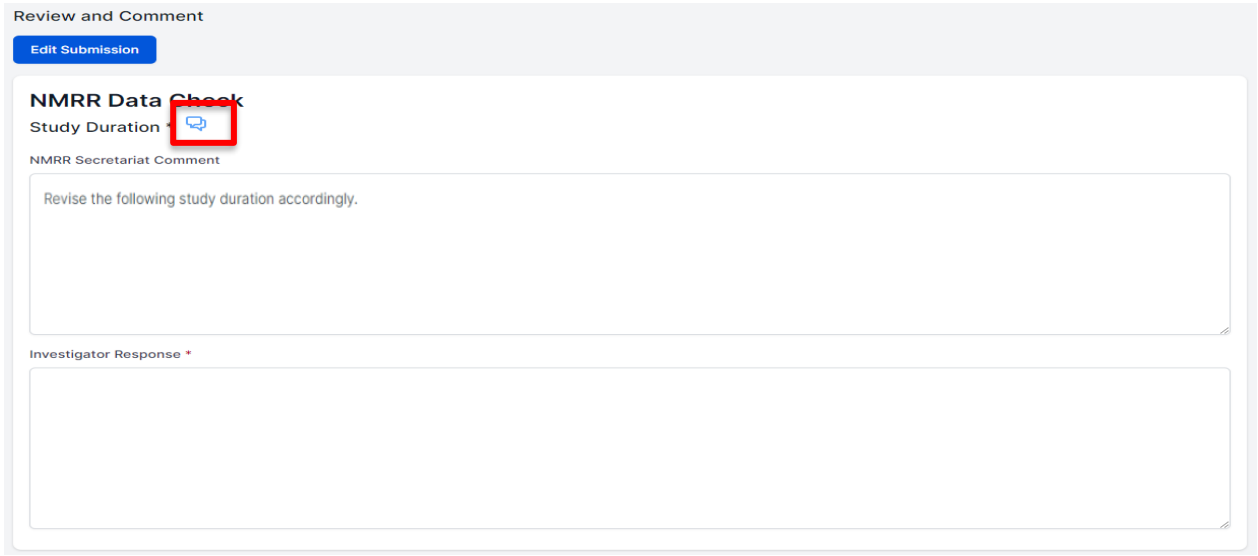
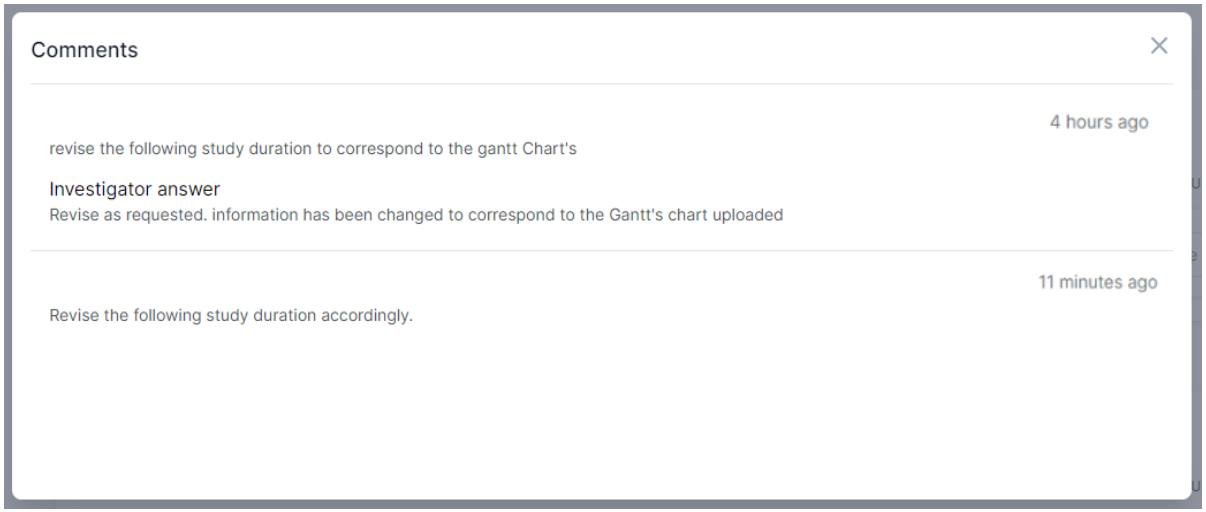
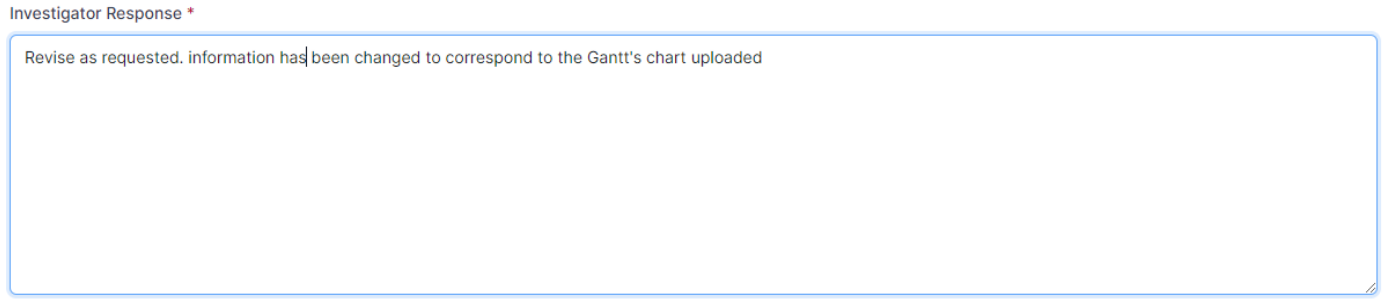
a copy of the document can be downloaded if needed by clicking the ⬇ if required.



