KEMENTERIAN KESEHATAN REPUBLIK INDONESIA

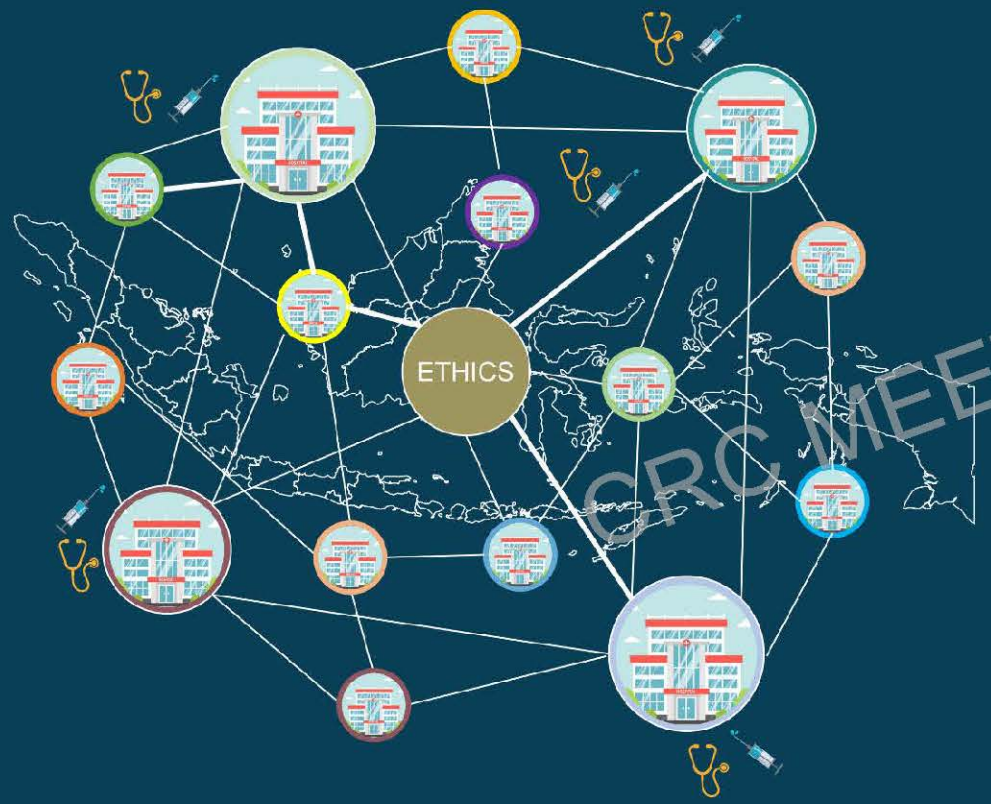
INA-CRC Indonesia Clinical Research Center

Centre for Health Services Policy
Health Policy Agency

THE SITUATION OF MULTICENTER

CLINICAL RESEARCH IN INDONESIA AND THE CENTRALIZATION OF ETHICS APPROVAL

March 29, 2023



CENTRALIZATION OF ETHICAL REVIEW:

SHARING EXPERIENCES FROM MREC, MOH MALAYSIA

DR LEE KENG YEE

SECRETARY

MEDICAL RESEARCH & ETHICS COMMITTEE, MINISTRY OF HEALTH, MALAYSIA

SINGLE IRB VS. CENTRAL IRB

- Both are designed to help streamline IRB review, and the terms are sometimes used interchangeably.

- **A Central IRB is the IRB of record that provides the ethical review for all sites participating in more than one multi-site study**

- **sIRB: An sIRB (Single Institutional Review Board) is the selected IRB of record that conducts the ethical review for participating sites of the multi-site study. Also known as the Reviewing IRB.**

- **Relying IRB: An IRB designating an agreement to cede review to an external IRB for a particular study**

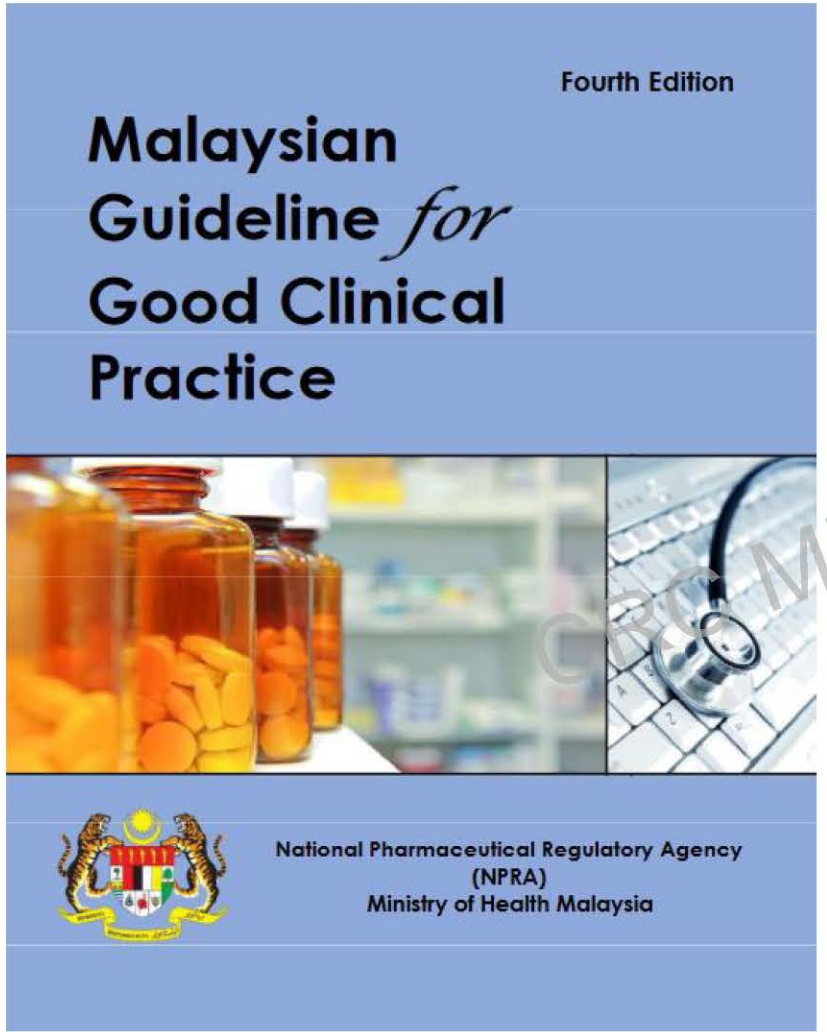
LEGAL BASIS

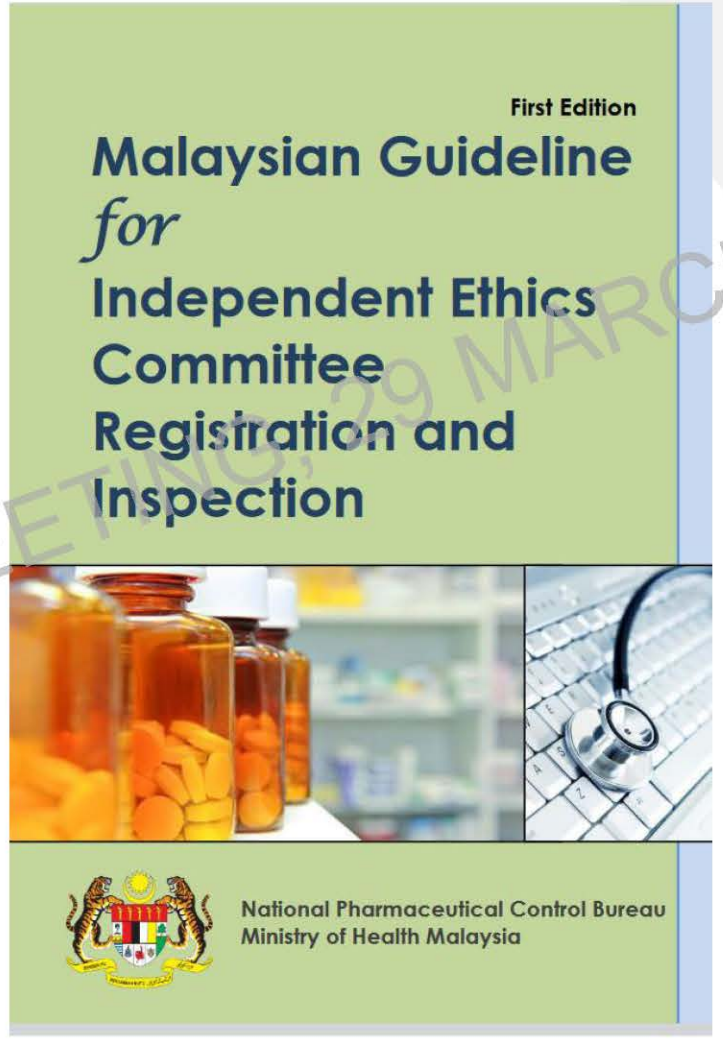
- Under the regulation 7(1), CDCR 1984, except as otherwise provided in these Regulations, no person shall manufacture, sell, supply, import or possess or administer any product unless the product is a registered product and the person holds the appropriate licence required and issued under these Regulations. The regulations provide the following mechanisms that allow individuals to gain limited access to unregistered product for clinical trials:

  - Regulation 12(1)(c): Clinical Trial Import Licence (CTIL)
    A Clinical Trial Import Licence in Form 4 in the Schedule, authorising the licensee to import any product for purposes of clinical trials, notwithstanding that the product is not a registered product.

  - Regulation 15(5): Clinical Trial Exemption (CTX)
    Any person who wishes to manufacture any products solely for the purpose of producing samples for clinical trials, for registration or issuance of notification note under these Regulations may on application be exempted by the DPS from the provisions of regulation 7(1) or regulation 18A.

