



Ministry of Health



Department of Medical Research

MINISTRY OF HEALTH



UNION MINISTER

Deputy Minister

**DEPARTMENT
OF
PUBLIC HEALTH**

**DEPARTMENT
OF
MEDICAL
SERVICES**

**DEPARTMENT
OF HUMAN
RESOURCES FOR
HEALTH**

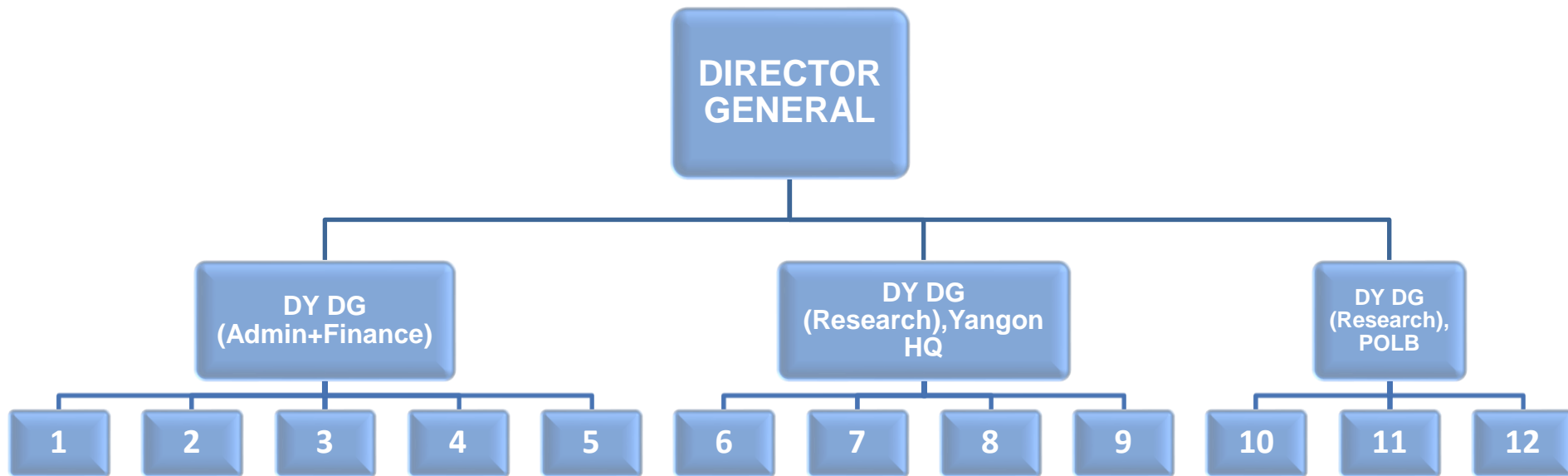
**DEPARTMENT
OF
MEDICAL
RESEARCH**

**DEPARTMENT
OF
FOOD & DRUG
ADMINISTRATION**

**DEPARTMENT
OF
TRADITIONAL
MEDICINE**



Organization Setup of Department of Medical Research (DMR)



- 1 Director (General Admin)
- 2 Director (Finance)
- 3 Director (Planning)
- 4 Director (Procurement & Distribution)
- 5 Director (Inspection)

- 6 Director (Blood Research)
- 7 Director (Poison Control)
- 8 Director (Vaccine Research)
- 9 Director (Advanced Molecular Research)

- 10 Director (Biomedical Research)
- 11 Director (Clinical Research)
- 12 Director (Socio-Medical Research)

Vision of DMR

**Achieving a healthier nation through
application of research findings**

Missions of the Department of Medical Research

Mission 1

To investigate **communicable diseases** with emphasis on emerging and re-emerging diseases affecting health of the people

Mission 2

To investigate **non-communicable diseases** affecting National Health

Mission 3

To investigate **nutritional factors and lifestyle changes** affecting health

Mission 4

To **strengthen research capacity** through development of infrastructure and human resources, necessary for medical research

Mission 5

To carry out **health systems research** highlighting effective and efficient health delivery systems including reproductive health

Missions (Continued)

Mission 6

To promote research on **accidental, occupational, environmental and climatic factors** affecting human health

Mission 7

To carry out research on **traditional medicine** for safe and effective utilization within the existing health care system

Mission 8

To promote research culture at medical and related health institutions and to **provide academic and technical training** for post graduate students

Mission 9

To enhance **technology development** and analytical services applicable in the diagnosis, management and control of common diseases or conditions

National Health Research Policy

National Health Research Policy has been approved by the Cabinet in 2017 with emphasis on 'Responsible Conduct of Research' and 'Research Ethics'.

