

Version 2.1
9 September 2009

Instruction for Users

Research registration and submission to NMRR

General instruction

- Submission of a research to NMRR for whatever purpose requires a user to provide information about the research.
- To submit the research, just click < Submit new research for registration, notification or approval > provides all required information online and click submit.
- Providing required information is done either by entering the required data or uploading required documents into the system.
- The simplest way to enter data is to copy and paste the text from your word processing package into the system.
- The Data Elements document define the data required and may be useful to help you capture the required data from other existing document such proposal, protocol, etc
- A required document is the “INVESTIGATOR’S AGREEMENT, HEAD OF DEPARTMENT’S AND INSTITUTIONAL APPROVAL (Version 2.0 15 Feb 2008) “. Download a prefilled forms from NMRR website. For each investigator, head of department or unit, and director of the institution (or applicable designee) that the study is going to be conduct, are required to sign and date this document. Then scan this signed and dated document and submit online in NMRR

Online registration is a simple 8 step process

- After clicking <Submit new research for registration, notification or approval >, just proceed step by step as described below
- After completing a step, just click <Update> or <Next> to move to next step.
- At any step, you may click <back> to move back one step
- You may also click any of the 8 steps listed on the left panel to move directly to that step
- If you encounter terms that you are not familiar, refer Data Elements document for definitions of these terms
- You do not have to complete all 8 steps in one session. Just do NOT click <Approve Research registration> in the last step and your registration will NOT be submitted yet. You can come back another day to complete the registration.

Step	Instructions
<p>1. Enter Title</p> <p>Purpose of submission on NMRR</p>	<p>Enter the research title (which is usually quite descriptive and long), and provide a short title too, in the text boxes.</p> <p>This is the first step where you may select relevant approving authority for specific purposes. Select the approval you require and the relevant approving authority. After completing a step, just click <Update> or <Next> to move to next step.</p>
<p>2. Select research type</p>	<p>Enter the Protocol number, specify the type of research (eg clinical, basic biomedical)</p> <p>For Clinical Research, also specify its subtype (eg clinical trial, epidemiology, economic study etc)</p>
<p>3. All research</p> <p>Clinical research</p> <p>Clinical trial</p> <p>Observational research</p>	<p>In the text boxes provide, enter information on “Research purpose, Research description, Keywords, Date start, Date completed, Link URL”.</p> <p>For clinical research, in the text boxes or where selections are provided, also provide information on “Recruitment status, Condition, Eligibility, Gender, Age limit, Acceptable Participant, Target Number of Subject”</p> <p>For clinical trial, also provide information on “Intervention, Intervention Type, Therapy Area, Study Phase, Purpose of Clinical trial, Allocation, Masking, Control treatment, Assignments, Endpoint and Outcome measure”</p> <p>For observational research, also provide information on “Purpose, Sample selection, Length of study, Timing of study”</p>

<p>4.Add/Drop sponsors</p>	<p>Provide information on sponsor of the research. Click <Add more sponsor>, enter the information, click <Add> and the sponsor will be added to a list below</p> <p>For each sponsor(s) specified above, you may, if you wish, enter one or more sponsor's contact person. Each person entered with email address will have access to view the research details in NMRR but will not be allowed to edit data, unless he or she is also the corresponding person (see Step 7 below)</p>
<p>5.Add/Drop investigators</p>	<p>Providing information on the Investigator(s) participating in this research is required for registration and submission. Click <Select Investigator>, and select the relevant investigator. Note that you can only select from list. The list comprises individuals who are registered on NMRR. So make sure all investigators participating in the research are registered before you may add them to the research as investigator. Then click <Add> and the investigator will be added to a list below Add as many investigators as necessary.</p>
<p>6.Add/Drop project staff</p>	<p>This is as in Step 5 above, except individuals added here are project staff supporting the research in various capacities, but are themselves not investigators. Add as many staff as necessary.</p>
<p>7.Add/Drop corresponding person</p>	<p>Select one person only to be the corresponding person for the research. Select this person from the list of sponsor contacts, OR investigators OR project staff. These are the individuals added in Step 4,5 and 6 above.</p>

