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CHAPTER 1:
User Registration into NMRR

1.0 Create New Account

1. Access to NMRR, go to website at http://www.nmrr.gov.my (Figure 1.0)

2. Click on the Create a New Account

3. A new user registration page will be displayed as Figure 1.0.1
4. It is compulsory to fill in all the empty boxes with red asterisk (**). Content of the New User Registration form are as below:

Section A: Personal Details

i. Email**
   - Please enter an existing email ID (e.g. abc@yahoo.com, example@moh.gov.my)
   - All the notification emails from NMRR will be send to this email account after you submit this online registration form

ii. Password**
   - The password created must be as minimum as 8 characters
   - REMINDER: The password should not be your email address's password

iii. Confirm Password**
   - Re-type your password inserted in (ii)

iv. Role**
   - There are 3 roles stated on the form. Please choose at least one role for your registration.
   - The NMRR system will list out your name in the User Database according to the role that you choose.
   - You are not allowed to change this role after you submit this online registration form. Please contact the NMRR Secretariat if you request to change your role after registration.

v. Title (Eg. Dr, Prof, Dato, Mr, Mrs, Ms.)**
   - Please state your title as it would be use in the correspondence mail.

vi. Name**
   - Please enter your full name according to your Identity Card

vii. Identification Card (IC) number**
   - Please enter your Identity Card OR passport number (applicable for international applicant)

viii. Date of birth**
   - Please select your birthday from calendar. Click on

ix. Sex/Gender**
   - Please state your gender : Male or female

x. Contact number**
   - Please enter an EXISTING contact number for easier and fast contact. The NMRR Secretariat may need to contact you in certain cases (eg. Urgent request to revise your research submission)

xi. Suffix (eg: FRCP, FRCS, MD, PhD)**
   - Please enter your highest qualification.
xii. Institution**

- You may select your institution from our available list
- Please refer to Figure 1.0.2 in order to fill in your institution's name
  - Please click on **Select Institution** to select institution from our established list
  - Please key in a word in one of the boxes on the upper panel to search for your institution.
  - Click on **Show** will list out the institutions related to your search.
  - Click on **Show All** will list out all the institutions in our database.
  - Click on **Select Establishment** to select your institution.

![Select Institution](image)

**Figure 1.0.2**

xiii. Department

- Please key in the department of your institution.
xiv. Designation
   - You may key in your current position. If you are a student, please state your designation as student.

xv. Mailing Address
   - Please key in your correspondence address for our mailing purpose.
   - It is compulsory to state in your state.

xvi. Academic Qualification
   - Please state your academic qualifications.

xvii. Clinical Specialty
   - Investigators may use the available list of clinical specialty to select sub specialty
   - If your clinical specialty does not listed in the our list, please select Others

Section B: Area of Research Interest

This area is mandatory if you select your role as Research Investigator. (Figure 1.0.3)

i. General Area**
   - Please select your general area of research interest.
   - You may select more than one choice.
   - If your area of research interest is not listed, you may click others.

ii. Disease Area
   - Please select your disease area.
   - You may select more than one choice.
   - If your area of research interest is not listed, you may click others.

iii. Therapeutic Area**
   - Please select your therapeutic area.
   - You may select more than one choice.
   - If your area of research interest is not listed, you may click others.

Figure 1.0.3
Section C: Validation Section

i. Validation word / letter**
   - If you can’t read the Validation Words, you may click on \textcolor{red}{Refresh Image} to refresh the image. (Figure 1.0.4)
   - Note that validation words/letter would change on each submission with an error message.

Section D: Upload Documents

Note: Please only upload files that have these extensions/ends with: .doc .xls .ppt .html .htm .jpg .gif .txt .pdf

i. Upload CV Document
   - Please upload your curriculum vitae (CV) or resume by click \textcolor{blue}{Choose File}

ii. Upload GCP Certificate
   - GCP is the Good Clinical Practices
   - Please tick on the box if you already sit for the GCP courses.
   - Please upload your GCP certificate by click \textcolor{blue}{Choose File} if you have the scan copy of the certificates.
   - Only applicable for Clinical Researchers.

5. Please check the information in the boxes noted ** are properly and completely filled.

6. Click \textcolor{blue}{Submit} to submit a complete registration OR click on \textcolor{blue}{Back} to refresh the new user registration form which will then be blank. (Figure 1.0.5)
7. You will receive a note that you have successfully completed user registration (Figure 1.0.6)

8. You will also receive a notification email through your email account that you submitted before.

Figure 1.0.6
1.1 Forget Password

1. If you forget password, click on Forget password?

2. Please key in your email address and click Submit. A new automatic generated password will be send to your email account. (Figure 1.1)

3. You can login with new password and change your password.
1.2 Check for Existing Account

1. To check whether you have an existing account with NMRR, please click on the button "Check for Existing Account".

2. You are advised to check for existing accounts. Duplicated accounts will be deleted.

3. Type your email address which you have registered for NMRR's new user registration. (Figure 1.0.2)

4. The result of account status will display. (Figure 1.2.1)
### 1.3 User Instructions/Documents

1. Please click on **Documents / User Instruction** to get information about NMRR.

2. You will be directed to this page. Refer Figure 1.3.

3. Click on the PDF icon to download the document.

---

**Table: Documents / User Instruction**

<table>
<thead>
<tr>
<th>Serial #</th>
<th>Document Title</th>
<th>Download</th>
<th>Current version</th>
<th>Date released</th>
<th>Responsible party</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>NIH Guidelines for Conducting Research in MOH</td>
<td>2.1</td>
<td>9 September 2009</td>
<td>NIH secretariat</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>User Instruction: Investigator registration &amp; New user account</td>
<td>2.1</td>
<td>9 September 2009</td>
<td>NIH secretariat</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>User Instruction: Research registration &amp; submission</td>
<td>2.1</td>
<td>9 September 2009</td>
<td>NIH secretariat</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>Template document Investigator Agreement, Head Of Departments and Institutional Approval Document</td>
<td>2.0</td>
<td>15 Feb 2008</td>
<td>NIH secretariat</td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>Template document NIH approval Document</td>
<td>2.0</td>
<td>15 Feb 2008</td>
<td>NIH secretariat</td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>Data elements for submission to NMRR</td>
<td>2.1</td>
<td>9 September 2009</td>
<td>NIH secretariat</td>
<td></td>
</tr>
<tr>
<td>8</td>
<td>NMRR Workflow chart</td>
<td>2.3</td>
<td>15 July 2009</td>
<td>NIH secretariat</td>
<td></td>
</tr>
<tr>
<td>9</td>
<td>Form 1289: NH For application to SIR for MRR funding</td>
<td>1.1</td>
<td>-</td>
<td>NIH secretariat</td>
<td></td>
</tr>
<tr>
<td>10</td>
<td>CRC's Clinical Trial Agreement (CTA) Template</td>
<td>1.0</td>
<td>19 December 2008</td>
<td>CRC/NIH/NSO</td>
<td></td>
</tr>
<tr>
<td>11</td>
<td>NMRC's SOP 2.1 &quot;Submission to the Medical Research &amp; Ethics Committee (MREC) of the Ministry of Health (MOH)&quot;</td>
<td>1.0 (Draft for comment)</td>
<td>15 December 2008</td>
<td>NMRC NIH</td>
<td></td>
</tr>
<tr>
<td>12</td>
<td>Guidelines For Application Of Clinical Trial Import Licence And Clinical Trial Exemption In Malaysia</td>
<td>2.0</td>
<td>4 December 2008</td>
<td>NPCB</td>
<td></td>
</tr>
<tr>
<td>13</td>
<td>Standar Nama Yang Terbit Untuk Pemahaman Status GRANDFATHER Oral Clinical Practice</td>
<td>1.0</td>
<td>4 December 2008</td>
<td>NPCB</td>
<td></td>
</tr>
<tr>
<td>14</td>
<td>CRC's SOP &quot;Engaging Ministry of Health (MOH) sites and investigators to participate in clinical research sponsored by external party&quot;</td>
<td>1.0</td>
<td>To be released</td>
<td>OGC</td>
<td></td>
</tr>
<tr>
<td>15</td>
<td>CRC's SOP &quot;Application to CRC for funding and other technical support for investigator initiated clinical research&quot;</td>
<td>1.0</td>
<td>To be released</td>
<td>CTO</td>
<td></td>
</tr>
<tr>
<td>16</td>
<td>Glossary of clinical research terms</td>
<td>1.0</td>
<td>25-09-2009</td>
<td>NIH secretariat</td>
<td></td>
</tr>
<tr>
<td>17</td>
<td>Frequently Asked Questions about NMRR</td>
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<td>25-09-2009</td>
<td>NIH secretariat</td>
<td></td>
</tr>
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<td>18</td>
<td>NMRR user's manual</td>
<td>1.0</td>
<td>25-09-2009</td>
<td>NIH secretariat</td>
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<td>19</td>
<td>CLINICAL TRIAL COMPENSATION GUIDELINES</td>
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<td>NPCB</td>
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<td>10-09-2009</td>
<td>NIH</td>
<td></td>
</tr>
<tr>
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<td>1.0</td>
<td>10-09-2009</td>
<td>NPCB</td>
<td></td>
</tr>
<tr>
<td>22</td>
<td>Director of Director of Pharmaceutical services on Clinical Trial Registration 2009</td>
<td>1.0</td>
<td>10 Dec 2009</td>
<td>NPCB</td>
<td></td>
</tr>
</tbody>
</table>

---

**Figure 1.3**

*Image showing a table with documents and user instructions for NMRR.*
CHAPTER 2:
Registering, and Submitting New Search for Registration, Approval or Notification

2.0 Log In to NMRR

1. Please login to register a new research.

2. Key in your Email address and Password and click **Public User Login** to login into NMRR Public User Main Menu. (Figure 2.0)
3. This is the layout for Public User Main Menu (Figure 2.0.1).