GUIDELINES

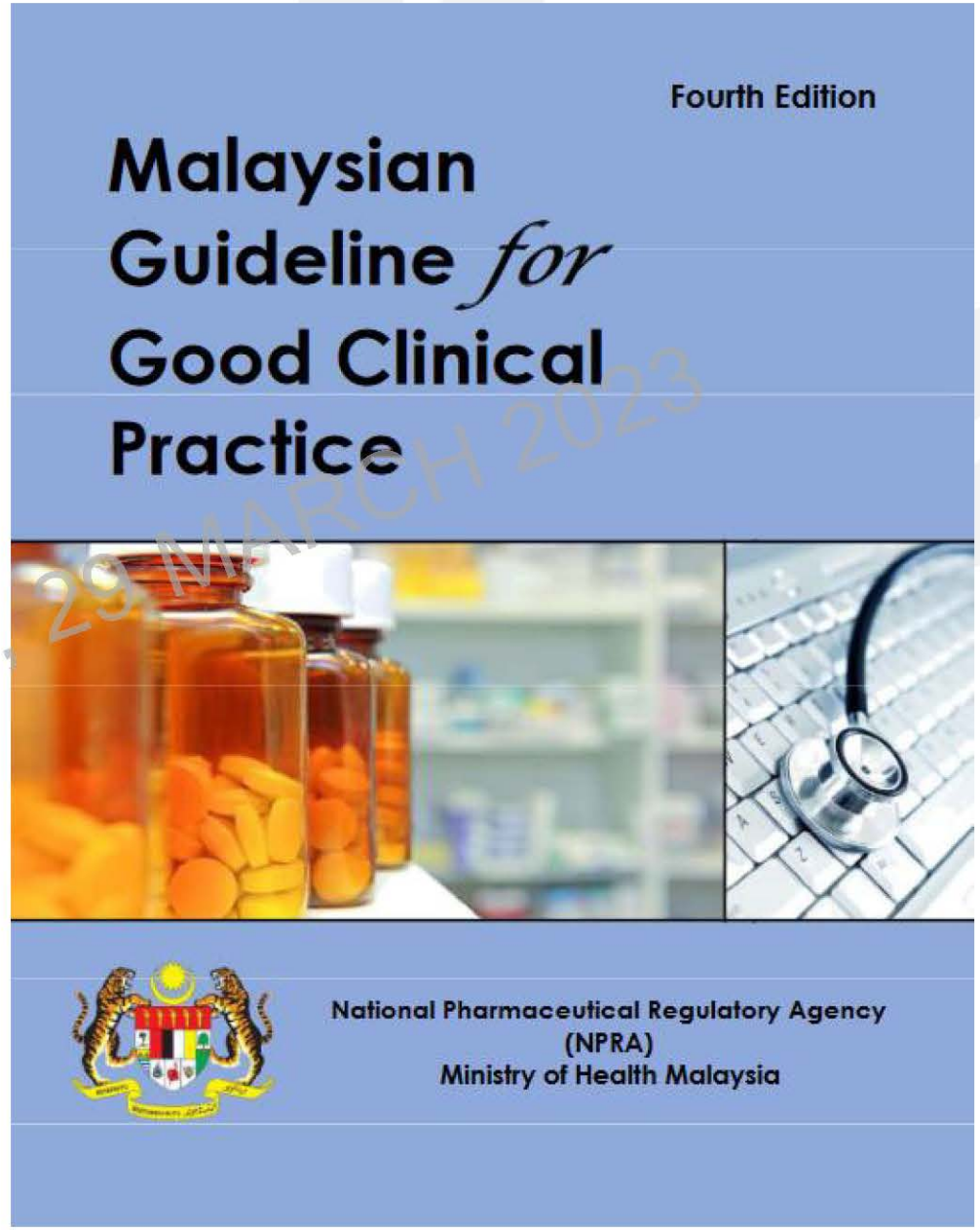




https://npra.gov.my/index.php/en/guideline-for-the-submission-of-product-samples-for-laboratory-testing /clinical-trial/clinical-trial-guidelines.html

MALAYSIAN GCP 3.2.7

- An institution without IRB/IEC may request **IRB/IEC of Ministry of Health, Malaysia** to make decisions on behalf of the said institution.



MINISTRY OF HEALTH, MALAYSIA

- 135 Hospitals, 11 Special Medical Institutions
- 1,057 Health Clinics, 1,749 Rural Clinics (Klinik Desa), 255 Community Clinics
- Dental Clinic: 63 Standalone Dental Clinics, 592 Dental Clinics in Health Clinics, 75 Dental Clinics in Hospital, 20 Dental Clinics in Other Institutes, 911 School Dental Clinics, 34 Mobile Dental Clinics

LIST OF IRB/IECS REGISTERED WITH NPRA

- IIUM Research Ethics Committee (IREC)
- Jawatankuasa Etika Penyelidikan (Manusia), USM [JEPeM]
- Jawatankuasa Etika Penyelidikan Perubatan, Pusat Perubatan Universiti Malaya
- Jawatankuasa Etika Penyelidikan, Universiti Kebangsaan Malaysia (JEPUKM)
- Jawatankuasa Etika Penyelidikan, Universiti Teknologi MARA (UiTM)
- Jawatankuasa Etika Universiti Untuk Penyelidikan Melibatkan Manusia, Universiti Putra Malaysia (JKEUPM)
- **Jawatankuasa Penyelidikan & Etika Penyelidikan Perubatan (MREC), Kementerian Kesihatan Malaysia (KKM)**
- Joint Ethics Committee School Of Pharmaceutical Sciences, Universiti Sains Malaysia (USM) – Hospital Lam Wah Ee On Clinical Studies
- Pantai Hospital Kuala Lumpur Research and Ethics Committee (PHKL REC) *provisionally listed*
- Sunway Medical Centre Independent Research Ethics Committee (SREC)
- Jawatankuasa Etika Penyelidikan Institut Jantung Negara
- Independent Ethics Committee Ramsay Sime Darby Health Care (IEC RSDHC)
- International Medical University (IMU) Joint Committee of the Research and Ethics Committee (IMUJC)
- UCSI Institutional Ethics Committee (UCSI IEC) *provisionally listed*

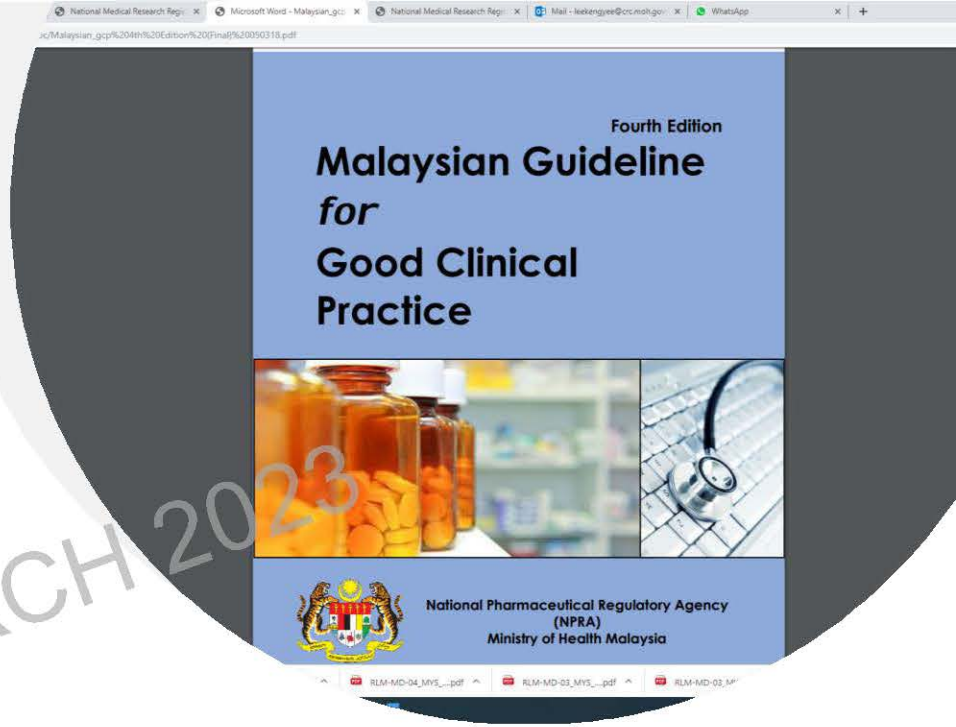
BRIEF INTRODUCTION OF MREC

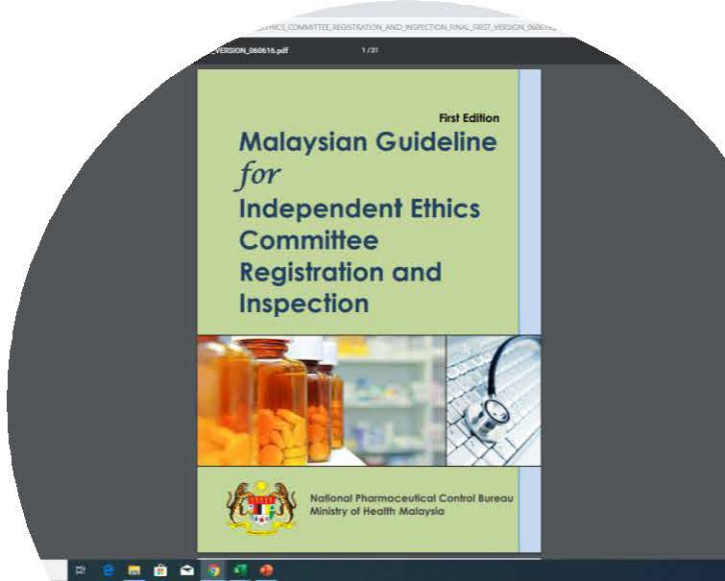
- The Medical Research and Ethics Committee (MREC) of the Ministry of Health (MOH) was established in 2002 to provide independent guidance, advice and decision on ethical issues of health research involving human subjects conducted by staff of the MOH or conducted by non-MOH researchers using facilities of the MOH.

- The MREC may act as an 'Independent Ethics Committee' for non-MOH institutions.

BRIEF INTRODUCTION OF MREC

- MREC operates under the authority of the Director-General (DG) of Health Malaysia.
- In accordance with:
- ‘Malaysian Guidelines for Good Clinical Practice (GCP)’
- Declaration of Helsinki
- International Ethical Guidelines for Biomedical Research Involving Human Subjects (CIOMS), and
- ICH Guideline of Good Clinical Practice.





BRIEF INTRODUCTION OF MREC

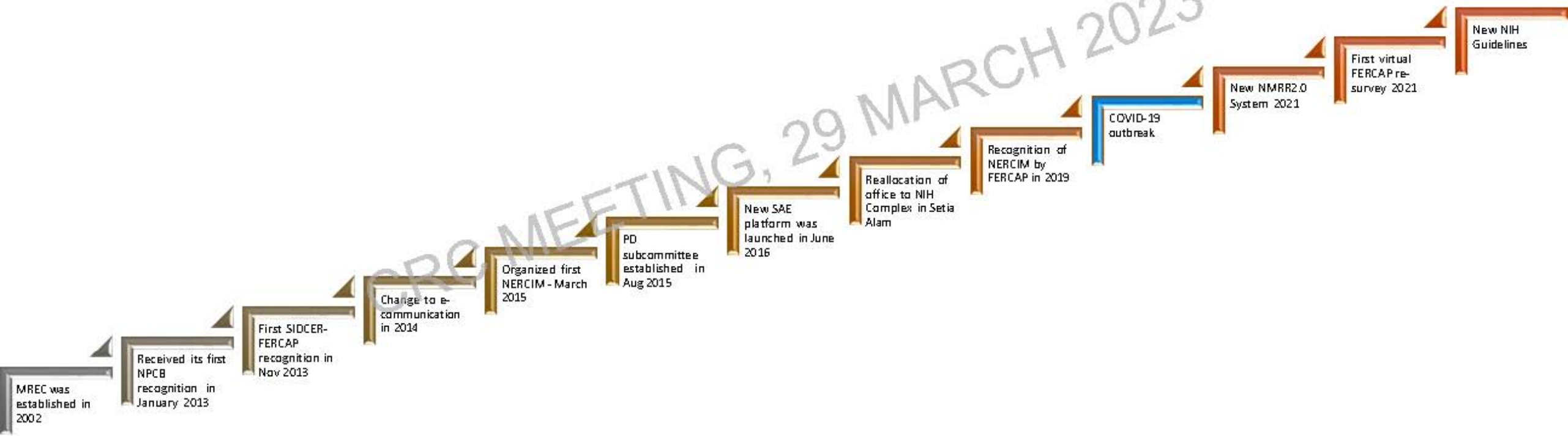
- The MREC will safeguard the rights, safety and well-being of all trial subjects.

