Institutional Review Board (DMR) submission processes

Dr Khin Hnin Pwint
Research Scientist (DMR)
Member of IRB, DMR

The research proposal must be submitted for consideration, comment, guidance and approval to the concerned REC before the study begins

The researcher must provide monitoring information to the committee, especially information about any serious adverse events (SAE)

The committee must have the right to monitor ongoing studies

Declaration of Helsinki – section 23

IRB Composition

- The Ministry of Health and Sports, Myanmar has *reformed* and *reorganized the structure* of ERC (DMR) as the 'Institutional Review Board' (DMR) in 2019
- 15 members with diverse expertise in biomedical, clinical, public health and social science.

  - Affiliated Member – 7
  - Non-affiliated member – 8
    - Community member – 2

IRB Process of Review

- Proposals will be **registered** when the complete application package is checked by the secretariat/secretary, and the required copies and processing fees (if applicable) is received.
- A registration number will be assigned and it should be quoted in all the correspondences.
- Investigators can expect the full committee review of their proposals within 6-8 weeks of submission.
- IRB office will correspond (by email) with the principal investigator 2 weeks before the meeting.

- The ethical review is done through **formal meetings** and the committee do not resort to decision through circulation of proposal.
- All members review the proposals, and **one primary reviewer** is assigned for each proposal to review in detail.
- In case of studies that entails minimal risk (criteria will be set by the IRB), **minimal risk review** may be carried out instead of formal meetings. Chair, secretary & 1-2 scientific members may review the minimal risk study and arrive at decisions.

- The principal investigator is required to **present at the meeting** to present the study.
- Decision is made through **consensus**, where possible, when it appears unlikely, ERC voting is recommended.
- Most of the studies require clarifications, minor amendments, scientific justifications, or major amendments.
- IRB's suggestions/comments has to be incorporated into the **revised version** which is to be sent within 2 weeks after the meeting.

- A conditional decision on applications will be re-reviewed following revision.
- A **negative decision** on an application will be supported by clearly stated reasons.
- The IRB may decide to **reverse its positive decision** on a study in the event of receiving information that may adversely affect the risk/benefit ratio.

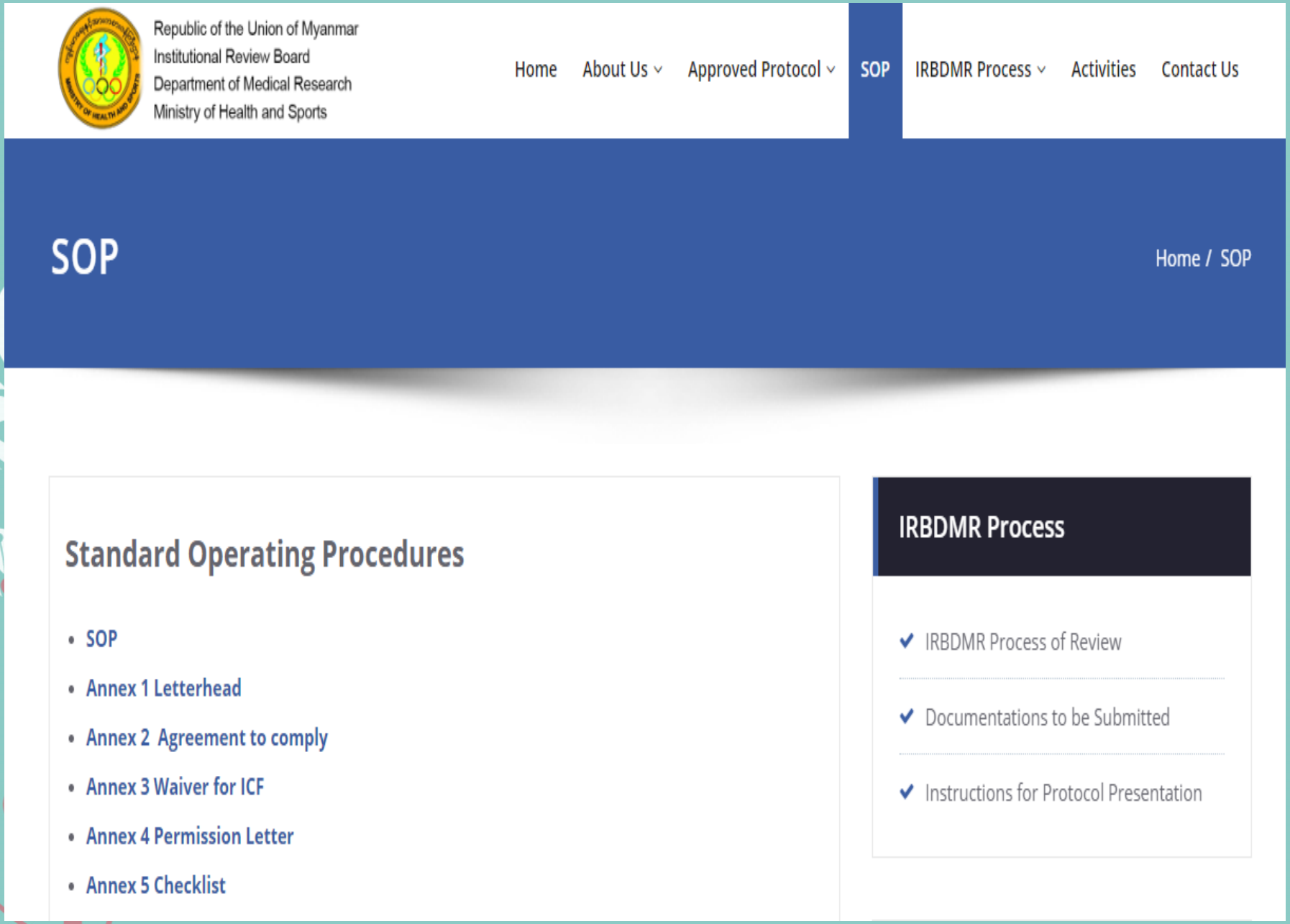
- The **discontinuation of a trial** may be recommended if the IRB finds that the goals of the trial have already been achieved midway or unequivocal results are obtained.
- **Subject experts** may be invited to offer their views but should not take part in the decision making process. However, her/his opinion must be recorded.

