

User Guideline for
*Investigator/Clinical Research Associate
(CRA) – New Research Registration &
Other Submission Purposes*

National Medical Research Register v2.0

National Institutes of Health (NIH)

Version 2.0, November 2023

Table of Contents

Prerequisite For Submission.....	1
Information/ Documents Required.....	1
1.0 – First Account Login: Profile Updates.....	7
1.1 – Details Editing (Basic Information, User Information, Institution Information) and New Password Setup.....	7
2.0 – New Research Submission / Registration	12
2.1a – Initial Research Submission / Registration	12
2.1b – Initial Research Submission / Registration with Scientific Review & Ethical Approval Submission.....	24
2.1c – Initial Research Submission / Registration with Grant (MRG) Submission.....	28
3.0 – Existing Research Submission.....	33
3.1 – Viewing an Existing Research Submission and Editing of Pending Submission	33
4.0 – History of Updates	36

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: <ul style="list-style-type: none">• Should logged in as Investigator or Clinical Research Associates (CRA)• Should have completed the profile page
1.3	User has a role selected during registration of NMRR account either as: <ul style="list-style-type: none">• Investigator• Clinical Research Associate (CRA)

Information/ Documents Required

* Mandatory field/items/parameter/documents

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

• NMRR Registration

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)

		<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 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

		<ul style="list-style-type: none"> 11. Reason Not to Provide Document 12. Investigator Documents (uploaded from Investigator & Sponsor section)
	Proof of Concept / Theoretical Research	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 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 will be auto calculate)

i. Cost Category

- Travel Transportation
- Rental
- Raw Materials
- Research Material Supplies
- Special Services
- Temporary Personnel
- Special Equipment Accessories
- Others (if any) – *to be included in this category if present*
 - a. Utilities
 - b. Food and beverages
 - c. Minor repair and modifications
 - d. Other relevant categories

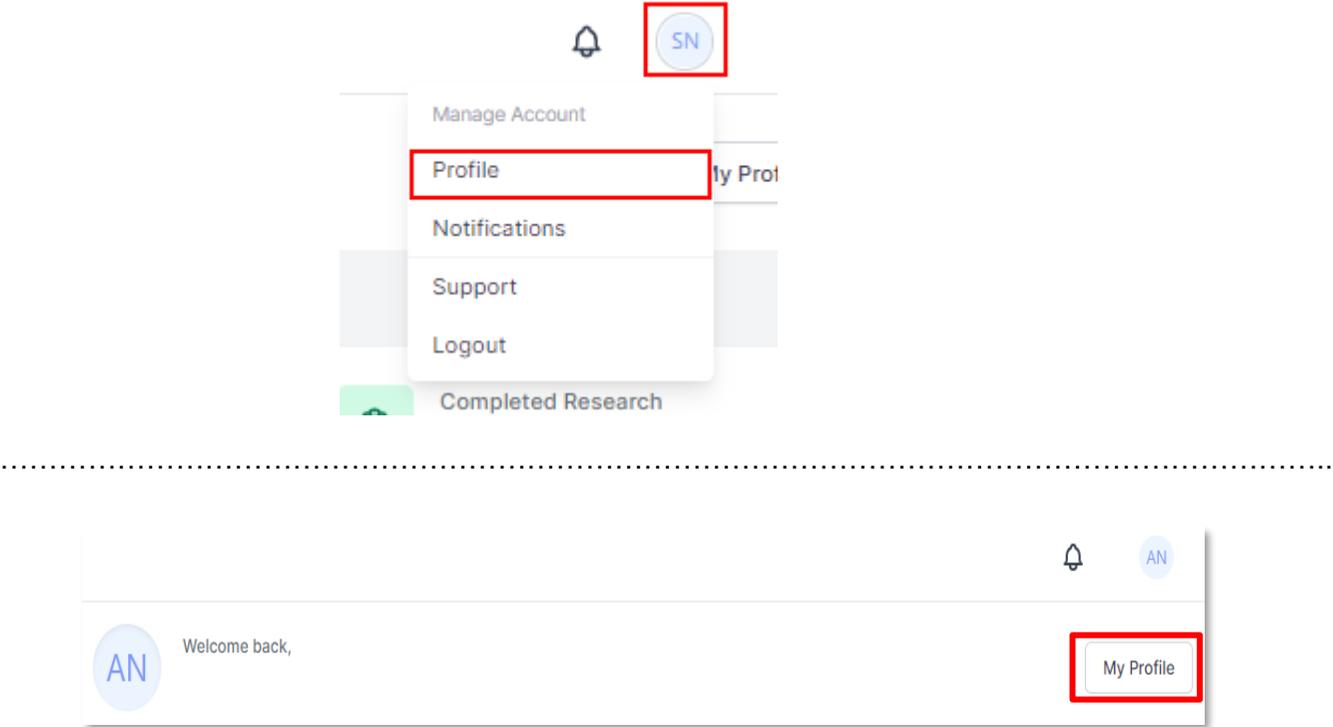
ii. Details Justification (for each category)

iii. Amount per Category

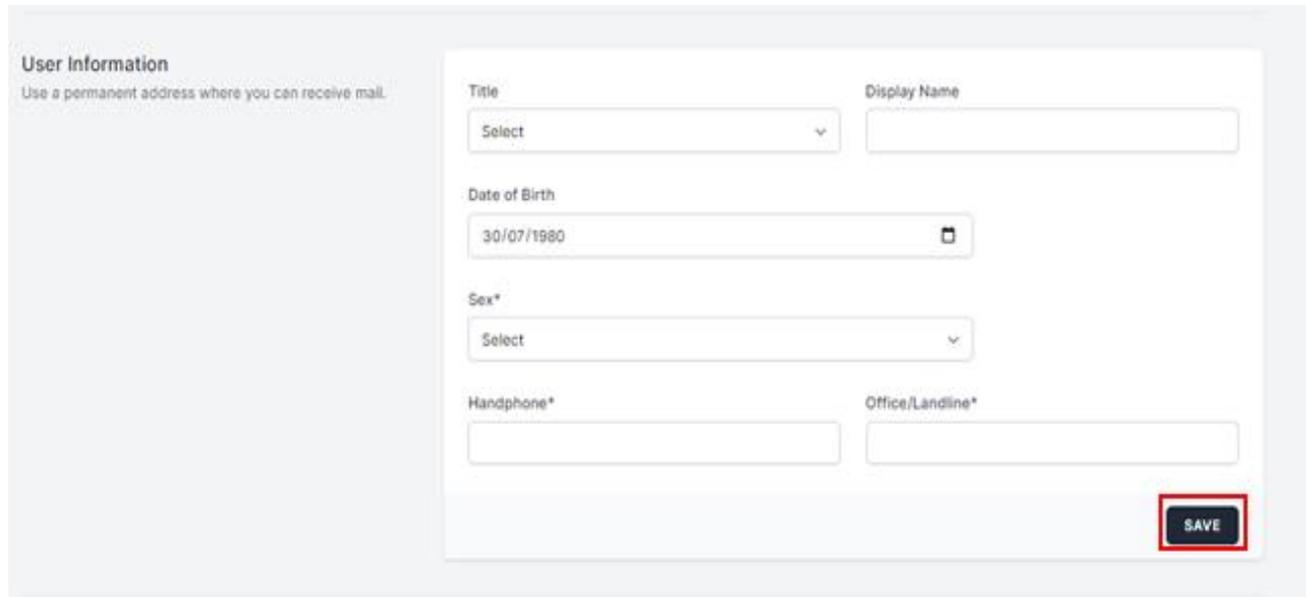
iv. Total per year

1.0 – First Account Login: Profile Updates

1.1 – Details Editing (Basic Information, User Information, Institution Information) and New Password Setup

