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MINISTRY OF HEALTH MALAYSIA
NATIONAL INSTITUTES OF HEALTH (NIH)

NATIONAL INSTITUTES OF HEALTH (NIH)

GUIDELINES FOR CONDUCTING RESEARCH IN MINISTRY OF HEALTH (MOH) INSTITUTIONS & FACILITIES

IMR
IPH
ICR
IHM
IHSR
IHBR
NIH MANAGER & REGISTRAR

NATIONAL INSTITUTES OF HEALTH (NIH)

GUIDELINES FOR CONDUCTING RESEARCH IN MINISTRY OF HEALTH (MOH) INSTITUTIONS & FACILITIES

3RD EDITION
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TERMINOLOGY AND ABBREVIATION

ACUC	:	Animal Care and Use Committee
Audit/Clinical Audit	:	A systematic analysis of the quality of medical care such as the diagnostic procedure in place and/or the treatment, the use of resources, and the resulting outcome. It is designed and conducted to produce information to identify opportunities for improvement and to provide a mechanism delivery of best care. It involves comparing intervention(s) / service(s) in use and measures against a standard clinical care / practice / guideline. Usually involves analysis of existing data but may also include administration of simple interview or questionnaire. There is no allocation to any intervention on patients/subjects. [1]
BA/BE	:	Bioavailability/Bioequivalence
BSO	:	Biological Safety Officer
Clinical Trial/Research	:	Any investigation in human subjects intended to discover or verify the clinical, pharmacological and/or other pharmacodynamics effects of an investigational product(s) and/or to identify any adverse reactions to an investigational product(s) and/or to study absorption, distribution, metabolism, and excretion of an investigational product(s) with the object of ascertaining its safety and/or efficacy. The terms clinical trial and clinical research is synonymous
CP	:	Corresponding Person
CKAPS	:	Cawangan Kawalan Amalan Perubatan Swasta
COI	:	Conflict of interest
Contained Use Activity (in Modern Biotechnology)	:	Refers to any operation including research and de-velopment, production or manufacturing operation involving LMO, or storage of LMO, undertaken with-in a facility, installation or other physical structure such that it prevents contact or impact of the LMO on the external environment.
CRC	:	Clinical Research Centre
CTIL	:	Clinical Trial Import License
CTX	:	Clinical Trial Exemption
FIH	:	First-In-Human
GCP	:	Good Clinical Practice
GCP Certificate	:	Certificate issued by NPRA to the investigator who is able to complete the GCP course and pass the exit exam at the end of the course
HRRC	:	Hospital Research Review Committee
HRRC Reviewer	:	Hospital Research Review Committee Reviewer appointed by the Hospital Director with the advice from Head of CRC
HRRC Secretariat	:	Secretariat for HRRC
IA-HOD-IA	:	Investigator Agreement - Head of Department-Institutional Agreement
IBBC	:	Institutional Biosafety and Biosecurity Committee

IBC	:	Institutional Biosafety Committee
ICMJE	:	International Committee of Medical Journal Editors
IEC	:	Independent Ethic Committee
Investigator	:	A person responsible for the conduct of the research at a research site. If research is conducted by a team of individuals at one or more research sites, the responsible leader of the team may be referred to as the Principal Investigator
IP	:	Intellectual Property
IRB	:	Institutional Review Board
IDMC	:	Independent Data-Monitoring Committee (also known as Data and Safety Monitoring Board, Moni-toring Committee or Data Monitoring Committee)
JPP-NIH	:	NIH Research Review Panel (*Jawatankuasa Penilaian Penyelidikan-NIH)*
JPP-NIH Secretariat	:	Secretariat for JPP-NIH
JPP- CRC	:	Clinical Research Center Research Review Panel *(Jawatankuasa Penilaian Penyelidikan-CRC)*
JPP-CRC Secretariat	:	Secretariat for JPP- CRC and all HRRCs
LMOs	:	Living Modified Organisms
MoA	:	Memorandum of Agreement
MCRCR	:	The Malaysian Code of Responsible Conduct in Research
Minimal Risk Research	:	Research in which probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or in the routine medical, dental, or psychological examination of healthy persons
Modern Biotechnology	:	Application of in vitro nucleic acid techniques, in-cluding recombinant DNA and direct injection of the nucleic acid into cells or organelles; or fusion of cells beyond the taxonomic family, that overcome natural physiological reproductive or recombina-tion barriers that are not technique used in tradi-tional breeding and selection.
MOH	:	Ministry of Health Malaysia
MOH Investigator	:	Investigator from MOH Facilities other than National Institutes of Health (NIH)
More than Minimal Risk Research	:	Research in which the probability of the occurrence of an adverse event is more than what is normally encountered and likelihood of serious harm is plausible which may cause a temporary or permanent effect to subject
MoU	:	Memorandum of Understanding
MREC	:	Medical Research & Ethics Committee
MRG	:	MOH Research Grant
MRG Secretariat	:	Secretariat MOH Research Grant
NCCR	:	National Committee for Clinical Research

NDA	:	Non-Disclosure Agreement: It is the legal contract that establishes a confidential relationship between 2 or more parties which shall be ready upon entering negotiations
NIH	:	National Institutes of Health. NIH comprises of 6 institutes:- i. Institute for Medical Research (IMR) ii. Institute for Public Health (IPH) iii. Institute for Health System Research (IHSR) iv. Institute for Clinical Research (ICR) v. Institute for Health Management (IHM) vi. Institute for Health Behavioural Research (IHBR)
NIH Investigator	:	Investigator from NIH facilities
NMRR	:	National Medical Research Register
NPRA	:	National Pharmaceutical Regulatory Agency
NRDHM	:	National Committee for Research and Development of Herbal Medicine
NSCERT	:	National Stem Cell Research and Ethics Subcommittee
PD	:	Protocol Deviation
PI	:	Principal Investigator
PUU	:	*Penasihat Undang-Undang*
RA	:	Research Agreement
Release Activity (in Modern Biotechnology)	:	Refers to any intentional introduction of living modi-fied organisms or products of such organisms into environment through activities or for purposes specified in the Second Schedule.
SAE	:	Serious Adverse Event
SADE	:	Serious Adverse Device Effect
Scientific Merit	:	The quality of the research with sound methodology and obligation to provide new information and evidence. [2]
Second Schedule	:	A list of microorganisms that can cause severe/lethal disease, high risk to individual and community and potential to be weaponized [3].
SME	:	Subject Matter Expert
SOP	:	Standard Operating Procedure
SRP	:	Scientific Review Panel
Sub-I	:	Sub Investigator. Any individual member of the research team designated and supervised by Principal Investigator at a research site to perform research related procedures and/or to make important research-related decisions (such as clinicians, medical personnel, associates, residents, research fellows)
Surveillance	:	A systematic collection and analysis of health- related data designed to help in organisation, implementation and health service delivery (for example in situation such as managing an outbreak). It helps the authority and public by identifying and understanding the risks associated. Personal data and samples may be collected with the intent to manage the incident. This may involve a systematic, statistical methods to allow timely public health action. Normally it does not involve an intervention. [1]

FOREWORD

The National Institutes of Health (NIH), a research arm of the Ministry of Health Malaysia has taken the responsibility to ensure all researchers are adhering to good research practice while conducting their research.

This guideline provides organised and systematic information on research procedures and requirements as well as research framework and principles that can comprehensively guide the researchers on the conduct of research in the Ministry of Health (MOH) facilities and institutions.

We hope that this document can also be utilised at multiple levels either nationally, across the stakeholders, and intra- or inter-agencies. This structured guideline compiles detailed procedures for every research stage starting from research registration to research product commercialisation. I believe the publication of this guideline will spur on the discovery of more research talents and entice interest in the young researchers to be actively involved with health research and contribute to our nation.

Finally, I would like to congratulate everyone who is directly involved in the documentation of this guideline. I hope this document will serve as a national reference for any research-related procedures. Being a researcher requires dedication, hard work, and inspiration. Even Albert Einstein once said that if we knew what we are doing, it would not be called research. Therefore, let us continue to search for scientific evidence via research and enhance the quality of healthcare services.

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Collaboration and Innovation Unit
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1. Introduction

The primary purpose of research in medicine is to investigate and to understand the causes, developments, and effects of health-related phenomena or events, and to improve the preventive, diagnostic, and therapeutic interventions. In order to achieve this objective, the proposed research or study must be thoroughly evaluated for its methodology, scientific validity, safety, quality, effectiveness, efficiency, and accessibility.

Based on the set of principles as outlined by the Declaration of Helsinki, it is necessary for an investigator to conduct research especially research that involves human subjects to contribute to the knowledge of science and to improve the healthcare, health delivery systems while maintaining and protecting the safety and wellbeing of the data and the subjects involved [4]. Furthermore, conducting research from planning, grant funding as well as recruiting and collecting data needs to be performed meticulously and monitored throughout the research period. Besides that, dissemination of research findings and protection of intellectual properties are also important aspects of research that need to be considered. This is to ensure that the investigators, key stakeholders, and most importantly society will benefit from the research.

This guideline is compiled to help investigators from the MOH as well as others who are involved in the conduct of any research involving the MOH facilities, subjects, samples or data. All requirements and information in this document were adapted from both international and local guidelines and regulations.

2. Definition of Research

Research is a systematic investigation involving the development of a hypothesis, testing, and subsequent evaluation of the hypothesis on a particular subject(s) to establish and discover new facts, principles or information [5,6,7]. In a general context, research could be a process to create new generalisable knowledge or using existing knowledge to develop new findings and/or outcomes. This process could be done using suitable methodologies that cover data collection, documentation of critical information, synthesis, analysis, and interpretation of data or information set by specific professional fields. From this point onwards, all acts of the abovementioned shall be referred to as research.

3. Policy Statement

3.1. General Policy of Research Conduct in MOH Malaysia
3.2. Category of Investigator
3.3. The Conduct of Research
3.4. Roles and Responsibilities of the Institutional/Facility Director, Head of Department (HOD), Clinical Research Centre (CRC) Unit and Research Review Committee (Panel/ Reviewers and Secretariats)
3.5. Ethical Review
3.6. MOH Research Grant Approval
3.7. Publication & Presentation Approval

Policy Statements

3.1 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.

3.2 Category of Investigator

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

i. MOH & NIH Investigator **
ii. Non - MOH Investigator
iii. Investigator applying for MOH Research Grant (MRG)

* Refer to policy statement 3.5
** 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.

3.3 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. **(Appendix 1)**;
   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.

ii. After obtaining ethical approval, and before the recruitment of subjects and/or data collection,
   a. Sites without a signed IA-HOD-IA form should obtain approval to conduct research at each site via the Site Approval Form **(Appendix 2)**. An investigator is required to fulfil any other site's requirements depending on the respective facilities/institution's SOP.

Policy Statements
iii. During the conduct of the research (recruitment of subjects and/or data collection). a. Any subsequent changes or additions to research 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.
3.4 Roles and Responsibilities of the Institutional/Facility Director, Head of Department (HOD), Clinical Research Centre (CRC) Unit and Research Review Committee (Panel/ Reviewers and Secretariats) Institutional/Facility Director, Head of Department (HOD), Clinical Research Centre (CRC) Unit Monitoring of research conducted at MOH institutions/facilities is under the responsibility of respective Institutional/Facility Director, Head of Department (HOD) and Clinical Research Centre (CRC) Unit (if available) Research Review Secretariat (JPP-NIH) i. Examine for completeness of all submitted research applications and documents; ii. Assign and distribute the research application to the JPP-NIH Panel or Reviewers for review and recommendation; and iii. Forward the completed reviewed research application with recommendations from the JPP-NIH Panel or Reviewers to MREC for further action and consideration. Research Review Committee (JPP-NIH Panel or Reviewers) i. Review the scientific merit of the research applications; and ii. Propose recommendations to support or reject the research applications based on the review. iii. For research with MRG application a. Propose recommendations to support or reject the MRG application; and b. Evaluate and monitor the progress of the MRG awarded research. Research Review Secretariat (JPP-CRC) i. Examine for completeness of all research applications and documents; ii. Assign and distribute the research application to relevant HRRCs; iii. Coordinate between all HRRCs.

Policy Statements	
	Research Review Secretariat (HRRC Secretariat) i. Assign and distribute the research application received from JPP-CRC Secretariat to HRRC Reviewers for review and recommendation; ii. Oversee and monitor the review process by the HRRC Reviewers; and iii. Forward the completed reviewed research applications with recommendations from HRRC Reviewers to MREC for further action and consideration. Research Review Committee (HRRC Reviewers) i. Review the scientific merit of the research applications; and ii. Propose recommendations to support or reject the research applications based on the review.
3.5	**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 (clinical trial) or interaction (questionnaire in health survey) with the individual or investigator has access to identifiable private information (medical record or personal data)" [8]. Submission to MREC for ethics review and approval is conducted online through NMRR.
3.6	**MOH Research Grant (MRG) Approval** The MRG Review Panel chaired by the Deputy Director-General of Health (Research and Technical Support) shall convene and gives final approval to research requesting funds that have been supported by the JPP-NIH Panel and have obtained MREC approval.
3.7	**Publication and Presentation Approval** All dissemination of scientific outputs such as abstracts for oral or poster presentation, research reports, journal articles, conference proceedings undertaken by MOH personnel OR utilising data of MOH patient/ sample/ personnel as subject OR funded by a MOH research grant shall require review and subsequent approval by the Director-General of Health prior to publication and presentation.

4. Research Registration and Submission

All research undertaken by MOH personnel or conducted in MOH institutions/facilities or using MOH data/patient/sample/personnel as subject or funded by MRG must be registered with NMRR prior to data collection and/or subject recruitment. Retrospective registration is only applicable (although not advisable unless in unavoidable circumstances) for research that does not require ethical review and approval by MREC, MOH (such as case study, systematic review, scoping review, and research involving non-human subjects). Submissions for ethical review and grant application should be made together during research registration. Submission for publication and presentation approval can be made either together* or after research registration. Submission to other regulatory authority or committee for specific research approval should be done either before, during or after research registration in NMRR depending on the requirement by the respective authority or committee. **Any research led by non-MOH investigators involving any MOH personnel as part of the research team is required to be registered as well.**

Applications submitted for research approval will be subjected to a scientific review as well as an ethical review. For Minimal Risk Research, the scientific review will be undertaken either by **JPP-NIH or HRRC** ①. Recommendations following this review will be forwarded to **MREC, MOH** for further consideration and ethical review. Meanwhile, the More than Minimal Risk Research and all Industry Sponsored Research (ISR) will be forwarded directly to **MREC** for review and ethical consideration ②. **(①, ② refer to Diagram 1: Scientific and Ethical Review Processing Flowchart)**

* Refer to **Diagram 4: Publication and Presentation Review Processing Flowchart**

Research applications submitted for MRG need to be submitted together with the application for MREC ethical review. Submissions for MRG will be reviewed by the JPP-NIH ①. Recommendations will be forwarded to the MREC, MOH for consideration and ethical review ②. Once ethical approval has been obtained, the research submission will be forwarded to the **MRG Review Panel** for final review and grant application approval ③. **(①, ②, ③ refer to Diagram 2: MRG Processing Flowchart)**

Research registration and submission for ethical approval, MRG application, Publication and Presentation approval can be applied online via the **National Medical Research Register (NMRR) at nmrr.gov.my.**

Registration of Clinical Trials in Malaysia involving investigational product(s) (including placebo) requires the research to be registered (compulsory) in the NMRR and notified to the National Pharmaceutical Regulatory Agency (NPRA).

4.1. National Medical Research Register (NMRR)

NMRR is a web-based tool developed in 2007 to support the implementation of the National Institutes of Health (NIH) guidelines on the conduct of research in MOH. It enables online registration, submission, review, and approval for research related to MOH. NMRR also serves as a publicly accessible database of medical research conducted in the country (generally in MOH) and these include clinical trials that are carried out in Malaysia.

The NMRR platform includes several modules namely research registration, submission for scientific and ethical review and approval, submission for a grant application, and submission for presentation and publication approval. The secretariat will coordinate and monitor the processes through this platform.

Documents and information required for research registration:

1. Investigator's Curriculum Vitae (CV);

2. Investigator's GCP Certificate (mandatory for all investigators conducting research involving humans such as interventional or clinical trials);

3. Research information* such as:

    i. Title;
    ii. Research Background;
    iii. Objective/s;
    iv. Sample Size;
    v. Inclusion and Exclusion Criteria/s;
    vi. Research Outcome;
    vii. Research Duration;
    viii. Research Site/s;
    ix. Research Team/Investigators;
    x. Sponsorship; and
    xi. Corresponding Person.

4. IA-HOD-IA form. This form is to be submitted by the PI, PI at the site, and at least one Sub-I (from site/s with no "PI at the site"). The purpose is to notify and to obtain approval from both the HOD and Institutional or Organisational Director from the place of investigator origin/ affiliation to conduct the research. This form is compulsory to be submitted in the NMRR by the PI and PI at the site. **(Appendix 1)**

*Kindly refer to nmrr.gov.my for further information

For further questions and inquiries, investigator may contact the NMRR Secretariat at:

Research Registry and Data Coordination Unit (NMRR Secretariat),
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Level 2, Block A,
National Institutes of Health (NIH),
No 1 Jalan Setia Murni U13/52,
Seksyen U13 Bandar Setia Alam,
40170 Shah Alam
Phone: +603-3362 8205/8079
Email: nmrr@moh.gov.my

5. Roles and Responsibilities of the Research Review Panel or Committee in Scientific Review

5.1. JPP-NIH

5.1.1. Establishment of JPP-NIH

Jawatankuasa Penilaian Penyelidikan NIH (JPP-NIH) was first established in May 2014 and is responsible for evaluating, reviewing, and supporting the scientific merit of research with or without MRG.

The JPP-NIH panel consists of two (2) panels based on research areas of:

i. Biomedical; and
ii. Public health or clinical.

Research protocols will be reviewed and evaluated via:

i. JPP-NIH Panel meeting (for research with MRG application); or
ii. JPP-NIH Expedited Review (for minimal risk research and/or research without MRG application).