4. Please refer to Table 1.0 for the definition for each term/phrases.

<table>
<thead>
<tr>
<th>Research Submission</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Submit new research for registration, notification or approval</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Stage 1 Submission screening by NMRR secretariat prior to further actions by relevant authority</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Unsubmitted research (not submitted yet by CP) (0)</td>
</tr>
<tr>
<td>2. Submissions being processed (Pending review &amp; decision) (0)</td>
</tr>
<tr>
<td>3. Incomplete submissions awaiting resubmission by CP (0)</td>
</tr>
<tr>
<td>4. Submissions with CP’s request to re-submit (Pending Secretariat’s OK for resubmission) (0)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Stage 2 Submission forwarded to relevant authority for processing</th>
</tr>
</thead>
<tbody>
<tr>
<td>5. Registered completed submissions (NMRR ID# issued), for further actions by the relevant authority (0)</td>
</tr>
<tr>
<td>6. Submissions needing revision (Pending resubmission by CP) (0)</td>
</tr>
<tr>
<td>7. Submissions with a Final Decision (0)</td>
</tr>
<tr>
<td>8. Submissions with Conditional Approval (pending additional document/data from CP) (0)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Stage 3 – Amendment after approval by relevant authority</th>
</tr>
</thead>
<tbody>
<tr>
<td>9. Submissions with CP’s request to amend (Pending Secretariat’s OK for submit amendment) (0)</td>
</tr>
<tr>
<td>10. Submissions needing Amendment (Pending resubmission by CP) (0)</td>
</tr>
<tr>
<td>11. Amendment being processed (Pending review &amp; decision) (0)</td>
</tr>
<tr>
<td>12. Amendment with final decision (0)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>All submissions</th>
</tr>
</thead>
<tbody>
<tr>
<td>13. All submissions (both registered with NMRR ID# and Unregistered) (3)</td>
</tr>
<tr>
<td>14. All Research Registration (Unique Research) (1)</td>
</tr>
</tbody>
</table>

Figure 2.0.1
<table>
<thead>
<tr>
<th>TERMS/PHRASES</th>
<th>DEFINITION</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Research Submission</strong>&lt;br&gt;Submit new research for registration, notification or approval</td>
<td>To submit NEW research for registration, submission for approval and notification to other applicable authorities.</td>
</tr>
<tr>
<td><strong>Stage 1</strong>&lt;br&gt;Submission screening by NMRR secretariat prior to further actions by relevant authority</td>
<td>In the first stage, the NMRR secretariat will screen your submission and check either your submission is complete or incomplete. You will only receive Research ID at this stage.</td>
</tr>
<tr>
<td>Unsubmitted research (Not submitted yet by CP)</td>
<td>List of researches that user had submitted the Research Title but has NOT completed the data entry or attach any documents and does NOT yet approve Research Registration, Submission or Notification.</td>
</tr>
<tr>
<td>Submissions being processed (Pending review &amp; decision)</td>
<td>List of researches that user had approved/completed Research Registration and Research Submission for approval by responsible authorities. User had received Research ID for reference. The NMRR Secretariat is yet to screen all the data and documents that user had inserted.</td>
</tr>
<tr>
<td>Incomplete submissions awaiting resubmission by CP</td>
<td>List of researches that were notified by the NMRR Secretariat which need to be re-submitted by user OR list of researches that user request to re-submit.</td>
</tr>
<tr>
<td>Submissions with CP's request to re-submit (Pending Secretariat's OK for resubmission)</td>
<td>List of researches that user have request to re-submit but NOT yet approve by NMRR Secretariat</td>
</tr>
<tr>
<td><strong>Stage 2</strong>&lt;br&gt;Submission forwarded to relevant authority for processing</td>
<td>The second stage consists of Research Approval by authorities (eg. NIH Institutes, MREC, NPCB and other ethical committees). Your completed research registration/submission that had been screen by NMRR Secretariat is forwarded to the NIH Institutes, MREC, NPCB and other IRB/IEC in order to be review and approve (according to your choice). User will receive NMRR ID for reference.</td>
</tr>
<tr>
<td>Registered completed submissions (NMRR ID# issued), for further actions by the relevant authority</td>
<td>List of researches that had been forwarded to second stage. Pending approval by applicable authorities (according to your choice).</td>
</tr>
<tr>
<td>Submissions needing revision (Pending resubmission by CP)</td>
<td>List of researches that are to be revised by user and re-submit.</td>
</tr>
<tr>
<td>Submissions with a Final Decision</td>
<td>Your research submissions that had receive final decision by the applicable authorities.</td>
</tr>
<tr>
<td>Submissions with Conditional Approval (pending additional document/data from CP)</td>
<td>Your research submissions that had receive final decision by the NIH/MREC/MRG Secretariat but require CP to send certain additional document to support your study.</td>
</tr>
<tr>
<td>Stage 3 Amendment after approval by relevant authority</td>
<td>This stage consist of researches which receive decision by MREC but requisite amendment</td>
</tr>
<tr>
<td>------------------------------------------------------</td>
<td>----------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Submissions with CP’s request to amend (Pending Secretariat’s OK for submit amendment)</td>
<td>List of researches requested by CP for amendment</td>
</tr>
<tr>
<td>Submissions needing Amendment (Pending resubmission by CP)</td>
<td>List of submissions require amendments by CP</td>
</tr>
<tr>
<td>Amendment being processed (Pending review &amp; decision)</td>
<td>List of submitted amendment awaiting for decision by MREC</td>
</tr>
<tr>
<td>Amendment with final decision</td>
<td>Amendment with decision by MREC</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>All submissions</th>
</tr>
</thead>
<tbody>
<tr>
<td>All submissions (both registered with NMRR ID# and Unregistered)</td>
</tr>
<tr>
<td>All Research Registration (Unique Research)</td>
</tr>
</tbody>
</table>

Table 1.0
2.1 Register New Research

1. Click on [Submit new research for registration, notification or approval](#) to register your new research project.

2. A new page will appear and you will need to enter Research Title, Abbreviation and Purpose of Submission. (Figure 2.1)

![Figure 2.1](image)

3. You will need to enter all the data requested by NMRR especially items with red asterisk (**)

4. Follow the procedures flow according the sections given in order to enter all the data required efficiently.
Section 1: Enter Title and Select Purpose of Submission

1. Enter your Research Title and Research Title Abbreviation

2. Make sure your Research Title Abbreviation is meaningful and related to your Research Title. Your Research Title Abbreviation will be displayed on research directory.

3. If your research collaborates with one or more of the NIH Institutes listed, please select the responsible institutes.

4. Please select Purpose of Submission according to the responsible and related approval authorities. You may view Figure 2.1.1 and Table 2.0 for more information on the responsible approval authorities.

5. Click on Update after you have completed the entry.
<table>
<thead>
<tr>
<th>RESPONSIBLE AUTHORITIES</th>
<th>DESCRIPTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Research Registration</td>
<td>This only applicable for research register into NMRR database</td>
</tr>
<tr>
<td>Research Submission to NIH for Approval</td>
<td>Authority that give an approval for Clinical Researches (Observational &amp; Interventional)</td>
</tr>
<tr>
<td>Clinical Research Centre (CRC)</td>
<td><a href="http://www.crc.gov.my">www.crc.gov.my</a></td>
</tr>
<tr>
<td>Institute for Medical Research (IMR)</td>
<td><a href="http://www.imr.gov.my">www.imr.gov.my</a></td>
</tr>
<tr>
<td>Institute of Public Health (IPH)</td>
<td><a href="http://www.iku.gov.my">www.iku.gov.my</a></td>
</tr>
<tr>
<td>Institute for Health Management (IHM)</td>
<td><a href="http://www.ihm.moh.gov.my">www.ihm.moh.gov.my</a></td>
</tr>
<tr>
<td>Institute for Health Systems Research (IHSR)</td>
<td><a href="http://www.ihsr.gov.my">www.ihsr.gov.my</a></td>
</tr>
<tr>
<td>Institute for Health Behavioral Research (IHBR)</td>
<td><a href="http://www.iptk.gov.my">www.iptk.gov.my</a></td>
</tr>
<tr>
<td>Research Submission to NIH for MREC Review and Approval</td>
<td>MOH Research Ethical Committee review and approve researches that are involving human beings (MOH patients, personnel or community)</td>
</tr>
<tr>
<td>Research Submission to NIH for MRG Application</td>
<td>Investigator whom intended to request for MOH Research Grants (Applicable for MOH staffs OR research collaborated with MOH)</td>
</tr>
<tr>
<td>Research Publication/Presentation Submission to NIH for DG Approval</td>
<td>Application for approval of publication OR presentation of papers/manuscript/posters etc.</td>
</tr>
<tr>
<td>Research Notification to Other IRB/IECs</td>
<td>Notification for selected independent ethical committee</td>
</tr>
<tr>
<td>Research Notification to Clinical trial &amp; Compliance Section NPCB</td>
<td>Notification to National Pharmaceutical Control Bureau (NPCB ) regarding research that requires CTIL/CTX</td>
</tr>
</tbody>
</table>