Documents to be submitted to IRB (DMR)

- Signed and dated Checklist of Ethics Review Proposal form
- A statement of agreement to comply with ethical principles set out in relevant guidelines
- All significant previous decision made by other ethical committee if applicable
- Proposal summary not more than two pages
- The protocol of the proposed research together with supporting documents and annexes
- Grant amount with estimated budget breakdown
- Informed consent forms, Assent forms, Permission forms if applicable
- Information to be provided to participant concerning research samples if applicable

- Consent/Assent document for taking/keeping biological samples if applicable
- Forms and questionnaires intended for research participants if applicable
- Materials for recruitment of participants if applicable
- Relevant documents and tools/products for the study if applicable
- Material Transfer Agreement if applicable
- Data Transfer Agreement if applicable
- Copy of MOU/LOA if applicable
- Investigators' curriculum vitae (updated, signed and dated) with recent passport size photo

- All of the above should be submitted in one continuous document with consecutive page numbers and a contents page.
- 18 complete hard copies should be submitted.



www.irbdmr.org.mm

Myanmar Health Research Registry (MHRR)

ျမန္မာနိုင္ငံက်န္းမာေရးဆိုင္ရာ
သုေတသနမွတ္ုတင္ျခင္ုိး

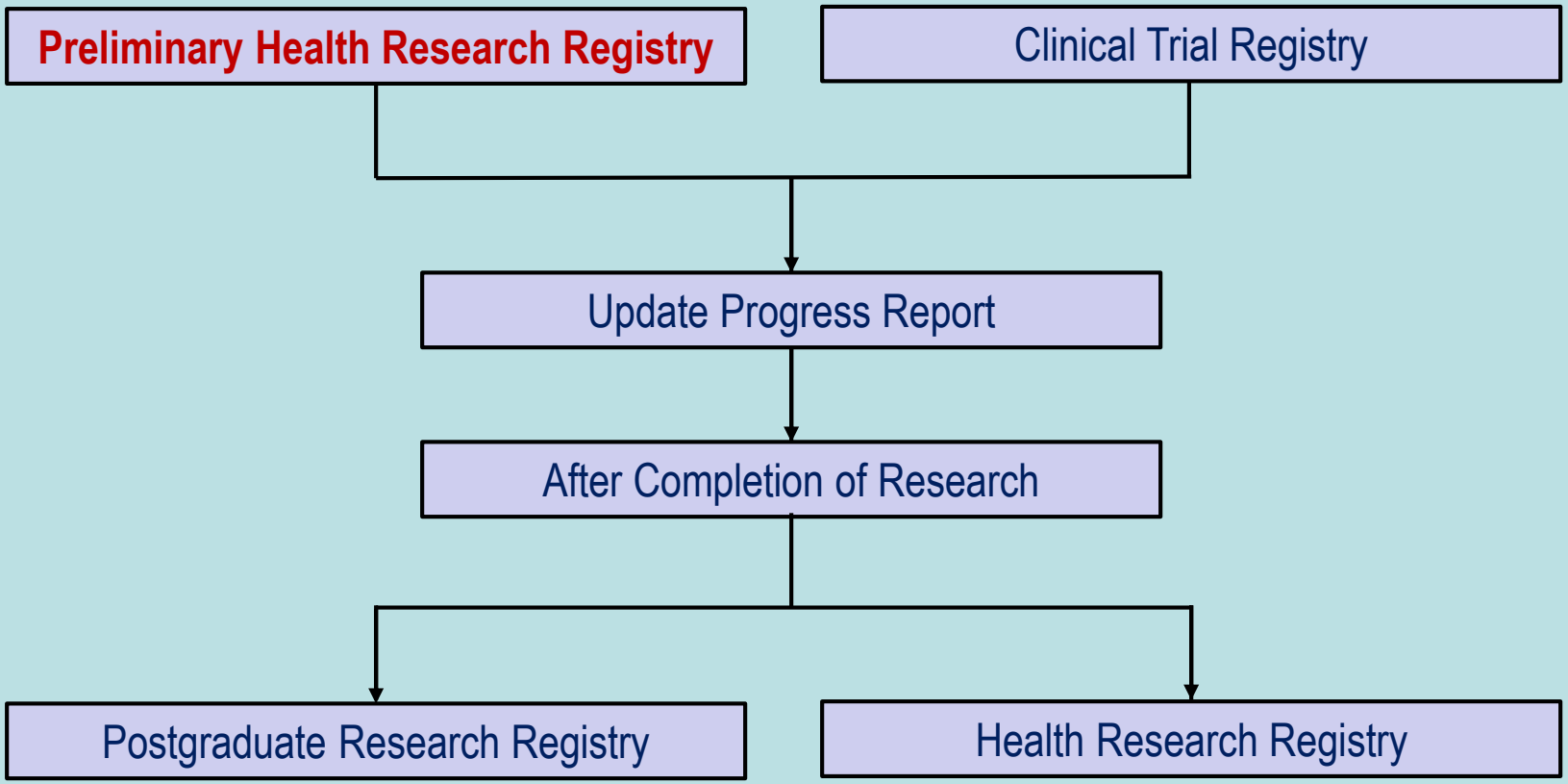
https://www.mhrr-mohs.com

Myanmar Health Research Registry

https://www.mhrr-mohs.com

- Publicly –available database of formally–approved health researches originated in Myanmar from year 2000 onwards
- Launched in 8th January 2018 (46th Myanmar Health Research Congress)