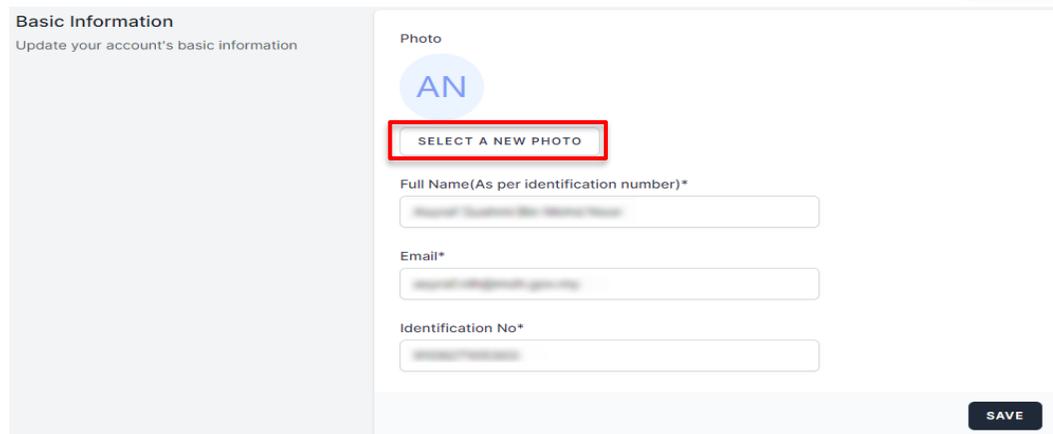
No	Step-by-step instructions	Remark
1.	<p>Log in as Investigator or CRA in NMRR. Click on the Login menu.</p>  <p>The screenshot shows a dark blue navigation bar with the following items: Home, Directory, FAQ, Documents, Login, and Register. The 'Login' item is highlighted with a red rectangular box.</p>	
2.	<p>Click user icon > Profile or My Profile tab located at top right of the landing page</p>  <p>The first screenshot shows a user icon with the initials 'SN' circled in red. A dropdown menu is open, with the 'Profile' option highlighted in a red box. Other menu items include 'Manage Account', 'Notifications', 'Support', and 'Logout'. Below the menu, there is a 'Completed Research' section.</p> <p>The second screenshot, separated by a horizontal dotted line, shows the user's profile area. It includes a 'Welcome back,' message, a user icon with initials 'AN', a notification bell, and a 'My Profile' button highlighted in a red box.</p>	

3 Insert basic user information, institution information and upload necessary documents. Save the information filed by clicking the **SAVE** button in every subsection.



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

.....
In basic information section, user will be able to upload profile picture by click on **SELECT A NEW PHOTO** tab.

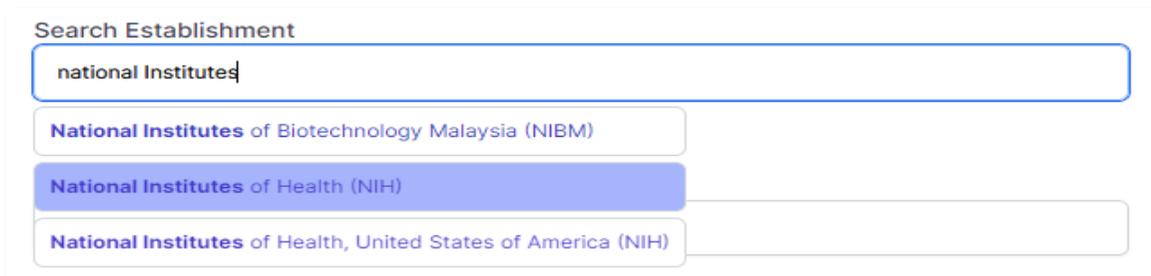


**** Information on user's email and identification No. is not editable. If user requires any changes to any of this information, please kindly get in contact with NMRR Secretariat for assistance.**

For Institutional Information, user is required to search on the establishment by typing the name of the establishment in the search box.



The screenshot shows a form titled 'Institution Information' with a sub-section 'New Establishment'. On the left, there is a warning: 'This information will be displayed publicly so be careful what you share.' On the right, under 'New Establishment', there is a search box labeled 'Search Establishment' with a '+' icon in the top right corner. The search box contains the text 'Search Establishment' and is highlighted with a red border.



The screenshot shows a search interface with the title 'Search Establishment'. The search input field contains 'national Institutes'. Below the input field, there are three search results listed in a dropdown menu: 'National Institutes of Biotechnology Malaysia (NIBM)', 'National Institutes of Health (NIH)', and 'National Institutes of Health, United States of America (NIH)'. The 'National Institutes of Health (NIH)' result is highlighted in blue.

If the search establishment is not appearing in the listing of establishment database, user can click on the ⊕ icon to request for support from the system administrator. User may also send an email with the establishment information such as the official name, address and establishment contact detail to NMRR Secretariat so that it can be added into the establishment database listing



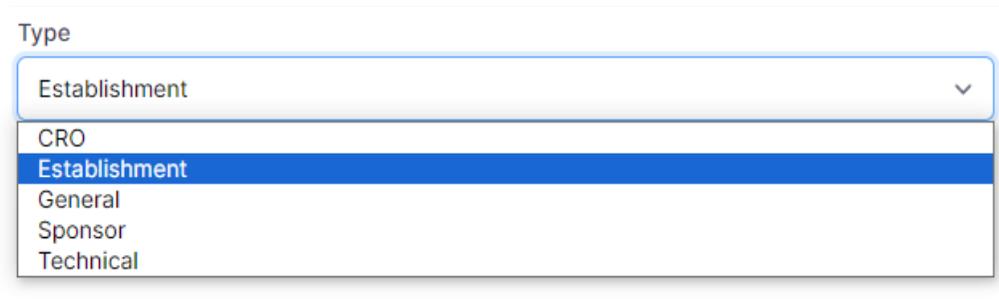
This screenshot is identical to the one above, showing the 'Institution Information' form. However, the '+' icon in the top right corner of the 'New Establishment' section is highlighted with a red square border.

Please ensure the institution information is up to date as this information will be displayed in the directory and will be extracted into the prefilled IAHODIA form that is accessible at the time of submission.

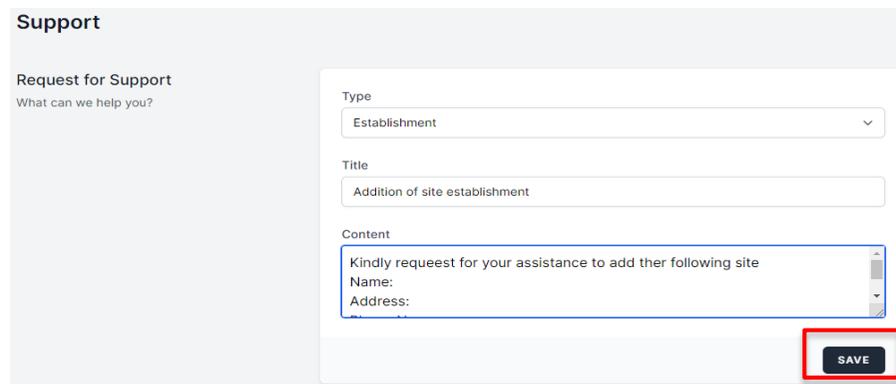
Once in the support page, user is required to choose the type of support required. Insert necessary information regarding the establishment in the content section. Click **SAVE** to submit the support request to the system administrator.