- The MREC is independent in its reflection, advice and decision.

COMPOSITION

- Consists of 2 panels (Red and Blue) with medical, scientific and layperson reviewers
- Full board meetings conducted twice a month
- Conducts initial ethical review and also post-approval processes

MREC Milestones

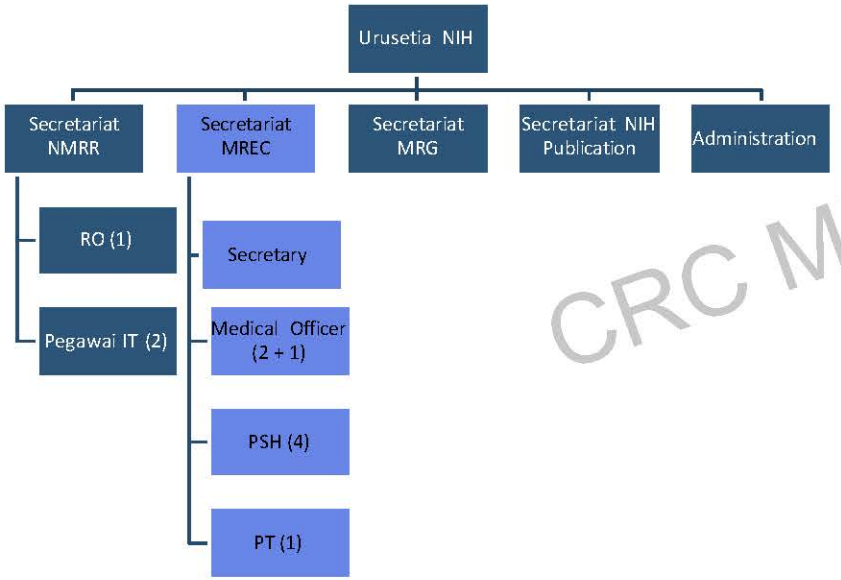


MOVETO SETIA ALAM

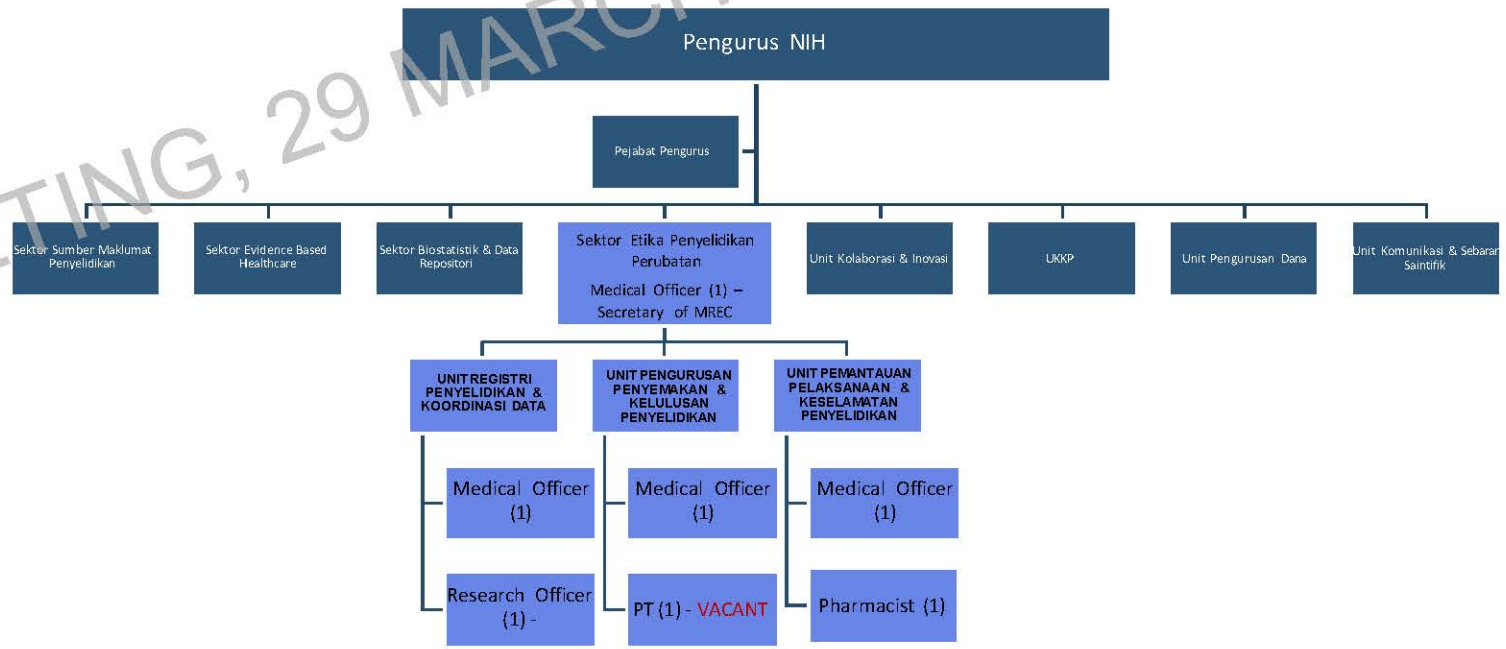
- Current address:
- **Blok A, Level 2, National Institutes of Health (NIH)**
  Jalan Setia Murni U13/52,
  Seksyen U13 Setia Alam,
  40170 Shah Alam, Selangor.
- Phone Number: 03-3362 8205 /8407 /8401