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 ✓ ticked),** 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.  	

14.	User may also see the history of review / comment and answers given during previous revision about the the same item or issue by clicking on the located next to each item/parameter of the checklist.  ……  	The query and answer for the previous revision will be shown in historical order with the latest query/comment given is displayed at the bottom of the list

15. Once all the responses have been answered, user is required **to scroll down to the end of the "Review & Comment" page**, and acknowledge the revision made before submitting the revision back to secretariat.



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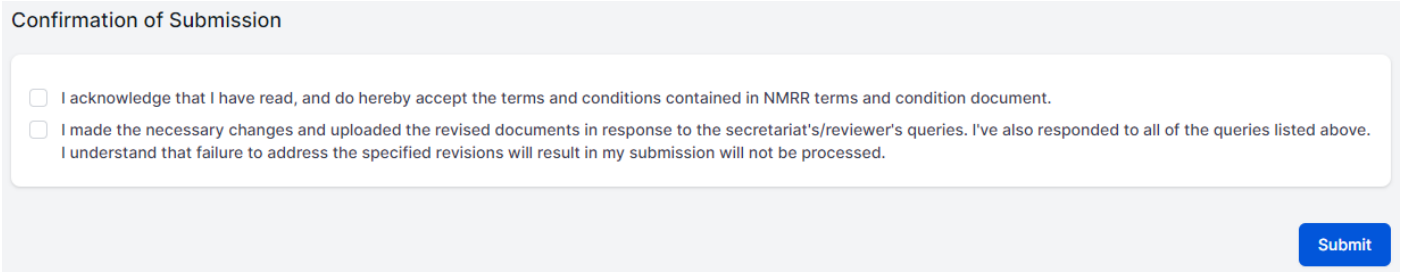