The screenshot shows a form titled "Support" with a sub-section "Request for Support" and the text "What can we help you?". A dropdown menu labeled "Type" is highlighted with a red border and contains the option "CRO".



A close-up of the "Type" dropdown menu. The menu is open, showing the following options: Establishment (highlighted in blue), CRO, General, Sponsor, and Technical.

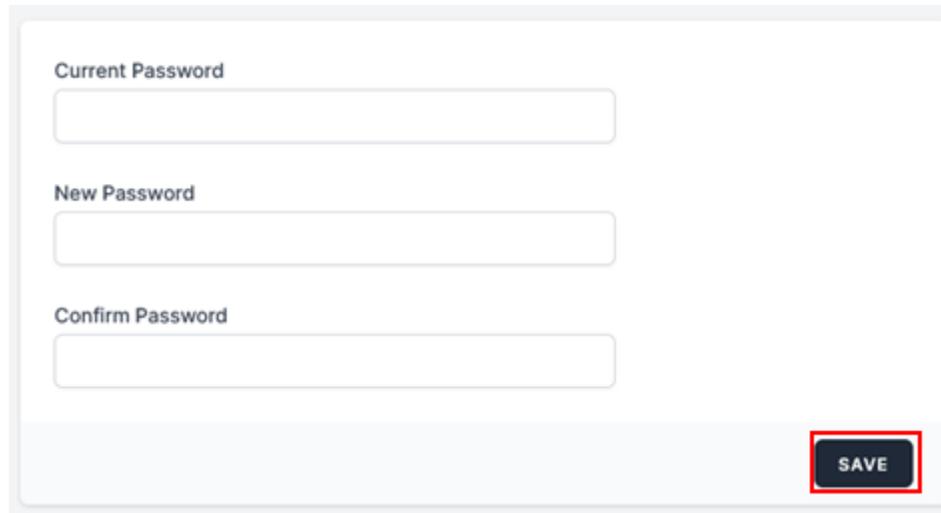


The screenshot shows the "Support" form with the "Type" dropdown set to "Establishment". The "Title" field contains "Addition of site establishment". The "Content" field contains the text "Kindly request for your assistance to add ther following site Name: Address:". A "SAVE" button is highlighted with a red border.

The following Information is required for the addition of a site establishment information into the database:

- Official name of the establishment (English & Malay)
- Full Address
- Phone No.
- Email Address

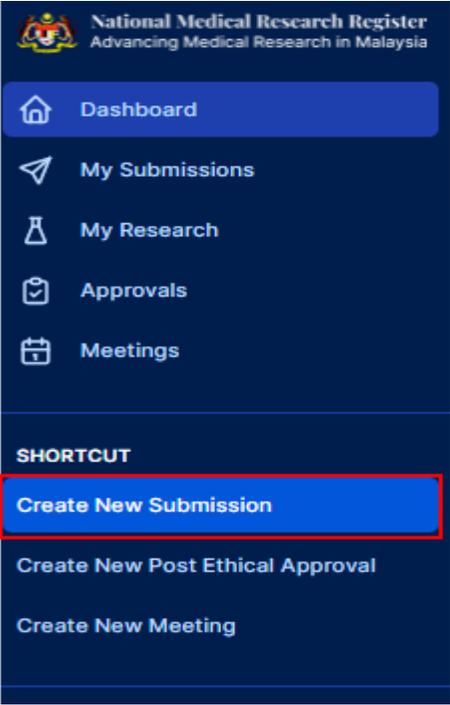
4. To update password, insert current and new password (The password must contain at least 8 characters (including at least one upper case alphabet and one number). Click the **SAVE** button to confirm the new password.



The screenshot shows a form for updating a password. It contains three input fields labeled "Current Password", "New Password", and "Confirm Password". A dark blue button labeled "SAVE" is located at the bottom right of the form and is highlighted with a red rectangular border.

2.0 – New Research Submission / Registration

2.1a – Initial Research Submission / Registration

No	Step-by-step instructions	Remark
1.	<p>Log in as Investigator or CRA in NMRR. Click on the  menu</p> 	
2.	<p>Scroll over the main menu located on the side of the display page, go to shortcut, and select Create New Submission</p> 	<p>Shortcut access “Create New Submission” is only available when user has chosen a role during the registration of NMRR account either as:</p> <ul style="list-style-type: none">• Investigator• Clinical Research Associate

3. Insert the information on the “New Submission Registration” > “General Information”. Basic General Information required are as follows:

- Submission type
- Research title
- Public title
- Research title abbreviation
- Protocol ID
- Research Scope

General Information

Submission Type *

Industry Sponsored Research (ISR) Investigator Initiated Research (IIR)

Research/Submission Title *

Official Research/Submission Title

Public Title *

A title written in simple language that is meant for the general population

Research Title Abbreviation *

Shortened forms of words and phrases to be more concise and for easier reference (e.g Some Research Title Study ='SoRT Study')

Protocol ID

The unique identification of the research protocol used to identify the document and its update assigned by the sponsor or investigator (The simplest ID for a protocol can be the version and version date e.g. Version 2.1 dated 20/03/2023)

Please make sure the ID corresponds to the document uploaded and changes made during each update

Research Scope *

Please Select...

Following that, user is then required to select the appropriate Research Type and click

[Create New Submission](#)

to proceed with the new initial research submission.

Research Type *

Please Select...

Choose appropriate type of research according to the methodology / study design

[Create New Submission](#)

Research Type *

Please Select...

Please Select...

- Interventional
- Observational
- Qualitative Research
- Mixed Method Research
- Proof of Concept / Theoretical Research
- Applied Research
- Registry / Biobanking / Clinical Database
- Clinical Audit / Quality Assurance / Quality Control
- Systematic Review / Scoping Review / Rapid Review / Meta-analysis / Meta-synthesis
- Special Write Up

Research Type *

Observational

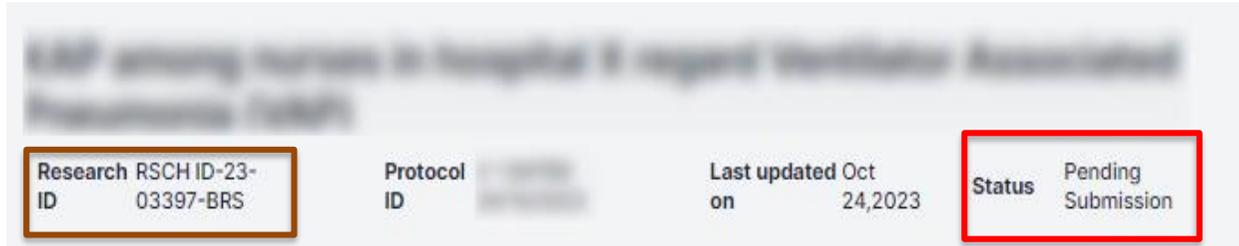
Choose appropriate type of research according to the methodology / study design

[Create New Submission](#)

The most important part for the new initial research submission is **to select the appropriate research type** as different research type will require different study information to be filled up for the registration and different research documents to be uploaded for the ethical approval submission

**** Please refer to the Data Elements & Parameters for NMRR Submission document for the definition of each research type**

4. A page will be displayed with the Information of the Submission is shown over the top part of the display page. At this point, a research ID will be issued indicating that a research submission has been successfully created.