Guideline Diagram of MHRR

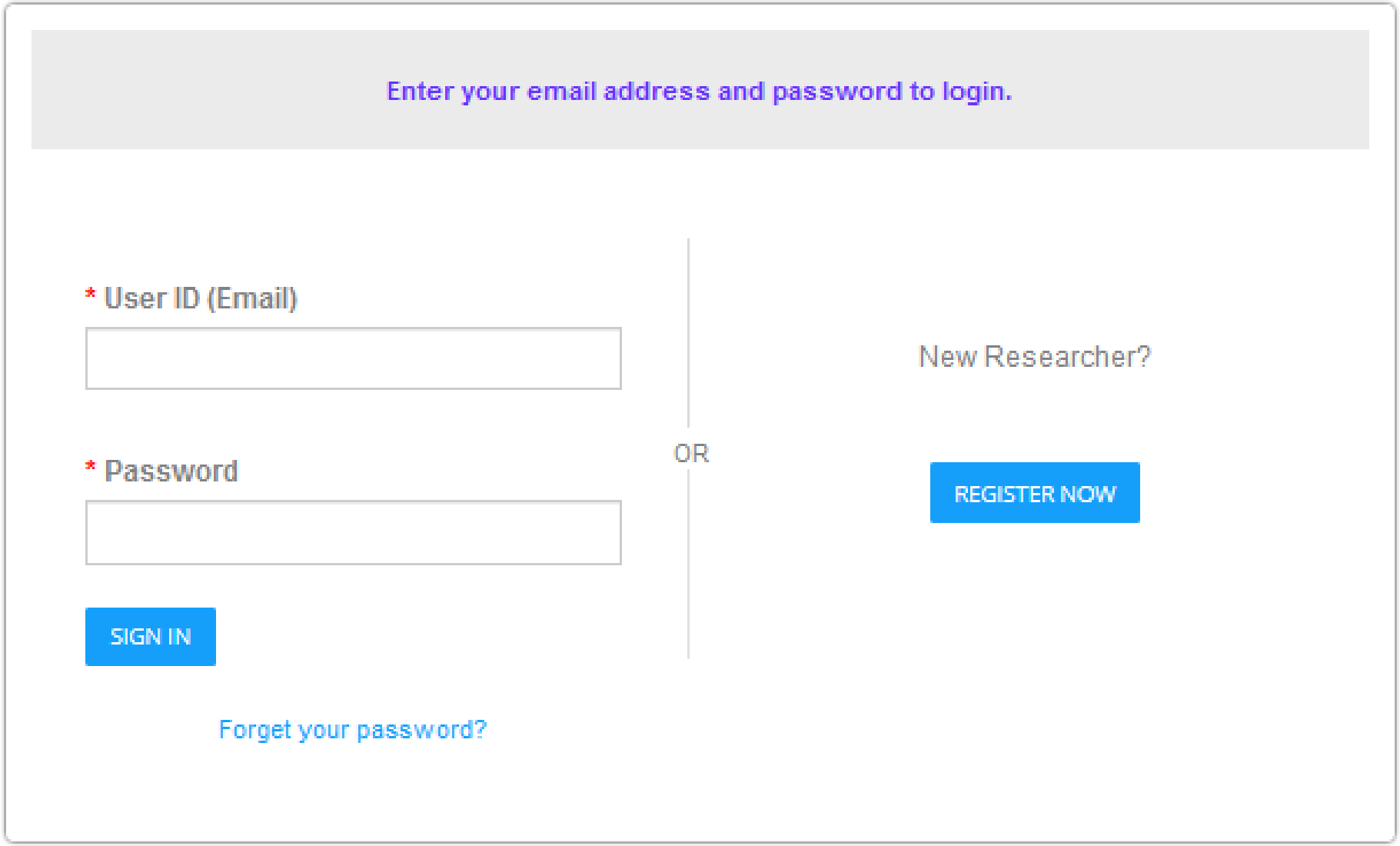


Registration status of 15th august 2019 Total –(380) research studies

Preliminary Research – 182

Health Research - 196

Clinical Trial Registry – 2


Enter your email address and password to login.
* User ID (Email)
* Password
SIGN IN
Forget your password?
OR
New Researcher?
REGISTER NOW

Documents required for submission to Myanmar Health Research Registry (MHRR)

- **All Myanmar citizen Researchers are eligible for this submission of MHRR online website.**

- **All Researchers can register their research starting from year 2000 up to now only.**

MHRR accepts Health Research Registry for Principal Investigator or main researcher who can submit own title of research paper, abstract, date of approval from Ethics Review Committee (ERC) and date, page, volume, year and name of published journal (local or international). Researcher needs to declare own research including title and research results or data that will be registered in MHRR website. If any problem occurs for duplication of research title and research data or results, researcher is totally responsible for solving this ownership problem. MHRR has not been concerned or took no responsibility for such duplication of research registry.

Researcher must also require registration number from WHO Clinical Trial Research Registry Platform for submission of Clinical Trial Research Registry in MHRR. Researcher consent should be required for research registration of our website as following-

Description of Abstract of paper / publication -- Yes / No
Description of Full paper (website address) ---- Yes / No