	<p>Please note that only the Corresponding Person can update data and edit revisions. All others with email address may have access to the research but will not be allowed to edit data.</p>
<p>8. Research Registration</p>	<p>This is final step for registration and pre-step to submit for approval form authorities. Click <Build PDF file> button to create the PDF file for submission. The PDF file contains the data and documents that you have submitted in Step 1 to Step 7 above. This constitutes your submission file.</p> <p>Review the pdf file in Step 3, and if you are satisfied, click <Approve Research Registration> to register your research.</p>
<p>9. SUBMISSION FOR APPROVAL</p> <p>9.1 Research submission to NIH for approval</p> <p>9.2 Research submission to MoH Research and ethics Committee for MREC review & approval</p>	<p>This is the final step where you may provide relevant documents base on purpose of submission.</p> <p>This submission base on respective institutions to authorities' approval submission. All research involved MoH facilities and MoH Staff should submit to NIH for review the proposal and approved by assigned NIH institutions. Also, provide research documents [Covering Letter to NIH, Study Proposal, Study Protocol or Protocol amendment, Informed Consent Form (English/ BM/Mandarin/ Tamil), Patient information sheet (English BM/Mandarin/Tamil), Questionnaire] and investigator documents and investigator documents</p> <p>This submission applicable if the research involves human subjects (patients/ respondents) in researches or clinical trials. Also, provide research documents [Covering letter to MREC, Investigator's brochure, Study Proposal, Study Protocol</p>

<p>9.3 Research submission to NIH for MRG application</p> <p>9.4 Research publication submission to NIH for DG approval</p> <p>9.5 Research notification to other IRB/IECs</p> <p>9.6 Research notification to Clinical Trials & Compliance Section NPCB</p>	<p>or Protocol amendment, Informed Consent Form (English/ BM/Mandarin/ Tamil), Patient information sheet (English BM/Mandarin/Tamil), Questionnaire , Patients diary, Advertisement for subject recruitment (<i>if applicable</i>), Insurance: Clinical trial , Clinical Trial Agreement (CTA)]</p> <p>For requiring MoH funding from National Institutes of Health, also provide research documents [Covering Letter to NIH, Study Proposal, Grant Chart] and investigator documents</p> <p>For publication purpose, All research publication must have approval from the DG of Health. Also provide information on research finding documents [Cover letter to NIH, Draft of research report, manuscript or abstract (publication)]</p> <p>This notification applicable if the research conducted by academician or university student. You will still have to submit manually for CTIL/CTA application</p> <p>This notification on CTIL / CTX application to NPCB. Also provide research documents [Cover letter to MREC, Approval Letter of MREC/other IRBs, proposal signature page.] You will still have to submit manually for CTIL/CTA application</p>
<p>10. Research documents</p>	<p>A list of documents for submission is provided; not all which may be applicable for your research. Attached the required file, much as you normally attached a file in email</p>
<p>11. Investigator's documents</p>	<p>For each investigator listed, upload his or her</p>

	<ul style="list-style-type: none"> • Curriculum Vitae • GCP certificate (for Clinical Trial only) • Scanned copy “INVESTIGATOR’S AGREEMENT, HEAD OF DEPARTMENT’S AND INSTITUTIONAL APPROVAL (Version 2.0 15 Feb 2008)”, which have been signed and dated as appropriate • Professional Indemnity
<p>12. “Approve research submission”</p>	<p>This is applicable for all purpose of submission. There are parallel submissions to respective institutions that selected above.</p> <p>The PDF file contains the data and documents that you have submitted in Step 1 to Step 8 as well as step 9 above. This constitutes your submission file.</p> <p>Review the pdf file in Step 4, and if you are satisfied, click <Approve research Submission> to send the submission to the relevant approving authority. Note that after you have approved the submission :</p> <ul style="list-style-type: none"> • Any subsequent changes you made to your data or document is not updated to this file. You cannot update this file until you are instructed to re-submit or you may request to re-submit. • Only the title of the submitted research and where available the research's journal publication will be published in the NMRR Research Directory. Other details on the submitted research including all documents (except journal publication if submitted) and contacts (sponsors/ investigators) information however will NOT published