Table 2.0
Section 2: Select Research Type

1. This section consists of research details that need to be filled in (Figure: 2.2.0)

   2.1 Protocol ID

   2.2.1 Student Academic Project (Please specify your qualification)

   2.2.2 Student Academic Project Specify

   2.3 Research Type
      - Please choose research type that is related to your study

   2.4 Clinical Research Sub Type
      (Only applicable if you choose Research Type: Clinical)

2. Click on [Update] to save your details and follow the next step
Section 3: All Research

1. This section consists of research details that needed to be filled in. Please make sure you provided all the required information especially in the field marked with red asterisks (**)

   3.0.1 Research Purpose
   - Fill in your research objectives and purposes.

   3.0.2 Research Description
   - Describe your research in general

   3.0.3 Keywords
   - Type in keywords (words / phrases) to make it easy for others to search your research title

   3.0.4 Research Date Start
   - You may click on to select date of research start
   - You may tick on the box if your research date is not applicable

   3.0.5 Research Date Completed
   - You may click on to select date of research complete
   - You may tick on the box if your research date is not applicable

   3.0.6 Research Duration
   - Click on blank to auto calculates duration

   3.0.7 Link URL
   - You may key in the website as reference for research proposal

   3.0.8 Recruitment Status
   - Status of recruiting the research subjects

2. Fill in data related to the primary disease or condition being studied using MeSH – for columns 3.0.9 – 3.0.15

   3.0.9 Condition

   3.0.10 Age limit

   3.0.11 Gender

   3.0.12 Eligibility

   3.0.13 Acceptable participant

   3.0.14 Target Number Subject

   3.0.15 Target number Subject in Malaysia
3. You may refer to our **User Instructions**, document title *Data elements for submission to NMRR (Version 2.1)* for more information/definition of keyword. (Figure 2.1.3)

4. Please click on **Update** to save all the data you have inserted and **Next** to continue to the next section.

5. Click **Back** to let the page blank and go to the previous section. (Table 2.1.4)
Section 3.1: Clinical Trial

1. You will have to fill the information below which is required for registration of Clinical Trial or Intervventional study: (Figure 2.3.2: Clinical trial)

3.1.1 Study phase
3.1.2 Purpose
3.1.3 Allocation
3.1.4 Masking
3.1.5 Control
3.1.6 Assignment
3.1.7 Endpoint
3.1.8 Outcome Measure
3.1.9 Intervention
3.1.10 Therapeutic Area

2. You may refer to our User Instructions, document title Glossary of clinical research terms (Version 1.0) for more information/definition of keyword. (Figure 2.1.5)

3. Please click on Update to save all the data you have inserted and Next to continue to the next section.

4. Click Back to let the page blank and go to the previous section.
Section 3.1: Observational Study

1. You will have to fill the information below which is required for registration of Clinical Trial or Observational Study: (Figure 2.1.6)

   3.2.1 Disease area (compulsory)
   - Please state the disease area, disease area specific disease and other specification

   3.2.2 Purpose
   - State the objective of the observational study

   3.2.3 Selection
   - State the method of collecting sample

   3.2.4 Duration

   3.2.5 Timing

2. You may refer to our User Instructions, document title Glossary of clinical research terms (Version 1.0) for more information/definition of keyword. (Figure 2.1.5)

   Figure 2.1.6

3. Please click on Update to save all the data you have inserted and Next to continue to the next section.

4. Click Back to let the page blank and go to the previous section.
Section 4: Add/Drop Sponsors

1. Sponsors are institutions/bodies that funded/sponsor your study/research.

2. To add sponsors, first you have to enter the name of sponsor’s institution - click on Add more sponsor in Add/Drop sponsors page (Figure 2.1.7)

3. Fill in the following details in sponsor’s information page.
   a) Sponsor Organization / Institution
      - Click on Select Institution and also Select Establishment choose your sponsor’s institution (Figure 2.1.7)
   b) Sponsor Type
   c) Funding Source and;
   d) Click Add or click Back to go back to the previous page.

Figure 2.1.7
4. To add in the contact sponsor information, click the sponsor name and choose the institution you just entered. Then, click on Select Sponsor Contact Name to select your sponsor contact name from our database. (Figure 2.1.8)

   a) If you know the exact name of contact name of related sponsor, you may type the name. Click on Show to search.

   b) Please click Show All to view all the name of sponsor contact name

   c) You may select contact name from the list by click Select Sponsor

5. Click on Add to add into sponsor contact name list.

6. Click Add more sponsor to enter more than one as many sponsors as required name.
7. If you want to view, update or delete the sponsor contact information from list, please click on the icons above. (Figure 2.1.9)

8. Refer below for icons definition:

<table>
<thead>
<tr>
<th>ICON</th>
<th>DEFINITION</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image" alt="View Icon" /></td>
<td>View</td>
</tr>
<tr>
<td><img src="image" alt="Update Icon" /></td>
<td>Update</td>
</tr>
<tr>
<td><img src="image" alt="Delete Icon" /></td>
<td>Delete</td>
</tr>
</tbody>
</table>

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**Figure 2.1.9**

---

---
Section 5: Add/Drop Investigators

1. At Investigator Information page, click to **Select Institution** choose investigators.  
   *(Figure 2.1.10)*

2. You can enter as many name into the investigator list.

3. Type in the investigator name and click **Show** or click **Show All** to show all the investigators' name listed on NMRR. Make sure your investigator has already registered as a user in NMRR

4. Click **Select Investigator** to select as investigator into investigator information page list.

---

**Figure 2.1.10**

---

**Figure 2.1.10**
5. Fill in the other following information in the investigator information page

a) Role
   - Select a role for the investigator according to their role in the study

b) Site where research is conducted (Figure 2.1.11)
   - You may select site establishment to conducting research form list, click on Select Institution to select institution site.
   - Type in the institution name and click Show or click Show All to show all the investigators’ name listed on NMRR. Make sure your investigator has already registered as a user in NMRR.
   - Click Select Establishment to select an institution into investigator information page list.

c) Department
   - You may type in the department where your investigator’s currently working. However, you may leave it blank.

d) State
   - Please select state where you want to conduct the research

e) Note
   - You may type note regarding the investigator.

Figure 2.1.11
6. If you want to view, update or delete the investigator name from list, please click on the icons above. (Figure 2.1.12)

7. Refer below for icons definition:

<table>
<thead>
<tr>
<th>ICON</th>
<th>DEFINITION</th>
</tr>
</thead>
<tbody>
<tr>
<td>View</td>
<td></td>
</tr>
<tr>
<td>Update</td>
<td></td>
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<tr>
<td>Delete</td>
<td></td>
</tr>
</tbody>
</table>

![Figure 2.1.12](image)

8. Please note that the person who registers the research would be auto assign as an investigator. Therefore, please do not select your name from investigator list unless correspondence person is a different person.

9. Click on Next to continue to the next section or Back to go to the previous section.
Section 6: Add/Drop Project Staff

1. Click **Select Project Staff** at Project Staff Information page (*Figure 2.1.13*)

2. Type in the project staff name and click **Show** or click **Show All** to show all the investigators’ name listed on NMRR. Make sure your investigator has already registered as a user in NMRR.

3. Click **Select Project Staff** to select as project staff into project staff information page list.

4. Fill in the tables for all the information needed:
   
   f) Role
      - Select a role for the project staff selected
   
   g) Institution
      - You may select site establishment to conducting research form list, click on **Select Institution** to select institution site.
      - Type in the institution name and click **Show** or click **Show All** to show all the investigators’ name listed on NMRR. Make sure your investigator has already registered as a user in NMRR.
      - Click **Select Establishment** to select an institution into investigator information page list.
   
   h) Central contact
      - You may tick if the person can provide centralized, coordinated recruitment information for the entire study
   
   i) Central contact backup
      - You may tick if the person can provide centralized, coordinated recruitment information for the entire study. This is for backup if central contact cannot be reached.
   
   j) Note
      - You may type note regarding the investigators.

5. Click on **Add** to add new project staff into the list.
6. If you want to view, update or delete the investigator name from list, please click on the icons above. (Figure 2.1.14)

7. Refer below for icons definition:

<table>
<thead>
<tr>
<th>ICON</th>
<th>DEFINITION</th>
</tr>
</thead>
<tbody>
<tr>
<td>![View Icon]</td>
<td>View</td>
</tr>
<tr>
<td>![Update Icon]</td>
<td>Update</td>
</tr>
<tr>
<td>![Delete Icon]</td>
<td>Delete</td>
</tr>
</tbody>
</table>

![Figure 2.1.14]
Section 7: Add/Drop Correspondence Person

1. Check that your name is selected in the Research Correspondence Person list. (Figure: 2.1.15)

2. Please note that ONLY the correspondence person could edit the proposal and other those involve in research could only read.

3. If you choose to give a correspondence authority to other user that involve in the research, click on the selected CP and click on **Update**

4. Reminder you will not be able to edit the selected NMRR application after you hand the correspondence authority to others.