Communication of public (people chatting) --------Yes / No
Description of own e-mail address ---------- Yes / No

Researchers Registry List

Show 10 entries

Search:

Registration Date	Research Registry No	Principle Investigator	Field	Title of Research
2018-05-03 00:00:00	HRID-00005_V1	Rie Takahahshi	Public Health	Baseline survey for the project â€œSupport strengthening service delivery for maternal and newborn health in Kyaukkyi Township of Bago Region, Myanmar
2018-05-03 00:00:00	HRID-00006_V1	Nang Thu Thu Kyaw	AIDS/HIV	Outcomes of hepatitis B and/or C co-infection in people living with HIV receiving care under Integrated HIV Care Program in Myanmar
2018-04-27 00:00:00	PRID-00004_V1	Myo Win Htun	Immunology	Involvement of epigenetic factors under the influence of iron and arsenic uptake in the early development of hepatocellular carcinoma in Myanmar
2018-04-23 00:00:00	HRID-00003_V1	Khine San Yin	Pathology	A study of Epidermal Growth Factor Receptor (EGFR) mutation in Myanmar Patients with Adenocarcinoma Lung
2018-03-23 00:00:00	HRID-00002_V1	Ohnmar	Neurology	A Multicentre, Collaborative, Prospective study to determine the association of Flaviviruses, and Arboviruses, including Dengue and Zika, with Guillian-Barre Syndrome in South and South-East Asia
2018-03-23 00:00:00	PRID-00001_V1	Hnin Nandar Htut	Public Health	Accessing Sleep Quality among Type 2 Diabetes Mellitus in a Private Hospital, Yangon, Myanmar

Registration Date	Research Registry No	Principle Investigator	Field	Title of Research

Contact to Admin :

mhrr-mohs.admin@mhrr-mohs.com

Dr Moh Moh Htun

mohmoh.htunn@gmail.com

O9-5136708


Thank
you