5.1.2. Appointment of Members

Panel members are appointed by the Deputy Director-General of Health (Research & Technical Support). These members are the subject matter experts (SME) in the field of biomedical, public health, and clinical areas including external members who are not within the NIH or MOH. Membership of the appointed panel will be granted for two (2) years. Additional external members or panels may be summoned on an ad hoc basis to review and evaluate the protocols that require their areas of expertise.

5.1.3. Chairperson(s)

The meetings will be chaired by different chairpersons depending on the type of research protocols as well as the chairperson's area of expertise. The chairpersons for the following panels are:

i. Biomedical Panel: Director of Institute for Medical Research (IMR); and
ii. Public Health or Clinical Panel: Director of Institute for Public Health (IKU) or Director of Institute for Clinical Research (ICR).

5.1.4. Meeting Conduct and Proceeding

JPP-NIH panel meetings will be held twice a month (every first and third Tuesday of the month). Members of the meeting consist of:

i. Relevant Cluster Heads;
ii. SMEs in related fields;
iii. External panel (MOH or Non-MOH);
iv. Research Methodologist (Biostatistician or Statistician); and
v. MOH Research Grant Management Member.

For further questions and inquiries, investigator may contact the JPP-NIH Secretariat at:

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Shah Alam, Selangor
Phone: +603 -3362 8888 ext 8316
Email: jppnih@moh.gov.my

5.2. JPP-CRC

5.2.1. Establishment of JPP-CRC

Jawatankuasa Penilaian Penyelidikan CRC (JPP-CRC) was established to support the implementation of the NIH Guideline to conduct research in the MOH institutions and facilities. JPP-CRC is mainly responsible for:

i. Monitoring and coordinating information within the HRRCs;
ii. Assignment of minimal risk research to the relevant HRRC sites for review. This will involve application from:
    a. MOH investigator who is not applying for MRG;
    b. Non-MOH investigator;
    c. Research that is planned to be conducted at MOH institutions and facilities such as hospitals, MOH health clinics (KK), District Health Offices (PKD), and others.

5.2.2. Appointment of Members

Members of the JPP-CRC secretariat are appointed by the Director of ICR consisting of:

i. Head of JPP- CRC Secretariat; and
ii. Members of JPP-CRC Secretariat.

For further questions and inquiries, investigator may contact the JPP-CRC Secretariat at:

Jawatankuasa Penilaian Penyelidikan CRC (JPP-CRC)
Block B4,
National Institutes of Health,
No.1, Jalan Setia Murni U13/52,
Seksyen U13, Setia Alam, 40170,
Shah Alam, Selangor
Phone: +603-3362 7700
Email: jppcrc@crc.moh.gov.my
URL: www.crc.gov.my

5.3. HRRC

5.3.1. Establishment of HRRC

The HRRC was established in all MOH hospitals that have a CRC Unit under the National CRC Network.

The responsibility of each member of the HRRC differs based on their individual roles:

i. HRRC Chairperson: oversees the overall review process of all research applications submitted from a particular hospital or from the coverage region of the particular HRRC;
ii. HRRC Reviewer: reviews assigned research applications and propose recommendations to MREC for further consideration; and
iii. HRRC Secretariat: responsible for the overall management of HRRC.

5.3.2. Appointment of Members

HRRC members are appointed by the Director of Hospital with the advice of the head of the Hospital CRC unit. It consists of:

i. Chairperson of HRRC;
ii. Manager of Hospital CRC or Hospital CRC staffs as the HRRC Secretariat; and
iii. HRRC Panel or Reviewers: the reviewer is appointed among the Hospital staff who are well experienced in research including doctors/pharmacists/nurses/ hospital staff who have attended the relevant courses pertaining to research review and critical appraisal.

For further questions and inquiries, investigators may contact the HRRC Secretariat in the CRC Unit at the respective MOH Hospital.

6. Ethical Review (Medical Research and Ethics Committee-MREC)

6.1. Introduction

MREC was established in 2002 to provide an independent ethical review on health research or other research protocols that involve human subjects and are conducted in MOH facilities or using data/patient/personnel from the MOH.

The constitution of MREC is in accordance with the 'Malaysian Guidelines for Good Clinical Practice (GCP)' and complies with the ethical principles as outlined in the Declaration of Helsinki, the International Ethical Guidelines for Biomedical Research Involving Human Subjects (CIOMS), and ICH Guideline of Good Clinical Practice.

For further questions and inquiries, investigator may contact the MREC Secretariat at:

Sector for Ethics and Research Surveillance (MREC Secretariat),
Level 2, Block A,
National Institutes of Health,
No.1, Jalan Setia Murni U13/52,
Seksyen U13, Setia Alam, 40170,
Shah Alam, Selangor.
Phone: +603-3362 8798/8399/8398
Email: mrecsec@moh.gov.my / mreciir@moh.gov.my / mrecisr@moh.gov.my

6.2. Research application for ethical review by MREC

i. Ethical review and consideration for MREC approval is required in all research involving human subjects that are conducted within or related to the MOH.*

ii. All applications forwarded to MREC for ethical review will undergo an initial screening process.

iii. In the event of incomplete documentation or requirement of additional information, the PI will be notified for corrective action/s before the application can be processed further to the next step of ethical review.

iv. Sites with a signed IA-HOD-IA form are not mandated to obtain additional site approval via the Site Approval Form **(Appendix 2)** unless required by the respective facilities or institution's SOP.

*The establishment of registries is under the purview of *Pusat Informatik Kesihatan (PIK)* and *Jawatankuasa Penilaian ICT (JPICT)* or *Jawatankuasa Teknikal ICT (JTICT)* of MOH and does not require ethical approval in the process of setting up. Ethical approval is only required when secondary data is to be extracted from the registry for research purposes.

6.3. Essential documents

i. Essential documents are documents that are individually and collectively permit evaluation of the conduct of a trial and the quality of the data produced. This serves to demonstrate the compliance of the investigator, sponsor, and to monitor the standards of Good Clinical Practice with all applicable regulatory requirements [9,10]. Please refer to Appendix 3 (adapted from the Malaysian GCP, 4th edition).

ii. Administrative requirements documents to be submitted to MREC for initial ethical review (Please refer to **Appendix 4**).

iii. Investigators may also be required to provide additional documents necessary for ethical review.

6.4. Risk assessment and type of MREC review

i. During risk assessment, research is categorised as:
   a. Minimal risk (low risk);
   b. Minor increase over the minimal risk (medium risk); or
   c. More than a minor increase over the minimal risk (high risk).

ii. The type of review will be based on the risk assessment:
   a. Low risk - expedited review by MREC Chairperson/Deputy Chairperson/ Secretary;
   b. Medium risk - expedited review by MREC Primary Reviewers; or
   c. High risk - MREC Full Board Review.

6.5. MREC Full Board meetings

i. MREC Full Board meetings are held as per scheduled or ad hoc if needed according to the SOP.

ii. Members of the committee are appointed by the Director-General of Health and consist of members from diverse backgrounds to ensure an adequate and thorough review of research documents. The committee consists of:
   a. Medical reviewers
   b. Scientific reviewers
   c. Layperson reviewers

6.6. Requirement for consent

i. Requirements for subjects' consent are as per the Malaysian GCP [10].

ii. Parental consent is required for minors below the age of 18 years old [10]. Assent is required for respondents between 7 years old to 18 years old. The language and terminology used in assent forms should be appropriate according to the age and more than one assent form may be required depending on the age range involved in any research.

iii. Investigators must first obtain permission from the parents or guardians for the participation of the minor in the research before soliciting assent from the minor [10].

iv. Dissent of the minor must be respected even if the parent or guardian has agreed to the participation of the minor.

v. Administrative requirements of the consent documents are listed in **Appendix 4**.

6.7. Post Ethical Approval

i. Amendment - Prior to the implementation of any amendments or changes to the **research documents/sites/research team/procedure**, the investigators must obtain prior **approval for amendment from MREC**. MREC reserves the right to withdraw previous ethical approval if changes are not completely declared when applying for approval of amendment/s.

ii. Ethical approval - The duration of ethical approval from MREC is for one year. The expiry date of the ethical approval is stated in the formal letter of approval. Application for renewal of ethical approval must be submitted to MREC should it be anticipated that the research cannot be completed within the original ethical approval time frame. This is done by submitting a **Continuing Review Form** of at least 2 months (60 days) prior to the expiry of the previous ethical approval.

iii. Closure/Termination/Suspension Notification - Any research that is closed/terminated/ suspended is required to be updated to the MREC
   a. Upon research completion, the PI is required to submit the Closure Notification to MREC.
   b. In the event of early termination or suspension of research, the PI is required to submit a termination or suspension Notification to MREC.

iv. Progress Report - As stated in the Malaysian GCP, the investigator is required to submit written summaries of the research status to the IRB or IEC (MREC) annually, or more frequently, if requested by the MREC based on the degree of the risk [10].

v. Protocol Deviations (PD) - Investigators should report to MREC on ANY deviation or changes to the protocol in order to eliminate immediate hazards to the subjects of the research. (Applicable for all interventional research)

vi. Serious Adverse Events (SAE) and Serious Adverse Device Effect (SADE) - All detected SAEs and SADEs should be reported immediately to MREC, the sponsor, and other regulatory authorities as required. (Applicable for all interventional research)

vii. Any research submission provided with an" Exemption from MREC Review" would not be required to submit any post-approval application as stated above. However, the research status or progress is still required to be submitted and updated in the NMRR.

viii. All Post Ethical Approval submissions should be made via the NMRR platform.

6.8. Waiver of informed consent

i. Applications for waiver of informed consent must be clearly justified with the reason documented in the protocol.

ii. The decision for waiver of consent from MREC follows the CIOMS guidelines 10 that stated: - **'Investigators must not initiate research involving humans without obtaining each participant's individual informed consent or that of a legally authorised representative unless investigators have received an explicit approval to do so from a research ethics committee'** [11].

iii. Prior to application for a waiver of informed consent, investigators should first seek to establish whether informed consent could be modified in a way that would preserve the participant's ability to understand the general nature of the investigation and to decide whether to participate [12].

iv. MREC may consider a modification or waiver of informed consent to research if ALL of the following criteria are fulfilled:
   a. The research would not be feasible or practicable to be conducted without the waiver or modification;
   b. The research has important social value;
   c. The research poses no more than minimal risks to the participants; and
   d. No personal identifying information is collected

v. Additional provisions may apply when waivers or modifications of informed consent are approved in the context of specific research.

6.9. Exemption from MREC Review

i. Applications for exemption from MREC review should be submitted as per the usual procedure for ethical review if needed.

ii. Exemptions will be considered if:

   a. Research utilises publicly available data or information that cannot be identified directly or indirectly through identifiers linked to the subjects;
   b. Taste and food quality evaluation and consumer acceptance research;
   c. Audits that have obtained respective institutional authorisation;
   d. Case reports with informed consent from patients; or
   e. Public health surveillance activities that are deemed not for research. The application needs to be supported with relevant documents authorised by a public health authority [13]. The documents should be uploaded into the NMRR system during research registration.

6.10. Additional information for Informed Consent Involving Biological Specimens Collection and Genetic Testing

i. Please refer to the Malaysian Guidelines on The Use of Human Biological Samples for Research [14].

ii. It is mandatory to have a separate informed consent for the conduct of genetic testing in which the purpose of the testing is outside of the primary objective of the research. The informed consent should not be combined with the routine informed consent form of the original or main research proposal and this should be made optional for the prospective subject

iii. If the investigator plans to store and use the excess biological samples or additional collection of the samples for future research, separate informed consent forms (multiple if applicable) are required for every additional consent needed such as:

   a. Consent to the specific planned research or additional genetic tests;
   b. Consent for storage and future use;
   c. Consent for access to medical records and information for data relevant to the bio-banking; and
   d. Consent for re-contacting the subject for more data.

7. Specific Requirements

For the following research types, additional approval from the respective committees should be obtained together or prior to the submission of the research application. The committees are as follows:

7.1. Research involving use of stem cell on human subjects: National Stem Cell Research and Ethics Subcommittee (NSCERT)

All research involving the use of stem cell or cell-based therapies on human subjects must adhere to the Malaysian Guidelines for Stem Cell Research and Therapy [15].

All applications for research involving the use of stem cell or cell-based therapies must fulfil the criteria listed in the Checklist for Research on Stem Cell and Cell-Based Therapies and provide the necessary supporting documents together with the checklist during the submission to NMRR. **(Appendix 5)**
For further questions and inquiries, investigator may contact the NSCERT Secretariat at:

Secretariat,
National Stem Cell Research and Ethics Subcommittee (NSCERT),
Medical Development Division,
Ministry of Health,
Level 5, Block E1, Parcel E,
Kompleks Kerajaan Persekutuan,
62590, Putrajaya
Phone: +603 - 8883 1153/1161
Fax: +603 - 8883 1155

7.2. Research involving use of herbal products and preparations on human subject: National Committee for Research and Development of Herbal Medicine (NRDHM)

NRDHM was initially established in the MOH in 2002 after approval by the Cabinet to spearhead the research and development (R&D) of herbal products. The Committee was restructured in 2011 in conjunction with the Economic Transformation Programs to develop herbal products as a new economic source.

The functions of NRDHM are to coordinate the R&D of herbal medicine (herbal products and standardised extracts) in the pre-clinical and clinical stages. The committee plays a role in assisting MREC as SMEs in reviewing the fitness and suitability of the herbal products intended to be used as an intervention in clinical trials.

NRDHM assists MREC by providing SME opinions in the review of the submitted research involving herbal medicine. The committee acts to provide a separate and independent review of the scientific merits, standardisation, safety, and possible risks of the herbal products that are intended to be used as an intervention in the submitted research proposals.

The proposals of clinical trials involving herbal products will be evaluated by reviewing the standardisation, quality, efficacy, and data safety. The details are usually obtained from the research protocol, investigator's brochure, Certificate of Analysis of the herbal item, and Certificate of Good Manufacturing Practice (GMP) from the manufacturer and other relevant supporting documents. The list of documents required is listed in **Appendix 6**.

For further questions and inquiries, investigator may contact the NRDHM Secretariat at:

Herbal Medicine Research Centre (HMRC),
Institute for Medical Research,
National Institutes of Health,
No.1, Jalan Setia Murni U13/52,
Seksyen U13, Setia Alam, 40170,
Shah Alam, Selangor
Phone: +603 -3362 8888 ext 7958
Email: jkkph_sec@moh.gov.my

7.3. Research involving Modern Biotechnology and Living Modified Organisms (LMOs): Institutional Biosafety & Biosecurity Committee (IBBC) or Institutional Biosafety Committee (IBC)

Research involving Modern Biotechnology and the use of LMOs requires an approval from the Department of Biosafety, Ministry of Environment and Water prior to the commencement of the research [3]. The application can be submitted through the IBBC/IBC of respective facility and institution (if available). For NIH investigators and any collaborative research with NIH, the submission should be sent to IBBC - IMR while for other MOH facility and institution, submission is to be sent to the respective IBBC/IBC (if available).

IBBC and IBC is a committee established to advise investigators who are dealing with research activities involving Modern Biotechnology and LMOs. Submission can be made concurrently to IBBC/IBC during the research registration in NMRR. Research involving Modern Biotechnology needs to submit **Research Proposal Declaration Form (Appendix 7 – For NIH investigator)*** and **Agree to Abide Form (Appendix 8 – For NIH investigator)***.

*Other IBBC/IBC might require different type of form to be submitted. Therefore, it is advisable to refer to respective IBBC/IBC for the requirement of the submission.

The IBBC/IBC will review all submitted documents to determine research requirement status. BSO and IBBC/IBC secretariat will then advise on either one of the following [16]:

a. If modern biotechnology is **NOT USED**, no further action is needed.

b. If modern biotechnology is **USED**, PI can either apply for;
   - Exemption Activity or
   - Notification for Contained Used Activity or
   - Release Activity

In addition to that, investigator involves with LMOs need to submit E Form (Notification for Contained Use and Import for Contained Use Activities Involving LMO for Biosafety Levels 1, 2, 3 and 4) and **Annex 2** (IBC Assessment of Project Proposal Involving Modern Biotechnology Activities) [17]. Both forms can be downloaded from the Department of Biosafety website. **(Diagram 5: Modern Biotechnology Research Notifications & Approval Flowcharts)**

For further questions and inquiries, NIH investigator may contact IBBC Secretariat at:

IBBC Secretariat,
IMR – Institutional Biosafety and Biosecurity Committee,
Infectious Diseases Research Centre,
Level 3, Blok C,
Institute for Medical Research,
National Institutes of Health,
No.1, Jalan Setia Murni U13/52,
Seksyen U13, Setia Alam, 40170,
Shah Alam, Selangor
Phone: +603- 3362 8888 ext 8995
Email: ibbcsecretariat@moh.gov.my

For other facility and institution, please contact the respective IBBC/IBC for more information.

7.4. Phase 1 Clinical Trial: Scientific Review Panel for Phase 1 Clinical Trial (FIH)

The Scientific Review Panel (SRP) for Phase 1 Clinical Trials is established to support the MREC, MOH in performing the scientific evaluation of First-In-Human (FIH) or First Dose in Human Trials on new drugs undertaken by and/or conducted in clinical trial sites in Malaysia [18].

SRP for Phase 1 Clinical Trials is under the Governance of the National Committee for Clinical Research (NCCR).

Submission to SRP for Phase 1 Clinical Trials should be done in parallel with the submission for ethical review to MREC and also notification to NPRA.

Documents submitted to SRP for Phase 1 Clinical Trials will be evaluated scientifically and recommendations will be then forwarded to MREC, MOH for further ethical evaluation. The list of documents required is listed in **Appendix 9**.