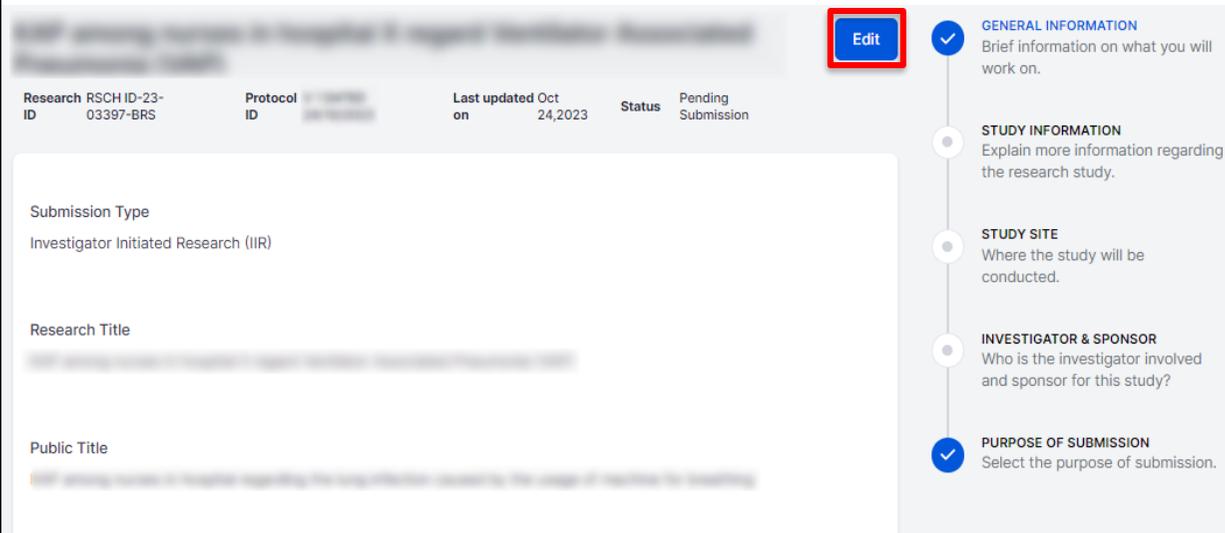
The Submission Status will be displayed as “**Pending Submission**”. This information can be seen over the top part of the display page

Research ID is a reference ID of the research submission from this point onwards. **However, this is not a NMRR Registration ID !!**

5. Over the right side of the page, user will be able to see the sections that are required to be filled up for the submission



6. To continue with the editing of the submission, click on the  button located next to the section listing



Research ID: RSCH ID-23-03397-BRS Protocol ID: [blurred] Last updated on: Oct 24, 2023 Status: Pending Submission

Submission Type
Investigator Initiated Research (IIR)

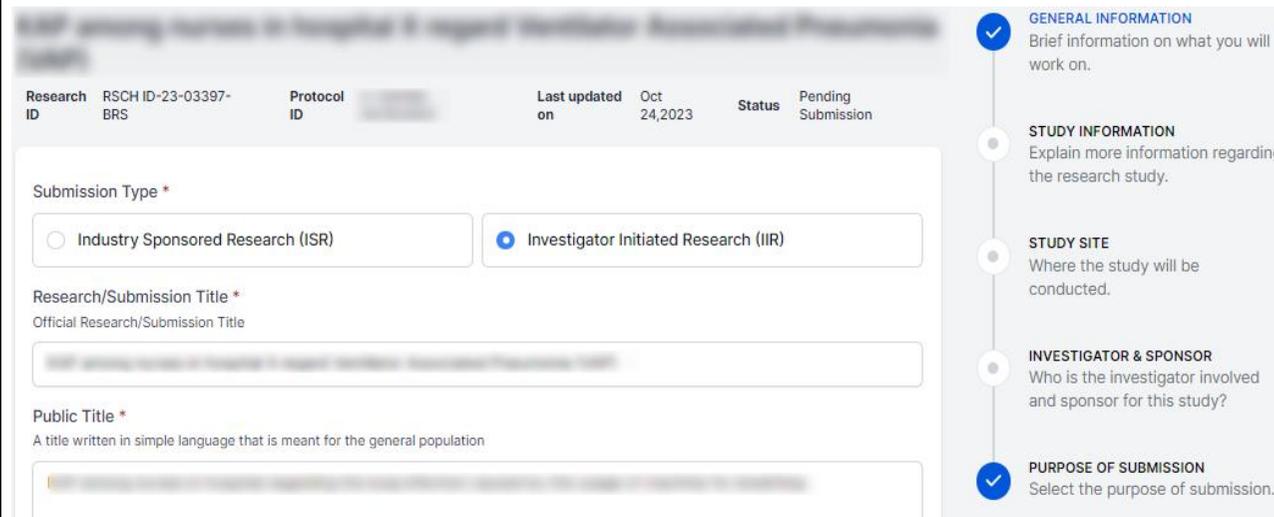
Research Title
[blurred]

Public Title
[blurred]

- ✓ GENERAL INFORMATION
Brief information on what you will work on.
- STUDY INFORMATION
Explain more information regarding the research study.
- STUDY SITE
Where the study will be conducted.
- INVESTIGATOR & SPONSOR
Who is the investigator involved and sponsor for this study?
- ✓ PURPOSE OF SUBMISSION
Select the purpose of submission.

.....

This will change the parameter field previously shown in “*view data*” mode into editable mode. User will be able to edit the information on the general information - if any.



Research ID: RSCH ID-23-03397-BRS Protocol ID: [blurred] Last updated on: Oct 24, 2023 Status: Pending Submission

Submission Type *
 Industry Sponsored Research (ISR) Investigator Initiated Research (IIR)

Research/Submission Title *
Official Research/Submission Title
[blurred]

Public Title *
A title written in simple language that is meant for the general population
[blurred]

- ✓ GENERAL INFORMATION
Brief information on what you will work on.
- STUDY INFORMATION
Explain more information regarding the research study.
- STUDY SITE
Where the study will be conducted.
- INVESTIGATOR & SPONSOR
Who is the investigator involved and sponsor for this study?
- ✓ PURPOSE OF SUBMISSION
Select the purpose of submission.

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 submission.

Research Type *

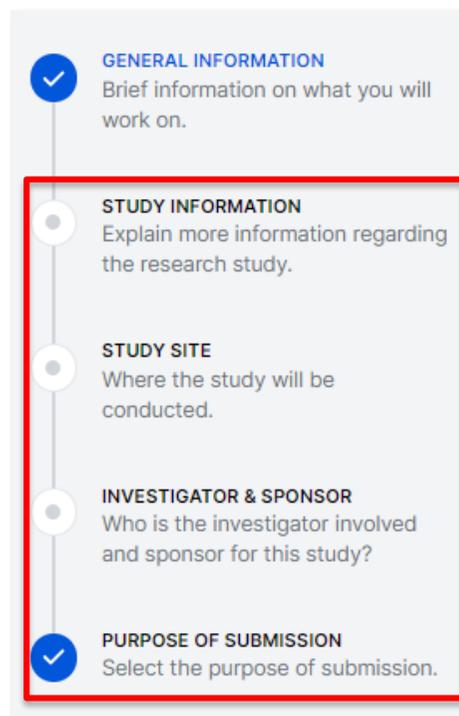
Observational

Choose appropriate type of research according to the methodology / study design

Cancel

Update

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



GENERAL INFORMATION
Brief information on what you will work on.