Human Resource of MREC Secretariat – New Structures

- Before NIH Restructuring

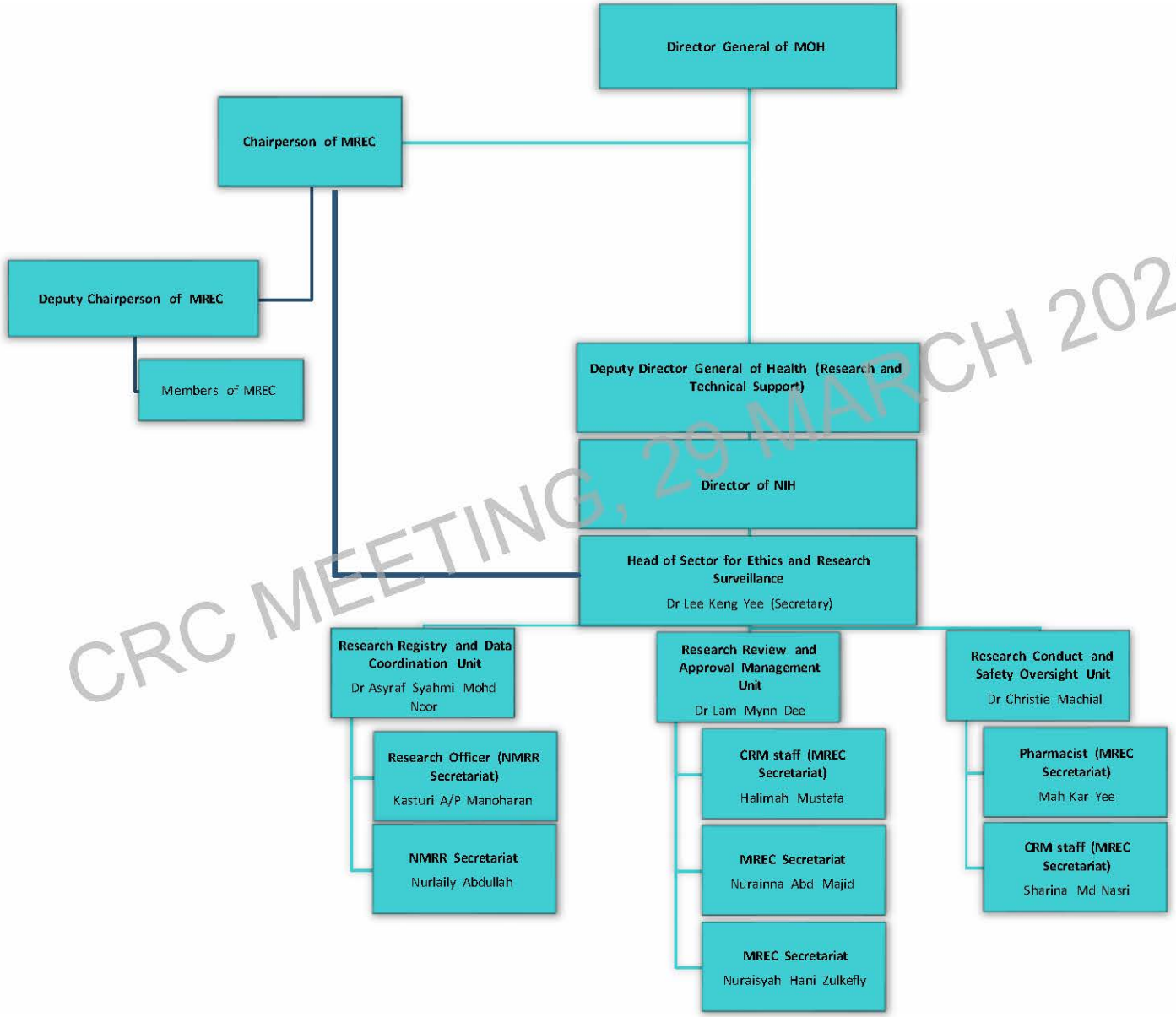


- After NIH Restructuring



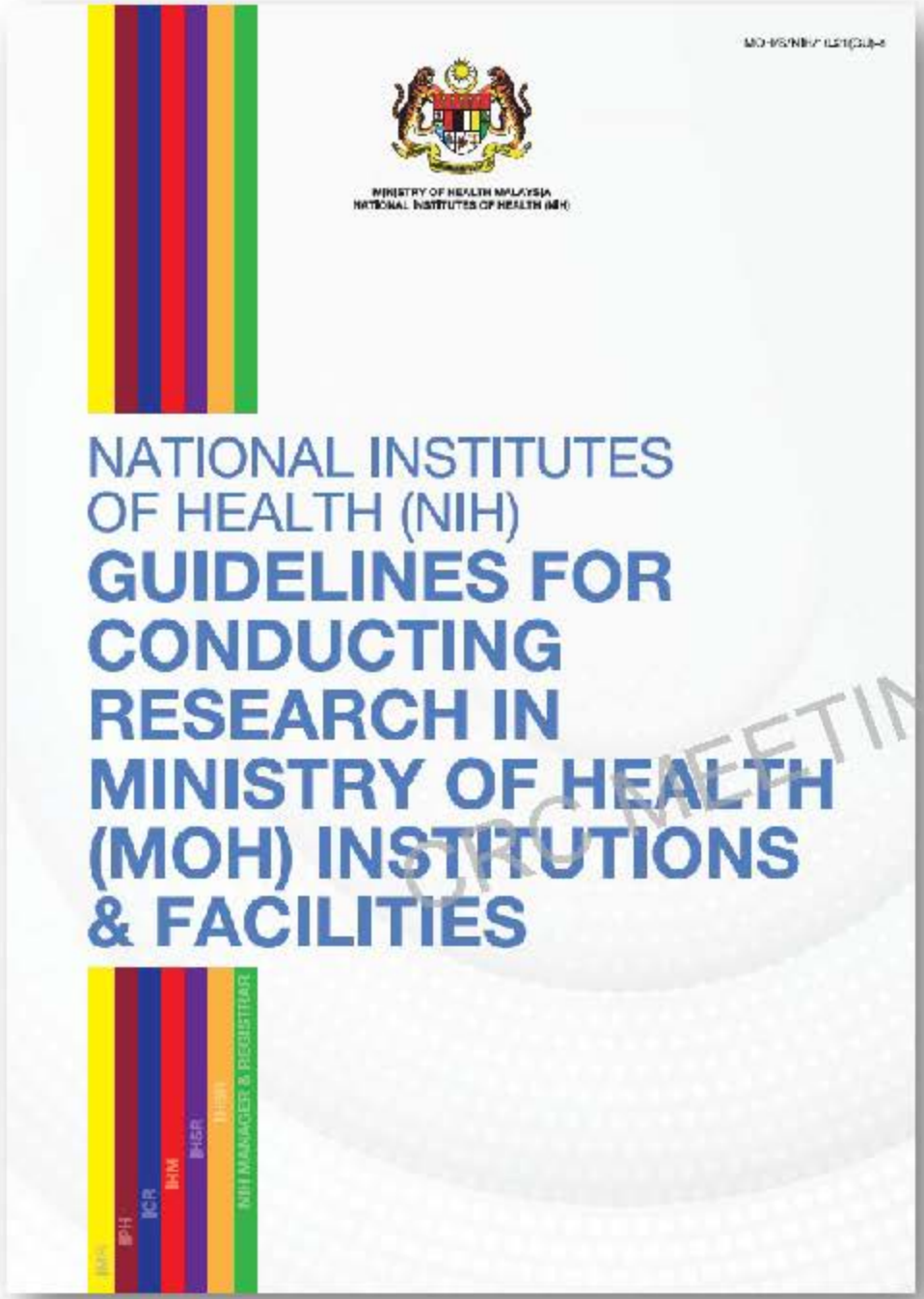
**IT support and administration – Administration and ICT NIH

MREC ORGANISATION CHART



QUALITY ASSURANCE AND REGISTRATION

- FERCAP Accreditation – latest 2022
- MREC is also member of the steering committee of FERCAP
- NPRA Inspection – done 2022
- OHRP registration active



This updated guideline is officially in use with the release of the Director General of Health Malaysia Circular No 4/ 2022 released on 31st January 2022 with regards to the conducts of research in the Ministry of Health (MOH)

NIH
INSTITUT KESIHATAN NEGARA
NATIONAL INSTITUTES OF HEALTH

Historical Overview of NIH Guidelines on the Conduct of Research In MOH, other related Guidelines/Circular

1st Edition

The guideline was first introduced in 2007 together with NMRR in the Director General of Health Circular Bil 9/2007

Research Dissemination

In 2013, a Director General of Health Circular Bil 1/2013 on the procedure for the approval of research dissemination was issued

2nd Edition & Upgrade

In 2014, NMRR has it first major upgrade & in 2015, the first update to the guideline was done

Historical Overview of NIH Guidelines on the Conduct of Research In MOH & other related Guidelines/Circular/Letter

MRG Guidelines

In 2015, a separate guideline on the application for MOH Research Grant (MRG) was released

Research Dissemination

In 2018,a letter by the Deputy DG on the updating criteria and procedure for the approval of research dissemination was issued

3rd Edition

In 2021, an updates to guideline is proposed in order to cater the changes in the current SOP & latest requirement

1. GENERAL POLICY OF RESEARCH CONDUCT IN MOH

All research conducted in MOH institutions and facilities must comply with the Declaration of Helsinki, International Ethical Guidelines for Biomedical Research Involving Human Subjects (CIOMS), ICH Guideline of Good Clinical Practice, Malaysian Good Clinical Practice, and other local regulatory requirements and guidelines.

2. CATEGORY OF INVESTIGATORS

All research related to MOH **(undertaken by MOH personnel OR conducted in MOH institutions/facilities OR using MOH data/patient/sample/personnel as a subject OR funded by MOH Research Grant)** shall require registration and approval* by the relevant authorities according to the following categories:

1. MOH & NIH Investigator **
2. Non - MOH Investigator
3. Investigator applying for MOH Research Grant (MRG)

* Refer to policy statement 5

**MOH and NIH investigator is considered as MOH personnel. The differentiation between the types of investigators is required due to different process flow during both scientific and ethical reviews and the approval of the submission

3. THE CONDUCT OF RESEARCH

i. Prior Approval by the MOH:

a. All research must be registered with the National Medical Research Register (NMRR);

b. Principal Investigator (PI), PI at the site, and at least 1 Sub-Investigator (Sub-I) (for each research site without PI at the site) must sign an Investigator Agreement and obtain approval from his or her HOD and Institutional/Organisational Director by using the IA-HOD-IA Form;

c. Investigator is advised to engage with relevant stakeholders prior to selecting the research sites; and

d. For **collaborative research** with any external organisation or entity outside of MOH, a Memorandum of Understanding (MoU) or Memorandum of Agreement (MoA) and Research Agreement (RA) between the related MOH division, institution or facility, and the external party must be obtained.

3. THE CONDUCT OF RESEARCH

ii. <u>After obtaining ethical approval, and before the recruitment of subjects and/or data collection</u>,

   a. **Sites without a signed IA-HOD-IA form** should obtain approval to conduct research at each site via the Site Approval Form. An investigator is required to fulfil any other site's requirements depending on the respective facilities/institution's SOP

3. THE CONDUCT OF RESEARCH

iii. <u>During the conduct of the research (recruitment of subjects and/or data collection).</u>

a. Any **subsequent changes or additions to research (amendment)** that has received prior ethical approval by MREC will require that such changes be submitted, reviewed, and approved by MREC before it can be incorporated into the research. These changes or additions include those affecting the i) research protocol and methodology, ii) research sites, iii) investigators, and iv) related documents.

b. Applications for **renewal of ethical approval** should be made **on a yearly basis** and should be submitted prior to the expiry of the ethical approval.

c. Research status or progress should be notified and updated in the NMRR.

d. The **Closure/Suspension/Termination of research** should be notified to MREC (for research that had already received ethical approval from MREC).

e. Investigator needs to submit an **End of Project or Final report** upon research completion (report can be uploaded in the NMRR). For research receiving MRG, the report should be submitted to the MRG Secretariat as well.

4. ROLES AND RESPONSIBILITIES OFTHE ROLES AND RESPONSIBILITIES OFTHE INSTITUTIONAL/FACILITY DIRECTOR, HEAD OF DEPARTMENT (HOD),CLINICAL RESEARCH CENTRE (CRC) UNIT

Institutional/Facility Director, Head of Department (HOD),Clinical Research Centre (CRC) Unit

a. Monitoring of research conducted at MOH institutions/facilities is under the responsibility of Institutional/Facility Director, Head of Department (HOD) and Clinical Research Centre (CRC) Unit (if available) of respective study site.

5. ETHICAL REVIEW

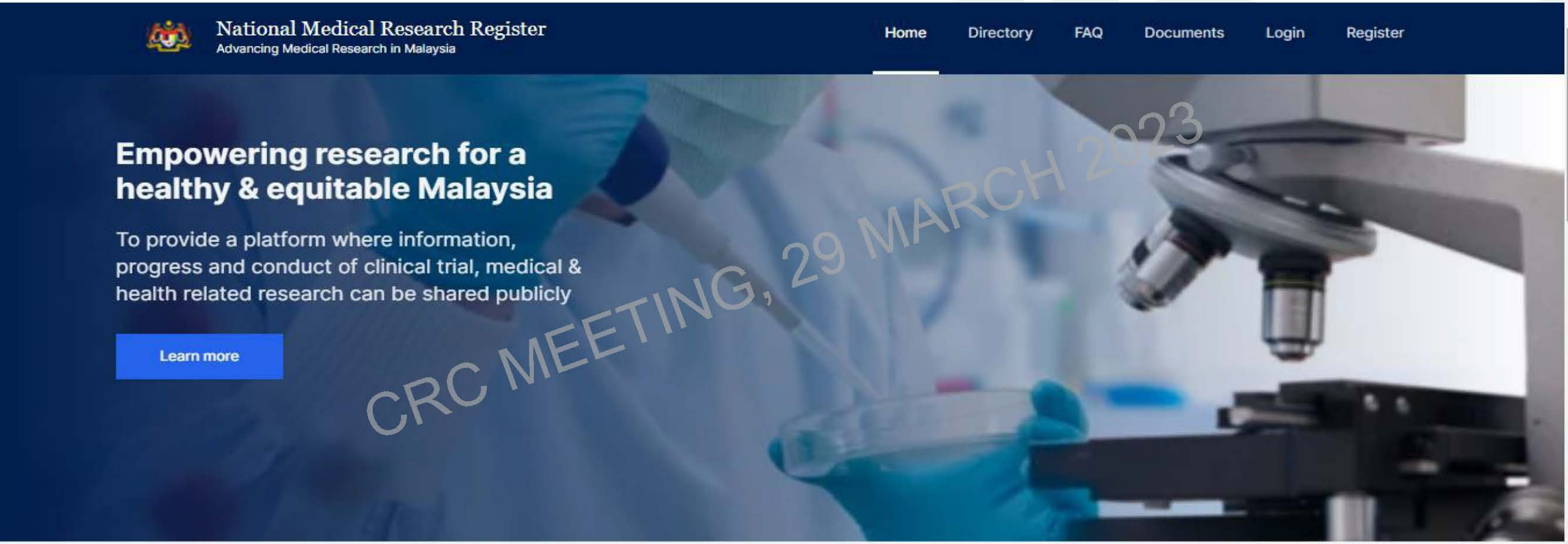
Research involving human subjects requires prior ethics review and approval by the Medical Research and Ethics Committee (MREC), MOH.

A **human subject** (in the context of research) is "a living individual about whom an investigator obtains either data through intervention (e.g.: clinical trial) or interaction (e.g.: questionnaire in health survey) with the individual or investigator has access to identifiable private information (e.g.: secondary data, medical record or personal data)".