For further questions and inquiries, investigator may contact the SRP for Phase 1 Clinical Trial Secretariat at:

Secretariat,
Scientific Review Panel (SRP) for Phase 1 Clinical Trial
D-26-06, Menara Suezcap 1,
KL Gateway, No. 2 Jalan Kerinchi,
Gerbang Kerinchi Lestari,
59200 Kuala Lumpur, Malaysia
Phone: +603 7931 5566
Email: contact@clinicalresearch.my

7.5. Research involving animal: Animal Care and Use Committee (ACUC)

The Animal Care and Use Committee (ACUC) is a scientific and ethical committee consisting of veterinary officers, medical officers, research officers, and various categories of identified officers from IMR, external panels from local universities, and the Department of Veterinary Services.

i. The categories of Biomedical Experiments are based on the Ethical Concerns for Non-Human Species. There are five categories of experiments involving animals that will be evaluated by the committee.

   a. Category A: Experiments involving either no living materials or use of non-living materials or use of plants, bacteria, protozoa or invertebrate animal species;
   b. Category B: Experiments on vertebrate animal species that are expected to produce little or no discomfort;
   c. Category C: Experiments that involve some minor stress or pain (short duration pain) to the vertebrate animal species;
   d. Category D: Experiments that involve significant but unavoidable stress or pain to the vertebrate animal species; and
   e. Category E: Procedures that involve inflicting severe pain near, at or above the pain tolerance threshold of conscious animals (unanaesthetised).

Submission to be made using Borang ACUC **(Appendix 10)**.

For further questions and inquiries, investigator may contact the ACUC Secretariat at:

Secretary,
***Jawatankuasa Penggunaan & Penjagaan Haiwan Dalam Penyelidikan* (ACUC)**
Ministry of Health
d/a Unit Sumber Haiwan
Makmal Institut Penyelidikan Perubatan
Jalan Pahang, 50588 Kuala Lumpur

7.6. Research involving *Orang Asli* (Aborigines): *Jabatan Kemajuan Orang Asli* (JAKOA)

Any research involving *Orang Asli* (Aborigines) requires approval from the *Jabatan Kemajuan Orang Asli* (JAKOA). PI can download the research application form from www.jakoa.gov.my. The completed form should be sent to the Research Unit of *Bahagian Perancangan dan Penyelidikan* (JAKOA) 14 days before the commencement of the research [19]. For further information, please contact the relevant secretariat via email; unitkajian@jakoa.gov.my or via phone at +603-2161 0577 ext 321/330.

7.7. Research involving Ministry of Education (MOE) facilities

Any research involving the MOE are required to register their research on the eRas system [20] at www.eras.moe.gov.my ***(Sistem Permohonan Menjalankan Penyelidikan Pendidikan Dalam Talian***). For further information, please refer to Bahagian Perancangan dan Penyelidikan Dasar Penyelidikan, MOE.

Bahagian Perancangan dan Penyelidikan Dasar Pendidikan,
Ministry of Education,
Level 1-4, Block E8, Complex E,
62604 Putrajaya.
Tel: +603-8884 6500

7.8. International Investigators (Malaysian and non-Malaysian residing overseas from foreign universities or entities)

Investigators are required to get permission from the **Economic Planning Unit (EPU)** to conduct the research in Malaysia [21,22].

For further information, please contact the relevant secretariat via email at

oridb@epu.gov.my or +603-8872 3254.

7.9. Clinical Trial Research including Industrial Sponsored Research (ISR) and Bioavailability/ Bioequivalence (BA/BE)

Clinical Research Malaysia (CRM) is responsible for the management of ISR and Bioavailability/ Bioequivalence (BA/BE) related research.

BA/BE research must be conducted at the BA/BE centres listed in the Bioequivalence Centre Compliance Programme, NPRA, MOH, Malaysia [23].

For further details, please refer to The Conduct of Bioavailability and Bioequivalence Research. [24,25]

8. MOH Research Grant (MRG)

8.1. Introduction

The MOH Malaysia Research Grant or MRG is a research fund that supports health research and development (R&D) activities based on the **priority areas** (research that will benefit the MOH-return of investment (ROI)) set by the MOH with the aim to improve population health and health delivery services.

The objectives of MRG are to i) provide funding to generate new scientific knowledge and discoveries, ii) to improve health delivery services, and iii) to encourage the development of innovative technologies among the MOH investigators.

8.2. Mode of Application

MRG applications can be submitted throughout the year via NMRR. Submissions must be made together with research registration, application to JPPNIH, and MREC.

**MRG applications for research that have received ethical approval will not be entertained.

8.3. Criteria for Application

i. The PI must be a MOH personnel;
ii. The research funding period shall not exceed three (3) years;
iii. PI is allowed to apply and submit only two (2) research submissions at a time;
iv. Investigators who are on study leave are not allowed to be PI. However, he/she can be a Sub-I;
v. PI who has change department/affiliation/resigns/on study leave must not continue his role as a PI. However, can still remain as a member of the research group. The PI must notify MRG Secretariat in writing and nominate a new PI whenever such a situation occurs. An amendment must be submitted to MREC under such circumstances (as per post ethical approval submission).

8.4. MRG Review Panel

The MRG Review Panel is chaired by the Deputy Director-General of Health (Research and Technical Support), MOH. Research that has been evaluated by the JPP-NIH Panel and has received MREC approval will be brought to the MRG Review Panel for evaluation. The decision made by the panel is final.

8.5. Priority in Research Evaluation

i. Research that can support and improve an existing policy, methodology, and solution model according to the needs of the MOH; or
ii. Research covering health issues for the purpose of increasing the value of life in the country and globally; or
iii. Research must identify and obtain the support of MOH stakeholders; or
iv. Research that has the potential to contribute to the national strategic plan.

8.6. Result Notification in the MRG Application

i. Approval letters will be sent to the PI and a copy of the approval letter will be forwarded to the respective HOD.

ii. Allocation will be disbursed to the PI through the relevant department.

8.7. Responsibility of Principal Investigator (PI)

i. PI is responsible for carrying out approved research.

ii. PI is required to sign the *"Surat Akujanji"*. Please refer to the ***Lampiran Aku Janji*** **(Appendix 11)**.

iii. PI must ensure that the research is carried out effectively to achieve the objectives and milestones within the stipulated period as well as the approved allocation;

iv. PI must present the research results to the stakeholders upon completion of the research;

v. Research progress reports must be submitted every 6 months to MRG Secretariat, NIH no later than July 15th and January 15th. Please refer to ***Lampiran Laporan Prestasi*** **(Appendix 12)**.

vi. A monthly research expenditure report must be submitted to the MRG Secretariat, NIH no later than the 15th of the following month. Please refer to ***Lampiran Laporan Kewangan*** **(Appendix 13)**.

8.8. Funding Scope

Further details on the categories and scopes of funding will be made available based on the current financial circulars applicable for that particular year.

***For collaborative research between MOH and non-MOH organisations, funding distribution will be made available only to the MOH department.**

In brief, the funding categories are as follows:

i. Travel and transportation - expenses on all domestic travels and transportations related to research;

ii. Utilities - all charges related to postage (excluding parcel post), telephone, telex, telegraph, cable, and others;

iii. Rental - rental for equipment, transportation and other items related to research activities;

iv. Food and beverages - expenses for purchasing food and beverages for research purposes;

v. Raw materials - expenses on oil and petrol for research purposes;

vi. Research supply and materials - expenses related to research-related supplies and materials (such as reagents, kits, consumables, animal bedding, stationeries, and others).

vii. Minor repair and modifications - expenses for minor repair and modifications of equipment, vehicles or other items related to research activities. The cost of maintaining the existing equipment during the implementation of the research is allowed;

viii. Services - covers printing, hospitality, honorarium, reimbursement to the research participants or subjects, service-based input, and others; training costs related to research such as workshops and others should be provided with strong justification to be supported by the JPP-NIH review panel and approved by the Grant Review Panel;

**Funding must not be used to pay for expenses incurred to attend seminars or conferences and publication fee

ix. Contract Personnel - salary and allowance for short-term personnel, which will be hired based on the research; and

x. Equipment and accessories - the amount allocated for this category should not exceed 40% of the approved total budget. Should any application exceed this limit, PI must provide strong justifications, specifications, quotations, and estimations for the purchase to the grant committee.

****For the purchasing of any ICT software and equipment, PI is required to seek professional advice from the ICT department at their locality prior to the JPP-NIH panel review meeting. The technical input from the ICT Department needs to be sent together with the application as supporting documents. Their evaluation must cover the plan and maintenance for related software and equipment during and after the completion of the research.**

8.9. Amendment to Grant Allocation

Any amendment to the allocation must be approved by the Deputy Director-General of Health (Research and Technical Support) who is also the Chairman of the MOH Research Grant (MRG) Review Panel. The completed form must be sent to the MRG Secretariat, NIH for approval. Please refer to ***Lampiran Pindahan Agihan*** **(Appendix 14)**.

8.10. Implementation and Research Conduct

All research must be carried out based on the approved methodology and allocation within the stipulated time. Approved research will be monitored by the MRG Secretariat based on the following aspects:

i. Financial performance;
ii. Research performance; and
iii. Outcome or Output.

8.11. Research Monitoring

PI is responsible for completing and submitting the financial reports and performance of research under his/her supervision as follows:

i. Research financial report - must be sent to the MRG Secretariat every month of no later than 15th of the following month;
ii. Research progress report - reports must be submitted semi-annually (on the 15th July and 15th January of the following year);
iii. Research findings monitoring report - reports must be submitted every fourth quarter before 15th January of the following year. Please refer to ***Lampiran Pemantauan Projek*** **(Appendix 15)**; and

iv. End of project report - the final research report must be submitted within three (3) months after the completion of the research. Please refer to ***Lampiran Tamat Projek*** **(Appendix 16)**.

****PI needs to adhere to the deadline. Failure to submit any required report by the due date will affect the consideration for next year's funding.**

8.12. Extension of Research

Application for extension of research period must be submitted to the MRG Secretariat, NIH before the research end date through the utility of relevant forms. Please refer to ***Lampiran Borang Permohonan Pelanjutan Tempoh Projek Penyelidikan*** **(Appendix 17)**.

8.13. Termination of Grant

Each PI must ensure the implementation of the research is in accordance with the Declaration of Helsinki, Malaysia GCP, Malaysian Code of Responsible for Conduct in Research (MCRCR), and other local regulatory requirements and guidelines.

Any violation of these codes of conduct may lead to the termination of the grant.
For further questions and inquiries, investigator may contact the MRG Secretariat at:

Research and Grant Management Unit,
Level 4, Block A,
National Institutes of Health,
No.1, Jalan Setia Murni U13/52,
Seksyen U13, Setia Alam, 40170,
Shah Alam, Selangor
Phone: +603 -3362 8888 ext 8405/8316
Email: nihmrg@moh.gov.my

9. Collaborative Research

Collaborative research can be defined as a partnership between investigators, institutions, organisations and/or communities who have a mutual or similar interest in certain areas of research at five different levels within the disciplinary, interdisciplinary, multi-disciplinary, trans-disciplinary or national/international level [26]. For any research collaboration, a Memorandum of Understanding (MoU), Memorandum of Agreement (MoA), and Research Agreement (RA) must be signed between all involved parties.

9.1. Memorandum of Understanding (MoU), Memorandum of Agreement (MoA), and Research Agreement (RA)

MoU is a document that describes a bilateral agreement indicating or expressing convergence of will between two or more parties. It is a legal instrument indicating the establishment of a partnership, which most likely results in a further definitive legal agreement [27]. An MoU does not require any parties to commit funds or other resources. MoA, on the other hand, details the obligations and commitments of all parties. It is legally binding and can be transferred into a contract [27].

For any collaborative research, an MoU or MoA must be signed between the Government of Malaysia (MOH or other ministries) and the collaborator. This can be either with private or public institutions in Malaysia or foreign entities.

RA is also required for research that involve collaboration between the MOH and external parties such as universities, non-governmental organizations (NGOs), the private sector, and others. An RA must be signed between the collaborating parties to underline the specification and details of the collaboration.

The personnel that are allowed to sign the legal documents shall be an officer delegated by the MOH on behalf of the Government of Malaysia (MOH or other ministries). Therefore, it is the responsibility of the investigators to ensure that the officer who will sign the legal agreement possess authorisation from the MOH.

The MoU or MoA between the NIH and any Public or Private institution will serve as an umbrella of MoU or MoA for all institutes under the NIH. Therefore, for investigators from any NIH institutes, if a new research collaboration is formed with an institution that already has an MoU or MoA with NIH, there is no requirement to sign for another MoU or MoA. **(Diagram 3: Research Collaborative Process Flowchart)**

A collaboration between NIH and any institution or entity will be managed under the advice of the Collaboration and Innovation Unit, NIH. Investigators outside of NIH may seek legal advice from the Office of Legal Advisor (Pejabat Penasihat Undang-Undang (PUU)), MOH for any possible MoU or MoA of collaborative effort. Any legal agreement needs to be submitted to the PUU Office, MOH to be reviewed on the terms of the legal content to ensure the rights and the interests of the Government of Malaysia will always be protected.

For submission to NMRR, an RA is sufficient for the purpose of submission of ethical review and consideration by MREC.

MoU/MoA/RA can be prepared by either party with the consent of both parties as long as the content and terms of the agreement have been agreed upon.

For further questions and inquiries, NIH investigator may contact the Collaboration and Innovation Unit, NIH at:

Collaboration and Innovation Unit,
Level 4, Block A,
National Institutes of Health,
No.1, Jalan Setia Murni U13/52,
Seksyen U13, Setia Alam, 40170,
Shah Alam, Selangor
No tel: +603- 3362 8078/8089

For further questions and inquiries regarding the legal requirement and advice, investigator may contact *Pejabat Penasihat Undang-Undang* at:

Penasihat Undang-Undang
Pejabat Penasihat Undang-Undang
Ministry of Health,
Level 11, Block E7, Complex E
Pusat Pentadbiran Kerajaan Persekutuan
62590 Wilayah Persekutuan Putrajaya
Tel :+603-8883 2611/2612/2621
Faks : +603-8888 9080

9.2. Authorship

In any research collaboration, the contribution of an individual or members of a party can be given a credit of authorship in any material planned for scientific dissemination. The consensus for authorship and the sequence must be discussed and agreed upon prior to research initiation.

The decision for the responsibility of authorship in publications should always be in accordance with the requirement stipulated by journals as part of their instructions to authors. For example, the International Committee of Medical Journal Editors (ICMJE) has developed criteria for authorship to distinguish and differentiate authors from contributors in issues related to quantity and quality of contribution that qualify individual authorship in all journal publications.

According to ICMJE, an individual can be considered as an author if he/she has given substantial contributions in terms of conceptual, design of the research, analysis, and data interpretation whereby he/she has critically drafted/reviewed/revised the important intellectual content and agree to be accountable for all aspects of the work where appropriate. For further guidance, please visit http://www.icmje.org/ for clarification [28].

10. Publication and Presentation

All scientific dissemination by the MOH personnel or related to the ministry's data/research must be approved by the Director-General of Health Malaysia. Applications for publication and presentation approval can be done through the NMRR.

10.1. Requirement for Publication and Presentation Submission

An investigator is required to have a full NMRR registration number (for any research that has not previously registered with NMRR), and state the following: ethical clearance and approval (if applicable), source of funding (if applicable), and conflict of interest amongst the authors.

MOH affiliated investigators are required to add the Ministry of Health Malaysia after their organisation name.

E.g., : Samad B, Medical Department, Sungai Buloh Hospital, Ministry of Health Malaysia.

10.2. Processing of Publication and Presentation Submission

Submission to NMRR for "Publication and Presentation Approval '' can be done throughout the research period, after the investigator has received ethical approval or decision from MREC or after the completion of the research. Investigators are reminded to always update the research status or progress in the NMRR, especially when there are changes to the initial submission.

The initial submission through NMRR for ethical review and approval by MREC and publication or presentation approval can also be done concurrently for research types that are exempted from MREC review, an example is in the case where an investigator wishes to have supporting documents (exemption letter) from the ethical committee for submission to journal publication. **(Diagram 4: Publication & Presentation Review Processing Flowchart)**

For approvals pertaining to publication, a processing period of a minimum of **14 working days** is required for each application.

In cases in which the initial journal rejected the investigator's manuscript, the letter of approval obtained can be used for submission to other journals. The investigators must update the journal's name in the NMRR once the manuscript is published.

NIH investigators are required to submit their manuscripts to a journal indexed in the Web of Science or Scopus.

For approvals pertaining to presentations, all investigators must submit the application a **minimum of 21 days prior to the presentation day**. Any submission that is less than 21 days will not be processed.

****Bulk submission for presentation approval can be done by the conference or seminar organising committee. The following criteria must be fulfilled:**

i. The abstract has been reviewed and supported for presentation by the scientific review panel of the respective organising committee; and
ii. The organising committee shall send a request for bulk submission for presentation approval to the Communication and Scientific Dissemination Unit.

A special NMRR access will be given to the secretariat of the organising committee for further administrative procedures based on the outlined SOP. No individual submission requesting presentation approval for a particular conference or seminar shall be further processed by the secretariat.

For further questions and inquiries, NIH investigator may contact the Publication and Presentation Secretariat at:

Communication and Scientific Dissemination Unit,
(Publication & Presentation Secretariat)
Level 4, Block A,
National Institutes of Health,
No.1, Jalan Setia Murni U13/52,
Seksyen U13, Setia Alam, 40170,
Shah Alam, Selangor
Phone: +603-3362 8431
Email: nihpub@moh.gov.my

11. Special Regulatory Requirement(s)

11.1. National Pharmaceutical Regulatory Authority (NPRA) – Clinical Trial Research

For research involving investigational product(s) including placebo requiring CTIL and/or CTX, the investigators or CP must apply for CTIL/CTX as per all applicable regulations by the NPRA [29,30]. Concurrent submission and registration with NMRR and the ethical committee (MREC in the case for MOH) are compulsory during the application for CTIL/CTX.

11.2. CKAPS *(Cawangan Kawalan Amalan Perubatan Swasta)* – Research Involving Private Facilities

For research site(s) involving private medical facilities, the facilities should be registered with CKAPS as per the regulation of the Private Healthcare Facilities & Services Act 1998 (Act 586) [31].

11.3. Medical Device Authority (MDA) – Research Involving Medical Devices

For research involving unauthorised or/and unregistered or/and unapproved use of medical devices in Malaysia as the investigational product(s), an application should be submitted to the Medical Device Authority (MDA) for review [32]. Letters or correspondence should be submitted together during the research registration and ethical review and consideration application in the NMRR.