STUDY INFORMATION
Explain more information regarding the research study.

STUDY SITE
Where the study will be conducted.

INVESTIGATOR & SPONSOR
Who is the investigator involved and sponsor for this study?

PURPOSE OF SUBMISSION
Select the purpose of submission.

Complete each section in a sequence order.

It is advisable to **complete each section's information thoroughly and in a sequence order** from the study information to the purpose of submission. This will assist in avoiding any errors in the procedure and omission of any information, particularly when obtaining the prefilled form that is accessible at the time of submission.

** Kindly refer to the **Data Elements and Parameters for NMRR Submission** document for the definition and further explanation regarding every requirement item and parameter available in each section.

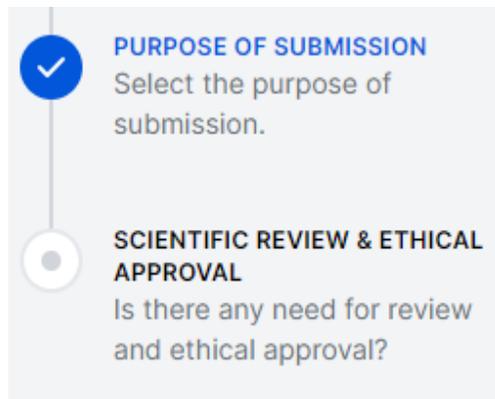
7.	<p>User is required to filled up all mandatory fields (marked with *)</p> <p>Research Level *</p> <p>Please Select... ▼</p>	
8.	<p>In the “Purpose of Submission” section , user is required to choose the purpose of research submission (for purposes other than registration – if any) by click on the <input type="checkbox"/> . If there is any , click <input type="button" value="Save"/> to continue.</p> <div style="border: 1px solid #ccc; padding: 10px; margin: 10px 0;"> <div style="background-color: #f0f0f0; padding: 5px; border: 1px solid #ccc; display: flex; align-items: center;"> ✓ <div> <p>PURPOSE OF SUBMISSION</p> <p>Select the purpose of submission.</p> </div> </div> <div style="margin-top: 10px;"> <div style="background-color: #f0f0f0; padding: 10px; border: 1px solid #ccc;"> <p>Purpose of Submission</p> <ul style="list-style-type: none"> <input checked="" type="checkbox"/> Research Registration <input type="checkbox"/> Scientific Review & Ethical Approval Submission <input type="checkbox"/> Grant (MRG) Submission <div style="text-align: right; margin-top: 10px;"> <input type="button" value="Save"/> </div> </div> </div> <p>For Ethical Approval Submission , the selection should be as follows :</p> <ul style="list-style-type: none"> <input checked="" type="checkbox"/> Research Registration <input checked="" type="checkbox"/> Scientific Review & Ethical Approval Submission <input type="checkbox"/> Grant (MRG) Submission </div>	<p>“Research Registration” is auto- selected once a new submission is created.</p>

For MOH Research Grant (MRG) Submission , the selection should be as follows:

- Research Registration
- Scientific Review & Ethical Approval Submission
- Grant (MRG) Submission

When is clicked, additional section will be available on the section listing , user is then required to complete the section accordingly

For Ethical Approval Submission



For MRG Submission



User may also select to notify the research submission to other authority (other Institutional Review Board(s) (IRBs) , Independent Ethics Committee(s) (IEC) and authority relevant to specific research type). This can be done by selecting the relevant authority accordingly and then click to save the selection.

**** Important reminder! - for Grant (MRG) application, selection of the purpose of submission “Grant (MRG) Submission” should be done together with the “Scientific Review & Ethical Approval Submission” during the initial new research submission.**

If “Grant (MRG) Submission” is not selected and submission has been forwarded to MREC Secretariat and processed for the ethical approval, application for grant will not be allowable and further request and appeal will not be entertained.

For Submission for Ethical Approval by the Medical Research & Ethics Committee (MREC), MOH please go point section 2.1b

Notification of Research to Other Authority

Other Ethical Review Committee

- IRB/IEC Jawatankuasa Etika Perubatan (UMMC)
- IRB/IEC Jawatankuasa Etika Penyelidikan (Manusia) - JEPeM (HUSM)
- IRB/IEC Jawatankuasa Penyelidikan & Etika UKM (RECUKM)
- IRB/IEC Joint Penang Independent Ethics Committee (JPEC)
- IRB/IEC Jawatankuasa Etika penyelidikan , Institut Jantung Negara (IJNREC)
- IRB/IEC Jawatankuasa Etika Penyelidikan (Manusia) Universiti Putra Malaysia (JKEUPM)
- IRB/IEC Jawatankuasa Etika Penyelidikan (UiTM)
- IRB/IEC Joint Ethics Committee on Clinical Studies of School of Pharmaceutical Sciences, USM-Hospital Lam Wah Ee (JEC-SPS, USM & HLWE)
- IRB/IEC Research Ethics Committee IIUM (UIA)
- IRB/IEC International Medical University(IMU) Joint-Committee on Research and Ethics (IMU JC)
- IEC Ramsay Sime Darby Health Care (IEC RSDHC)
- IRB/IEC Sunway Medical Centre Independent Research Ethics Committee (SREC)

Other Authority

- National Pharmaceutical Regulatory Agency (NPRA)
- National Stem Cell Research and Ethics Subcommittee (NSCRET)
- First in Human Research Committee
- National Committee for Research and Development of Herbal Medicine (NRDHM)

Save

Other Authority

- National Pharmaceutical Regulatory Agency (NPRA)
- National Stem Cell Research and Ethics Subcommittee (NSCRET)
- First in Human Research Committee
- National Committee for Research and Development of Herbal Medicine (NRDHM)

Save

A popup up will appear indicating the selection have been succesfully saved

Save

Notification of Research to Other Authority successfully updated.

9. To be able to submit the research submission, user is required to complete all the requires sections. Only after all sections is blue-ticked ✓ , the last section “Confirmation of Submission” will be displayed and accessible to user. Click on the section to access the confirmation of the submission

GENERAL INFORMATION
Brief information on what you will work on.

STUDY INFORMATION
Explain more information regarding the research study.

STUDY SITE
Where the study will be conducted.

INVESTIGATOR & SPONSOR
Who is the investigator involved and sponsor for this study?

PURPOSE OF SUBMISSION
Select the purpose of submission.

SCIENTIFIC REVIEW & ETHICAL APPROVAL
Is there any need for review and ethical approval?

CONFIRMATION OF SUBMISSION
Final check before submitting the application.

Read and acknowledge the statement by clicking on the

Confirmation of Submission

I acknowledge that I have read, and do hereby accept the terms and conditions contained in NMRR terms and condition document.

Submit

I acknowledge that I have read, and do hereby accept the terms and conditions contained in NMRR terms and condition document.