APPROVAL SUBMISSION & OTHER REQUIREMENTS (CHAPTER 6)

1. Introduction
2. Research Application for Ethical Review
3. Essential Documents
4. Risk Assessment & Type of MREC Review
5. MREC Full Board Meeting
6. Requirement for Consent
7. Post Ethical Approval
8. Waiver of Informed Consent
9. Exemption from MREC Review
10. Additional Information for Informed Consent Involving Biological Specimen Collection & Genetic Testing

NATIONAL MEDICAL RESEARCH REGISTER (NMRR) VERSION 2.0 – WWW.NMRR.GOV.MY



Medical Research

Explore & find out more about the medical research that has been registered in various fields

View Research Directory

Investigators & Researchers

Talented investigator & researcher from various backgrounds & specialities

View Investigators & Researcher Directory

ETHICAL PRINCIPLES AND IMPORTANCE OF RISK ASSESSMENT

ETHICAL PRINCIPLES

Non maleficence

Obligation not to inflict harm on others.

Justice

Fairness, equality, and equitable treatment.

Autonomy

Respect a person's freedom to choose what's right for them.

Beneficence

All choices and options are offered with the intent to do good.

WHY IS RISK ASSESSMENT IMPORTANT?

To justify imposing any research risks on participants in health research, the research must have **social and scientific value**.

Risk is an estimate of two factors:

1) How likely it is that a participant will experience a physical, psychological, social or other harm
2) The magnitude or significance of the harm

'Researcher, sponsor and the research ethics committee must ensure that risks to participants are **minimized** and **appropriately balanced**…'

Ref: Guideline 4, International Guidelines for Health-Related Research Involving Humans. Geneva: Council for International Organizations of Medical Sciences (CIOMS); 2016

RISK ASSESSMENT

- Potential benefits and risks of **each individual research procedure** must be evaluated

- **Aggregate** risks and potential individual benefits of the entire study must be assessed.
  - For example, a study may involve numerous procedures that each pose limited risks, but these risks may add up to an overall significant level of risk

Ref: Guideline 4, International Guidelines for Health-Related Research Involving Humans. Geneva: Council for International Organizations of Medical Sciences (CIOMS); 2016

MREC SCREENING PROCESS

Screening for completeness of documents

- All components of document present as per checklist?
- If incomplete, investigator to revise and submit complete documents before proceeding

Risk Assessment and Review Type Pathway

- 3 categories of risk: Low, medium and high risk studies
- 3 types of review: Expedited by chair, expedited by primary reviewers, and full board review

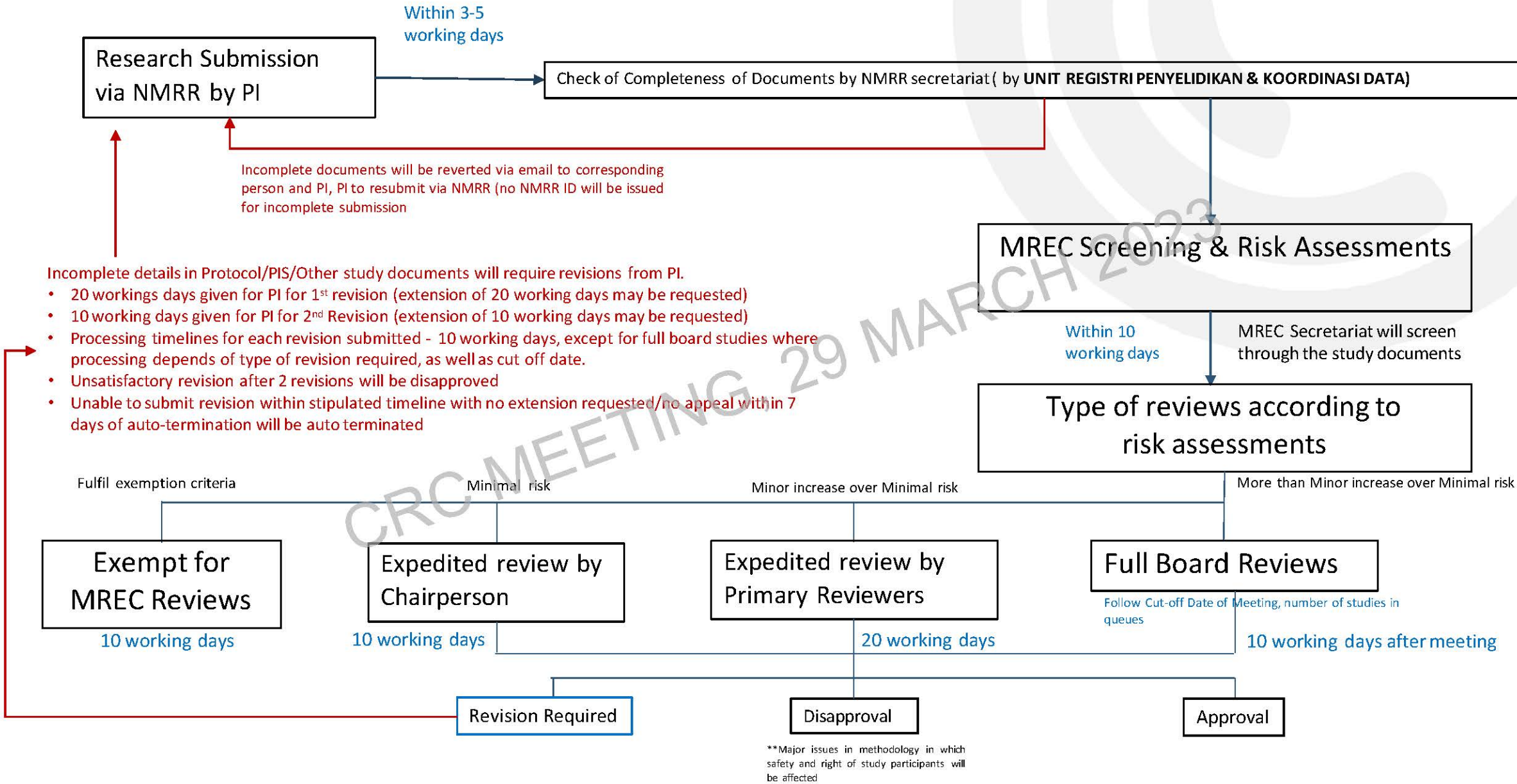
RISK ASSESSMENT

Low risk	Medium risk	High risk	Exemption
Retrospective records review	Questionnaire / interview involving sensitive questions	Randomized controlled trial	Systematic review / scoping review
Questionnaire	Vulnerable subjects (excluding retrospective studies)	Interventional study	Audit with no patient data involved
Biospecimen: blood < 5ml	Biospecimen collection: • 5 to 20 ml of blood • Other biological specimens (tissue, etc)	Experimental product / procedure OR standard procedure / product through randomization	Taste and food quality evaluation
Archived lab sample (with proper permission)	Genetic tests	Potential to induce physical/psychological stress	Case report (provided that consent has been obtained from subjects)
Audio recording with clear privacy statement	Storage for future studies	Involves additional radioactive imaging procedure	

↓ Expedited by Chairperson/Deputy Chair/Secretary

↓ Expedited by Primary Reviewers

↓ Full board review



CHECKLIST - PROTOCOL

General information	Methodology	Ethics and Data management
Version number and date	**Study design and objectives**, duration of subject participation (suggest table format)	Ethical considerations
Name and institution of all investigators	**Study procedures (in detail)** – description of intervention, including randomization procedure, blinding, etc	Means for protecting privacy and confidentiality of data and specimens
Sponsor	Study population and sample size (with calculation)	Description of informed consent process
Study sites	Inclusion and exclusion criteria	Risk/benefit assessment
Background	**Subject follow up,** especially safety assessments	Duration and means of storage/archiving of study data
Literature review	Endpoints/outcome	Study data disposal after period of storage
	Collection, storage and use of biospecimens (additional optional consent is applicable for storage)	Information on reimbursement/compensation
	Statistical methods and analysis	Whether study data will be informed to subject

CHECKLIST - PIS

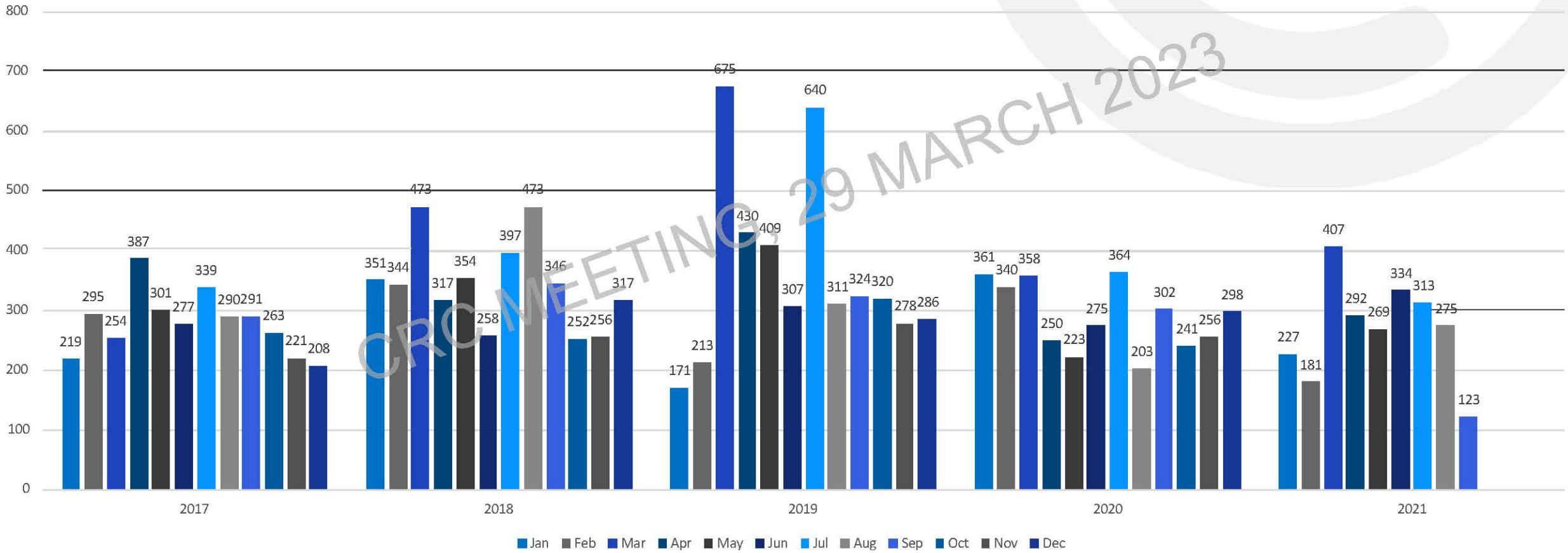
General information	Methodology	Ethics and data management
Version number and date	Explanation of study purpose and procedures in **layperson** terms	Voluntary participation
Name and institution of all investigators	Risks and expected benefits of standard treatment AND experimental treatment	Means for protecting privacy and confidentiality of data and specimens
Sponsor	Sequence and duration of all study activities (suggest table format)	Whether study data will be informed to subject
Study sites	Expected number of subjects	Contact information of investigator and MREC
	Collection, storage and use of biospecimens	Signature page – should have name, IC number, signature and date of ALL signatories
	Information on expected expenses and reimbursement	Access to medical records and study data