![Figure: 2.1.15]
Section 8: Research Registration

1. After you have completed all the data in section 1 until Section 7, click on **Next** to Step 8 to submit your research in 8.0 Research Registration.

2. Please click on [Build PDF File](#) to convert all your data from Section 1 to section 7 into a PDF file.

3. Please make sure a PDF icon appear on the page *(Figure 2.1.16)*

4. If any of table with sign ** is incomplete, an error message will appear. Please check again your data according to the message error and click on update. *(Figure 2.1.17)*

5. Then, click on [Approve Research Registration](#) to proceed to Research Submission.
This research has not been registered.

**Research Registration**

- **Research ID:** 1469
- **Research Title:** testing/859
- **NMRR:**

Up till now, you have been entering data concerning your research. You may be ready to register your research with NMRR now.

Please click **"Build PDF File"** to create the file for registration. The PDF file containing your registration data will appear below when it is created. This constitutes your registration data file.

Please review the PDF file, and click **"Approve Research Registration"** to approve the file for research registration purpose.

**ERROR MESSAGES**

- **Stage 1**
- **Stage 2**
- **Stage 3**

---

**Figure 2.1.17**

**Figure 2.1.18**
2.2 Research Submission to Applicable Authority for Approval

1. There are several approval authorities that are responsible for research conducted in MOH sites, involving MOH patients and also involving MOH personnel.

2. The Applicable Authority Approval Submission section will appear according to your selection in Section 1: Enter Title and Select Purpose of Submission. (refer to page 15 and page 16)

9.1 Research Submission to NIH for Approval

1. Click on the appeared institutes’ names and filled in where necessary.

   **Step 1**

   a) You will need to type in cover letter for your submission

   b) The letter should be address to NIH Secretariat. State in your purpose of submission and list of documents attach for us

   c) Then click on **Update**

---

**Figure 2.2.0**

- A covering letter explaining the purpose of your submission is required. Please enter the text in the box below. The simplest way is to copy and paste the text from your word processing package into the system.
Step 2

a) These are the research documents you will need to submit for the NIH approval:
(Please refer to NMRR Glossary for unfamiliar term)
- Study Protocol or Protocol Amendment (Applicable for Clinical Trial ONLY)
- Study Proposal
- Patient Information Sheet & Informed Consent Form (English)
- Patient Information Sheet & Informed Consent Form (Malay)
- Patient Information Sheet & Informed Consent Form (Other Language)
- Study Clinical Report Form
- Patient’s Diary
- Questionnaire

b) Click on Upload Research’s Documents. Note that the system will only convert file from .doc .xls .html .htm .jpg .gif .txt .pdf and avoid using symbols (/ , ^, @, #,) in file name (Figure 2.2.1)

<table>
<thead>
<tr>
<th>No.</th>
<th>Items</th>
<th>Version</th>
<th>Date</th>
<th>File Name</th>
<th>PDF</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Study Protocol or Protocol amendment</td>
<td>Document No</td>
<td>Version No</td>
<td>Version Date</td>
<td></td>
</tr>
<tr>
<td></td>
<td>&quot;Study Protocol - Required for ALL research except for submission for grant funding where a proposal document is sufficient. A comprehensive and detailed document that describes the objective(s), design, methodology, statistical considerations, and organization of a research&quot;</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Study Proposal</td>
<td>Document No</td>
<td>Version No</td>
<td>Version Date</td>
<td></td>
</tr>
<tr>
<td></td>
<td>&quot;Required if no protocol is submitted. A brief document that describes the rationale, objective(s), design, methodology, statistical considerations, and organization of a proposed research.&quot;</td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>3</td>
<td>Patient information sheet &amp; Informed Consent Form (English)</td>
<td>Document No</td>
<td>Version No</td>
<td>Version Date</td>
<td></td>
</tr>
<tr>
<td></td>
<td>&quot;Required for all human subject research only. Patient information sheet is a document containing information about a research intended for prospective research subject. Informed consent form is a form to document subject’s consent to participate in the research.&quot;</td>
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<tr>
<td>4</td>
<td>Patient information sheet &amp; Informed Consent Form (BM)</td>
<td>Document No</td>
<td>Version No</td>
<td>Version Date</td>
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<tr>
<td></td>
<td>&quot;Required for all human subject research only. Patient information sheet is a document containing information about a research intended for prospective research subject. Informed consent form is a form to document subject’s consent to participate in the research.&quot;</td>
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<tr>
<td>5</td>
<td>Patient information sheet &amp; Informed Consent Form in other applicable languages</td>
<td>Document No</td>
<td>Version No</td>
<td>Version Date</td>
<td></td>
</tr>
<tr>
<td></td>
<td>&quot;Patient information sheet &amp; Informed Consent Form in other applicable languages (e.g. Mandarin, Tamil, etc). These must be accompanied by a signed and dated certification by a suitably qualified translator(s). In submitting the translation(s), sponsor(s) and investigator(s) accept full responsibility for the validity of the certified translation(s).&quot;</td>
<td></td>
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<tr>
<td>6</td>
<td>Study Clinical Report Form (CRF)</td>
<td>Document No</td>
<td>Version No</td>
<td>Version Date</td>
<td></td>
</tr>
<tr>
<td></td>
<td>&quot;Required where applicable only. Clinical Report form is a printed, optical, or electronic document used to record protocol required information for each subject in the study.&quot;</td>
<td></td>
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<tr>
<td>7</td>
<td>Patient’s diary</td>
<td>Document No</td>
<td>Version No</td>
<td>Version Date</td>
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<td></td>
<td>&quot;Required where applicable only. A patient takes the medication according to the treatment schedule will measure treatment compliance.&quot;</td>
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<tr>
<td>8</td>
<td>Questionnaire</td>
<td>Document No</td>
<td>Version No</td>
<td>Version Date</td>
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<tr>
<td></td>
<td>&quot;Required where applicable only. Questionnaire that will be distributed to respondents or patients during research conducted.&quot;</td>
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</tr>
</tbody>
</table>
c) Click on [Choose File] and browse for the file in your


d) Note that you have to enter the Document No, Version No and Version Date. If your document does not have any of the following, please follow this guide to enter value: (Figure 2.2.2)

Document No = 1
Version No = 1
Version Date = Date of Document Uploaded

![Figure 2.2.2]

e) Click on [Attach File] to attach the specific file and wait until a red PDF icon appears.

f) If the icon display in the PDF column. It indicates that the file is still being converted to PDF file.

g) Click F5 button on your keyboard OR click on Refresh until all the PDF has been successfully converted and you observe that the PDF icon has changed from grey to red. You may click the icon to view the file.

h) Repeat the above steps until you have uploaded all the necessary documents.

i) Click on [Update] to update data and [Next] or [Back] to go to the main page.

j) NOTE: if you did not submit one or more of the documents that are applicable to your research, please explain in the text box.
NOTES : After you have uploaded a type of document (eg. Proposal, CV), the document will be automatically uploaded where the same type of document is required in other submissions.

Step 3

a) These are the investigator's documents you will need to submit for the NIH approval: *(Please refer to NMRR Glossary or unfamiliar term)*
   - Investigator Agreement, Head of Department and Institutional Form (IA-HOD-IA)
     *(You may get this form under column Pre-filled IA-HOD-IA. Click the PDF icon and save OR print the form)*
   - Professional Indemnity *(Applicable for Clinical Trial ONLY)*
   - Curriculum Vitae (CV) OR resume
   - Good Clinical Practice (GCP) Certificate

b) Click on **Upload Investigator’s Documents**, Note that the system will only convert file from .doc .xls .html .htm .jpg .gif .txt .pdf and avoid using symbols (/, ^, @, #,) in file name.
   *(Figure 2.2.3)*

c) Click on **Choose File** and browse for the file in your

d) Click on **Attach File** to attach the specific file and wait until a red PDF icon appears.

e) If the icon display in the PDF column. It indicates that the file is being converted to PDF file.
f) Click F5 button on your keyboard or click on Refresh until all the PDF has been successfully converted and observe that the PDF icon has changed from grey to red. You may click the icon to view the file.

g) Repeat the above until you have uploaded all the necessary documents.

h) Click on Update to update data and Next or Back to go to the main page.

NOTES: After you have uploaded a type of document (e.g., Proposal, CV), the document will be automatically uploaded where the same type of document is required in other submissions.

Step 4

a) Click on Build PDF File to build the PDF file from all the documents you uploaded and make sure this icon will appear. It approves that your files have been converted into PDF. (Figure 2.2.4)

Step 5

a) Click on Approve Submission to send your research submission to NIH Institutes for approval (Figure 2.2.4)
9.2 Research Submission to NIH for MREC Review and Approval

1. Purpose of Research Submission to NIH for MOH Research Ethics Committee (MREC) Review and Approval to request ethics approval for a research. This is compulsory for research that involves human subject, research conducted in MOH sites and research requires/gathers data from MOH patients or personnel.

2. NOTES FOR STUDENTS: If you are doing research involving human subjects inside your university, please get the approval letter from Ethics Committee in the university (if any)

**Step 1**

a) Click any of the boxes that you feel necessary

b) Note that MREC provides ethical approval in three different method:
   i. Full board meeting (priority for Clinical Trial Interventional)
   ii. Expedited Review
   iii. Exemption from ethical review

c) You may choose type of MREC review process and click on [Update]. However, MREC Secretariats have the right to issue type of approval towards the applied research

![Image](image-url)
Step 2

a) You will need to type in cover letter for your submission

b) The letter should be addressed to NIH Secretariat. State in your purpose of submission and list of documents attach for us

c) Then click on Update.