Submit

To submit the research submission, click on the button.

I acknowledge that I have read, and do hereby accept the terms and conditions contained in NMRR terms and condition document.

Submit

10. Once a new research submission has been successfully submitted, user will be brought the submission listing page.

Submissions

Keyword Status Select All

EXCEL PDF Show 10 entries

#	RESEARCH ID	NMRR ID	TITLE	RESEARCH SCOPE	RESEARCH TYPE	STATUS	MRG STATUS	DAY TO SUBMISSION	ACTION
1	RSCH ID-			Health Management	Observational	Processing Submission by NMRR Secretariat		0	

Showing 1 to 1 of 1 entries

Previous 1 Next

The status of a successful new submission of a Research Submission will change from **“Pending Submission”** to **“Processing Submission by NMRR Secretariat”**

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

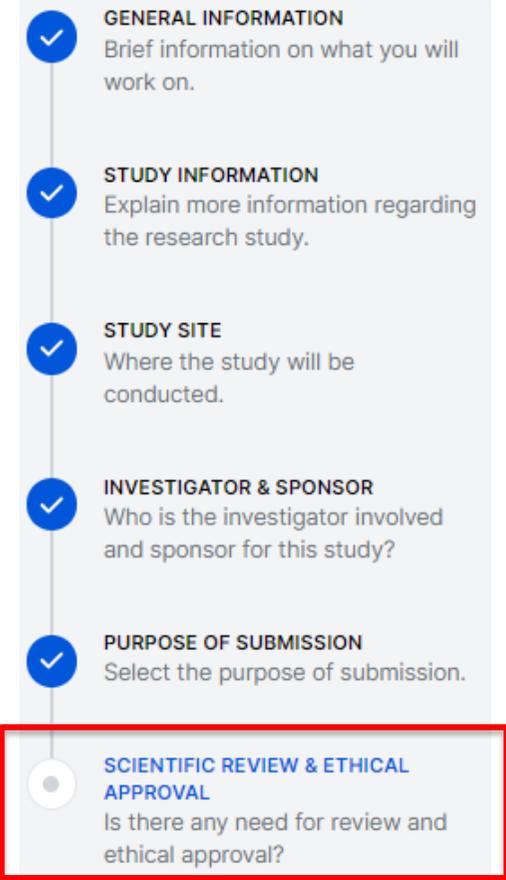
- Show icon to view the data of initial New Submission

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 **“Processing Submission by NMRR Secretariat”**

Research ID Protocol ID Last updated on Oct 06, 2023

Status Processing Submission by NMRR Secretariat

2.1b – Initial Research Submission / Registration with Scientific Review & Ethical Approval Submission

No	Step-by-step instructions	Remark
1.	<p>Once all the sections required for NMRR Registration has been filled-up and completed , user is then required to complete the section for MREC Ethical Approval Submission .This section is accessible by clicking the “Scientific Review & Ethical Approval ”</p>  <p>GENERAL INFORMATION Brief information on what you will work on.</p> <p>STUDY INFORMATION Explain more information regarding the research study.</p> <p>STUDY SITE Where the study will be conducted.</p> <p>INVESTIGATOR & SPONSOR Who is the investigator involved and sponsor for this study?</p> <p>PURPOSE OF SUBMISSION Select the purpose of submission.</p> <p>SCIENTIFIC REVIEW & ETHICAL APPROVAL Is there any need for review and ethical approval?</p>	

2. In this section, user is required to upload necessary documents for the MREC Ethical Review & Approval submission

Research Documents

Cover Letter to MREC
This document are required *

+ Select or drag files | PDF

Declaration of Conflict of Interest (COI form) ↓
This document are required *

+ Select or drag files | PDF

Study Protocol
This document are required *

+ Select or drag files | PDF

Save

3. To upload a document, click on the  icon to acces the document file or drag the document over the box available. Once a document has been uploaded, user is required to label the version and version date for each file uploaded . File name can also be changed if needed.

Project Gantt Chart

This document are required *

+ Select or drag files | PDF

Save

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

Compulsory document is marked with the instruction **“This document(s) is/are required*”**. **Different research type will require different documents to be uploaded**

A screenshot of a document upload form. On the left, there is a PDF icon, the text 'PDF', '122.93 KB', and a 'Download' link. On the right, there are three input fields: 'Name' with the value 'gantt chart observational (training NMRR).pdf', 'Version *' which is empty, and 'Version Date *' with a date picker showing 'mm/dd/yyyy'.

To save the uploaded document, click the  button located at the end of the each subsection

A screenshot of a document upload form, similar to the one above but with the 'Version *' field filled with '1' and the 'Version Date *' field filled with '12/30/2023'.



A popup up will appear indicating the subsection and document(s) uploaded have been successfully saved.

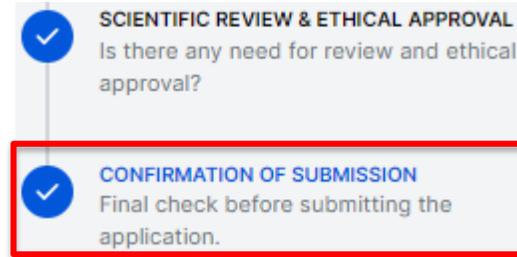


 Information successfully updated.

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

Please ensure that each subsection with a complete uploaded document(s) is saved separately.

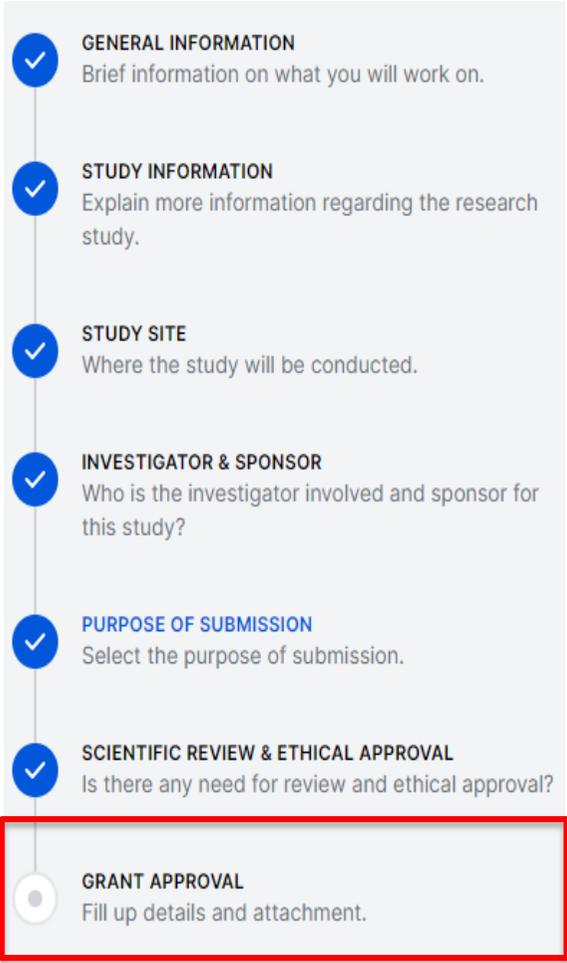
4. Once all mandatory documents are uploaded, user may submit the research submission to be processed by clicking the  button in the “Confirmation of Submission” section as mentioned in the instruction steps **no 9 in 2.1a**



Once all the mandatory documents are uploaded, the “Scientific Review & Ethical Approval” section will be ticked  indicating that the section is complete.