Storage and future research on biospecimens requires a SEPARATE consent form

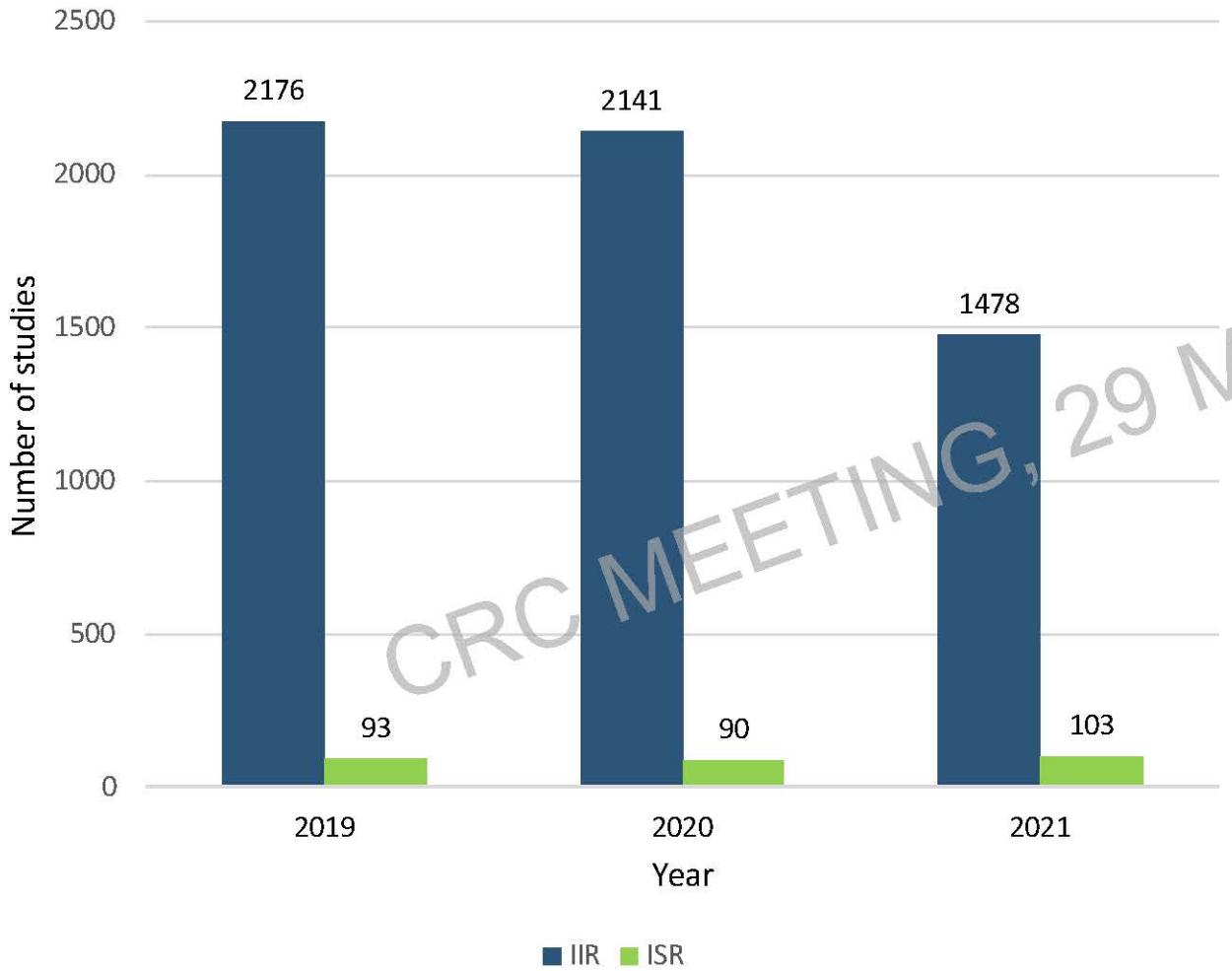
Assent forms are separate for ages 7-12 and 13-less than 18 years old

MREC WORKLOAD STATISTICS

NUMBER OF NMRR REGISTRATION 2017-2021 (MONTHLY CENSUS)

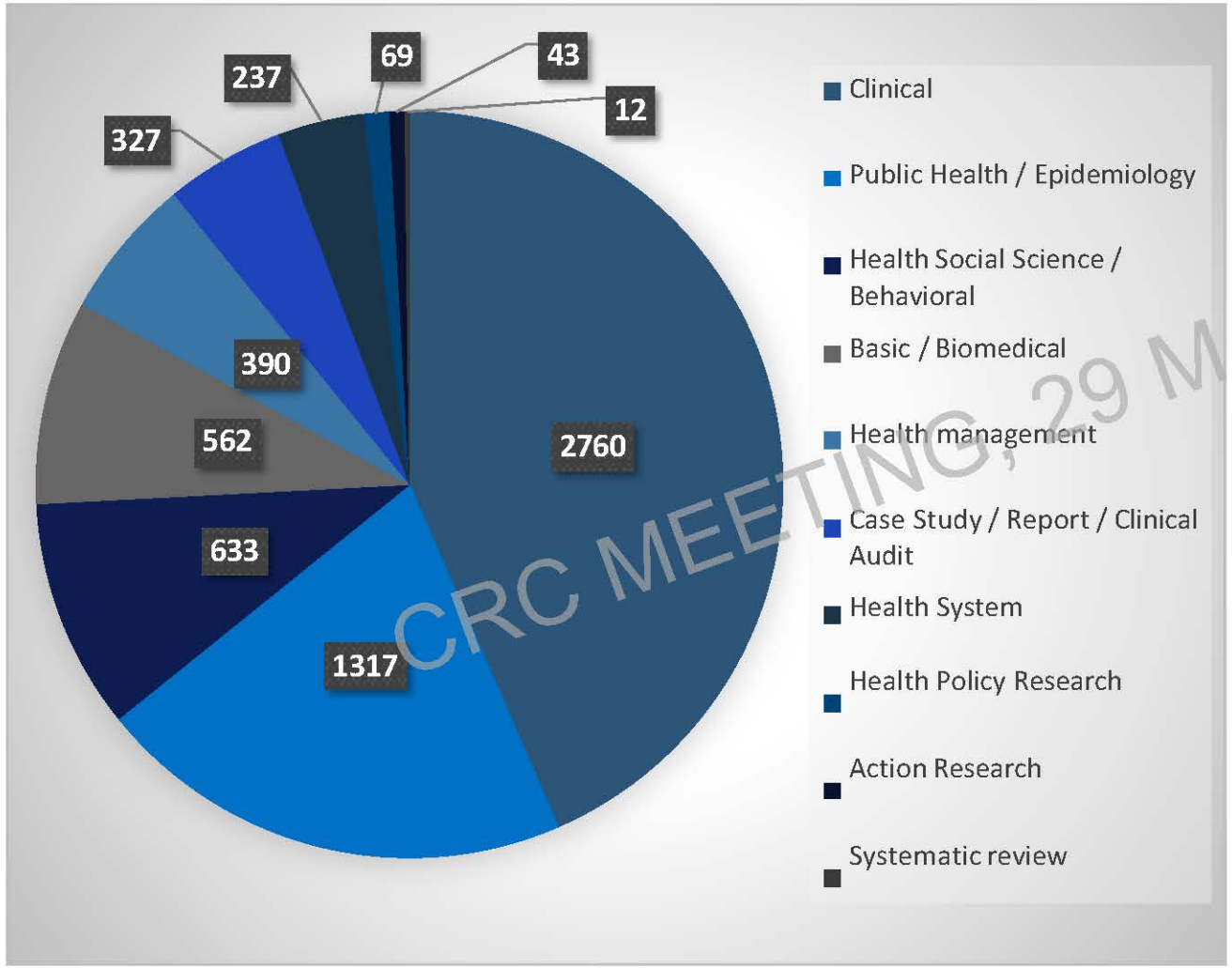


Number of approved IIR and ISR studies from 2019 until Nov 2021



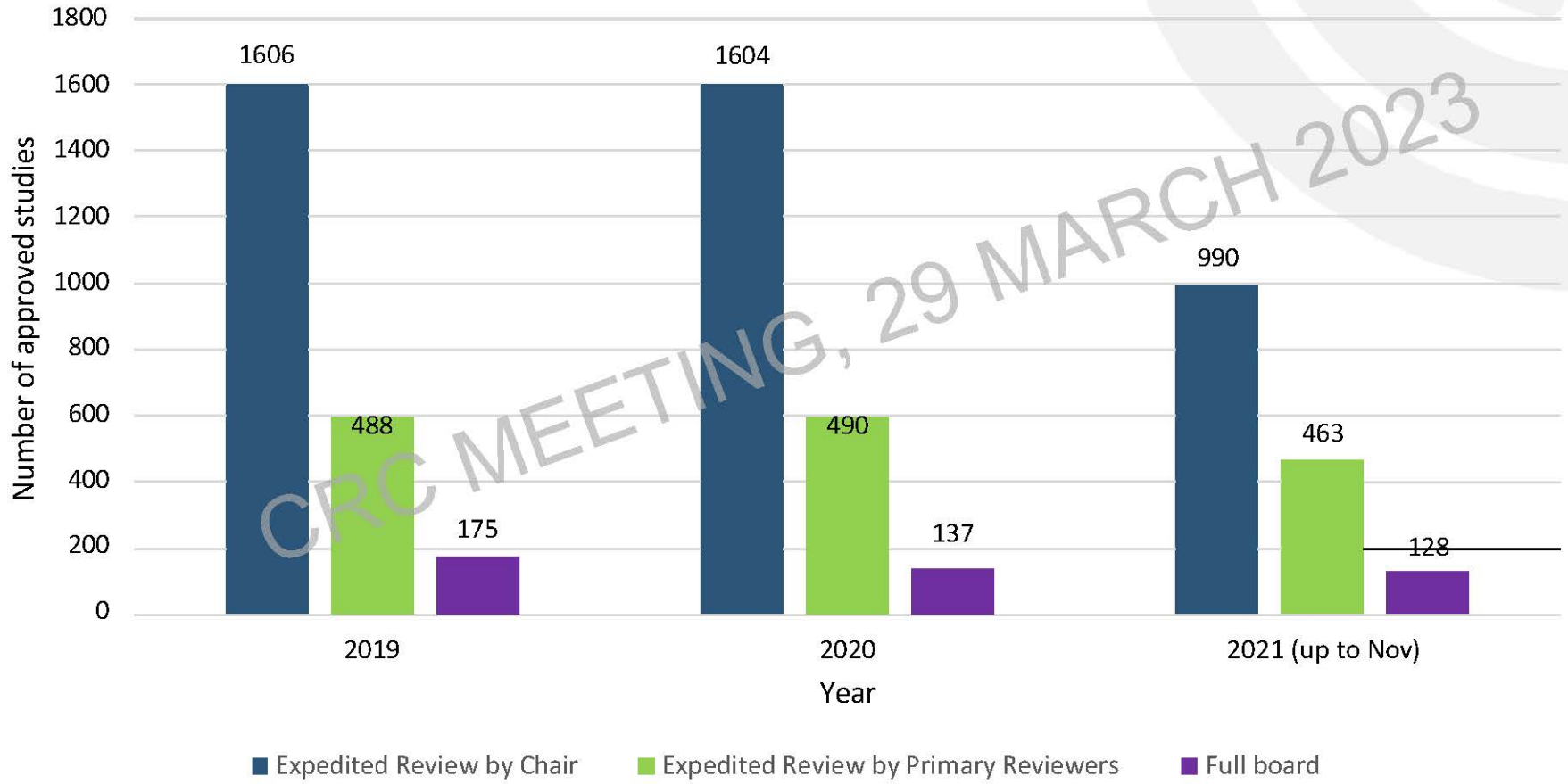
	2019	2020	2021
IIR	95.9%	96.0%	93.5%
ISR	4.1%	4.0%	6.5%