Under the policy directives of MoHS, '**National Code for the Responsible Conduct of Research**' is critical to promote good research governance.

DMR and other Health and Health related Universities in Myanmar hold primary responsibility to oversee the responsible and ethical conduct of research in the country.

National Health Research Policy

- ❖ To promote ethical conduct of health research through **strong and standardized Ethics Review Committees** in academic institutions and health research institutions with extensive networking
- ❖ To establish a well-functioning system of **“Responsible Conduct of Research”** in health research and academic institutions

Brief History of IRB/ ERC in Myanmar

- **1980: The First Ethics Review Committee in Myanmar** was established at the Department of Medical Research (DMR), Ministry of Health.
- **1998: The first REC in Myanmar Medical Universities** was formed at University of Medicine 1, Yangon.
- **2018: 18 RECs** in Myanmar.
- **Currently: 2 IRB (MOH and DMR) and 16 ERCs**

1980-2011- ERC at DMR was chaired by the Director General, DMR as an institute authority.

2012-to date - Chaired by an External Expert and members are appointed by the Union Minister

Milestones

- ❖ ERC at DMR : **The First Medical Research Ethics Review in Myanmar**
- ❖ **2012: Attained the Federal Wide Assurance Registration** (FWA 00018816) at the Office of Human Research Protection (OHRP), USA
- ❖ **2018: Attained accreditation from FERCAP**
- ❖ **2019: Transformed into IRB** (DMR) and rejuvenated with young members to work hand in hand with senior and experienced members
- ❖ **2020: Renewal of the FWA** registration at OHRP, USA (FWA 0007357) valid till 2023

DMR- Ethics Review Committee

- DMR-IRB plays a **leading role** in promotion of research ethics in areas of health.
- Strengthen **research ethics capacity** of researchers in health institutions.
- Provides **technical and ethical guidance** on research studies conducted in Myanmar.
- Reviews research proposals from **public as well as NGO and private sector.** (Federal Wide Assurance)
- Review more than **100 proposals** per year.

DMR- Institutional Review Board Activities

- **Conducting proposal reviews**
- **Monitoring high risk research projects**
- **Conducting training workshops**
- **Participating in the Symposia at the Annual Myanmar Health Research Congresses**
- **Participating in International Research Ethics Conferences & a Multi country study**
- **Scientific publications**

Constitution and Membership

- **Appointed: Chairperson, DG as a Vice-Chair and two community members**
- **Nominated: 11 academic members covering areas of expertise in biomedical, clinical, public health, epidemiology, and social science**
- **Member Secretary and Secretariat: DMR Staff, appointed by the Vice-Chair as an institute authority**
- **Affiliated members [8]; Non-Affiliated members [7]; Total: 15**

DMR_IRB Guidelines

International, national and institutional guidelines

WHO: Operational Guidelines for Ethics Committees (2000)

WHO: Basic concepts for REC capacity-building (2009)

WHO: Standards & Operational Guidance for Ethics Review (2011)

WMA: Declaration of Helsinki (1964-2013)

CIOMS: Guidelines (2002, 2009, 2016)

USA: Belmont Report (1979)

USA OHRP: IRB Guidelines (series)

Myanmar DMR Guidelines (2006) and revised in 2019 and 2020

IRB-DMR Review (Jan-Dec, 2020)

Number of protocols reviewed through Full Board Review	65	Common types of protocols reviewed through Full Board review	<ul style="list-style-type: none"> - Public health & socio-behavioral (27) - Lab & Genetics (16) - Clinical (8) - > One aspect(14)
Number of protocols reviewed through Expedited Review	63	Common types of protocols reviewed through Expedited Review	<ul style="list-style-type: none"> - Public health & socio-behavioral (40) - Lab & Genetics(22) - Clinical (1)
Number of protocols Exempted from Regular Review	8	Common types of protocols Exempted from Regular Review	<p>Protocols involving secondary data/residual biological materials</p> <ul style="list-style-type: none"> - Lab & Genetics (3) - Public Health & Socio-behavioral Science (1) - Clinical (0) - Mixed (4)
Total	136		