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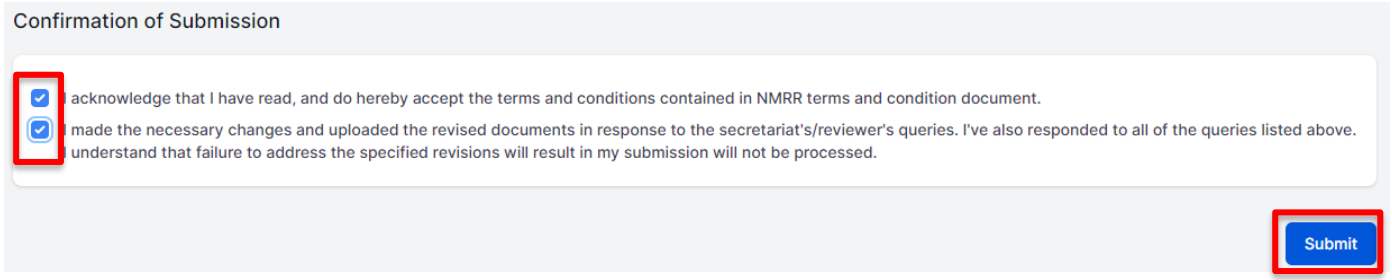
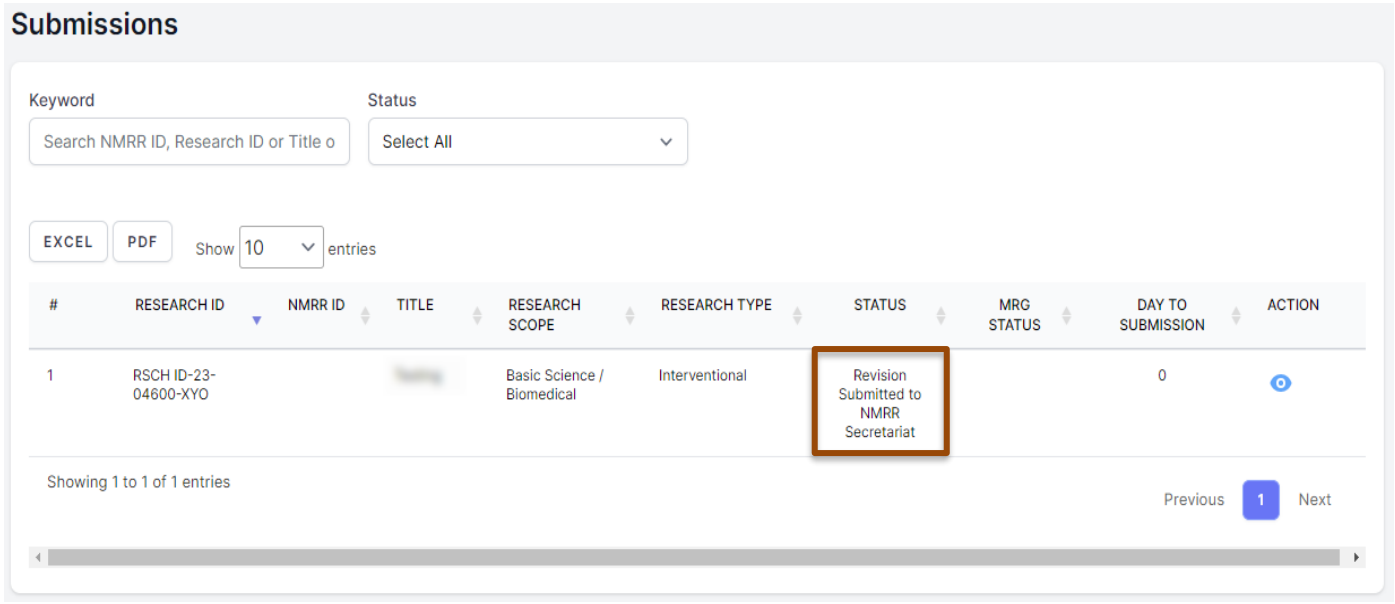
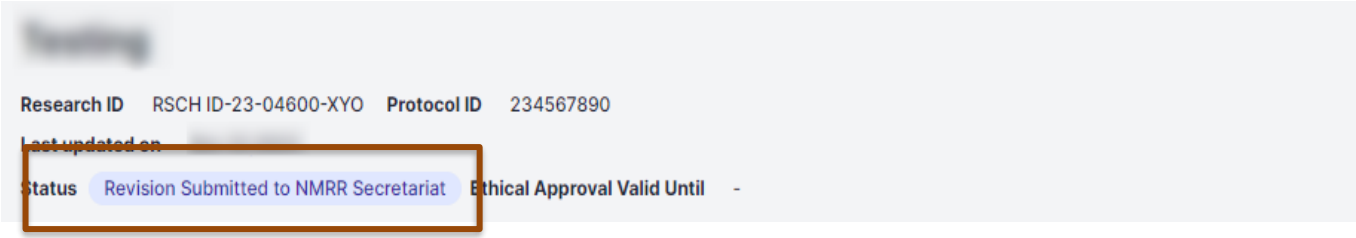
Click at the ☐ to acknowledge that the revision has been made acccordingly. Once both statement have been acknowledge , User can then finally submit the revision submission by click on the Submit



16. Once the revision submission has been successfully submitted, user will be brought back the submission listing page.



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*"**



The status of a successful new submission of a Research Submission will 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)**