Number of approved research according to type/area from 2019 till Nov 2021

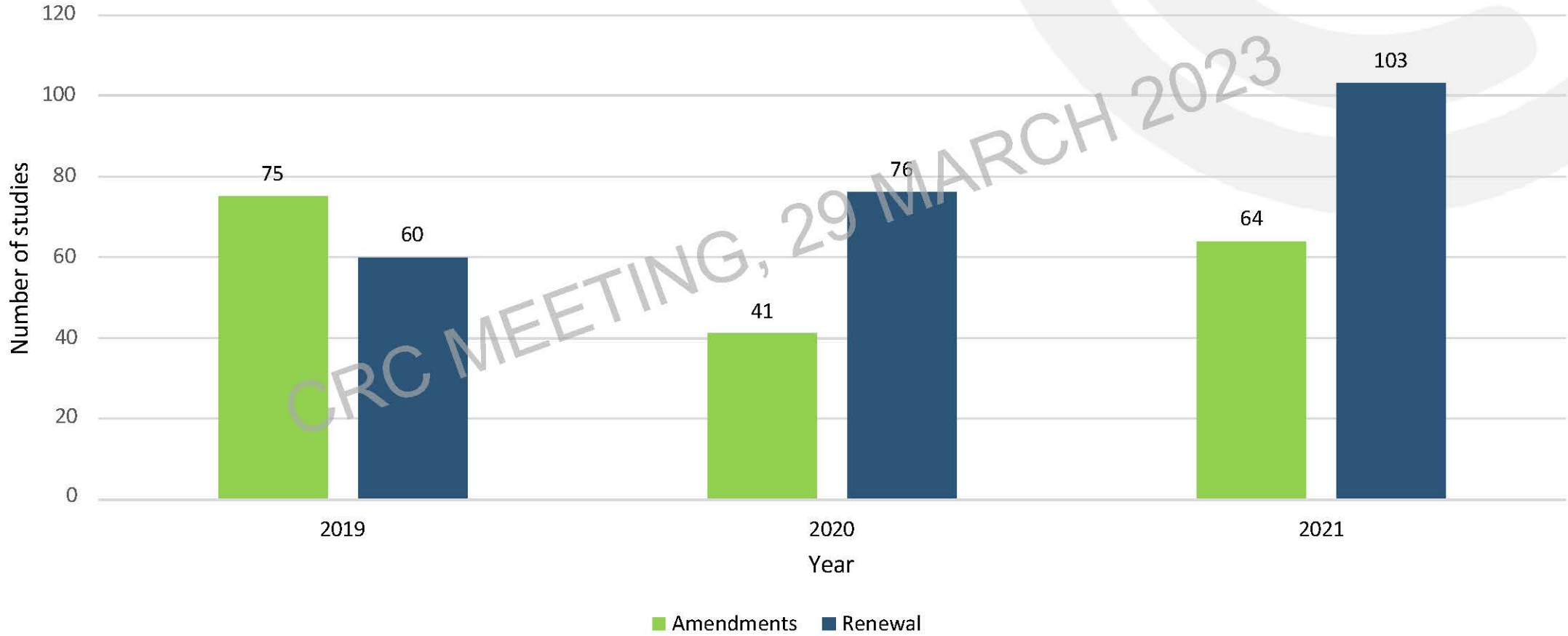


Research Area	Percentage (%)
Clinical	43.5
Public Health / Epidemiology	20.7
Health Social Science / Behavioral	10.0
Basic / Biomedical	8.9
Health management	6.1
Case Study / Report / Clinical Audit	5.1
Health System	3.7
Health Policy Research	1.1
Action Research	0.7
Systematic review	0.2

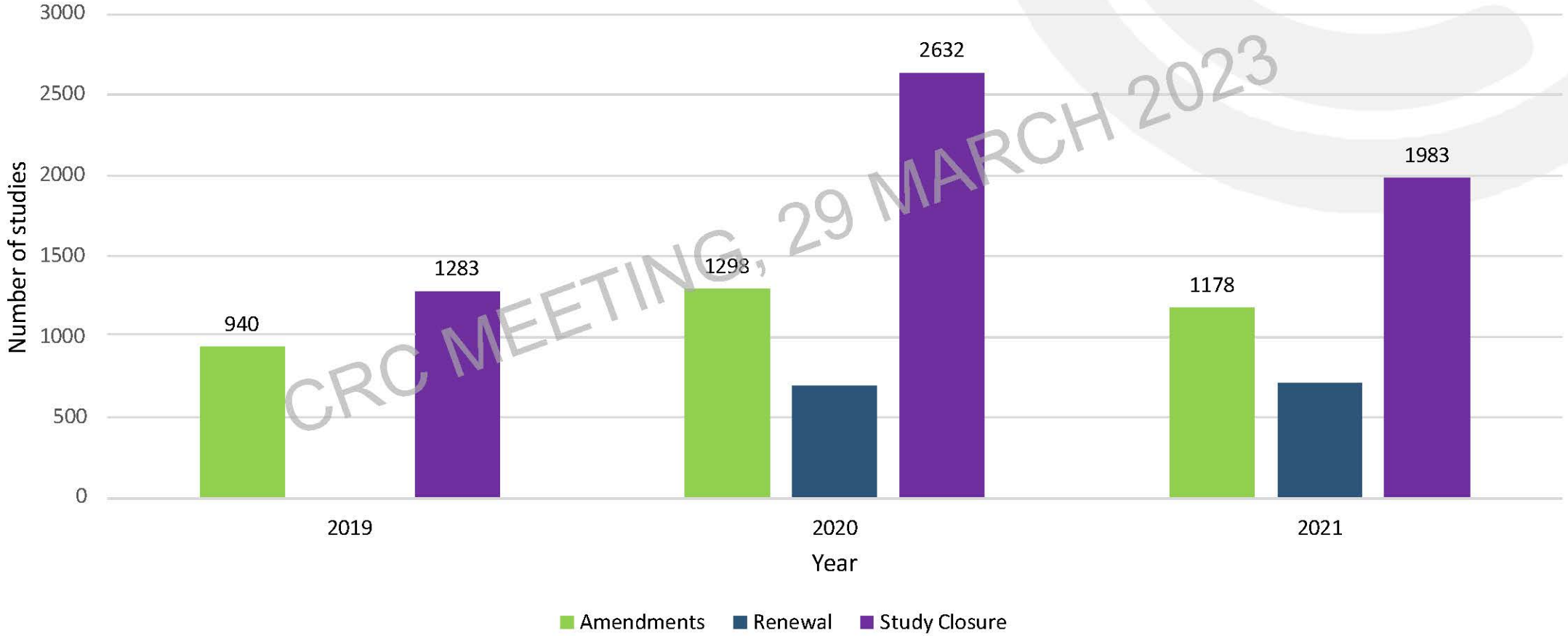
NUMBER OF APPROVED STUDIES ACCORDING TO REVIEW PATHWAY FROM 2019 TILL NOV 2021



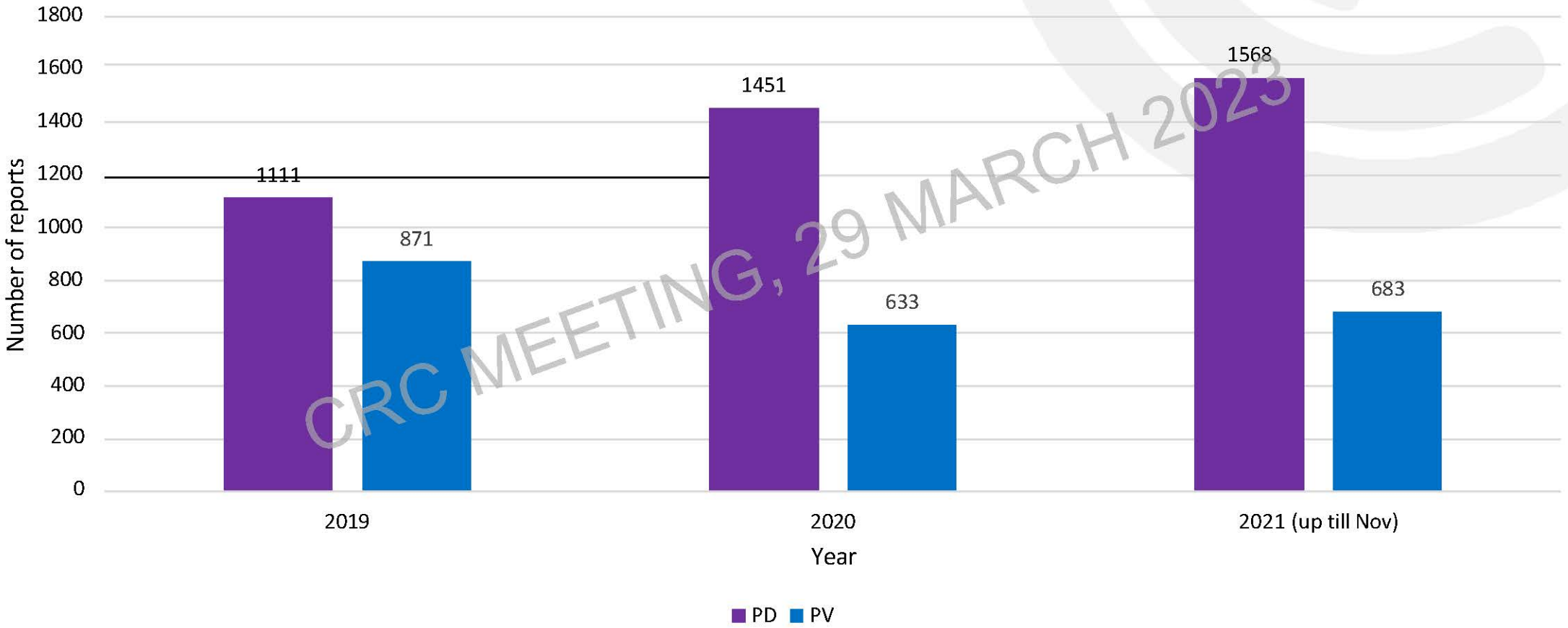
NUMBER OF AMENDMENTS AND RENEWAL APPROVED BY FULL-BOARD FROM 2019 UNTIL NOV 2021