IRB-DMR Review

2019- Total number reviewed and approved: 143

Amendments & Extensions: 0

Reviewed & Exempted: 9

2020- Total number reviewed and approved: 123

Reviewed & Deferred - 2

Reviewed & Withdrawn- 1

Amendments & Extensions: 0

Reviewed & Exempted: 10

2022- Total number reviewed and approved: 14

2023 Amendments & Extensions: 1

Reviewed & Exempted: 6

Reviewed & Disapproved- 1

IRB-DMR Review

2023-Total number reviewed and approved: 19

2024 Amendments & Extensions: 2

Reviewed & Exempted: 23

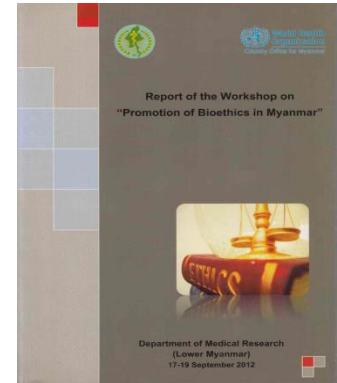
2024- Total number reviewed and approved: 23

2025 Amendments & Extensions: 3

Reviewed & Exempted: 8

INSIGHT

2012: WHO funded Workshop on Bio Ethics held at DMR in Yangon pointed out the importance of IRB/RECs to follow the National and International Research Ethics Guidelines.



2014: Training Course related to International Conference on Harmonization and Guideline for Good Clinical Practice (ICH-GCP) at DMR in collaboration with QUINTILES.



2014: Symposium on Responsible Conduct of Research, 42nd Myanmar Health Research Congress



2017: WHO-TDR supported Workshop on Implementation Research Proposal Development including Ethics Principles

IRB- DMR Specific Training Activities

- 2013-** Capacity Building Workshop for Members of Ethical Review Committees of Health Institutions in Myanmar
- 2014-** Clinical research ethics training
- 2017-** NIH web-based training course on “Ethical and Clinical Aspects of Clinical research”
NIH web-based training course on ‘Protecting Human Research Participants’
- 2018-** RCR and Research Ethics Training for Trainers of Medical and related Universities

IRB- DMR Specific Training Activities

2019- Capacity Building Workshop for IRB Members,
MOHS, Myanmar (17-18th July, 2019)

2020- ICH-GCP Training Workshop
(13-14 February 2020)
- Responsible Conduct of Research and Research
Ethics (10-15 July, 2020)

2025 Nov- Capacity Building Workshop for Members of
Ethical Review Committees of Health Institutions in
Myanmar

IRB- DMR Participation Activities

- **Participation in international conferences related to Bioethics**
- **Participation in FERCAP multi-country COVID-19 perception survey**
- **Engagement of the IRB Chair as one of the country coordinators of FERCAP to arrange for accreditation process of REC/IRBs**

IRB- DMR Publications

IRB Publications (2020)

1. Aung HM, Wai KT, Oo YTN, Thu HM, Htun ZT, Silverman H. Strengthening quality ethics review in a developing country. *Journal of Global Bioethics Enquiry*. Dec 2020.
2. Pwint KH, Aung HM, Yadanar P, Aye NS, Show KL, Oo ZZ, Thwin T, Wai KT. Expedient reviews during the COVID-19 pandemic period: concept to current practice of the Institutional Review Board in the resource-constrained scenario. *Journal of Bioethics and Applications*. Dec 2020.

IRB Publications (2021)

3. Show KL, Thwin T, Aye NS, Htun ZT, Wai KT. Ethical oversight of implementation research in rural settings of a developing country during the COVID-19 outbreak. *Journal of Global Bioethics Enquiry*. Mar 2021.
4. Aye NS, Aung HM, Pwint KH, Yadanar P, Show KL, Thwin T, Wai KT. Ethical issues raised for public health and socio-behavioural research focused on containment of the COVID-19 pandemic. *Journal of Global Bioethics Enquiry*. Mar 2021.

IRB- DMR Publications

IRB Publications (2022)

5. Dadi L, Thandar M, Thwin T, Wai KT. Introducing a Transformative Intervention for Trainers of Research Ethics Education in Medical and Health Related Field in Developing Regions: A viewpoint. *Journal of Global Bioethics Enquiry*. Dec 2022.

IRB Publications (2023)

6. Thwin T, Show KL, Naing PA, Wai KT. Ensuring Procedural Guidance for Research Ethics and Research Integrity in Proposals using Human Biospecimens in Resource-limited Settings. Ethical Viewpoint. *Journal of Global Bioethics Enquiry*. March 2023.

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