11.4. Human Tissue and Biological Samples of Import or Export License

It is a requirement for the investigators to apply for an import or export permit for the importation or exportation of human tissue and its biological samples for the purposes of clinical trial and research. Human tissue and biological samples importation or exportation activities are subjected to the governing acts and regulations as stated in the Guideline for Importation and Exportation of Human Tissue or Its Part *(Garispanduan Pengimportan Dan Pengeksportan Tisu Manusia Atau Mana-Mana Bahagiannya)* [33]. Submission for the permit can be applied via an online application using the BLESS system at (https://www.bless.gov.my) [34].

11.5. Biosafety Act 2007, Act 678 and Biosafety Regulations 2010 - Research Involving Modern Biotechnology and LMOs

National Biosafety Board was established under the Biosafety Act 2007, Act 678 and Biosafety Regulations 2010 in order to regulate the release, importation, exportation and contained use of LMOs. This is to ensure adequate protection to the entity (human, plants and animal health, the environment and biological diversity) involved in the research whereby the risk may be imminent and unclear [35-36]. PI should always take the responsibility to ensure all requirements are followed during the entire conduct of the research. Notification and Approval to conduct a Modern Biotechnology and LMOs research should be applied and obtained prior to research commencement.

12. Intellectual Property (IP) and Commercialisation

12.1. Types of IP

i. IP is the legal rights resulting from intellectual activities including research and development where it aims to protect the ownership of intellectual goods and services.

ii. There are five (5) types of intellectual properties that may result from research activities. They are:
   a. Trademark - words, designs, and other markings that identify and distinguish a specific product from other products.
   b. Patent - new and novel inventions (product, technology and/or process).
   c. Industrial design - two-dimensional or three-dimensional appearance or ornamental shape of an item or product.
   d. Copyright - literary works including computer programmes and artistic works such as photographs, drawings, and models.
   e. Trade secret - confidential information including formulas, formulation, knowhow, and computer source code.

iii. Trademark, patent, and industrial patent require formal registration to protect the legal IP rights while copyright requires only voluntary notification. On the other hand, trade secrets are protected by restricting access to the documents and non-disclosure agreements.

12.2. IP Review for Worthiness and Marketability

i. NIH investigators are required to send applications to file an IP for any potential products/process/logo and others to the Collaboration and Innovation Unit, NIH.

ii. IP Review Committee in NIH will review for any potential research outputs for its worthiness, urgency, and marketability before deciding to approve for IP registration process.

iii. NIH investigators should fill up an IP Review Form whereby this form is in a Likert scale format in which an application will be reviewed in terms of potential marketability, urgency, and demand value by users or customers (Appendix 18).

iv. MOH investigators (other than NIH) may contact their relevant unit or department in each organisation for any internal procedures to file intellectual properties of any potential products.

v. Once approved, the investigators may proceed to register the patent, trademark or industrial designs with the Intellectual Property Corporation of Malaysia (MyIPO). Further information can be obtained at https://www.myipo.gov.my/en/home/ [37].

vi. For the IP registration process, the registration process needs to be facilitated by IP companies and hence act as IP agents to conduct patent professional search and all subsequent processes until the patent rights are granted. The process can be lengthy and time consuming depending on the requirements of the patent as well as the location of the patent right.

vii. Patent maintenance requires annual patent renewal cost, which can be very costly when it involves overseas patent rights. The annual patent renewal cost normally will be funded by the respective department or organisation.

12.3. IP Patenting Process

i. Investigators will need to conduct a preliminary search after obtaining the approval for patent registration. The search may include a comparison with the currently available products.

ii. Information on the research products shall be disclosed after a meeting is conducted between the investigators and the potential companies. This is in order for the IP agents to have precise and sufficient information for the execution of the subsequent process. NDA shall be signed during the meeting.

iii. The assigned IP agent is required to conduct a comprehensive patent professional search based on the information obtained earlier.

iv. If it is found that the research product(s) is a novel discovery, patent drafting will be initiated by the IP agent. Further information may be needed from the investigators to properly draft the patents based on the specific areas of interest that they intend to protect.

v. Once completed, the IP agent will file a patent request to the Intellectual Property Corporation of Malaysia (MyIPO). The patent request will be examined for its novelty and impact **(Diagram 6: Patent Preliminary Search)** [38].

12.4. Commercialisation

i. The potential patented products may be commercialised by collaborating with the right industrial partner for mass production. Match-making between the investigators with the patent and industry will be initiated.

ii. Royalty rights will be discussed and finalised in the MoA between MOH and the industry partners based on patent ownership rights and contributions.

iii. Further information on the commercialisation mechanism at the MOH level can be retrieved from *"Garis Panduan Mekanisme Pengkomersialan Produk Inovasi KKM"* which can be downloaded at https://pengurusan.moh.gov.my/v3/download. MOH investigators are subjected to adhere to this guideline [39].

iv. MOH investigators shall refer to the following unit regarding relevant procedures on the commercialisation:

Innovation and Quality Unit,
Management Service Division,
Ministry of Health,
Level 7, Block E7, Complex E
Pusat Pentadbiran Kerajaan Persekutuan
62590 Wilayah Persekutuan Putrajaya.
Phone: +603-8883 2864
Fax: +603-8889 4971

v. Grants for commercialisation can also be applied from the Ministry of Science, Technology and Innovation (MOSTI) under the Industrial and Commercialization Funds [40]. For support and reference, the Fund Division from Technology Development Sector of MOSTI had published few guidelines to guide investigators on grant application process [41-42].

For further questions and inquiries, investigator may contact the Fund Division Secretariat, at:

Fund Division
Technology Development Sector
Ministry of Science Technology and Innovation (MOSTI)
Level 4, Block C4, Complex C
Federal Government Administrative Centre
62662 Putrajaya, Malaysia
Direct line: + 603 - 8885 8315 / 8320 / 8618 / 8556
Main Line: +603- 8885 8000
Fax: +603-88884050

13. Research Monitoring, Feedback and Complaints (Research Misconduct)

In the interest of ensuring the safety, quality and the integrity of research and its data, PI is accountable to comply with the requirements as stated in the guidelines during the conduct of the research. Therefore, in order to ensure it is done in such manner especially in IIR, institutional/facility director, HODs and CRC Unit (if available) is responsible to monitor the research conducted at their respective sites. On the other hand, monitoring of ISR usually will get the support from sponsor and/or CRO.

13.1. Independent Data Monitoring Committee (IDMC)

For IIR involving clinical trial, it is advisable to establish an independent data-monitoring committee (IDMC) to evaluate the progress of the trial at particular interval (if necessary) in order to ensure the safety of the subjects and scientific integrity of the trial is maintained during the interim between trial initiation and trial completion. IDMC which comprises of independent experts' functions to analyse interim data of particular research to assure the ethical aspects, safety and vulnerability of the study is not compromised, thus ensuring the subjects rights is adequately protected throughout their participation [43-44]. IDMC may recommend to the site(s) whether to continue, modify, or stop a trial, depending on the evaluation especially*:

a. When the study endpoint is such (e.g., mortality outcome) that it might be ethically vital to terminate the trial early if the primary question(s) is/are definitely answered or when there is a finding of futility.
b. When there are scientific reasons for a particular safety issue
c. The study is being performed on vulnerable populations.
d. The study is being performed in a population at a high risk of death or other serious outcomes.
e. The study is large, involving multiple centres and requires complex interpretation of data.
f. When the study is expected to be long, and compelling new information either external or internal to the trial might require modifications in order to ensure the continued scientific value of the trial.

*Adapted from: Guidance for Clinical Trial Sponsors, Establishment and Operation of Clinical Trial Data Monitoring Committees, U.S. Department of Health and Human Services, Food and Drug Administration. (2006) [45].

IDMC is recommended to have written operating procedures and maintain written records as per Malaysian GCP requirement. [10,43].

13.2. Feedback and Complaints

Any complaint of research misconduct by any investigator either during the conduct of the research or dissemination of results is a serious allegation and should be thoroughly investigated. All feedbacks and complaints pertaining to this matter should be managed in a manner that provides protection to the interest and emphasises the safety of all individuals and/or subjects involved while maintaining the integrity, credibility, quality of the research and to some extent, privacy and sensitivity of the data and the personal information that have been collected.

Complaints that can arise include:

i. Failure to comply with or negligent of the code and regulation and/or;
ii. Misconduct or breaches of the code and regulation [46].

Complaints can be formally lodged with the MOH (Deputy Director-General of Health - Research & Technical Support) or to any research secretariat (NMRR Secretariat, JPP-NIH Secretariat, MREC Secretariat, MRG Secretariat or Publication Presentation Secretariat) or the director of the hospital or facility involves. Formal complaints should be lodged together with proof of the misconduct. In order to protect the confidentiality, the complainant's background shall be kept anonymous at any time unless required by the authority.

Any complaint shall prompt the relevant authorities to investigate the alleged misconduct. Any serious allegation involving the safety of the subjects and fabrication of data may cause the personnel in charge, site or research to be suspended pending investigation. The ethical approval can be withdrawn by MREC if the allegation is proven to be true.

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15. Appendices

Diagram 1 : Scientific & Ethical Review Processing Flowchart
Diagram 2 : MRG Review Processing Flowchart
Diagram 3 : Research Collaborative Process Flowchart
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Appendix 14 : *Pindahan Agihan*
Appendix 15 : *Laporan Pemantauan*
Appendix 16 : *Laporan Tamat Projek*
Appendix 17 : *Pelanjutan Tempoh*
Appendix 18 : Invention Disclosure Evaluation Form

DIAGRAM 1: **SCIENTIFIC & ETHICAL REVIEW PROCESSING FLOWCHART**

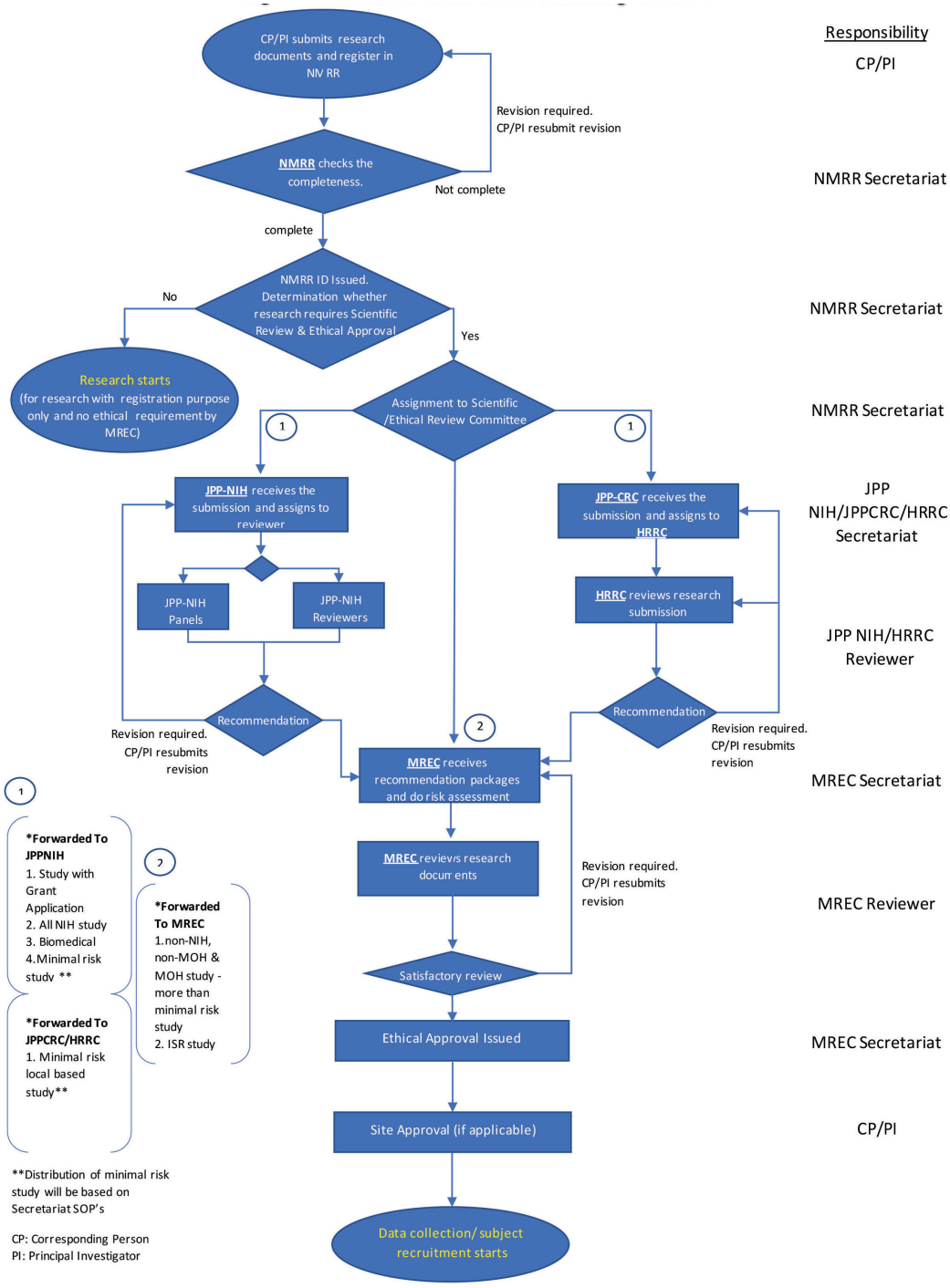
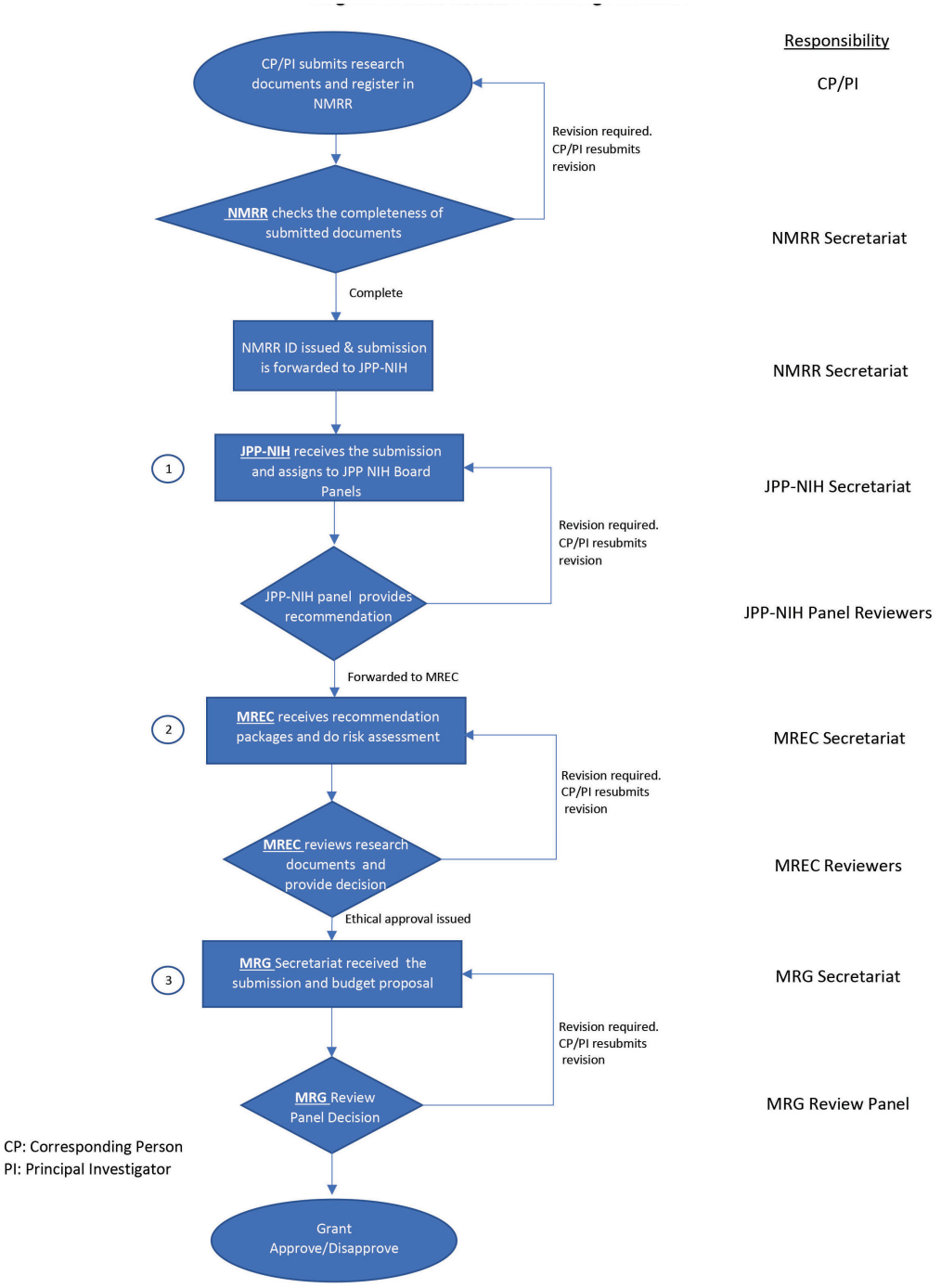
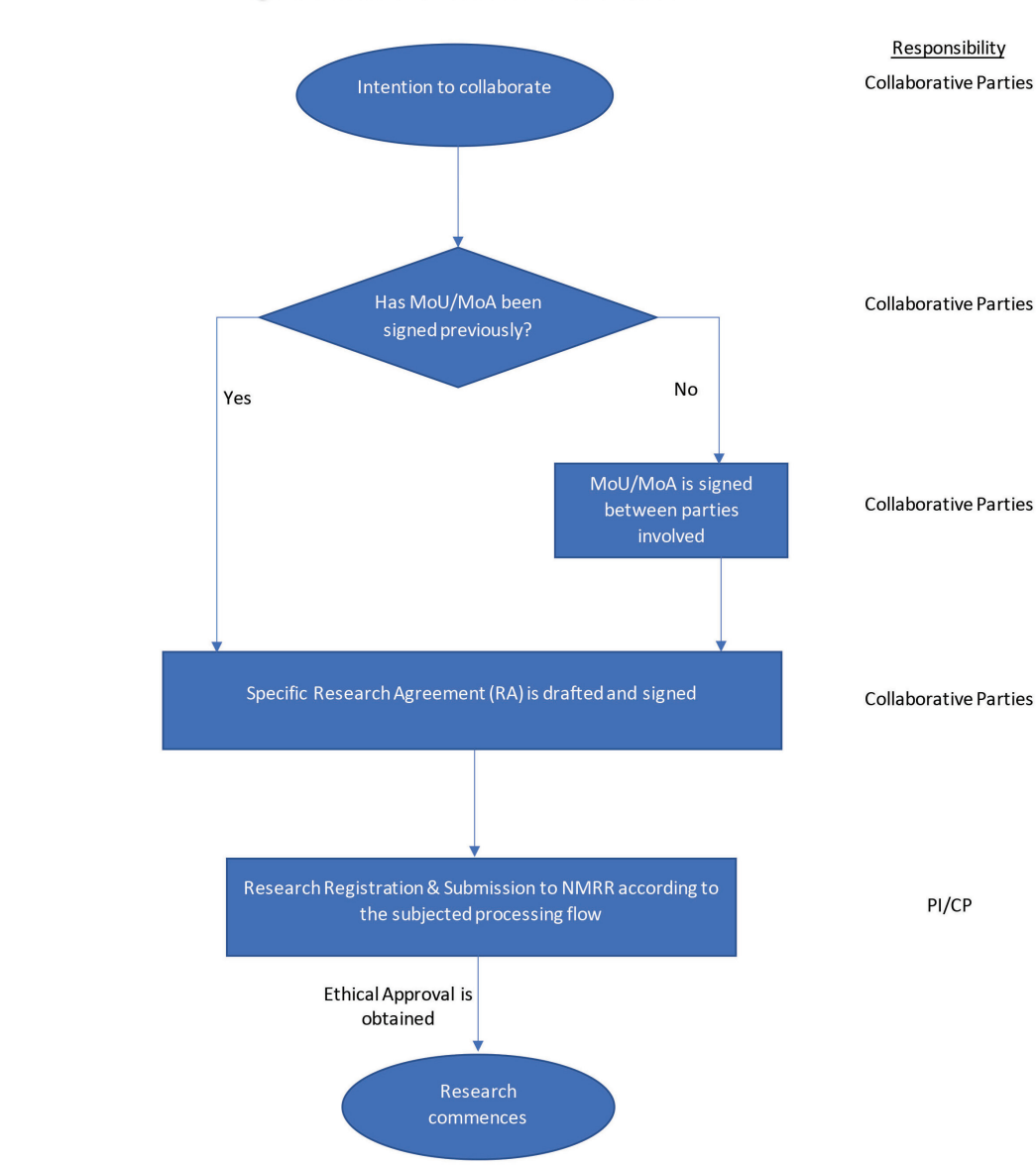