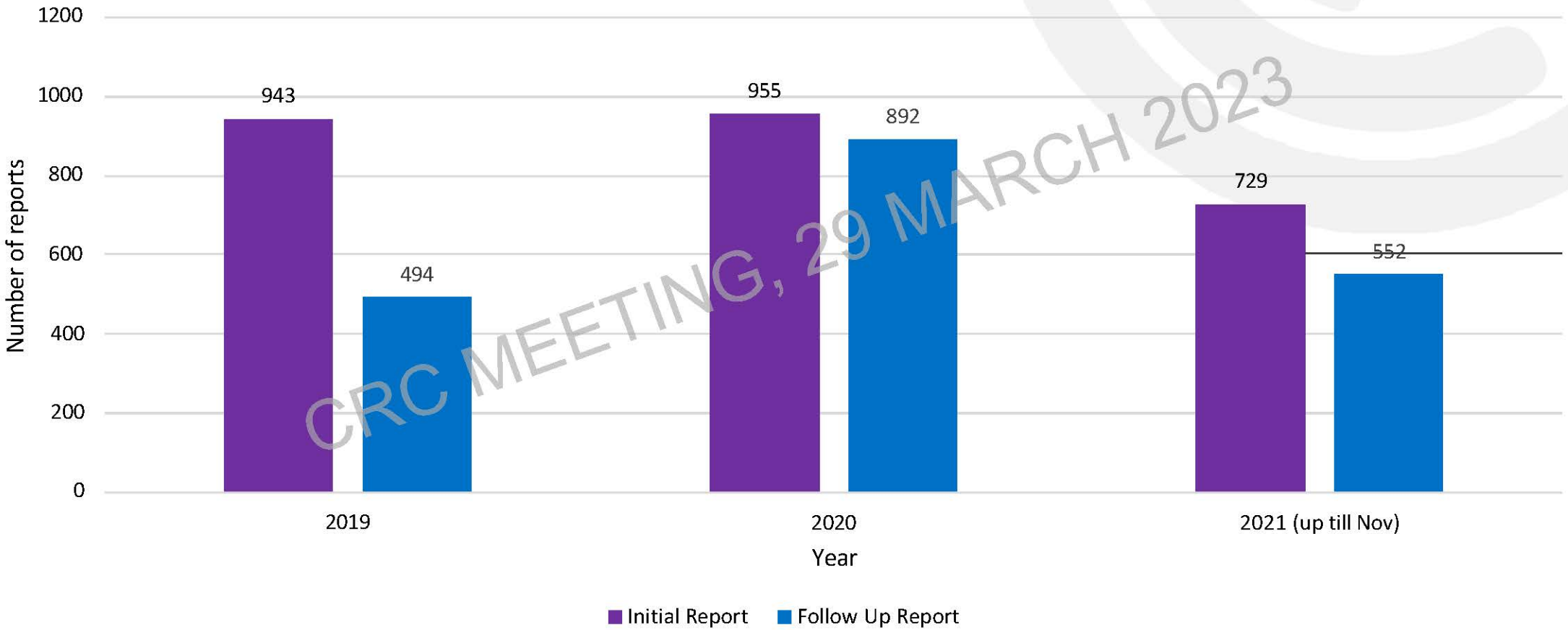
NUMBER OF AMENDMENTS, RENEWAL AND STUDY CLOSURE ENDORSED FROM 2019 UNTIL NOV 2021



NUMBER OF PROTOCOL DEVIATIONS (PD) AND PROTOCOL VIOLATION (PV) ENDORSED IN FULL-BOARD FROM 2019 TILL NOV 2021



NUMBER OF SERIOUS ADVERSE EVENTS INITIAL REPORT AND FOLLOW UP REPORT ENDORSED IN FULL-BOARD FROM 2019 TILL NOV 2021



NUMBER OF PROTOCOL DEVIATIONS (PD), PROTOCOL VIOLATION (PV) AND SERIOUS ADVERSE EVENTS (SAE) REPORTS FROM 2019 TILL NOV 2021

	PD	PV	SAE	TOTAL
2019	1111	871	1437	3419
2020	1451	633	1847	3931
2021	1568	683	1281	3532
Total	4130	2187	4565	10882

MREC COMPLIANCE REVIEW

- **As per MCGP 3.2.2 - The IRB/IEC should perform its functions according to written operating procedures, should maintain written records of its activities and minutes of its meetings, and should comply with GCP and with the applicable regulatory requirement(s).**
- MREC conducted compliance reviews to ensure safety and rights of study participants are always protected according to MGCP

Year	Type	IIR	ISR
2018	Routine	1	2
	Triggered	1	5
2019	Routine	3	5
	Triggered	0	1
Total		5	13

THE PURPOSE OF THE COMPLIANCE REVIEW IS TO:

a. Confirm if the Principal investigator (PI) is complying with protocol and regulatory requirements. Assist the PI in complying with Regulations and Protocol.

b. Confirm if the PI is taking appropriate and timely action to ensure protection of the rights, safety and well-being of research subjects at all times.

c. Provide assurance to the public as well as to the Ministry of Health Malaysia that MREC is providing the continued oversight of studies and ensuring that rights, safety and well-being of research subjects are safeguarded.

SCOPE

This procedure applies to all research approved by the MREC and covers 3 types of compliance review:

a) full scope;

b) limited scope; and

c) for cause.

Limited Scope Review - Only selected elements in Review Checklist will be checked

For Cause Review is a review conducted in response to

a. Complaints about a study, received from sponsor, study monitor or any other source.

b. Concerns noted in the regular monitoring of a study, e.g. too many deaths /SAEs and/or protocol violations.

c. Investigator not complying with the requests from MREC.

QUANTUM AND FREQUENCY OF COMPLIANCE REVIEWS

- Each year the MREC strives to conduct FS or LS Compliance Reviews on not less than 5% of the total number of MREC approved studies conducted in the preceding year. Compliance Reviews are only done for studies that have been conducted for at least 1 year.

PREPARATION FOR COMPLIANCE REVIEW

- In preparation for the FS or LS Compliance Review the team reviews study documents and gathers information pertaining to the study. These include but not limited to:
  - A copy of the latest protocol
  - A copy of the Investigator Brochure
  - A copy of the latest Informed Consent Form and advertisement (if applicable)
  - Minutes of all MREC meetings where the study was discussed
  - All the study information shared by the Investigator with the MREC including protocol deviations, SAEs, progress reports, etc.
  - Any other information available
- In preparation for a FCR the team reviews relevant documents and gathers pertinent information for which the FCR is required.
- The CR team has the authority to request additional documents not submitted earlier for the registration of the study.
- At least 10 or 10% of the total number of subjects recruited for each treatment group, whichever is more, shall be reviewed.

ESSENTIAL DOCUMENTS

- Approval letters from MREC
- Signed Protocol and Investigator Brochure
- Insurance Certificate or Letter of Indemnity
- Instructions for handling Investigational Product
- Contract/ Clinical Trial Agreement
- Informed Consent Form
- Recruitment procedures and its Approval (e.g. any advertisement)
- Updates/Progress Reports submitted to MREC
- Financial Disclosures

STAFFING AND INFRASTRUCTURE

- Curriculum Vitae and training records for study team
- Availability of infrastructure and equipment based on the study requirements and its maintenance records
- Oversight or monitoring performed by sponsor/CRO

INFORMED CONSENT DOCUMENTATION

- Different versions (if applicable) of ICF used and its approval by MREC
- Compliance of ICF document with Malaysia GCP requirements.
- Select patients consent records and review the process followed
- Availability of consent forms for all screened subjects
- Timely re-consent from subjects in case of update of documents.

- **Review of Patient Records**
  - Subject eligibility per protocol
  - Compliance to Protocol processes and timelines
  - Correct use and dose of Investigational Product
  - Review of AE/SAE reporting and its management
  - Investigator follow up and medical care

- **Review of SAE reports**
  - Confirm the accuracy details after verification with patient records.
  - Verify if the SAEs have been reported in timely manner to MREC

- **Review the Investigational Product (IP)**
  - Storage and security of IP
  - Accountability of IP and disposal records
  - Environment monitoring of IP
  - If necessary, the CR team visits other facilities involved in the study including Laboratory or Radiology department.

THE FINDINGS SEVERITY IS DEFINED AS FOLLOWS:

Critical:	Major:	Minor:
• Conditions, practices or processes that adversely affect the rights, safety or well being of the subjects and/or the quality and integrity of data	• Conditions, practices or processes that might adversely affect the rights, safety or wellbeing of the subjects and/or the quality and integrity of data.	• Conditions, practices or processes that would not be expected to adversely affect the rights, safety or well being of the subjects and/or the quality and integrity of data

- A closing meeting will be held on the day the CR is completed.
- The CR team prepares draft CR report within **30 working days** of completion of the review
  - **Part 1 , Section A** on the general information
  - **Part 1, Section C** on Executive summary
  - **Part 1, Section D** on Introduction
  - **Part 1, Section E** on Scope
  - **Part 1, Section F** on Recommendation using the following:
    - Continue trial
    - Withhold new subject recruitment until assessment and verification of CAPA by CR team
    - Suspend ethics approval for the site to conduct new trials until assessment and verification of CAPA by CR team
    - Suspend ethics approval for the trial
  - **Part 1, Section G** on Summary of Findings severity

- Investigator or representative completes **Part 1, Section B** for Acknowledgement of receipt of the CR report and sends signed Acknowledgment back to the MREC Secretariat.

- The study investigator provides responses to the findings and completes **Part 2, Section B** for the CAPA within **20 working days** from the receipt of the findings.
  - If recommendation is to suspend ethics approval for the trial, investigator need not fill in **Part 2, Section B.**

- If there is no response from the investigator after the deadline, the Secretary sends a reminder requesting the investigator to submit the respond to the findings **not later than 7 working days** from the date of the reminder letter. If the investigator fails to respond after the second deadline, the CR team will bring to the attention of the MREC panel for subsequent actions to be taken.

- The CR team reviews the CAPA and provides necessary comments. The Findings and CAPA will be presented to the earliest Panel meeting for endorsement.

- The CR team leader will update and verify the CR report and follow up on the CAPA until sufficiently satisfied with the actions taken and the findings closure.

- The Secretary will track and the findings on the Issue Tracking Log and updates the Panel that endorsed the findings, on the progress of the CAPA.

REGULAR TRAINING - ANNUALLY

- FERCAP – Annual Conference
- NERCIM training – CME monthly as well as training at least 2 times per year
- Internal training
  - MREC Members orientation
  - MREC SOP Training
  - MREC Training for Subcommittee (PD & SAE)
  - MREC Members training
  - GCP training for members
  - Other training related to ethics

BENEFIT & CHALLENGES OF CENTRAL IRB

- FDA, OHRP, NIH, etc all support the use of central IRBs to improve the efficiency of conducting multi-site trials
- Enhance research partnerships
  - Industry - sponsored research
  - Cooperative group research
  - Inter-institutional academic relationships
- Ensure consistency between investigative sites by utilizing a single IRB
- Avoid individual reviews by local IRBs
- Respond to country's need

- Challenges: Manpower to ensure efficiency of the IRBs, Oversight

THANKYOU