Step 3

a) These are the research documents you will need to submit for the NIH approval:
(Please refer to NMRR Glossary or unfamiliar term)
   i. Covering Letter to MREC [COMPULSORY]
   ii. Study protocol and study amendment
   iii. Investigator’s brochure
   iv. Patient information Sheet and Informed Consent Form (English)
   v. Patient information Sheet and Informed Consent Form (BM)
   vi. Patient information sheet & Informed Consent Form in other applicable language (Mandarin, Tamil etc)
      These must be accompanied by a signed and dated certification by a suitably qualified translator(s). In submitting the translation(s), sponsor(s) and investigator(s) accept full responsibility for the validity of the certified translation(s)
   vii. Study CRF / Questionnaire / Patient’s diary
   viii. Advertisement for subject recruitment
   ix. Trial indemnification : Insurance / Letter of indemnity
   x. Research Agreement / Clinical Trial Agreement (CTA)

b) Click on Upload Research's Documents. Note that the system will only convert file from .doc .xls .html .htm .jpg .gif .txt .pdf and avoid using symbols (/ , ^, @, #,) in file name (Figure 2.2.6)

c) Click on Choose File and browse for the file.

d) Note that you have to enter the Document No, Version No and Version Date. If your document does not have any of the following, please follow this guide to enter value:
   Document No = 1
   Version No = 1
   Version Date = Date of Document Uploaded

e) Click on Attach File to attach the specific file and wait until a red PDF icon appears.

f) If the icon display in the PDF column. It indicates that the file is still being converted to PDF file.
Step 3

The table below lists the documents that will be required. Please click on the "Upload Research's Documents" to attach the required documents.

<table>
<thead>
<tr>
<th>No.</th>
<th>Items</th>
<th>Version</th>
<th>Date uploaded</th>
<th>File Name</th>
<th>PDF</th>
</tr>
</thead>
<tbody>
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<td>Covering Letter to MREC</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>* Required for MREC approval - Please list all investigators and their roles, participating sites and all documents for MREC approval. Please state reasons if any waiver is requested. Note: This is a formal signed cover letter from the Principal Investigator to the MREC Secretary.</td>
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</tr>
<tr>
<td>2</td>
<td>Study Protocol or Protocol amendment</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>* Required for all research except for submission for grant funding where a proposal document is sufficient. A comprehensive and detailed document that describes the objectives, design, methodology, statistical considerations, and organization of a research.</td>
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<tr>
<td>3</td>
<td>Study Proposal</td>
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<td></td>
<td>* Required if no protocol is submitted</td>
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<tr>
<td></td>
<td>A brief document that describes the rationale, objectives, design, methodology, statistical considerations, and organization of a proposed research.</td>
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<tr>
<td>4</td>
<td>Investigator's brochure</td>
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<td></td>
<td>* Required for clinical trial only</td>
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<tr>
<td></td>
<td>A compilation of the clinical and non-clinical data on the investigational product(s) which is relevant to the study of the investigational product(s) in human subjects (ICH GCP 1.56)</td>
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</tr>
<tr>
<td>5</td>
<td>Patient information sheet (English) &amp; Informed Consent Form (English)</td>
<td></td>
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<td></td>
<td></td>
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<tr>
<td></td>
<td>* Required for all human subject research only</td>
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<tr>
<td></td>
<td>Patient information sheet is a document containing information about a research intended for prospective research subject. Informed consent form is a form to document subject's consent to participate in the research.</td>
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<tr>
<td>6</td>
<td>Patient information sheet (BM) &amp; Informed Consent Form (BM)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>* Required for all human subject research only</td>
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</tr>
<tr>
<td></td>
<td>Patient information sheet is a document containing information about a research intended for prospective research subject. Informed consent form is a form to document subject's consent to participate in the research.</td>
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</table>

Figure 2.2.6

g) Click F5 button on your keyboard or click on Refresh until all the PDF has been successfully converted and you observe that the PDF icon has changed from grey to red. You may click the icon to view the file.

h) Repeat the above until you have uploaded all the necessary documents.

i) Click on Update to update data and Next or Back to go to the main page.

j) Note that if you did not submit one or more of the documents that are applicable to your research, please explain in the text box.

NOTES: After you have uploaded a type of document (eg. Proposal, CV), the document will be automatically uploaded where the same type of document is required in other submissions.

Step 4

a) These are the investigator’s documents you will need to submit for the NIH approval: (Please refer to NMRR Glossary or unfamiliar term)
   a. Investigator Agreement, Head of Department and Institutional Form (IA-HOD-IA)
      (You may get this form under column Pre-filled IA-HOD-IA. Click the PDF icon and save the form)
   b. Professional Indemnity
      (Applicable for Clinical Trial especially industry Sponsored Study)
   c. Curriculum Vitae (CV) OR resume
   d. Good Clinical Practice (GCP) Certificate
Step 4

The table below lists the investigator’s documents that will be required. Please click on **Upload Investigator’s Documents** to attach the required documents.

- IA-HOD-IA - Investigator’s Agreement
- CV - Curriculum Vitae
- GCP - Good Clinical Practice certification
- GCP Grandfather Status - refers to those junior investigators who were granted special exemption from GCP certification by the Director General of Health

<table>
<thead>
<tr>
<th>No</th>
<th>Investigator Name</th>
<th>Institution</th>
<th>Professional Indemnity</th>
<th>CV</th>
<th>GCP</th>
<th>GCP Grandfather Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Nur Rahilah Binti Haji Abd Rahman</td>
<td>Clinical Research Centre, Kuala Lumpur Hospital</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Note that after you have uploaded a type of document (e.g., CV), the document will be automatically uploaded where the same type of document is required in other submissions.

*Figure 2.2.7*

b) Click on **Upload Investigator’s Documents**. Note that the system will only convert file from `.doc .xls .html .htm .jpg .gif .txt .pdf` and avoid using symbols `(/, ^, @, #,)` in file name. *(Figure 2.2.7)*

i) If the icon 📄 display in the PDF column. It indicates that the file is being converted to PDF file.

j) Click F5 button on your keyboard or click on Refresh until all the PDF has been successfully converted and you observe that the PDF icon has changed from grey to red. 📄 You may click the icon to view the file.

k) Repeat the above until you have uploaded all the necessary documents.

l) Click on **Update** to update data and **Next** or **Back** to go to the main page.

NOTES: After you have uploaded a type of document (e.g., Proposal, CV), the document will be automatically uploaded where the same type of document is required in other submissions.

**Step 5**

a) Click on **Build PDF File** to build the PDF file from all the documents you uploaded and make sure this icon 📄 will appear. It approves that your files have been converted into PDF extension.

**Step 6**

a) Click on **Approve Submission** to send your research submission to NIH Institutes for approval
9.3 Research Submission to NIH for MRG Application

1. This section is for investigators whom wish to request and apply grant/funding/sponsor from Ministry of Health (MOH).

2. Mainly, only research done in the MOH facilities and involving MOH residents (including patients) will be funded by MOH.

**Step 1**

a) Please provide the following information about your proposed research (** required to fill in)

i. CAM Disease / Cross Cutting **
   Please visit www.nih.gov.my for more details. These are the areas of priority areas for health research in year 2010:
   - Cancer
   - Cerebrovascular Disease and Stroke
   - Diabetes Mellitus
   - Infectious Diseases
   - Ischaemic Heart Disease
   - Mental Illnesses
   - Respiratory Illnesses
   - Road Traffic Injuries
   - Health Policy and Systems
   - Medical Biotechnology
   - Pharmaceuticals and Medical Devices

ii. Research Scope **
   Please visit www.nih.gov.my for more details

iii. Relative rank **
iv. Direct customers / beneficiaries of the project **
v. Outputs expected from the project **
vi. Factors **

vii. Technical risk **
viii. Budget Risk **
ix. Anticipated date Started **
x. Duration (in months) **
xi. Project Status **

xii. Modification of previous project
xiii. Extension of previous project

b) Click on Update to update all your documents for submissions.

**Step 2**

a) You are required to fill in the Costing Worksheet

b) Click on Costing Worksheet and new page will appear (Figure 2.2.8)
c) Fill in the amount of cost in the costing worksheet

![Costing Worksheet]

The table below shows the estimates of your research costing. Please fill in the Costing Worksheet and check the data below.

<table>
<thead>
<tr>
<th>Cost category</th>
<th>Total RM</th>
<th>RM</th>
<th>RM</th>
<th>RM</th>
</tr>
</thead>
<tbody>
<tr>
<td>OS21000: Travel &amp; Transportation (In Country)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>OS22000: Travel &amp; Transportation (Overseas)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>OS24000: Rentals</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>OS25000: Raw Materials</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>OS27000: Research materials and Supplies</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>OS29000: Special services</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>OS29000: Temporary &amp; contract personnel</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>OS35000: Special equipment and Accessory</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>OTHERS (Please list as OS)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

![Disbursement Schedule]

<table>
<thead>
<tr>
<th>Department Organization</th>
<th>Total Cost</th>
<th>Year Cost</th>
<th>Year Cost</th>
<th>Year Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>TOTAL</strong></td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
</tr>
</tbody>
</table>

Costing Details

Please use Appendix B of JTP/KKM-3ver1 form, Please click [Add] for the sample.