DIAGRAM 2: **MRG REVIEW PROCESSING FLOWCHART**



CP: Corresponding Person
PI: Principal Investigator

DIAGRAM 3: **RESEARCH COLLABORATIVE PROCESS FLOWCHART**



CP: Corresponding Person
PI: Principal Investigator

DIAGRAM 4: **PUBLICATION & PRESENTATION REVIEW PROCESSING FLOWCHART**

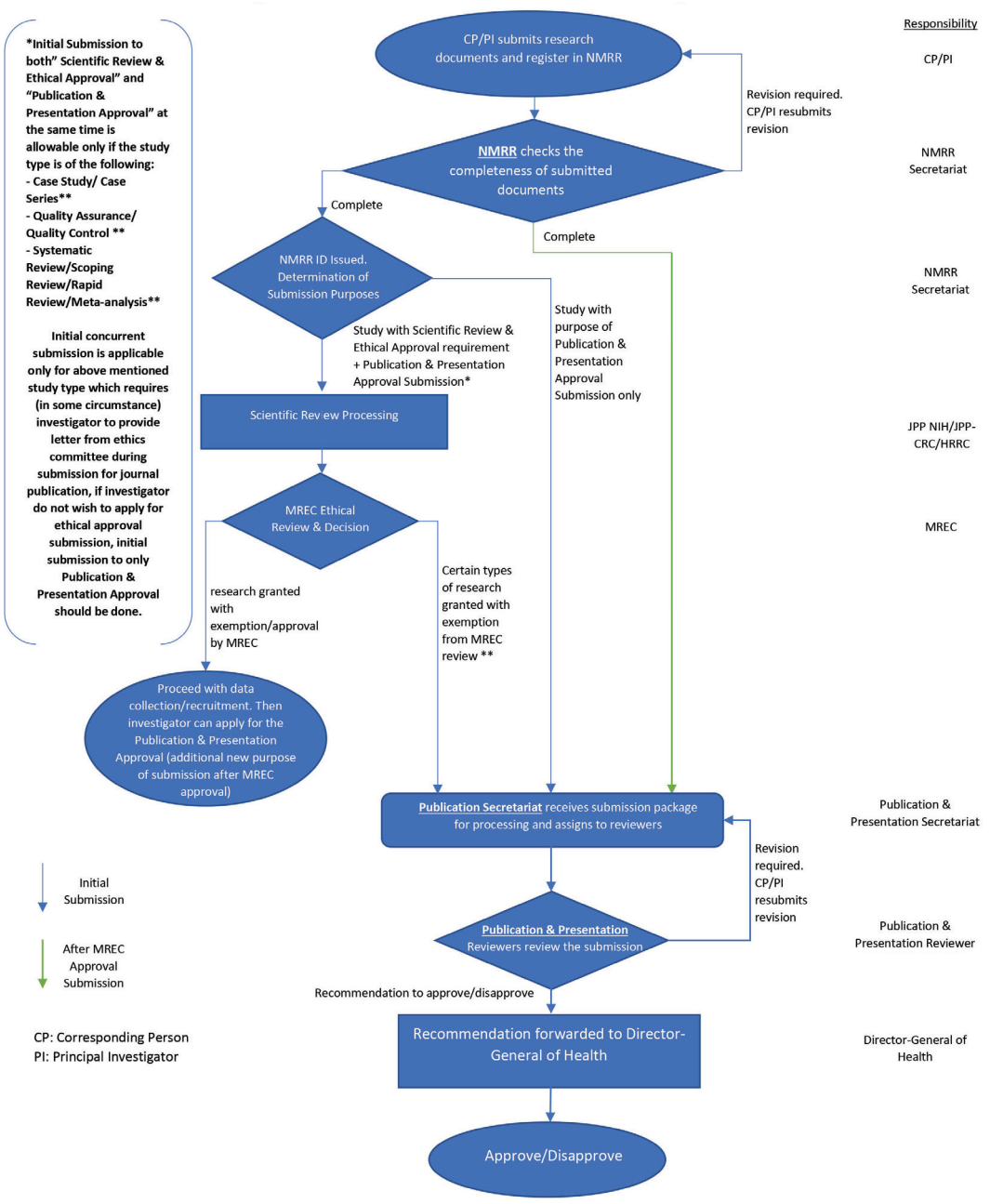
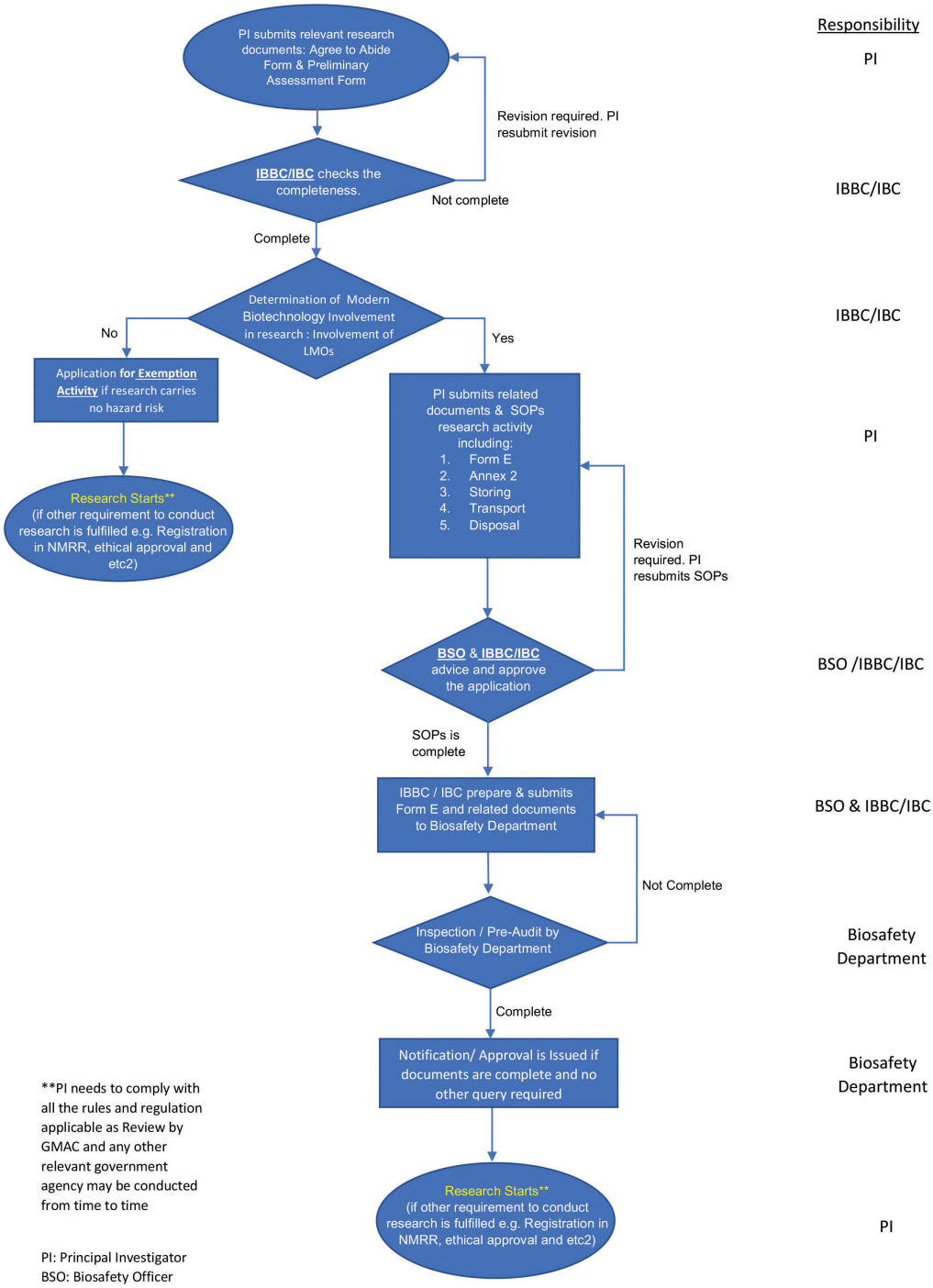


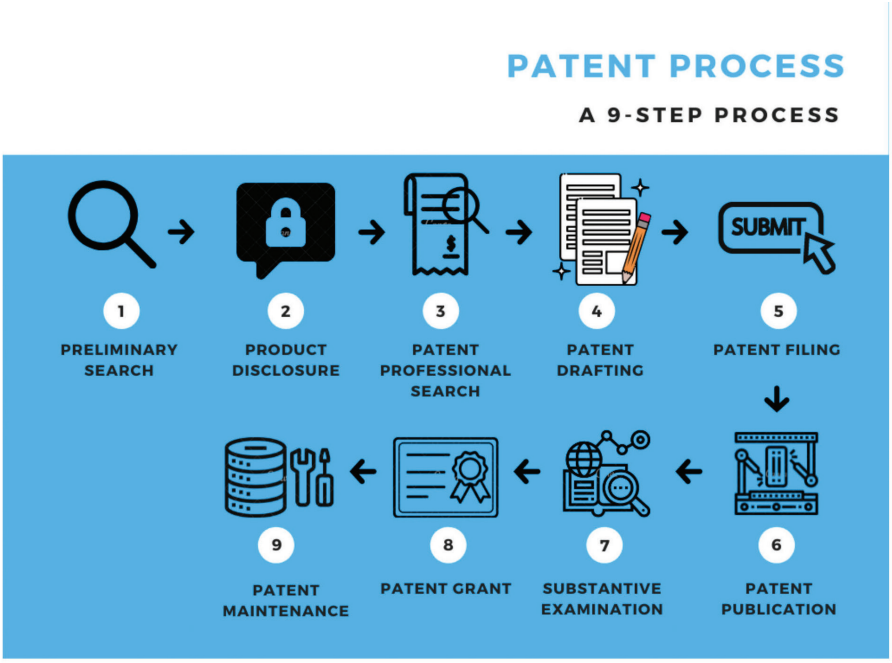
DIAGRAM 5: **MODERN BIOTECHNOLOGY RESEARCH NOTIFICATIONS & APPROVAL FLOWCHARTS**



**PI needs to comply with all the rules and regulation applicable as Review by GMAC and any other relevant government agency may be conducted from time to time

PI: Principal Investigator
BSO: Biosafety Officer

DIAGRAM 6: **PATENT PRELIMINARY SEARCH**



APPENDIX 1: **IA-HOD-A FORM**

Ver 4.0 November 2021 *NMRR/FORM/IAHODIA*

INVESTIGATOR'S AGREEMENT, HEAD OF DEPARTMENT AND ORGANISATIONAL / INSTITUTIONAL APPROVAL
PERSETUJUAN PENYELIDIK DAN KEBENARAN KETUA JABATAN DAN PENGARAH ORGANISASI/INSTITUSI

This document is intended for online submission for formal research registration. It is issued as the Investigator's Agreement to participate in the research as well as the investigator's **Head of Department and Director's Approva**l. Please upload this document in the required section in NMRR upon completion.
**Note: This form is NOT to be used for obtaining permission to conduct the research at the named / selected study site(s).

*Dokumen ini adalah untuk penghantaran 'online' mengikut prosedur rasmi pendaftaran penyelidikan. Borang ini dikeluarkan sebagai pengakuan penyelidik untuk menjalankan penyelidikan dan persetujuan serta kebenaran daripada **Ketua Jabatan dan Pengarah masing-masing**. Sila lengkapkan borang ini dan memuat naik ke dalam sistem NMRR di seksyen yang telah ditetapkan.*
***Nota : Borang ini BUKAN digunakan untuk tujuan mendapatkan keizinan untuk menjalankan penyelidikan di lokasi kajian yang dipilih.*

Research Title *[Tajuk Penyelidikan]*	< prefill>		
Research ID *[Nombor Pendaftaran]*	< prefill>	**Protocol Number (if available)** *[Nombor Protokol (jika ada)]*	< prefill>

INVESTIGATOR'S AGREEMENT *[PERSETUJUAN PENYELIDIK]*	
I have understood the above mentioned proposed research and I agree to participate as an investigator and being responsible to conduct the research. *Saya faham atas cadangan penyelidikan di atas dan bersetuju untuk mengambil bahagian serta bertanggungjawab untuk melaksanakan penyelidikan tersebut.*	
Name *[Nama]*	< prefill>
IC number *[Nombor K/P]*	< prefill>
Institute *[Institusi]*	< prefill>
Signature and Official stamp *[Tandatangan dan Cop Rasmi]*	
Date *[Tarikh]*	

HEAD OF DEPARTMENT'S AGREEMENT *[PERSETUJUAN KETUA JABATAN]*	
I agree to allow the above named investigator to conduct the above titled research. I am also responsible to monitor the above mentioned research conducted by investigator under my department. *Saya bersetuju dan membenarkan pegawai seperti penama di atas untuk menjadi penyelidik di dalam projek penyelidikan seperti yang dinyatakan.Saya juga akan bertanggungjawab dalam memantau penyelidikan yang akan dijalankan oleh penyelidik dibawah seliaan jabatan saya.*	
Name of Head : *[Nama Ketua Jabatan]*	
Signature and Official stamp *[Tandatangan dan Cop Rasmi]*	
Date *[Tarikh]*	

INSTITUTIONAL'S AGREEMENT *[PERSETUJUAN INSTITUSI/FASILITI]*	
I acknowledge and approve the above named investigator to conduct the above mentioned research. Monitoring of the research by the Institution or Facility Director , Head of Department and CRC Unit (if any) will be done to ensure the quality and integrity of research conducted. *Saya mengesahkan dan mengambil maklum penglibatan penyelidik ini di dalam penyelidikan seperti yang tertera.Pemantauan penyelidikan oleh pihak institusi / fasiliti ,ketua jabatan dan CRC unit (sekiranya ada) akan dilakukan bagi menjamin kualiti dan integriti penyelidikan yang dijalankan.*	
Name of Director *[Nama Pengarah]*	
Signature and Official stamp *[Tandatangan dan Cop Rasmi]*	
Date *[Tarikh]*	

This is computer generated. Borang ini adalah cetakan komputer. [<prefill date generated>]

Site Approval Form (Revision 2/2021)
***sila pilih atau masukkan maklumat berkaitan dalam ruangan yang tertera [ ]**

Rujukan kami:
Tarikh:

Pengarah [*Institusi /Fasiliti*]
[*Alamat institusi / Fasiliti*]

YBhg Dato' /Dr. /Tuan /Puan,

PERMOHONAN KEBENARAN PENGGUNAAN [*nama institusi/fasiliti*] UNTUK MENJALANKAN AKTIVITI PENYELIDIKAN

Dengan hormatnya saya merujuk kepada perkara tersebut di atas.

2. Saya "[nama penuh pemohon]" , "[jawatan dalam pasukan penyelidikan]" untuk kajian bertajuk, "[*nombor pendaftaran NMRR - Tajuk Penyelidikan*]" ingin memohon kebenaran untuk menggunakan institusi/fasiliti YBhg Dato'/Dr./Tuan/Puan dalam menjalankan aktiviti penyelidikan seperti maklumat yang tertera. Penyelidikan ini telah pun mendapat "[kelulusan etika / pengecualian semakan]" daripada Jawatankuasa Etika Penyelidikan Perubatan JEPP (*Medical Research Ethics Committee MREC*), Kementerian Kesihatan Malaysia. Bersama-sama ini disertakan lampiran [surat kelulusan/pengecualian semakan] MREC (Lampiran 1) serta lampiran salinan protokol kajian (*protocol)* dan makluman ringkas berkaitan aktiviti penyelidikan yang akan dijalankan (Lampiran 2).