Different research type may also require certain documents to be uploaded and submitted to MREC **(even it is not a mandatory document during NMRR Submission)**. Therefore, user is advised to be aware of the required documents. User may refer to MREC Secretariat or its SOP for more information.

2.1c – Initial Research Submission / Registration with Grant (MRG) Submission

No	Step-by-step instructions	Remark
1.	<p>Once all the sections required for NMRR Registration & the “Scientific Review & Ethical Approval ” have been filled-up and completed , user is then required to complete the section for MOH Research Grant (MRG) Submission . This section is accessible by clicking the “ Grant Approval ” section.</p> 	<p>Reminder!! Submission for Grant (MRG) Application would require user to select both “Scientific Review & Ethical Approval” and “Grant (MRG) Submissions” together during the initial new research registration submission. Once research submission has been registered and issued NMRR ID, the selection of Grant (MRG) Submission will not be accessible in the Purpose of Submission Section.</p>

2. User is then required to insert the information on the costing details of the Grant (MRG) Application . Insert the information on the Year of Research Conduct required for the Grant coverage, followed by the justification and the amount required for each cost category available .

Costing Details

[Download Costing\(PDF\)](#)

TOTAL GRANT COST: RM 0.00

Year 1

COST CATEGORY	JUSTIFICATION	AMOUNT (RM)
Travel Transportation		0
Rental		0
Raw Materials		0

Submission for MOH Research Grant (MRG) is open throughout the year. Submission of the costing details should cover the proposed research funding up to 3 years or less. For more information regarding grant application, please refer to NIH Guidelines for Conducting Research in Ministry of Health (MOH) Facilities & Institutions ,3rd Edition, 2021.

User can fill up the proposed funding costing detail for the research submission up to 3 years.

Year 1	Year 2	Year 3
2023		

3. Once the information and amount of funding has been added, click on  at the end of the costing details to save the information.

Year 1

2023

COST CATEGORY	JUSTIFICATION	AMOUNT (RM)
Travel Transportation	1) Travel claim (TnT) coverage during data collection for 2 person - (500km x rate **x 4 days) 2) Flight Ticket for 2 ways x 2 person - Destination : KLIA 1 to KK (RM 1200)	5000
Rental	Machine Rental for analysis by Company X for 1 year = RM 35000	35000





A popup will appear indicating the costing detail has been successfully saved and updated.

Total funding for each year and the overall funding for the entire submission will be auto calculated by the system. User may also download a copy of the funding costing detail by clicking on the  located at the top of the Costing Details.

User is advised to describe the justification for each necessary costing category in detail. This will help during the processing and review of the MRG Submission by the JPP NIH and MRG Review Panel.

Costing Details

Download Costing(PDF)

TOTAL GRANT COST: RM 40,000.00

Year 1

2023

COST CATEGORY	JUSTIFICATION	AMOUNT (RM)
Travel Transportation	1) Travel claim (TnT) coverage during data collection for 2 person - (500km x rate * 2 * 4 days)	5000

4. Once all necessary details have been added and save , user may submit the research submission to be processed by clicking the **Submit** button on the “Confirmation of Submission” section as mentioned in the instruction steps **no 9 in 2.1a**

SCIENTIFIC REVIEW & ETHICAL APPROVAL
Is there any need for review and ethical approval?

GRANT APPROVAL
Fill up details and attachment.

CONFIRMATION OF SUBMISSION
Final check before submitting the application.

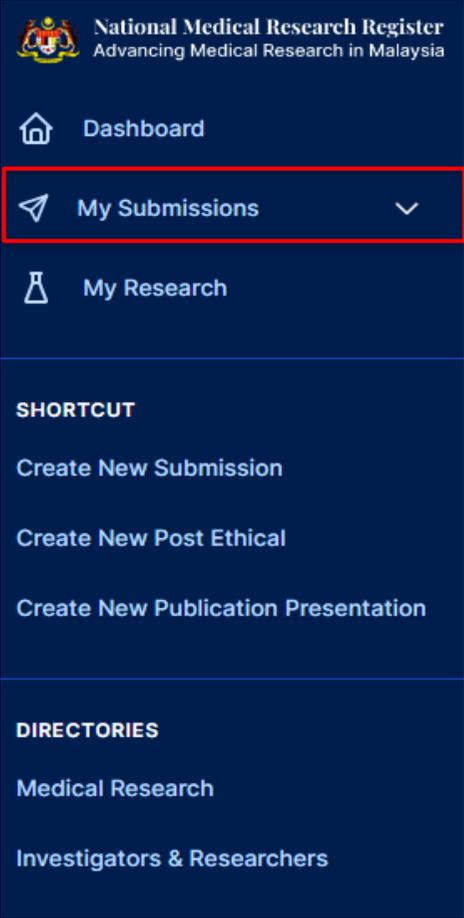
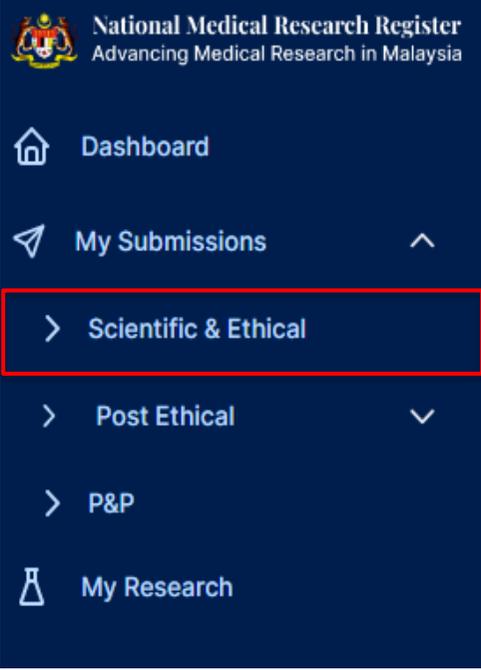
the “Grant Approval” section will be ticked indicating that the section is complete. The Confirmation of Submission will only appear once all the section is complete.

2.1d – Initial Research Submission / Registration with Publication or Presentation Approval Submission

- This will be available during the next phase update once the Publication & Presentation module is officially launched (go-live).