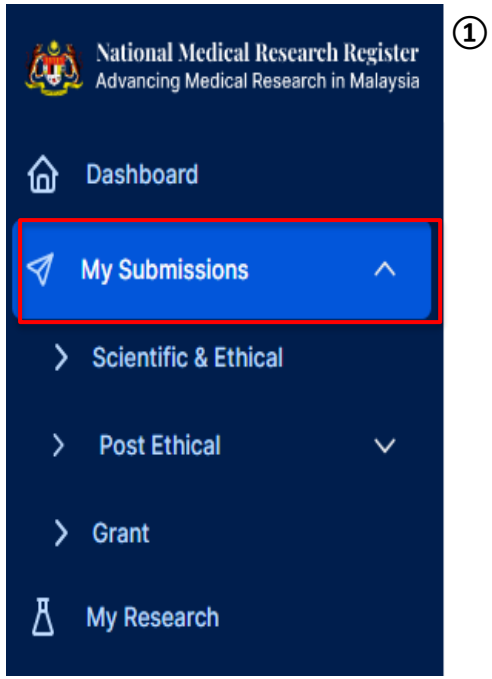
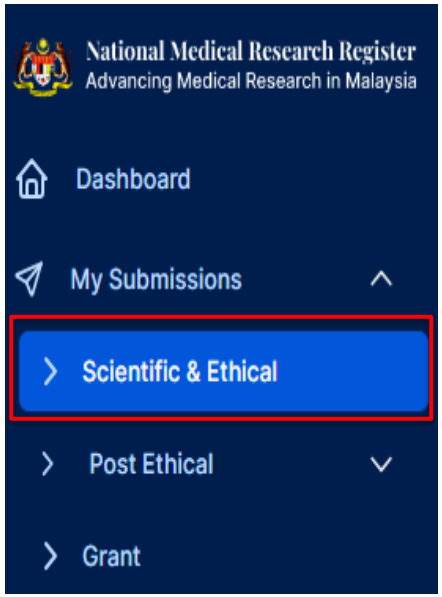
In the Submission Listing, the following action icon is accessible to user:

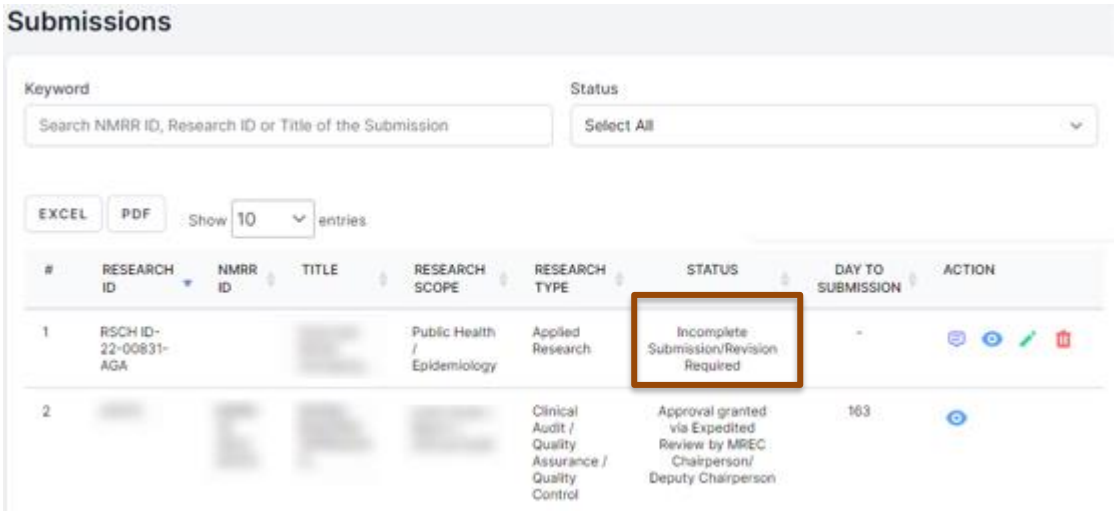
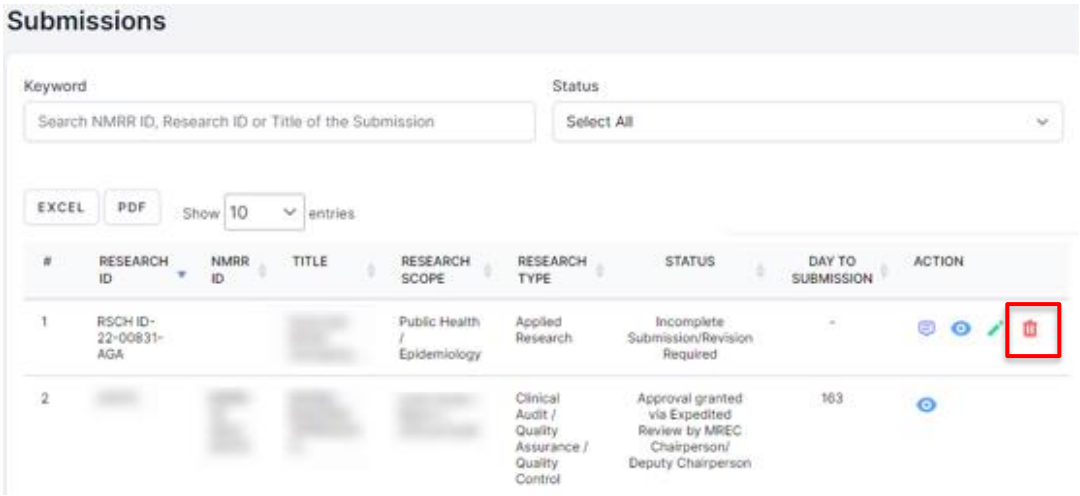
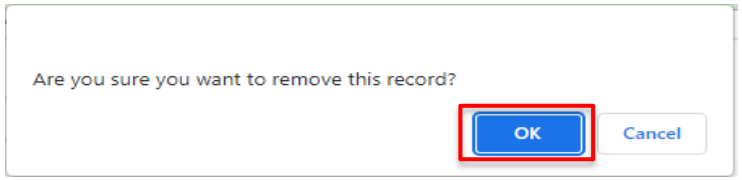
- Show icon to view the data of Submission