1. [Appendix Costing Details File Path]
2. [Appendix Costing Details Uploaded by]
3. [Appendix Costing Details Uploaded Date Time]

Figure 2.2.8

d) To add other Department Organization in the Disbursement Schedule, click on [Add]. Then, key in your data. To remove the Department Organization, click on [Remove].

e) Please upload the soft copy of Appendix B in the JTP/KKM-3ver1 form that has been completed. (Figure 2.2.9)

f) Key in all the amount/data needed and click on [Calculate & Update] to total the amount and [Next] or [Back] to go back to the main menu.
Step 3

a) You will need to type in cover letter for your submission

b) The letter should be address to MRG Secretariat. State in your purpose of submission and list of documents attached for the secretariat

c) Then click on Update

Step 4

a) Please upload all the documents required for MRG application
   i. Study Proposal
   ii. Research Grant : Costing Worksheet
   iii. Project Activity

b) Click on Upload Research’s Documents. Note that the system will only convert file from .doc .xls .html .htm .jpg .gif .txt .pdf and avoid using symbols (/, ^, @, #) in file name.
   (Figure 2.2.10)
c) Click on [Choose File] and browse for the file.

d) Note that you have to enter the Document No, Version No and Version Date. If your document does not have any of the following, please follow this guide to enter value:
- Document No = 1
- Version No = 1
- Version Date = Date of Document Uploaded

e) Click on [Attach File] to attach the specific file and wait until a red PDF icon appears.

f) If the icon [display in the PDF column. It indicates that the file is converted to PDF file.

g) Click F5 button on your keyboard or click on Refresh until all the PDF has been successfully converted and you observe that the PDF icon has changed from grey to red. You may click the icon to view the file.

h) Repeat the above until you have uploaded all the necessary documents.

i) Click on [Update] to update data and [Next] or [Back] to go to the main page.

j) Note that if you did not submit one or more of the documents that are applicable to your research, please explain in the text box.

NOTES: After you have uploaded a type of document (eg. CV), the document will be automatically uploaded where the same type of document is required in other submissions.
**Step 5**

a) These are the investigator's documents you will need to submit for the NIH approval: *(Please refer to NMRR Glossary or unfamiliar term)*

i. Investigator Agreement, Head of Department and Institutional Form (IA-HOD-IA)
   
   *(You may get this form under column Pre-filled IA-HOD-IA. Click the PDF icon and save the form)*

ii. Professional Indemnity
   
   *(Applicable for Clinical Trial especially industry Sponsored Study)*

iii. Curriculum Vitae (CV) OR resume

iv. Good Clinical Practice (GCP) Certificate

b) Click on **Upload Investigator's Documents**. Note that the system will only convert file from *.doc *.xls *.html *.jpg *.gif *.txt *.pdf and avoid using symbols (/, ^, @, #,) in file name. *(Figure 2.2.11)*

c) If the icon display in the PDF column. It indicates that the file is still in the process of being converted to PDF file.

d) Click F5 button on your keyboard or click on Refresh until all the PDF has been successfully converted and you observe that the PDF icon has changed from grey to red. ![icon]

You may click to view the file.

e) Repeat the above steps until you have uploaded all the necessary documents.

f) Click on **Update** to update data and **Next** or **Back** to go to the main page.

**NOTES :** After you have uploaded a type of document (eg. CV), the document will be automatically uploaded where the same type of document is required in other submissions.

**Step 5**

---

*The table below lists the Investigator's documents that will be required.*

Please click on **Upload Investigator's Documents** to attach the required documents.

* IA-HOD-IA - Investigator's Agreement, Head of Department and Institutional Approval document
* Professional Indemnity - Professional indemnity refers to insurance or letter from investigators or CRC to indemnify (legal and financial coverage) the sponsor and institution against claims arising from the trial due to professional malpractice and/or negligence of the investigator
* CV - Curriculum vitae
* GCP - Good Clinical Practice certification
* GCP Grandfather Status - refers to those senior investigators who were granted special exemption from GCP certification by the Director General of Health

<table>
<thead>
<tr>
<th>No</th>
<th>Investigator Name</th>
<th>IA-HOD-IA</th>
<th>Professional Indemnity</th>
<th>CV</th>
<th>GCP</th>
<th>GCP Grandfather Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Nor Rahiah Binti Haji Abd Rahman</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Institution</td>
<td>Clinical Research Centre, Kuala Lumpur Hospital</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Role</td>
<td>Principal / Coordinating Investigator</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Note that after you have uploaded a type of document (eg. CV), the document will be automatically uploaded where the same type of document is required in other submissions.

*(Figure 2.2.11)*
**Step 6**

a) Click on [Build PDF File](#) to build the PDF file from all the documents you uploaded and make sure this icon ![PDF](#) will appear. It approves that your files have been converted into PDF extension.

**Step 7**

a) Click on [Approve Submission](#) to send your research submission to NIH Institutes for approval
9.4 Research Publication Submission to NIH for DG Approval

1. This section is applicable for DG Approval on publication and presentation.

   **Step 1**

   a) Click **Add/Remove Author** to select or remove author of the publication. (*Figure 2.2.12*)

   b) Then, type in all the data required in table boxes:
      i. Publication Title
      ii. Title of Target journal (manuscript)
      iii. Title of Meeting (For abstract intend for meeting)
      iv. Select potential targeted users

   c) Click on [Update] to update all the information you have keyed in.

   ![Figure 2.2.12](image)

   **Step 2**

   a) You will need to type in cover letter for your submission

   b) The letter should be address to NIH Secretariat. State in your purpose of submission and list of documents attach for us

   c) Then click on [Update]
Step 3

The table below lists the documents that will be required. Please upload the required documents.

<table>
<thead>
<tr>
<th>No.</th>
<th>Items</th>
<th>Version</th>
<th>Date uploaded</th>
<th>File Name</th>
<th>PDF</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Study Protocol or Protocol amendment</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Draft of research report, manuscript or abstract #1</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>3</td>
<td>Draft of research report, manuscript or abstract #2</td>
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<tr>
<td>4</td>
<td>Draft of research report, manuscript or abstract #3</td>
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<td>5</td>
<td>Draft of research report, manuscript or abstract #4</td>
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<td>Draft of research report, manuscript or abstract #5</td>
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<td>Draft of research report, manuscript or abstract #8</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Figure 2.2.13

a) Please upload all the documents required for MRG application
   i. Study Protocol
   ii. Draft of Research Report, Manuscript and Abstract
      (You can upload until 10 items)

b) Click on **Upload Research’s Documents**. Note that the system will only convert file from .doc .xls .html .htm .jpg .gif .txt .pdf and avoid using symbols (/, ^, @, #,) in file name (Figure 2.2.13)

c) Click on **Choose File** and browse for the file

d) Note that you have to enter the **Document No, Version No and Version Date**. If your document does not have any of the following, please follow this guide to enter value:
   a. **Document No = 1**
   b. **Version No = 1**
   c. **Version Date = Date of Document Uploaded**

e) Click on **Attach File** to attach the specific file and wait until a red PDF icon appears.
f) If the icon 📄 display in the PDF column. It indicates that the file is being converted to PDF file.

g) Click F5 button on your keyboard or click on Refresh until all the PDF has been successfully converted and you observe that the PDF icon has changed from grey to red. 📄 You may click the icon to view the file.

h) Repeat the above steps until you have uploaded all the necessary documents.

i) Click on Update to update data and Next or Back to go to the main page.

j) Note that if you did not submit one or more of the documents that are applicable to your research, please explain in the text box.

NOTES : After you have uploaded a type of document (eg. CV), the document will be automatically uploaded where the same type of document is required in other submissions.

Step 4

a) Click on Build PDF File to build the PDF file from all the documents you uploaded and make sure this icon 📄 will appear. It approves that your files have been converted into PDF extension.

Step 5

a) Click on Approve Submission to send your research submission to NIH Institutes for approval.

Figure 2.2.14
9.5 Research Notification to Other IRBs/IECs

1. For students or researchers from university, you will need to notify your University Ethics Committee once you register in NMRR.

2. You will see PDF icon on Submitted PDF During Registration column.

3. If the icon does not appear, click F5 or refresh until it appears.

4. Click on **Send Notification** to notify other IRB/IECs you selected (*Figure 2.2.15*)
9.6 Research Notification to Clinical Trials & Compliance Section to NPCB

1. This section is to notify National Pharmaceutical Control Bureau (NPCB) related to the Clinical Trial Import License (CTIL) and Clinical Trial Application (CTA) procedure. This is important for researchers/entrepreneur who wants to import new drugs into this country.

2. Starting from 1 January 2010, NPCB has made NMRR ID as a compulsory in applying CTIL/CTX. However, all the documents related to CTIL/CTX application must be submitted manually to National Pharmaceutical Control Bureau (NPCB) according to their procedure.

3. Fill in all the data that needs to be included by following the steps

   **Step 1**
   
   a) You will need to type in cover letter for your submission
   
   b) The letter should be address to MRG Secretariat. State in your purpose of submission and list of documents attach for us
   
   c) Then click on **Update**

   **Step 2**
   
   a) Please upload all the documents required for MRG application
   
      i. Protocol signature page (Annex A)
      
      ii. IRB/IEC Approval Letter (submit upon receipt)

---

**Figure 2.2.16**

The table below lists the documents that will be required when you upload the required documents.

