

## FREQUENTLY ASKED QUESTIONS

#	Frequently asked questions
1.	<p><b>What is a Clinical Trial?</b>  <b>A Clinical Trial is any researches that study the effects of a health care intervention in human subjects (patients or healthy volunteers). A ‘ health care intervention’ can be a drug, vaccine, surgical treatment, device, behavioral modification, preventive measure or process of care change, that would lead to a change in health-related outcome. All clinical trials need prospective registration in a Clinical Trial Registry.</b></p>
2.	<p><b>What is the NMRR?</b>  <b>The NMRR is a web-based integrated system accessible at <a href="http://www.nmrr.gov.my">www.nmrr.gov.my</a> that streamlines the application, review and approval process to conduct research in the MOH. Designed to simplify procedures, the system enables investigators to submit relevant documents to be reviewed by the respective authorities such as NIH and MREC. It is a not-for-profit Registry, with free and open access to researchers, clinicians, and the general public.</b></p>
3.	<p><b>Does the NMRR meet international requirements for a Trial Registry?</b>  <b>The NMRR is yet to be a recognised Primary Registry in the World Health Organisation International Clinical Trials Registry Platform (ICTRP) Registry Network or recognised by the International Committee of Medical Journal Editors (ICMJE). An application for recognition has been made to the WHO as the NMRR believes it complies with all the specified international requirements.</b></p>
4.	<p><b>When is NMRR likely to be compulsory?</b>  <b>NMRR is the preferred system for applying to the review bodies including MREC. From May 2007, NIH new guideline states that all research done from 2006 should be registered in NMRR</b></p>
5.	<p><b>Who manages the NMRR?</b>  <b>The appointed NMRR secretariats in all the NIH Institutes and MREC manage the NMRR.</b></p>
6.	<p><b>Who can access the NMRR?</b>  <b>The NMRR is an internet-based register, with worldwide free and open access to registered researchers, clinicians, and the general public.</b></p>

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7.	<b>Does the investigator or sponsor need to register with NMRR?</b> <b>Yes. All members of the research project should register stating their roles.</b>
8.	<b>Must all principal investigators and sub-investigators register with NMRR?</b> <b>For MREC submission, all principal investigators must be registered in the NMRR. Sub-investigators can be added later.</b>
9.	<b>What if a principal investigator is not registered in the NMRR- can the CRA register for him?</b> <b>Please get the PI to register himself in the NMRR</b>
10	<b>Should medical students submit their CV? Or only the supervisors / clinicians supervising the research have to do so?</b> <b>All investigators/researchers, and this applies to students as well, need to submit their CV</b>
11	<b>My supervisor has registered with NMRR but her name is not in the list of investigators. How is this so and what can we do to make her name visible in the name list?</b> <b>This is because your supervisor did not choose the Investigator role or chose a different role during registration. After verifying the email ID, your supervisor has to contact CRC to change his/her role.</b>
12	<b>If my supervisor did not register, may I register for them?</b> <b>You have to get him/her registered. You can do it for him/her if you have his/her email address, IC and HP numbers; with your supervisor's permission. He/She will get an email notification and password from the system and he/she can then update his/her user information as well as change the password.</b>
13	<b>Who can register a clinical trial with the NMRR?</b> <b>All investigators, from Malaysia, can register a clinical trial with the NMRR. The responsibility for registering a trial lies with the principal investigator or principal sponsor of the trial. For multi-centre trials, the lead principal investigator or lead sponsor should take the responsibility for registration.</b>

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14	<p><b>If there is more than one person from the same company likely to be involved in the submission for an application of research approval, should they use one common login and password, or should each of them have a separate log-in and password?</b></p> <p><b>This is an internal company decision. However, applicants must be aware, that using the same login and password for several people could result in a loss of control of the information in an application. Applications can be transferred to others for completion of different parts of an application or to permit review and collaboration</b></p>
15	<p><b>As the sponsor of the trial, can we complete all of the applications?</b></p> <p><b>Sponsors of trials may choose to support researchers by completing forms on their behalf. Where the PI is responsible for signing off the application to a particular review body, they should satisfy themselves that their application is accurate. The individual PI must also be in a position to communicate with the relevant review bodies on the application.</b></p>
16	<p><b>What training is being provided in the NMRR?</b></p> <p><b>NMRR is designed to be an intuitive system where all applicants can learn to use with the aid of comprehensive on-line guidance, supported by the Helpdesk and other published sources of advice on applications. A public user guideline is also available in the NMRR website.</b></p>