3.0 – Existing Research Submission

3.1 – Viewing an Existing Research Submission and Editing of Pending Submission

No	Step-by-step instructions	Remark
1.	<p>Scroll over the main menu located on the side of displayed page, go to “My Submission”. Then Click on the “Scientific & Ethical”</p> <p style="text-align: center;">①</p>  <p style="text-align: center;">②</p> 	

2. A list of all existing Research Submission will be displayed.

Submissions

Keyword: RSCH ID-23-04600-XYO Status: Select All

EXCEL PDF Show 10 entries

#	RESEARCH ID	NMRR ID	TITLE	RESEARCH SCOPE	RESEARCH TYPE	STATUS	MRG STATUS	DAY TO SUBMISSION	ACTION
1				Basic Science / Biomedical	Interventional	Pending Submission		-	  

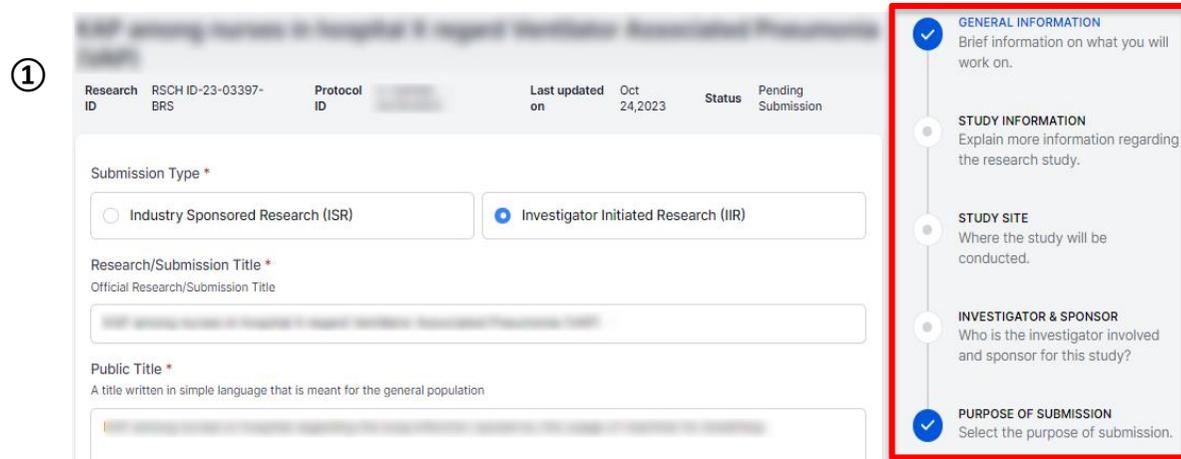
Showing 1 to 1 of 1 entries Previous 1 Next

Submission that is still hasn't been submitted for NMRR processing has a status of **"Pending Submission"**

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

- 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 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)

3. By clicking the  icon, user will be brought to the editing page of “General Information” section. User may then continue editing at each section necessarily and then submit the research submission as steps mentioned in **point No.7 in section 2.1a onwards**.



①

Research ID: RSCH ID-23-03397-BRS
 Protocol ID: [REDACTED]
 Last updated on: Oct 24, 2023
 Status: Pending Submission

Submission Type *
 Industry Sponsored Research (ISR) Investigator Initiated Research (IIR)

Research/Submission Title *
 Official Research/Submission Title

Public Title *
 A title written in simple language that is meant for the general population

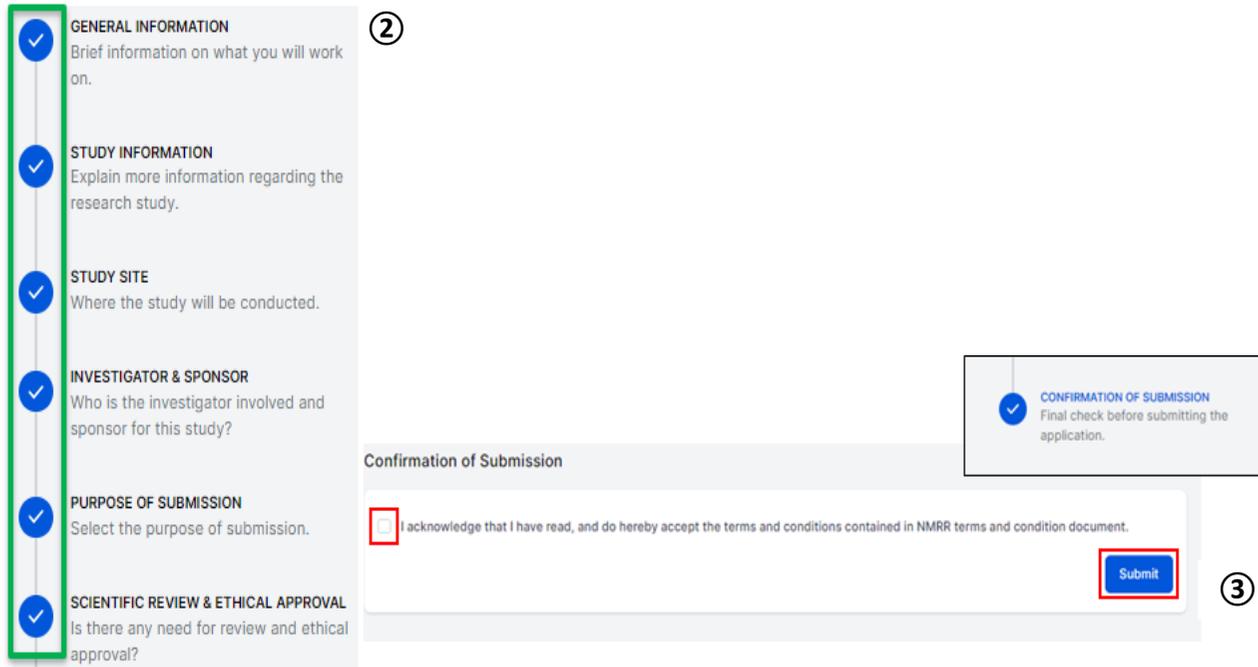
GENERAL INFORMATION
 Brief information on what you will work on.

STUDY INFORMATION
 Explain more information regarding the research study.

STUDY SITE
 Where the study will be conducted.

INVESTIGATOR & SPONSOR
 Who is the investigator involved and sponsor for this study?

PURPOSE OF SUBMISSION
 Select the purpose of submission.



②

GENERAL INFORMATION
 Brief information on what you will work on.

STUDY INFORMATION
 Explain more information regarding the research study.

STUDY SITE
 Where the study will be conducted.

INVESTIGATOR & SPONSOR
 Who is the investigator involved and sponsor for this study?

PURPOSE OF SUBMISSION
 Select the purpose of submission.

SCIENTIFIC REVIEW & ETHICAL APPROVAL
 Is there any need for review and ethical approval?

CONFIRMATION OF SUBMISSION
 Final check before submitting the application.

Confirmation of Submission
 I acknowledge that I have read, and do hereby accept the terms and conditions contained in NMRR terms and condition document.

Submit

③

① If user has any editing or changes made to the general information section, click **Update** button located at the end of the general information section. If there are no any, continue the editing by clicking / select the other section from the listing

② To be able to submit the research submission, user is required to complete all the requires sections (make sure all sections are blue-ticked).

③ User is then required to acknowledge the submission in the conformation of submission section which will appear after the completion of all sections and then click the **Submit** button to send to submission for NMRR Processing.

The status of a successful new submission of a Research Submission will change from **“Pending Submission”** to **“Processing Submission by NMRR Secretariat”**

4.0 – History of Updates

No.	Update Version	Date of Update	Description of Updates	Prepared by (Checked by)	Endorsement Signature
1.	Version 1.0	10 April 2021	Manual & guideline for registration of account, profile updates, initial research submission, submission of revision	NMRR Secretariat	
2.	Version 1.1, May 2022	9 May 2022	Further explanation on the steps and manual relevant to submission of research for registration and other purposes. Additional description on new features in revision submission.	NMRR Secretariat	
3.	Version 2.0	21 November 2023	<ol style="list-style-type: none"> 1. Re-organization of steps and manual for profile updates, initial research registration & other purposes of submission and view and editing of submission with a pending status (addition on further explanation and remark to further help the submission). 2. Splitting of steps for revision & deletion of submission into another document for preparation of incorporation of the document into NMRR SOP 	NMRR Secretariat	