<table>
<thead>
<tr>
<th>No.</th>
<th>Name</th>
<th>Document No.</th>
<th>Version No.</th>
<th>Version Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Protocol signature page (Annex A)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>IRB/IEC Approval Letter (submit upon receipt)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Note that after you have uploaded a type of document (e.g., Protocol), the document will be automatically uploaded where the same type of document is required in other submissions.

---

**Investigator Information**

<table>
<thead>
<tr>
<th>Investigator Name</th>
<th>Institution</th>
<th>Professional Information</th>
<th>CV</th>
<th>GCP</th>
<th>Grandfather Station</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dr. John Doe</td>
<td>Hospital A</td>
<td>Professional</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Note that after you have uploaded a type of document (e.g., CV), the document will be automatically uploaded where the same type of document is required in other submissions.
b) Click on **Upload Research's Documents**. Note that the system will only convert file from .doc .xls .html .htm .jpg .gif .txt .pdf and avoid using symbols (/, ^, @, #,) in file name.

c) Click on **Choose File** and browse for the file in your

d) Note that you have to enter the **Document No, Version No** and **Version Date**. If your document does not have any of the following, please follow this guide to enter value:
   - **Document No** = 1
   - **Version No** = 1
   - **Version Date** = **Date of Document Uploaded**

e) Click on **Attach File** to attach the specific file and wait until a red PDF icon appears.

f) If the icon display in the PDF column. It indicates that the file is still being converted to PDF file.

g) Click F5 button on your keyboard or click on Refresh until all the PDF has been successfully converted and you observe that the PDF icon has changed from grey to red. You may click the icon to view the file.

h) Repeat the above until you have uploaded all the necessary documents.

i) Click on **Update** to update data and **Next** or **Back** to go to the main page.

j) Note that if you did not submit one or more of the documents that are applicable to your research, please explain in the text box.

**NOTES**: After you have uploaded a type of document (eg. CV), the document will be automatically uploaded where the same type of document is required in other submissions.

**Step 3**

a) These are the investigator's documents you will need to submit for the NIH approval: (*Please refer to NMRR Glossary or unfamiliar term*)
   a. Investigator Agreement, Head of Department and Institutional Form (IA-HOD-IA)
      *(You may get this form here, under column Pre-filled IA-HOD-IA. Click the PDF icon and save the form)*
   b. Professional Indemnity
      *(Applicable for Clinical Trial especially industry Sponsored Study)*
   c. Curriculum Vitae (CV) OR resume
   d. Good Clinical Practice (GCP) Certificate
b) Click on **Upload Investigator’s Documents**. Note that the system will only convert file from .doc .xls .html .jpg .gif .txt .pdf and avoid using symbols (/^@,#,) in file name.  
*Figure 2.2.7*

c) If the icon 📦 display in the PDF column. It indicates that the file is still in the process of being converted to PDF file.

d) Click F5 button on your keyboard or click on Refresh until all the PDF has been successfully converted and you observe that the PDF icon has changed from grey to red. 📦 You may click to view the file.

e) Repeat the above until you have uploaded all the necessary documents.

f) Click on **Update** to update data and **Next** or **Back** to go to the main page.

**NOTES:** After you have uploaded a type of document (e.g., CV), the document will be automatically uploaded where the same type of document is required in other submissions.

**Step 4**

a) Click on **Build PDF file** to build the PDF file from all the documents you uploaded and make sure this icon 📦 will appear. It approves that your files have been converted into PDF extension.

**Step 5**

a) Click on **Approve Submission** to send your research submission to NIH Institutes for approval
CHAPTER 3: Procedure in Re-submission and Amendment

3.0 Making Re-submission of Research Application

1. Note that this new version (Version 4.0), user can ONLY make Request to Re-submit in Stage 1. After your application reach Stage 2 or Stage 3, you will have to wait for the approval authority decision in order to make any changes in the documents or data.

2. Click on [Submissions being processed (Pending review & decision)] to view your completed Research Registration and Submission. (Figure 2.2.17)

3. Click on [Request to Re-submit]

4. Enter the reason of your re-submission and click on [Save] (Figure 2.2.18)

5. User will get an email notification once the NMRR Secretariat approve the request

6. Once user received an email notification by secretariat, user can view your research re-submission in [Incomplete submissions awaiting resubmission by CP]

7. Click on [View/Edit submission] to make amendments on the data and documents. (Figure 2.2.19)

8. Click on [Build PDF File] to build the PDF file from all the documents you uploaded and make sure this icon will appear. It approves that your files have been converted into PDF extension.
9. Please open the file by clicking the icon 📄 and make sure you build the PDF file from the new data or documents you entered.

10. Click on 📄 to build the PDF file from all the documents you uploaded and make sure this icon 📄 will appear. It approves that your files have been converted into PDF extension.

11. Please open the file by clicking the icon 📄 and make sure the built PDF file includes the new data or documents you entered.

12. Click on Approve Submission to approve your research submission to NIH Institutes for approval.

13. Check your email sent by NMRR with subject title 'National Medical Research Register acknowledge research registration and submission'
3.1 Making Amendments for MREC Documents

1. Note that this new version (Version 4.0), user can make amendments in the Stage 3 after your application received the approval from MREC

2. In Stage 2, click on [Submissions with a Final Decision] to view your research that has final decision by the approval authority. *(Figure 2.2.20)*

3. Click on [Request for Amendment]

4. Enter the reason of your re-submission and click on [Save] *(Figure 2.2.21)*

5. User will get an email notification once the NMRR Secretariat approve the request

6. Once user received an email notification by secretariat, user can view your research re-submission in [Submissions needing Amendment (Pending resubmission by CP)]

7. Click on [View/Edit submission] to make amendments on the data and documents. *(Figure 2.2.22)*

8. Click on [Build PDF file] to build the PDF file from all the documents you uploaded and make sure this icon  will appear. It approves that your files have been converted into PDF extension.
Public User Module

Submissions with a Final Decision

<table>
<thead>
<tr>
<th>No.</th>
<th>Research ID</th>
<th>Approval Type</th>
<th>Action</th>
<th>Research Title Abbreviation</th>
<th>Correspondence</th>
<th>Initial Submission Date By CP</th>
<th>Last Submission Date By CP</th>
<th>Date Accepted By RECR</th>
<th>Submission Decision History</th>
<th>Test Label</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>6063</td>
<td>Ethics Approval - MRR/Research Ethics Committee</td>
<td>Request for Amendment</td>
<td>Malpractice in Medical Research (MRR)</td>
<td>#0004</td>
<td>23-04-2010</td>
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<td>23-04-2010</td>
<td>22-04-2010</td>
<td>History</td>
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<tr>
<td>2</td>
<td>6064</td>
<td>Ethics Approval - MRR/Research Ethics Committee</td>
<td>Re-submission</td>
<td>Research Registration</td>
<td>N/A</td>
<td>12-04-2010</td>
<td>11:09:05</td>
<td>Enter Reason</td>
<td>N/A</td>
<td>N/A</td>
</tr>
</tbody>
</table>

Figure 2.2.21

[Diagram of a user interface showing submitter decision process]

ENTER REASON
9. Please open the file by clicking the icon 📄 and make sure you build the PDF file from the new data or documents you entered.

10. Click on **Build PDF file** to build the PDF file from all the documents you uploaded and make sure this icon 📄 will appear. It approves that your files have been converted into PDF extension.

11. Please open the file by clicking the icon 📄 and make sure the built PDF file includes the new data or documents you entered.

12. Click on **Approve Submission** to send your research amendments to NIH Institutes for approval.

13. Check your email sent by NMRR with subject title 'National Medical Research Register acknowledge research registration and submission'
### 4.0 Buttons: Different picture on the buttons represent different Functionalities