3. Penyelidik dari institusi/fasiliti YBhg Dato'/Dr./Tuan/Puan yang terlibat dan bertanggungjawab dalam penyelidikan ini adalah seperti berikut: (jika berkenaan)
   i. [Nama penyelidik #1]
   ii. [Nama penyelidik #2]

4. Bahagian/Jabatan/Unit dibawah pengurusan YBhg Dato' /Dr. /Tuan /Puan yang akan terlibat dalam penyelidikan ini adalah seperti berikut:
   i. [Bahagian/Jabatan/Unit #1]
   ii. [Bahagian/Jabatan/Unit #2]

5. Aktiviti penyelidikan yang akan dijalankan di Bahagian/Jabatan/Unit yang terlibat adalah seperti berikut:
   i. [Aktiviti #1]
   ii. [Aktiviti #2]

Diharapkan agar perkara ini mendapat pertimbangan dan seterusnya kebenaran daripada pihak YBhg Dato' /Dr. /Tuan /Puan.

Sekian, terima kasih.
Saya yang menjalankan amanah,

…….
(Nama Ketua Penyelidik)
s.k.
<Ketua Jabatan Ketua Penyelidik>
< Ketua Jabatan tapak penyelidikan yang terlibat >
<Nama penyelidik (investigators) yang terlibat di lokasi yang berkaitan>

Site Approval Form (A)

LAMPIRAN 1

Surat Kelulusan/Pengecualian Semakan MREC

LAMPIRAN 2

Ringkasan Projek Penyelidikan

Tajuk Penyelidikan:

Nama dan Jabatan Ketua Penyelidik:

Nombor pendaftaran NMRR:

No rujukan surat MREC:

Tarikh cadangan mula penyelidikan:

Tarikh jangkaan tamat penyelidikan:

Objektif penyelidikan:

Ringkasan metodologi penyelidikan:

Protokol (salinan protokol penuh yang telah diluluskan oleh MREC)

Revision 2 /2021

Site Approval Form (B)

BORANG MAKLUMBALAS PERMOHONAN KEBENARAN PENGGUNAAN <nama institusi/fasiliti> UNTUK MENJALANKAN PENYELIDIKAN

Tajuk Penyelidikan :
Nama dan Jabatan Ketua Penyelidik :

Pihak <nama institusi/fasiliti> dengan ini membuat keputusan seperti berikut : -

☐ Membenarkan projek penyelidikan dijalankan.

☐ Tidak membenarkan projek penyelidikan dijalankan

Pihak penyelidik bertanggungjawab dalam memastikan kajian dijalankan secara berintegriti mengikut tatacara yang telah ditetapkan oleh pihak institusi/fasiliti dan Kementerian Kesihatan Malaysia. Pemantauan oleh pihak institusi atau fasiliti/ketua jabatan/CRC unit(sekiranya ada) akan dilakukan dari semasa ke semasa bagi memastikan kajian yang dijalankan adalah berpandukan garis panduan dan pekeliling sedia ada.

Sekian.

Disokong oleh ,

……
(<Nama Ketua Jabatan di mana penyelidikan akan dijalankan>)
Tarikh:

Diluluskan oleh ,

.....
(< Nama Pengarah institusi/fasiliti di mana penyelidikan akan dijalankan>)
Tarikh:

s.k.
<Ketua Unit CRC institusi/fasiliti terlibat (sekiranya ada)>
<Nama penyelidik (investigators) di institusi/fasiliti yang terlibat(jika berkaitan)>

Revision 2 /2021

APPENDIX 3: **ESSENTIAL DOCUMENTS IN FILES OF RESEARCHER/INSTITUTION**

Initial Submission prior to the study commencement

During this planning stage the following documents should be generated and should be on file of investigators/institution before the trial/research formally starts:

	Document	Purpose
1.	INVESTIGATOR'S BROCHURE (where applicable)	To document that relevant and current scientific information about the investigational product has been provided to the investigator
3.	SIGNED PROTOCOL AND AMENDMENTS, IF ANY, AND SAMPLE CASE REPORT FORM (CRF)	To document investigator and sponsor agreement to the protocol/amendment(s) and CRF
4.	INFORMED CONSENT FORM (including all application translation)	To document the informed consent
5.	ANY OTHER WRITTEN INFORMATION	To document that subjects will be given appropriate written information (content and wording) to support their ability to give fully informed consent
6.	ADVERTISEMENT FOR SUBJECT RECRUITMENT (if used)	To document that recruitment measures are appropriate and not coercive
7.	FINANCIAL ASPECTS OF THE STUDY (where applicable)	To document the financial agreement between the investigator/institution and the sponsor for the trial
8.	INSURANCE STATEMENT (where required)	To document that compensation to subject(s) for trial-related injury will be available
9.	SIGNED AGREEMENT BETWEEN INVOLVED PARTIES (where applicable)	To document agreements
10.	DATED, DOCUMENTED APPROVAL/ FAVOURABLE OPINION OF INSTITUTIONAL REVIEW BOARD (IRB)/ INDEPENDENT ETHICS COMMITTEE (IEC) (where applicable)	To document that the trial has been subject to IRB/IEC review and given approval/ favourable opinion. To identify the version number and date of the document(s)
11.	REGULATORY AUTHORITY(IES) AUTHORIZATION/ APPROVAL/ NOTIFICATION OF PROTOCOL (where required)	To document appropriate authorization/approval/notification by the regulatory authority(ies) has been obtained prior to initiation of the trial in compliance with the applicable regulatory requirement(s)
12.	CURRICULUM VITAE AND/ OR OTHER RELEVANT DOCUMENTS EVIDENCING QUALIFICATIONS OF INVESTIGATOR(S) AND SUBINVESTIGATOR(S)	To document qualifications and eligibility to conduct trial and/or provide medical supervision of subjects

	Document	Purpose
13.	NORMAL VALUE(S)/ RANGE(S) FOR MEDICAL/LABORATORY/TECHNICAL PROCEDURE(S) AND/OR TEST(S) INCLUDED IN THE PROTOCOL (where applicable)	To document normal values and/or ranges of the tests
14.	MEDICAL/LABORATORY/ TECHNICAL PROCEDURES/TESTS (where applicable)	To document competence of facility to perform required test(s), and support reliability of results
15.	INSTRUCTIONS FOR HANDLING OF INVESTIGATIONAL PRODUCT(S) AND TRIAL RELATED MATERIALS (where applicable)	To document instructions needed to ensure proper storage, packaging, dispensing and disposition of investigational products and trial-related materials
16.	SHIPPING RECORDS FOR INVESTIGATIONAL PRODUCT(S) AND TRIAL RELATED MATERIALS (where applicable)	To document shipment dates, batch numbers and method of shipment of investigational product(s) and trial- related materials. Allows tracking of product batch, review of shipping conditions, and accountability
17	DECODING PROCEDURES FOR BLINDED TRIALS (where applicable)	To document how, in case of an emergency, identity of blinded investigational product can be revealed without breaking the blind for the remaining subject's treatment
18.	TRIAL INITIATION MONITORING REPORT (where applicable)	To document that the site is suitable for the trial

Initial Submission prior to the study commencement

During this planning stage the following documents should be generated and should be on file of investigators

	Document	Purpose
1.	INVESTIGATOR'S BROCHURE UPDATES (where applicable)	To document that investigator is informed in a timely manner of relevant information as it becomes available
2.	ANY REVISION TO: - protocol/amendment(s) and CRF - informed consent form - any other written information provided to subjects - advertisement for subject recruitment (if used)	To document revisions of these trial related documents that take effect during trial/research
3.	DATED, DOCUMENTED APPROVAL/FAVOURABLE OPINION OF INSTITUTIONAL REVIEW BOARD (IRB) / INDEPENDENT ETHICS COMMITTEE (IEC) OF THE FOLLOWING (where applicable) : - protocol amendment(s) - revision(s) of: - informed consent form - any other written information to be provided to the subject - advertisement for subject recruitment (if used) - any other documents given approval/favorable opinion	To document that the amendment(s) and/or revision(s) have been subject to IRB/IEC review and were given approv-al/ favourable opinion. To identify the version number and date of the document(s)
4.	REGULATORY AUTHORITY(IES) AUTHORIZATIONS/ APPROVALS/ NOTIFICATIONS WHERE REQUIRED FOR: - protocol amendment(s) and other documents	To update whenever changes to investigators have been approved via amendment.
5.	CURRICULUM VITAE FOR NEW INVESTIGATOR(S) AND/OR SUBINVESTIGA-TOR(S)	To document instructions needed to ensure proper storage, packaging, dispensing and disposition of investigational products and trial-related materials
6.	UPDATES TO NORMAL VALUE(S)/RANGE(S) FOR MEDICAL/LABORATORY/ TECHNICAL PROCEDURE(S)/TEST(S) INCLUDED IN THE PROTOCOL	To document normal values and ranges that are revised during the trial
7	UPDATES OF MEDICAL/ LABORATORY/TECHNICAL PROCEDURES/TESTS (where required)	To document that tests remain adequate throughout the trial period
8.	DOCUMENTATION OF INVESTIGATIONAL PRODUCT(S) AND TRIAL RELATED MATERIALS SHIPMENT	To document shipment dates, batch numbers and method of shipment of investigational product(s) and trial- related materials. Allows tracking of product batch, review of shipping conditions, and accountability

	Document	Purpose
9.	RELEVANT COMMUNICATIONS OTHER THAN SITE VISITS - letters - meeting notes - notes of telephone calls	To document any agreements or significant discussions re-garding trial administration, protocol violations, trial conduct, adverse event (AE) reporting
10.	SIGNED INFORMED CONSENT FORMS	To document that consent is obtained in accordance with GCP and protocol and dated prior to participation of each subject in trial. Also to document direct access permission
11.	SOURCE DOCUMENTS	To document the existence of the subject and substantiate integrity of trial data collected. To include original documentsrelated to the trial, to medical treatment, and history of subject
12.	SIGNED, DATED ANDCOMPLETED CASE RE-PORT FORMS (CRF)	To document that the investigator or authorised member of the investigator's staff confirms the observations recorded
13.	DOCUMENTATION OF CRF CORRECTIONS	To document all changes/additions or corrections made to CRF after initial data were recorded
14.	NOTIFICATION BY ORIGINATING INVESTIGATOR TO SPONSOR OF SERIOUS ADVERSE EVENTS AND RELATED REPORTS	Notification by originating investigator to sponsor of serious adverse events and related reports
15	NOTIFICATION BY SPONSOR AND/OR INVESTIGATOR, WHERE APPLICABLE, TO REGULATORY AUTHORITY(IES) AND IRB(S)/IEC(S) OF UNEXPECTED SERIOUS ADVERSE DRUG REACTIONS AND OF OTHER SAFETY INFORMATION	Notification by sponsor and/or investigator, where applicable, to regulatory authorities and IRB(s)/IEC(s) of unexpected serious adverse drug reactions
16.	NOTIFICATION BY SPONSOR TO INVESTIGATORS OF SAFETY INFORMATION	Notification by sponsor to investigators of safety information
17.	INTERIM OR ANNUAL REPORTS TO IRB/IEC AND AUTHORITY(IES)	Interim or annual reports provided to IRB/IEC
18.	SUBJECT SCREENING LOG	To document identification of subjects who entered pre-trial screening
19.	SUBJECT IDENTIFICA-TION CODE LIST	To document that investigator/institution keeps a confidential list of names of all subjects allocated to trial numbers on enrolling in the trial. Allows investigator/institution to reveal identity of any subject
20.	SUBJECT ENROLLMENTLOG	To document chronological enrollment of subjects by trial number
21.	INVESTIGATIONAL PRODUCTS ACCOUNTA-BILITY AT THE SITE	To document that investigational product(s) have been used accordingly to the protocol
22.	SIGNATURE SHEET	To document signatures and initials of all persons authorized to make entries and/or corrections on CRFs
23.	RECORD OF RETAINED BODY FLUIDS/TISSUE SAMPLES (IF ANY)	To document location and identification of retained samples if assays need to be repeated

After Completion or Termination of the Trial

After completion or termination of the trial, all of the documents identified in the previous sections should be in the file together with the following:

	Document	Purpose
1.	INVESTIGATIONAL PRODUCT(S) ACCOUNTABILITY AT SITE	To document that the investigational product(s) have been used according to the protocol. To documents the final accounting of investigational product(s) received at the site, dispensed to subjects, returned by the subjects, and returned to sponsor
2.	DOCUMENTATION OF INVESTIGATIONAL PRODUCT DESTRUCTION	To document destruction of unused investigational products by sponsor or at site (if destroyed at site)
3.	COMPLETED SUBJECT IDENTIFICATION CODE LIST	To permit identification of all subjects enrolled in the trial in case follow-up is required. List should be kept in a confidential manner and for agreed upon time
4.	FINAL REPORT BY INVESTIGATOR TO IRB/IEC WHERE REQUIRED, AND WHERE APPLICABLE, TO THE REGULATORY AUTHORITY(IES)	To document completion of the trial
5.	CLINICAL STUDY REPORT	To document results and interpretation of trial

Adapted from: **MALAYSIAN GUIDELINE FOR GOOD CLINICAL PRACTICE, 4TH EDITION**

APPENDIX 4: **EXPLANATORY NOTES ON ADMINISTRATIVE REQUIREMENTS OF DOCUMENTS SUBMITTED FOR MREC INITIAL ETHICAL REVIEW**

No.	Document	Explanatory notes
Investigator's documents		
1.	IA-HOD-IA form	Required for all research submitted to MREC. Investigator's agreement, head of department's and institutional approval to be completed for all Principal Investigators (including Coordinating PI and PI at site)
2.	Curriculum Vitae	Required for all investigators in a study. A summary of the investigator's education, professional history, and job qualifications or other documentation evidencing the investigator's qualifications.
3.	GCP certificate	Required for all investigators in an Interventional Study The certificate indicates successful participation in a Malaysian GCP workshop. The certificate is issued upon passing the workshop exit exam.
4.	Declaration of Conflict of Interest by Principal Investigator	Required for all research submitted to MREC. Document to be completed by the Corresponding Principal Investigator on behalf of the study team to declare any conflict of interest.
Research documents		
5.	Cover letter	Required for all research submitted to MREC. A letter accompanying a submission to explain the purpose of the submission and list of documents submitted.
6.	Study Protocol/Proposal	Required for all research submitted to MREC. A document that describes the background and rationale for the study, objective(s), design, methodology, statistical considerations, and organization of a research. For studies fulfilling criteria for application of waiver of informed consent, kindly state this clearly in the protocol and provide justification.
7.	Investigator's brochure	Required for interventional studies A compilation of the clinical and non-clinical data on the investigational product(s) which is relevant to the study of the investigational product(s)/device(s) in human subjects (ICH GCP 1.36)
8.	Information Sheet & Informed Consent Form	Required for all human subject research Document containing research information intended for subjects and to document subject's consent to participate in the research. Compulsory to have in English and Bahasa Malaysia languages, unless otherwise specified in study proposal/ protocol. Optional for other languages (Simplified Chinese/Tamil and etc)

Research documents		
9.	Assent Forms	Required for all human subject research involving minors Document containing research information intended for minors and to document minor's assent for participation in the research. Separate assent information sheets are required for subjects aged 7-12 years, and 13 to less than 18 years. Language used must be age appropriate. Compulsory to have in English and Bahasa Malaysia languages, unless otherwise specified in study proposal/ protocol. Optional for other languages (Simplified Chinese/Tamil and etc)
10.	Parental Information Sheet & Consent Forms	Required for all human subject research involving minors Document containing research information intended for parents of minors and to document parental consent for participation in the research. Compulsory to have in English and Bahasa Malaysia languages, unless otherwise specified in study proposal/ protocol. Optional for other languages (Simplified Chinese/Tamil and etc)
11.	Optional Patient Information Sheet (PIS) & Informed Consent Form (ICF) for future research / genetic, pharmacodynamic / pharmacogenomic / other studies.	Required if future usage of biospecimens in research and genetic testing Document containing information and Form to document subject's consent to participate in an optional sub-study or optional future research component. Compulsory in English and Bahasa Malaysia languages. Optional for other languages (Simplified Chinese/Tamil and etc)
12.	Study Clinical Report Form (CRF) / Data Collection Form/Questionnaire	Required whenever used in study Document containing all information collected in the study or questions answered by study participants
13.	Interview/FGD Guide	Required for studies involving interview/focus group discussions. Document containing information on interview questions / topics of discussion for focus group discussions.
14.	NSCERT Checklist	Required for all research that involves stem cells and cell-based therapies Document containing checklist of documents for all studies involving stem cells. Only completed forms will be forwarded to NSCERT (National Stem Cell Research and Ethics Committee).
15.	Approval letter from NRHDM	Required for research that involves herbal products A document / letter stating the National Committee On Research and Development for Herbal Medicine's recommendation / opinion on the safety of the products to be used in the study.
16.	Approval / exemption letter from MDA	Required for research that involves medical devices. A document / letter containing the Medical Device Authority's registration / exemption for the device to be used in the study.

Research documents		
17.	Advertisement	Required whenever used in study Advertisement for subject recruitment
18.	Trial indemnification : Insurance / Letter of indemnity	Required for all high risk/interventional studies. Insurance or letter to indemnify (legal and financial coverage) the investigator and institution against claims arising from the trial, except for claims that arise from malpractice and/or negligence.
19.	Memorandum of Understanding/ Research Agreement	Required for all collaborative research. Document containing information about agreement/ understanding between collaborative parties for the conduct of research. Kindly refer to the 'Collaboration' section in NIH Research Guidelines for further info.

General info:

- All study documents should have version number, date and page number stated on every page.
- Version number and date should be updated whenever documents are revised.