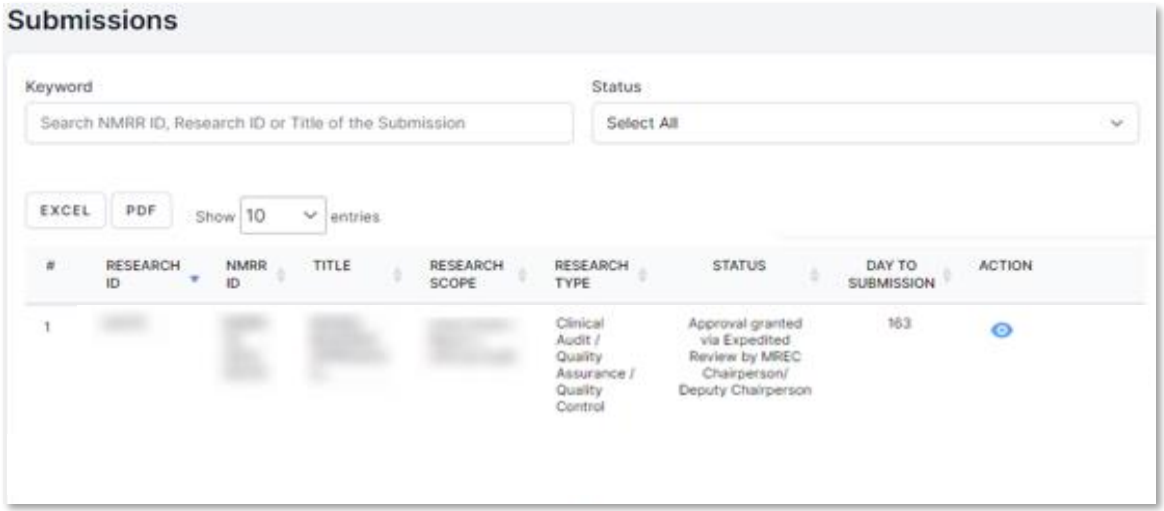
**** The steps of revision submission will be the same across any level of processing (Research Registration by NMRR, Scientific Review & Ethical Approval by either JPP-NIH and MREC, and Grant Approval by MRG). Please refer to Flowchart for Research Submission/Scientific & Ethical Review Processing and 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"  ①  ②	

2.	A list of all existing Research Submission will be displayed. 	**Only Research Submission with either status "Pending Submission" and "Incomplete Submission/Revision Required" – Submission without an assigned NMRR ID is able to be deleted by user.** **Icon delete (🗑) will be accessible to user under tne "Action" column in the intended submission.**
4.	To delete a Research Submission, click on the delete 🗑 icon over the intended submission. Click OK to confirm the deletion of the Research Submission.  ..... 	Deletion of an Amendment Submission will be only available for submission that has never been submitted to MREC Secretariat for processing.

	…… Once it is clicked, the Research Submission will be deleted and removed from the Submission listing .  	

-The End-

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		