<table>
<thead>
<tr>
<th>Button</th>
<th>Function</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="button_icon" alt="" /></td>
<td>To Edit/Update record</td>
</tr>
<tr>
<td><img src="button_icon" alt="" /></td>
<td>To view record / Search record</td>
</tr>
<tr>
<td><img src="button_icon" alt="" /></td>
<td>To delete record</td>
</tr>
<tr>
<td><strong>Select Investigator</strong></td>
<td>To select investigator's list</td>
</tr>
<tr>
<td><strong>Select Institution</strong></td>
<td>To select institution's list</td>
</tr>
<tr>
<td><strong>Select Sponsor or Contact Name</strong></td>
<td>To select contact name's list</td>
</tr>
<tr>
<td><strong>Clear Value</strong></td>
<td>To clear the data</td>
</tr>
<tr>
<td><strong>Select Sponsor</strong></td>
<td>To select sponsor</td>
</tr>
<tr>
<td><strong>Select Establishment</strong></td>
<td>To select establishment</td>
</tr>
<tr>
<td><strong>Select Project Staff</strong></td>
<td>To select project staff</td>
</tr>
<tr>
<td><strong>Show All</strong></td>
<td>Click “Show All” to show all records (ignoring any criteria entered)</td>
</tr>
<tr>
<td><strong>Show</strong></td>
<td>After entering selection criteria, click “show” to view all the records that fulfils the criteria entered.</td>
</tr>
<tr>
<td><strong>Change Password</strong></td>
<td>To change password</td>
</tr>
<tr>
<td><strong>Add</strong></td>
<td>To add record</td>
</tr>
<tr>
<td><strong>Update</strong></td>
<td>To update and save record</td>
</tr>
<tr>
<td><strong>Back</strong></td>
<td>To go back to previous page</td>
</tr>
<tr>
<td><strong>Submit</strong></td>
<td>To submit record</td>
</tr>
<tr>
<td><strong>Refresh Image</strong></td>
<td>To refresh image</td>
</tr>
<tr>
<td><strong>Build PDF File</strong></td>
<td>To convert file in PDF</td>
</tr>
<tr>
<td><strong>Approve Submission</strong></td>
<td>To submit to NMRR for approval</td>
</tr>
<tr>
<td><strong>Request for Amendment</strong></td>
<td>To request resubmission for make amendments</td>
</tr>
<tr>
<td><strong>Choose File</strong></td>
<td>To Browse file</td>
</tr>
<tr>
<td><strong>Attach File</strong></td>
<td>To attach browsed file</td>
</tr>
<tr>
<td><strong>Next</strong></td>
<td>To go next page</td>
</tr>
<tr>
<td>![check_box_icon]</td>
<td>This box indicated you may either check or uncheck for input. If the check box is empty (unchecked), click to check the box. If the check box is checked, click to uncheck the check box. This indicates multiple selections (you may check more than one box in the frame)</td>
</tr>
<tr>
<td>![enable_icon]</td>
<td>Indicate that note has enable</td>
</tr>
<tr>
<td>![disable_icon]</td>
<td>Indicate that note is disable</td>
</tr>
<tr>
<td>![editable_icon]</td>
<td>Non editable check box button</td>
</tr>
<tr>
<td>Non editable radio button</td>
<td>You may only select one input from the radio button choices. Click on to select the item.</td>
</tr>
<tr>
<td>---------------------------</td>
<td>--------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Dropdown List box</td>
<td>This box indicates you will have to select your input from the list. You may only select one in put from the list. Click on the arrow at the right hand side of the box. A list of choices will be available for your selection.</td>
</tr>
<tr>
<td>Editable text box</td>
<td>Text box that requires data entry.</td>
</tr>
<tr>
<td>Non editable text box</td>
<td>The box that does not allowed data entry. It may also be disabled due to value entered in another entry. Eg. If others is not checked, then other specify field will be disabled/ not editable.</td>
</tr>
<tr>
<td>Editable text box</td>
<td>Indicates for notification and</td>
</tr>
</tbody>
</table>
### 4.1 Sample of IA-HOD-IA form

**INVESTIGATOR'S AGREEMENT, HEAD OF DEPARTMENT'S AND INSTITUTIONAL APPROVAL**

**PERSETUJUAN PENYELIDIK, PENGESEHAN KETUA JABATAN DAN INSTITUSI**

This document is intended for online submission for purpose of formal research review and approval. It is to be used in lieu of other equivalent manually printed document such as Borang JTP-KKM 1-2 and Borang JTP-KKM 3. After completing the form below and obtaining the required signatures, please scan this document and submit online.

**Dokumen ini adalah untuk penghantaran atas tatalim (online) mengikut prosedur formal pengecualian dan persetujuan penyelidikan. Borang ini dikhaskan sebagai gantian dokumen kertas manual yang sepadan seperti Borang JTP-KKM 1-2 dan Borang JTP-KKM 3. Selepas melengkapkan borang di bawah dan mendapatkan semua isyarat yang diperlukan, sila mahuok dokumen ini dan bentar atas tatalim.**

#### Research Title:

[Tezikh Penyelidikan]

<table>
<thead>
<tr>
<th>Protocol Number if available</th>
<th>[Nomor Protokol jika ada]</th>
</tr>
</thead>
</table>

**Investigator agreement [Perjanjian penyelidik]**

I have understood the above titled proposed research and I agree to participate in the research as an investigator.

Saya faham cadangan penyelidik yang bertajuk di atas dan saya bersedia mengikuti bahagian dalam projek tersebut sebagai penyelidik.

<table>
<thead>
<tr>
<th>Name of Investigator</th>
<th>[Nama Penyelidik]</th>
</tr>
</thead>
<tbody>
<tr>
<td>IC number</td>
<td>[Nombor IC]</td>
</tr>
<tr>
<td>Institution</td>
<td>[Institusi]</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Signature &amp; Official stamp</th>
<th>[Tanda tangan dan Cap Razani]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date</td>
<td>[Tarikh]</td>
</tr>
</tbody>
</table>

**Head of Department Agreement [Perjanjian Ketua Jabatan]**

I agree to allow the above named investigator to conduct or to participate in the above titled research.

Saya membenarkan pegawai yang bernama di atas untuk membantu penyelidik dalam projek penyelidik tersebut di atas.

<table>
<thead>
<tr>
<th>Name of Head</th>
<th>[Nama Ketua]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name of Department and Institution</td>
<td>[Jabatan dan Institusi]</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Signature &amp; Official stamp</th>
<th>[Tanda tangan dan Cap Razani]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date</td>
<td>[Tarikh]</td>
</tr>
</tbody>
</table>

**Institutional approval [Pengekalan Institusi]**

This section may be omitted if any of the NIH institute is authorized to approve on behalf of institution. Refer NIH for details. [Bahagian ini boleh dihapus jika salah dan daripada institusi NIH diberi kuasa pengekalan atas sukaran institusi tersebut. Rujuk NIH untuk maklumat lanjut]

I agree to allow the investigator(s) named above to conduct or to participate in the above titled research. Where applicable, I further agree to allow my institution to be one of the sites participating in the research.

Saya membenarkan pegawai yang bernama di atas mengikuti pengekalan selaku penyelidik dalam projek penyelidik tersebut. Jika sesuai, saya juga membenarkan institusi ini mengambil bahagian dalam projek tersebut.

<table>
<thead>
<tr>
<th>Name of Director (Nama pegawai)</th>
<th>[Nama pegawai]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name of Institution (Nama institusi)</td>
<td>[Nama institusi]</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Signature &amp; Official stamp</th>
<th>[Tanda tangan dan Cap Razani]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date</td>
<td>[Tarikh]</td>
</tr>
</tbody>
</table>
4.2 **Sample of NIH Approval**

**NATIONAL INSTITUTE OF HEALTH’S APPROVAL FOR CONDUCTING RESEARCH IN THE MINISTRY OF HEALTH MALAYSIA**

This is an auto computer-generated document. It is issued by one of the research institute under the National Institutes of Health (NIH). These are the Institute for Medical Research (IMR), Clinical Research Centre (CRC), Institute of Public Health (IPH), Institute for Health Management (IHM), Institute for Health Systems Research (IHSR) and Institute for Health Behavioural Research (IHBR).

**Dokumen ini adalah cetakan berkomputer. Borang ini disediakan oleh salah satu insitut dibawah National Institutes of Health (NIH) iaitu Institut Penyelidikan Penubatan (IMR), Pusat Penyelidikan Klinikal (CRC), Institut Kesihatan Umum (IKU), Institut Pengurusan Kesihatan (IPK), Institut Pengurusan Sistem Kesihatan (IPS), Institut Penyelidikan Kesejahteraan Kesihatan (IPK).

| Unique NMRR Registration ID | [NMR ID field] |
| Research Title | [Research title field] |
| Protocol Number if available | [Protocol ID field] |

<table>
<thead>
<tr>
<th>#</th>
<th>Investigator Name</th>
<th>Institution Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>[Name of investigator]</td>
<td>[Name of Institution]</td>
</tr>
<tr>
<td>2.</td>
<td>[Name of investigator]</td>
<td>[Name of Institution]</td>
</tr>
<tr>
<td>3.</td>
<td>[Name of investigator]</td>
<td>[Name of Institution]</td>
</tr>
</tbody>
</table>

I have reviewed the above titled research and approve of its design and conduct.

**Saya telah menyesak kajian yang beringkait seperti di atas dan meluluskan reka bentuk dan pelaksanaannya.**

| Name of Director | [Nama pengarah] |
| NIH Institute (IMR, CRC, IPH, IHM, IHSR and IHBR) | [Nama institusi dalam NIH] |
| Signature & Official Stamp | [Tanda tangani dan Cakera] |
| Date | [Tarihi] |
4.3 Sample of MREC Approval Letter

MEDICAL RESEARCH & ETHICS COMMITTEE
MINISTRY OF HEALTH MALAYSIA
(7)dlm.KKM/NIHSEC/08/XXX/PXX-X
22 July 2009

Investigators’ Names
Investigators’ Address

Protocol Title:
E.g. : A Randomized, Controlled and Double Blind Study of Extraction from Cucumber

Protocol No.: 1568364xx

Documents received and reviewed with reference to the above study:

The Medical Research & Ethics Committee, Ministry of Health Malaysia operates in accordance to the International Conference of Harmonization Good Clinical Practice Guidelines.

Project Sites: Hospital Sultanah Aminah, Hospital Pulau Pinang, Hospital Kuala Lumpur

Decision by Medical Research & Ethics Committee:
(√) Approved
( ) Conditionally Approved
( ) Disapproved

Date of Approval: 22 July 2009

Chairman
Medical Research & Ethics Committee
Ministry of Health Malaysia