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17	<p><b>If the study involves tracing patient information from record files only, do they require ethics approval too?</b> <b>You should apply for an Ethic's approval (MREC) if your project contains any of the following:</b></p> <ul style="list-style-type: none"><li><b>a) Any studies with direct intervention (e.g. change of medication/management plan, invasive project )</b></li><li><b>b) Taking any samples (e.g. blood and tissues sample)</b></li><li><b>c) If there is any likelihood of causing physical or psychological harm (e.g. causing pain or anxiety)</b></li><li><b>d) If respondents may not be able to give informed consent (e.g. mental impairment/ disability/ children)</b></li><li><b>e) Observation of people without their knowledge (e.g. Hand-washing study)</b></li><li><b>f) All interviews or questionnaires administration.</b></li><li><b>g) All extraction and use of data from whatever sources (e.g. medical records, registries, and patient's database)</b></li><li><b>h) Respondents in other agencies/institution (e.g. army, school)</b></li></ul>
18	<p><b>How long is the process of obtaining approval using NMRR?</b> <b>NMRR provides the application for review by regulatory bodies. Each body has different timescale for review and approval. NMRR speeds up the overall process for researchers by eliminating duplication in form filling and encouraging parallel applications to review bodies. Completed submission will take 45 to 60 working days to obtain NIH and MREC approval.</b></p>

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19	<p><b>How long is the process to obtain approval by MREC using NMRR?</b> <b>Submission should be three (3) weeks prior to the next MREC meeting to ensure the submission is in queue for the upcoming meeting. MREC boardmembers meet every third (3rd) Tuesday of each month. Approval letter (if study is approved) will be issued within ten (10) working days after the MREC board meeting.</b></p>
20	<p><b>Does the 60 days timeline as described on the online ethics application form apply to NMRR?</b> <b>Yes. NMRR does not change the review timeline for ethics applications.</b></p>
21	<p><b>How long are the forms stored on NMRR for?</b> <b>Any forms you (corresponding person) generate will remain in your account until you delete them or arrange for them to be permanently transferred to another person.</b></p>
22	<p><b>Will I need to update trial information?</b> <b>All investigators are expected to update the trial information at regular intervals. They are required to provide a brief progress report at six months, one year, and every year thereafter until trial completion.</b></p>
23	<p><b>Can we submit hard copy documents to MREC if the sponsor does not allow online submission for certain study documents e.g. IB?</b> <b>No, this is not allowed.</b></p>
24	<p><b>What authorizations or signatures do I need for NMRR?</b> <b>Different authorizations are required in NMRR depending on the type of study and the review bodies that are applicable. Details of these are given within NMRR. NMRR does not change the requirements for review of any regulatory body or NIH organization.</b></p>

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25	<p>For the investigator approval letter that we need to get the signature of the head of department and the director of the hospital that we chose, does all investigators need to fill the form or only one of us?</p> <p><b>Each investigator has to sign the Investigator Agreement. The Head of Department (HOD) is the hospital HOD and not the HOD of the partner educational institution.</b></p>
26	<p>If the investigator is head of department too, does he/she need to sign both part: investigator agreement and HOD approval?</p> <p><b>Yes. The Investigator should sign in both as Investigator and head of Department.</b></p>
27	<p>How do I manage version control with different applications at different times for one project?</p> <p><b>The owner of the application controls who the data is transferred to for collaboration, authorization or review. Once an application has been printed for submission, any subsequent changes to data that has been previously submitted to a review body (even if in a different form for a different review body) will raise a warning in NMRR. The applicant will be warned that the changes may require an amendment to a previous submission.</b></p>
28	<p>What is GCP training certificate?</p> <p><b>GCP is Good Clinical Practice and is required for all investigators when you intend to do a Clinical Trial. For non-clinical trial, GCP certificate is not required.</b></p>
29	<p>Can I use NMRR for applications like grant applications?</p> <p><b>Currently, application for MOH grant is via NMRR. There are documents to provide information to funders and other review bodies.</b></p>
30	<p>Who can apply for NIH grant ?</p> <p><b>Only MOH staffs are eligible to apply for the research grant. For projects, which involve collaboration with non-MOH researchers, the principal investigator of the project must be a MOH staff.</b></p>