EXPLANATORY NOTES ON ADMINISTRATIVE REQUIREMENTS OF DOCUMENTS SUBMITTED FOR POST APPROVAL APPLICATIONS

No.	Document	Explanatory notes
Investigator's documents		
1.	Curriculum Vitae	Required whenever any changes to study team/investigators are submitted for consideration. A summary of the investigator's education, professional history, and job qualifications or other documentation evidencing the investigator's qualifications.
2.	GCP certificate	Required whenever any changes to the study team/ investigators of an interventional study are submitted. The certificate indicates successful participation in a Malaysian GCP workshop. The certificate is issued upon passing the workshop exit exam.
3.	Declaration of Conflict of Interest by Principal Investigator	Required whenever any changes to study team/investigators are submitted for consideration.. Document to be completed by the Corresponding Principal Investigator on behalf of the study team to declare any conflict of interest.
Research documents		
4.	Cover letter	Required for amendments, protocol deviations, serious adverse events, closure, interim reports, AOR submissions to MREC. A letter accompanying a submission to explain the purpose of the submission and list of documents submitted.
5.	Study Protocol/Proposal	Required whenever any changes to the document are submitted to MREC for consideration. A document that describes the background and rationale for the study, objective(s), design, methodology, statistical considerations, and organization of a research. For studies fulfilling criteria for application of waiver of informed consent, kindly state this clearly in the protocol and provide justification.
6.	Investigator's brochure	Required whenever any changes to the document are submitted to MREC for consideration. A compilation of the clinical and non-clinical data on the investigational product(s) which is relevant to the study of the investigational product(s)/device(s) in human subjects (ICH GCP 1.36)
7.	Information Sheet & Informed Consent Form	Required whenever any changes to the document are submitted to MREC for consideration. Document containing research information intended for subjects and to document subject's consent to participate in the research. Compulsory to have in English and Bahasa Malaysia languages, unless otherwise specified in study proposal/protocol. Optional for other languages (Simplified Chinese/Tamil and etc)

Research documents		
8.	Assent Forms	Required whenever any changes to the document are submitted to MREC for consideration. Document containing research information intended for minors and to document minor's assent for participation in the research. Separate assent information sheets are required for subjects aged 7-12 years, and 13 to less than 18 years. Language used must be age appropriate. Compulsory to have in English and Bahasa Malaysia languages, unless otherwise specified in study proposal/ protocol. Optional for other languages (Simplified Chinese/Tamil and etc)
9.	Parental Information Sheet & Consent Forms	Required whenever any changes to the document are submitted to MREC for consideration. Document containing research information intended for parents of minors and to document parental consent for participation in the research. Compulsory to have in English and Bahasa Malaysia languages, unless otherwise specified in study proposal/ protocol. Optional for other languages (Simplified Chinese/Tamil and etc)
10.	Optional Patient Information Sheet (PIS) & Informed Consent Form (ICF) for future research / genetic, pharmacodynamic / pharmacogenomic / other studies.	Required whenever any changes to the document are submitted to MREC for consideration. Document containing information and Form to document subject's consent to participate in an optional sub-study or optional future research component. Compulsory in English and Bahasa Malaysia languages. Optional for other languages (Simplified Chinese/Tamil and etc)
11.	Study Clinical Report Form (CRF) / Data Collection Form/Questionnaire	Required whenever any changes to the document are submitted to MREC for consideration. Document containing all information collected in the study or questions answered by study participants
12.	Interview/FGD Guide	Required whenever any changes to the document are submitted to MREC for consideration. Document containing information on interview questions / topics of discussion for focus group discussions.
13.	Advertisement	Required whenever any changes to the document are submitted to MREC for consideration. Advertisement for subject recruitment
14.	Trial indemnification : Insurance / Letter of indemnity	Required whenever any changes to the document are submitted to MREC for consideration. Insurance or letter to indemnify (legal and financial coverage) the investigator and institution against claims arising from the trial, except for claims that arise from malpractice and/or negligence.
15.	Memorandum of Understanding/ Research Agreement	Required whenever any changes to the document are submitted to MREC for consideration. Document containing information about agreement/ understanding between collaborative parties for the conduct of research. Kindly refer to the 'Collaboration' section in NIH Research Guidelines for further info.

Lampiran 1

CHECKLIST FOR RESEARCH ON STEM CELL AND CELL-BASED THERAPIES

Phase/Process	Key requirements	Researcher (Please tick \/)	Secretariat MREC (Please tick \/)
1. Pre-clinical studies (investigators must show their own data and not from other laboratories)	• Approval letter from animal ethics committee is recommended	☐	☐
	• Accreditation of animal research facility in institution requiring GLP compliance	☐	☐
	• Evidence that the pre-clinical studies was subjected to rigorous and independent peer review and regulatory oversight	☐	☐
	• Safety data in small animals	☐	☐
	• Safety data in large animals	☐	☐
	• Comprehensive toxicology data in small animals (including contamination, acute infusional toxicity, deleterious immune responses, unexpected behavior of the cellular product, and tumorigenesis)	☐	☐
	• Comprehensive toxicology data in large animals (including risks of contamination, acute infusional toxicity, deleterious immune responses, unexpected behavior of the cellular product, and tumorigenesis)	☐	☐
	• Proof of principle of the desired effect (that the cells have repaired the damage/disease) – unequivocal efficacy data	☐	☐
	• Show biological distribution data	☐	☐
	• Show evidence of physiologic integration and long-lived tissue reconstitution	☐	☐
	• Show that differentiation (either *in vitro* before transplantation or *in vivo* after transplantation) occur only along the desired lineages	☐	☐
	• Design based on clinical expectations	☐	☐
	• Mechanistic studies to show biology (done by the group)	☐	☐
	• GLP compliant	☐	☐

1

Lampiran 1

CHECKLIST FOR RESEARCH ON STEM CELL AND CELL-BASED THERAPIES

Phase/Process	Key requirements	Researcher (Please tick \/)	Secretariat MREC (Please tick \/)
	• Evidence that the pre-clinical data has been submitted to the NPCB	☐	☐
2. Phase I trials	• Comprehensive pre-clinical studies have been done and data showed safety and efficacy in animals (performed by the group) is recommended	☐	☐
	• Procedures on how the cells be tracked in terms of homing to the target area, viability and longevity of the cells	☐	☐
	• Procedures on how the safety be monitored	☐	☐
	• Procedures to assess risks of tumorigenicity by an independent body must be implemented	☐	☐
	• Procedures to assess short, medium and long term side effects	☐	☐
	• GCP compliance	☐	☐
3. Phase II trials	• Data from Phase I trials (performed by the group themselves and if the trial is not performed by the group, explain why the data should be used for this trial)	☐	☐
	• Procedures on how the cells be tracked in terms of homing to the target area and viability of the cells	☐	☐
	• Optimisation of dose, route, regimen, patient population, endpoints, and controlled	☐	☐
	• Procedures on how the safety be monitored	☐	☐
	• Independent data safety monitoring board	☐	☐
	• Plan to assess short, medium and long term side effects	☐	☐
	• GCP compliance	☐	☐

Lampiran 1

CHECKLIST FOR RESEARCH ON STEM CELL AND CELL-BASED THERAPIES

4. Phase III trials	• Data from Phase II trials (performed by the group themselves)	☐	☐
	• Design to show safety and efficacy	☐	☐
	• Independent data safety monitoring board	☐	☐
	• GCP compliance	☐	☐
	• Conduct 'randomised' control	☐	☐
5. Cell processing and manufacturing	• Evidence by a letter of conformance for GMP compliance and issued by relevant authority	☐	☐
	• Show evidence of relevant processes: Standard operating procedures, quality standards, environmental control, equipment qualification, analytical methods, audits, staff training, etc.	☐	☐
	• Cell processing and manufacture of any product must be conducted under scrupulous, expert, and independent review	☐	☐
	• Demonstrate that the product is safe, pure and potent	☐	☐
6. Product registration	• Show that the product has been registered with the National Pharmaceutical Control Bureau before use in human trials	☐	☐
	• License for clinical trial has been obtained	☐	☐
7. Cell characterization (pre-requisite to clinical trials)	• History of the cells in the stem cell or cell-based product	☐	☐
	• Biological characterisation of cell type	☐	☐
	• Demonstration of purity	☐	☐
	• Demonstration of potency (e.g. cells produce insulin in a physiological manner)	☐	☐
	• Manufacturing standards and independent certification, where relevant	☐	☐
	• Evidence that cells are free from contamination	☐	☐

Lampiran 1

CHECKLIST FOR RESEARCH ON STEM CELL AND CELL-BASED THERAPIES

	• Evidence of viability and longevity of cells after transplantation (to determine the likely duration of the therapeutic effect)	☐	☐
	• Evidence that cells will home into the area of damage or repair	☐	☐
	• Evidence of genomic stability during culture	☐	☐
8. Investigators and researchers	• Is the Principal Investigator trained in cell transplantation? (Show evidence of credentialing)	☐	☐
	• Are other investigators trained in cell transplantation? (Show evidence of credentialing)	☐	☐
	• Qualifications of scientists and researchers	☐	☐
	• Registration with National Medical Research Register, Ministry of Health (MOH)	☐	☐
9. Centres performing therapy (Information for patients)	• Registration with PHCFS Act, Ministry of Health	☐	☐
	• Informing subjects about the human embryonic cell source, if applicable	☐	☐
	• The unique risks; and disclose honestly that the treatment have not been tried before	☐	☐
	• Utmost clarity on the potential benefit	☐	☐
	• Disclosing financial and non-financial conflicts of interest	☐	☐
	• Provide monitoring patients long term	☐	☐
	• Providing a clear, timely, and effective plan for adverse event reporting	☐	☐

	NATIONAL COMMITTEE FOR RESEARCH AND DEVELOPMENT IN HERBAL MEDICINE (NRDHM) ***JAWATANKUASA KEBANGSAAN PENYELIDIKAN DAN PEMBANGUNAN PERUBATAN HERBA (JKPPH)***

SUBJECT-MATTER EXPERT REVIEW OF STUDY PROTOCOL

1. Please find below the details of information that are required to be included in the study proposal and Investigator's Brochure (if relevant) for studies that involve herb/s as the test item.

*2. This form is meant as a **checklist** only, it is not meant to be filled in.*

3. NRDHM will be reviewing the study protocol and Investigator's brochure (if relevant).

A. BACKGROUND INFORMATION

1	Study protocol title	
2	Principal investigator	Name Contact details (Address, phone number/s, email)
3	Clinical Research Organization	Name Contact details (Address, phone number/s, email)
4	Sponsor	Name Contact details (Address, phone number/s, email)

B. STUDY DESIGN

5	Objective(s) of the study	
6	Endpoint(s) of the study	
7	Type of study	• eg Cohort, Cross over trial, RCT etc • Sampling size calculation
8	Control group	Details on the comparison group (Placebo or standard treatment)
9	Target group of treatment	• Intended group: Adult, Adolescent / Teenager, Children, Women of Childbearing age • Intended Disease /condition
10	Duration of treatment	Please state specifically how long the treatment is planned for: 1. Not more or equal to 14 days 2. More than 14 days till 3 months 3. Long term (More than 3 months)
11	Mode of delivery	How will the test item be taken by the patients? Oral, Topical application, Intravenous, Subcutaneous and others
12	Dosing	Amount and frequency New dose?

13	Concomitant treatment(s)	List the concomitant treatment(s)

C. DETAILS OF TEST ITEM

14	Details of test item	• Type of product (refer Attachment A) • Ingredient(s) ○ Single plant ○ Combinations: name all ingredients ○ Part(s) of plant(s) used ○ Use of protected/ endangered species • All reported claim(s) • Intended use(s) for this study • Type of preparation (Eg Fresh, Freeze dried, Spray dried etc) • Method of extraction (To name the method used) • Standardized extract (To name marker(s))
15	Data of test item	*## Below are the minimal data required for all test items including fresh product* • Summary of Product Characteristic ○ (Invented) Name of medicinal product, strength, pharmaceutical form. Eg: xx 10mg tablet. ○ Description of pharmaceutical form • Standardization of extract • Analytical Method Validation • Quality data: In-Process Quality Control (IPQC), Finished Product Quality Control (FPQC) • Stability data (Container closure system, storage condition, proposed shelf-life) *## Below are the additional data for manufactured test item* • Certificate of GMP • Certificate of Analysis • Description of Pharmaceutical Development • Protocol of Analysis • Standard labelling requirements • Bioavailability/ bioequivalent study

D.EFFICACY CLAIMS SUBSTANTIATION

16	Efficacy Claim with Traditional Knowledge	**Sources of information** (refer Attachment B) ## The references could be any of the following: 1. Standard reference (Reference textbooks, pharmacopoeia, monographs) 2. Recommendations on usage from reference regulatory authorities or reference organizations 3. Good quality scientific evidence from human observational studies: Case report / studies / series 4. Report prepared by expert committees/expert opinion (subject to Authority approval) 5. Published scientific reviews and meta-analysis 6. Documented/reported negative marker (e.g. Traditionally used for abortion) or adverse events
17	Efficacy claim with Pharmacological studies (Preclinical studies) **(OECD-GLP Compliance)** (Note**:** All non-clinical should be conducted in OECD/GLP compliance laboratory. This requirement will be mandatory in the very near future)	**Primary pharmacodynamics**. Study primary mode of action related to therapeutic activity – *In vitro* and *in vivo* **Secondary pharmacodynamics**. Study the additional mode of action of compound. **Toxicokinetic and pharmacokinetic study:** i. Metabolic and plasma protein binding data ii. ADME iii. Biochemical drug interaction iv. Nonclinical characterization of human metabolite(s) **Safety pharmacology.** Assessment on core battery (Central Nervous System, Respiratory system, Cardiovascular System)

E. SAFETY DATA

18	Safety Data Based On Toxicology Study (OECD-GLP Compliance) (Note**:** All non-clinical should be conducted in OECD/GLP compliance laboratory. This requirement will be mandatory in the very near future)	**Genotoxicity** 1. *In vitro* test i. Ames test / Bacteria reverse mutation assay ii. Metaphase chromosome aberration assay iii. Mouse lymphoma L5178Y cell thymidine kinase gene mutation assay (MLA)

		iv. Comet assay 2. *In vivo* studies i. Micronuclei in erythrocytes (in blood and bone marrow) ii. Chromosome aberrations in metaphase cells in bone marrow **Single-acute toxicity** i. Rodent ii. Non-rodent **Repeated dose (28 days)** i. Rodent ii. Non-rodent **Repeated dose (90 days)** i. Rodent ii. Non-rodent **Repeated dose (6 months/1 year)** i. Rodent ii. Non-rodent **Carcinogenicity** (Expected clinical use is continuous for at least 6 months) **Reproductive toxicity** (Depending on study population: Male, female, embryo-fetal (prior to Phase III))
19	Specialized Toxicity Studies	1. Local tolerance (eg skin/eyes/GIT etc) 2. Hepatotoxicity 3. Phototoxicity 4. Immunotoxicity 5. Juvenile animal toxicity 6. Abuse toxicity
20	Assessment In Human (Clinical)	1. Estimation of initial safety and tolerability 2. ADME study 3. PK/PD study 4. Efficacy and safety profiling 5. Confirmatory study of efficacy 6. Primary endpoints identification (Please state) 7. Documentation: i. Clinical study reports ii. Published clinical papers iii. Latest periodic safety update report (PSUR)

F. INVESTIGATOR'S BROCHURE (IB)

21	Investigator's Brochure *(The IB is a requirement for herbal test item(s) going for **clinical trials**)*	The content/format of IB should follow section 7.5 (Appendix 2) page 71 Malaysian Guideline for GCP 3rd edition *TITLE PAGE (Example)* **TITLE OF STUDY** Sponsor's Name: Product: Research Number: Name(s) Chemical, Generic *(if approved)* Trade Name(s) *(if legally permissible and desired by the sponsor)* Manufacturer: **INVESTIGATOR'S BROCHURE** Edition Number: Release Date: Replaces Previous Edition Number: Date: *CONTENTS OF INVESTIGATOR'S BROCHURE (Example)* **CONFIDENTIALITY STATEMENT (optional)** **SIGNATURE PAGE (optional)** **TABLE OF CONTENTS** **SUMMARY (preferably not exceeding two pages)** **1.0 INTRODUCTION** 1.1 References **2.0 PHYSICAL, CHEMICAL, AND PHARMACEUTICAL PROPERTIES AND FORMULATION** 2.1 Introduction 2.2 Product description *(eg: (invented) name of medicinal product, strength, pharmaceutical form)* 2.3 Manufacturing of Product *(eg: GMP certificate)* 2.4 Quality Control Tests *(eg: In-Process Quality Control (IPQC), Finished Product Quality Control (FPQC))* 2.5 Quality Assurance 2.6 Stability *(eg: Container closure system, storage condition, proposed shelf-life)* 2.7 Attachments (may include certificate of analysis)

		2.8 References **3.0 NON CLINICAL STUDIES** 3.1 Introduction 3.2 Nonclinical Pharmacology 3.3 Pharmacokinetics and Product Metabolism in Animals 3.4 Toxicology study 3.5 Non-clinical study Report, tabulated overview 3.6 Conclusion 3.7 References **4.0 CLINICAL STUDIES (if any)** 4.1 Introduction 4.2 Types of Studies 4.3 Clinical study synopsis, tabulated overview 4.4 Conclusion 4.5 References **5.0 EFFECTS IN HUMANS** 5.1 Pharmacokinetics and Product Metabolism in Humans 5.2 Safety and Efficacy 5.3 Marketing Experience 5.4 References **6. SUMMARY OF DATA AND GUIDANCE FOR INVESTIGATOR** 6.1 Mechanism of Action, administration 6.2 Use in treatment, duration of action 6.3 Precautions 6.5 Warnings 6.6 Potential Adverse Effects 6.7 Overdose 6.8 Directions for Storage, maintenance **9. APPENDICES (if any)**

Attachment A: Definitions

a) **Traditional medicine** (as defined under the Control of Drugs and Cosmetics Regulations 1984):

Any product used in the practice of indigenous medicine, in which the drug consist solely of one or more naturally occurring substances of a plant, animal or mineral, of parts thereof, in the unextracted or crude extract form, and a homeopathic medicine. It shall not include any sterile preparation, vaccines any substance derived human parts, any isolated and characterized chemical substances.

Traditional medicines are allowed to have General and Medium claim. For general and medium claim, it must be based on documented history of use and philosophy of the respective traditional medicine

b) **Finished Herbal Product**

Finished herbal products consist of herbal preparations made from one or more herbs. If more than one herb is used, the term "mixture herbal product" can also be used. Finished herbal products and mixture herbal products may contain excipients in addition to the active ingredients. However, finished products or mixture herbal products to which chemically defined active substance have been added, including synthetic compounds and/ isolated constituents from herbal materials, are not considered to be herbal.

Finished Herbal Product is allowed to have Medium and High claim but no general claim. For this high and medium claim, there is no history of traditional use to support the claim and the product must only contain herbal ingredients only.

c) **Herbal Remedy**

Any drug consisting of a substance or a mixture of substances produced by drying, crushing or comminuting, but without subjecting to any other process, a natural substance or substances of plant, animal or mineral origin, or any part of such substance or substances.

d) **Homeopathic Medicine**

Any pharmaceutical dosage form used in the homeopathic therapeutic system in which diseases are treated by the use of minute amounts as of such substances which are capable of producing in healthy persons symptoms similar to those of the disease being treated.

e) **Health supplement**

A health supplement (HS) means any product that is used to supplement a diet and to maintain, enhance and improve the health function of human body. It is presented in a small unit dosage forms (to be administered) such as capsules, tablets, powder, liquids and shall not include any sterile preparations (i.e. injectable, eyedrops). It may contain one or more, or the following combination:

i. Vitamins, minerals, amino acids, fatty acids, enzymes, probiotics, and other bioactive substances;
ii. Substances derived from natural sources, including animal, mineral and botanical materials in the forms of extracts, isolates, concentrates and metabolite;
iii. Synthetic sources of ingredients mentioned in (i) and (ii) may only be used where the safety of these has been proven.

Level of claim	Definition
General or Low Nutritional claim	Intended use for general health maintenance. The benefits derived from supplementation beyond normal intake.
Medium claim (Functional claim)	Maintains or enhances the structure of function of the human body, excluding disease-related claims.
Disease reduction claim (High claim)	Significantly altering or reducing a risk factor of a disease or health related condition.

Reference: Drug Registration Guidance Document (DRGD), First Edition January 2013. Revised November 2014 available from http://portal.bpfk.gov.my/index.cfm?&menuid=137.

Attachment B: Illustrative Substantiation Evidence

Reference texts

a. Malaysian Herbal Monograph Volume 1, 2 or 3
b. NKEA Malaysian Herbal Monograph (www.globinmed.com).
c. Martindale, latest edition. The Complete Drug. Pharmaceutical Press, 2009.
d. The ABC Clinical Guide to Herbs. American Botanical Council.
e. WHO Monographs on Selected Medicinal Plants.
f. British Pharmacopoeia.
g. United States Pharmacopoeia.
h. Indian Pharmacopoeia.
i. Chinese Pharmacopoeia.
j. Natural Standards (www.naturalstandard.com)
k. Office of Dietary Supplements, National Institutes of Health – Dietary Supplement Fact Sheets
l. (http://ods.od.nih.gov/Health_Information/Information_About_Individual_Dietary_Supplements.aspx)

Organizations

a. American Nutraceutical Association (www.ana-jana.org)
b. CODEX Alimentarius
c. Global Information Hub for Integrated Medicine (http://www.globinmed.com)
d. National Centre for Complementary and Alternative Medicine (http://nccam.nih.gov/)
e. Office of Dietary Supplements, National Institutes of Health (USA) (http://ods.od.nih.gov)

Reference regulatory authorities

a. Australia TGA
b. Chinese Health Authority on Chinese medicinal herbs
c. European Commission
d. Health Canada
e. United States FDA

Notes:

1. *This list is not meant to be exhaustive and will be reviewed from time to time.*
2. *The Authority will nonetheless conduct a detailed evaluation of the evidence included in the report to ensure that the health claim is substantiated.*
3. *The Authority will be willing to consider review other than the listed above, if the standards of evidence are consistent with those of the Authority.*
4. *All references must be current.*

Reference: Appendix 4 Guideline on registration of health supplements. Drug Registration Guidance Document (DRGD), page 201, First Edition January 2013. Revised November 2014. Available from http://portal.bpfk.gov.my/index.cfm?&menuid=137.

Additional References:

Organizations:

a. http://www.oecd.org

b. http://www.ich.org

Reference regulatory authorities

a. http://bpfk.moh.gov.my

Note that different level of evidence carries different weightage for efficacy claims substantiation.

IMR INSTITUTE FOR MEDICAL RESEARCH MALAYSIA

IMR INSTITUTIONAL BIOSAFETY & BIOSECURITY COMMITTEE (IMR IBBC)
PRELIMINARY ASSESSMENT FORM

Email: ibbcsecretariat@moh.gov.my

INSTRUCTION :

For activities involving the use of infectious and potentially infectious agents/materials and biological toxins in their natural unmodified and genetically modified. Preliminary assessment form is used to identify new proposal(s) or activity. Submission is to be made by email and accompanied by an original signed document to IMR-IBBC Secretariat.

SECTION A : PRINCIPAL INVESTIGATOR'S (PI's)/HEAD OF DEPARTMENT (HOD) INFORMATION

Name			
Unit			
Centre			
Office Phone No		**Mobile No**	
Email			

SECTION B : PROJECT INFORMATION

1.	**Purpose: (Please Tick ✓)**	**Research**	
		Teaching	
		Lab Service	
		Consultancy	
		Others (Please specify):	
2.	**Project / Activity Title:**		
3.	**JPP-IMR No / NMRR No.**		
4.	**Duration:** **(Please Attached Gantt chart)**		
5.	**Project Status:** **(Please Tick ✓)**	**New**	
		Ongoing	
		Funded	
6.	**Collaboration Project:** **(Please State)**	**Name of University/ Research Institute /Industry/ NGO :**	
		Grant No: **(If available)**	
		Funders:	

Note:

Please email the complete document to ibbcsecretariat@moh.gov.my within 14 working days from notifiaction date.

IMR/IBBC/01
Version : 1.0
Date : 20.05.2021

6.	**Brief summary of the project (including objectives and expected outcome):** *(300 – 500 words)*					
7.	**Name(s) of infectious or potentially infectious agent/material or biological toxin to be used in the study: (eg: SARS-CoV-2, dengue, diphtheria)**					
7a.	**Risk group of agent/ material or toxin (refer to *Act 342- seventh Schedule, WHO, OIE)**	**1**	**2**	**3**	**4**	**Unknown**
7b.	**Risk group of agent/material or toxin (refer to Plant Quarantine Act 1976) – if relevant**					
7c.	**Risk assesment Evaluation**	**Yes**		**No**		
7d.	**Involve modern biotechnology techniques in LMO / GMO agent**	**Yes**		**No**		
		If yes :				
		State the recipient (s) :				
		State the donor (s) :				

Note:

Please email the complete document to ibbcsecretariat@moh.gov.my within 14 working days from notifiaction date.

**** Please refer to Biosafety Guideline: Risk Assesement of Genetically Modified Organism (Appenddix 2) (page 86-95)*

I hereby declare that all information provided in this application is accurate to the best of my knowledge.

Signature and stamp of Principal Investigator

Date

FOR IBBC/IBC OFFICIAL USE ONLY

IBBC Ref. No:		
Decision by IBBC:	**Examption Activity**	
	Notification to JBK and Fill up Form E	
Signature and Stamp of Biosafety Officer / IBBC Secratariat:		
Date:		

Note:
Please email the complete document to ibbcsecretariat@moh.gov.my within 14 working days from notifiaction date.

APPENDIX 8: **IBBC Agreement to Abide**

Biosafety Officer
Institutional Biosafety and Biosecurity Committee IMR
Institute for Medical Research

Dear Sir / Madam
Agreement to Abide to the Document 'Regulating Research in IMR in Accordance with Biosafety Act 2007, *Act 678* and Biosafety Regulations 2010' for Researchers di IMR

As refer to the above matter.

I, Click or tap here to enter text. Principle Investigator to the research proposal entitled Click or tap here to enter text. Read, understand and agree to abide the to the regulation as mentioned in the "**Regulating Research in IMR in Accordance with Biosafety Act 2007, *Act 678* and Biosafety Regulations 2010".**

Thank you

……..
Name **:** Click or tap here to enter text.
Unit **:** Click or tap here to enter text.
Date **:** Click or tap here to enter text.
Phone no **:** Click or tap here to enter text.
Email **:** Click or tap here to enter text.

APPENDIX 9: **Essential Documents Required for First-In-Human (FIH) / First Dose in Human Trials Submission**

No	Document	Explanatory notes
	Investigator's documents	
1.	IA-HOD-IA form	Required for all FIH research submitted to MREC. Investigator's agreement, head of department's and institutional approval, to be completed for all Principal Investigators (including Coordinating PI and PI at site)
2.	Curriculum Vitae	Required for all FIH research submitted to MREC. A summary of the investigator's education, professional history, and job qualifications or other documentation evidencing the investigator's qualifications
3.	GCP certificate	Required for all FIH Interventional Study The certificate indicating successful participation in a Malaysian GCP workshop. The certificate is issued upon passing the workshop exit exam.
4.	Declaration of Conflict of Interest by Principal Investigator	Required for all FIH research submitted to MREC. Document to be completed by the Corresponding Principal Investigator on behalf of the study team to declare any conflict of interest.
5.	Advanced Cardiovascular Life Support (ACLS) Certificate	Required for all FIH research submitted to MREC. The certificate indicates investigators are trained in this advanced course which highlights the importance of high-performance team dynamics and communication, systems of care, recognition and intervention of cardiopulmonary arrest, immediate post-cardiac arrest, acute dysrhythmia, stroke, and acute coronary syndromes (ACS).
	Research documents	
6.	Covering letter	Required for all FIH research submitted to MREC. A letter accompanying a submission to explain the purpose of the submission and list of documents submitted.
7.	Study Protocol	Required for all FIH research submitted to MREC. A document that describes the objective(s), design, methodology, statistical considerations, and organization of a research. The protocol usually also gives the background and the rationale for the study, but these could be provided in other protocol referenced documents.
8.	Investigator's brochure	Required for all FIH research submitted to MREC. A compilation of the clinical and non-clinical data on the investigational product(s) which is relevant to the study of the investigational product(s) in human subjects (ICH GCP 1.36)
9.	Investigational Medicinal Product Dossier (IMPD) or Chemistry, Manufacturing and Control (CMC) data	Required for all FIH studies submitted to MREC Document containing Investigational Medicinal Product Dossier (IMPD) or Chemistry, Manufacturing and Control (CMC) data.
10.	Non-Investigational Medicinal Product (NIMP) dossiers	Required if applicable Dossier on the NIMP agents used in the study (eg: challenge agents)

11.	Pharmacy Manual	Required if available Reference document for pharmacist in the handling of the investigational product
12.	TSE certificates/ statement	Required if applicable Document to certify that the Investigation product is manufactured completely from synthetic or manufactured raw materials and does not contain any raw materials produced from or substances derived from animal origin
13.	Informed Consent Form	Required for all FIH research submitted to MREC. Form to document subject's consent to participate in the research. Compulsory to have in English and Bahasa Malaysia languages. Optional for other languages (Simplified Chinese/Tamil and etc)
14.	Patient information sheet	Required for all FIH research submitted to MREC. Document containing information about research intended for prospective research subject. Compulsory to have in English and Bahasa Malaysia languages. Optional for other languages (Simplified Chinese/Tamil and etc)
15.	Optional Patient Information Sheet (PIS) & Informed Consent Form (ICF) for future research / genetic, pharmacodynamic / pharmacogenomic/other studies.	Required if applicable Document containing information and Form to document subject's consent to participate in an optional sub-study or optional future research component. Compulsory to have in English and Bahasa Malaysia languages. Optional for other languages (Simplified Chinese/Tamil and etc)
16.	Site Accreditation Document	Required for all FIH studies submitted to MREC Evidence that site is listed under NPRA's Phase I Unit Inspection & Accreditation Programme
17.	Clinical Trial Insurance	Required for all FIH studies submitted to MREC Trial Insurance certificate for the study
18.	Checklist for First-in-Human Research Protocol	Required for all FIH studies submitted to MREC A completed form that indicates the completion of the protocol submitted

ACUC 02/17

BORANG PERMOHONAN KELULUSAN
ETIKA PENGGUNAAN HAIWAN DALAM PENYELIDIKAN
JAWATANKUASA PENGGUNAAN & PENJAGAAN HAIWAN (ACUC)
KEMENTERIAN KESIHATAN MALAYSIA (MOH)

1. Sila lengkapkan borang permohonan ini mengikut keperluan maklumat yang telah ditetapkan oleh ACUC-MOH. Permohonan yang tidak lengkap akan dipulangkan kepada pemohon dan akan menyebabkan **kelewatan** dalam memperoleh kelulusan.

2. Sila hantar borang ini bersama salinan;-

   i. kertas kerja penyelidikan (*research proposal*) yang menerangkan dengan lengkap bahagian prosedur yang menggunakan haiwan dalam `penyelidikan
   ii. *Gantt chart* - warnakan bahagian yang melibatkan haiwan sahaja
   iii. tiga article terkini yang digunakan untuk *literature review* sebagai panduan dari segi penggunaan

      - baka haiwan
      - bilangan haiwan, dan
      - procedure yang dijalankan atas haiwan

   iv. Sijil/deklarasi pembekal jika haiwan yang digunakan adalah jenis living modified organism (LMO) mengikut takrifan Akta Biokeselamatan 2007

3. Semua maklumat hendaklah ditaip atau ditulis dengan jelas.

4. Mukasurat tambahan boleh dilampirkan sekiranya mana-mana ruang yang disediakan dalam borang ini tidak mencukupi.

5. Sila hantar borang permohonan yang lengkap ini kepada:-

Setiausaha
Jawatankuasa Penggunaan & Penjagaan Haiwan Dalam Penyelidikan
(ACUC)- Kementerian Kesihatan Malaysia (MOH)

d/a Unit Sumber Haiwan Makmal
Institut Penyelidikan Perubatan
Jalan Pahang, 50588 Kuala Lumpur

1. Butiran Maklumat Penyelidik

Nama Penyelidik		**Latar Belakang Penyelidik berkaitan dengan (i) penyelidikan (ii)penggunaan haiwan makmal dan (iii)latihan yang berkaitan**
Ketua Penyelidik (Pemohon)		
Penyelidik Bersama (jika ada) & Ahli Penyelidik yang terlibat menjalankan prosedur kerja sepanjang kajian dijalankan		

2. Alamat Pejabat : _____
(Ketua Penyelidik sahaja)

_____

No. Tel & No. Fax : _____

Alamat E-mail : _____

Tajuk Projek : _____

_____

3. a) No. Rujukan Projek yang diluluskan oleh Institusi: _____

b) Sila sertakan salinan surat Kelulusan Cadangan Projek/No. Rujukan Projek dari institut Tuan/Puan.

4. Adakah projek ini telah dibincang dengan Pegawai Veterinar?

☐ Ya ☐ Tidak

5. Butiran mengenai haiwan yang akan digunakan:
(Jika terdapat lebih daripada satu jenis haiwan, sila lengkapkan bersama maklumat tambahan di dalam borang)

Spesis haiwan :	Umur :
Jantina :	Jumlah :
Punca haiwan :	

6. Keterangan mengenai projek yang akan melibatkan penggunaan haiwan makmal.

a. Objektif Projek: _____

b. Tarikh mula tempoh penyelidikan: _____
c. Tarikh tamat tempoh Penyelidikan: _____
d. Prosidur yang akan dilakukan ke atas haiwan termasuk penjagaan haiwan pra, semasa dan pasca projek (Penerangan secara *layman* dan mudah difahami):

e. Terangkan justifikasi menggunakan haiwan dalam projek ini:

f. Adakah projek ini melibatkan bahan-bahan toksik yang berjadual:

☐ Ya Nyatakan jenis bahan toksik: _____

_____

☐ Tidak

g. Adakah projek ini melibatkan agen-agen berjangkit:

☐ Ya Nyatakan jenis agen berjangkit: _____

_____

☐ Tidak

h. Adakah projek ini melibatkan haiwan jenis LMO:

☐ Ya Nyatakan jenis LMO terlibat: _____

_____

☐ Tidak

i. Adakah Adakah projek ini melibatkan haiwan yang telah dimasukkan bahan Genetik, *plasmid* atau *construct* atau gene editing?

☐ Ya Nyatakan jenis bahan:

_____

☐ Tidak

j. Sila nyatakan "Takat Akhir Haiwan" (Humane End-Point) yang ditetapkan dalam projek ini:

_____

_____

_____

_____

_____

k. Adakah haiwan akan dimusnahkan atau dilupuskan selepas kajian?

☐ Ya Nyatakan cara pelupusan: _____

_____

☐ Tidak Jelaskan: _____

_____

_____

7. Senarai peralatan, drug dan lain-lain bahan kimia/reagent yang akan digunakan ke atas haiwan tersebut

a) Senarai peralatan

Bil	Nama Peralatan

b) Ubat pelali (anaesthetic)

Bil	Nama Ubat	*Concentration*	*Dosage*

c) Bahan kimia/reagent

Bil	Nama bahan kimia /reagent	Dos

8. Klasifikasi projek (Sila rujuk kepada *Table 1*)

☐ A ☐ B ☐ C ☐ D ☐ E

9. Lokasi di mana haiwan akan ditempatkan

_____

_____

10. Dengan ini saya juga mengaku bahawa saya telah membaca Akta Kebajikan Haiwan 2015, dan mematuhi semua syarat penggunaan haiwan yang ditetapkan bawah Akta ini dan peraturan-peraturan yang berkaitan.

_____ _____

Tarikh (Cop dan tandatangan Ketua Penyelidik)

Untuk Kegunaan Jawatankuasa ACUC-MOH

Tarikh borang diterima : _____

Keputusan 'ACUC' : _____

Tarikh keputusan dibuat : _____

No rujukan kelulusan : _____

Table 1 : Categories of Biomedical Experiments Based on Increasing Ethical Concerns for Non-human Species.

Categories	Examples and Comments
Category A Experiments involving either no living materials or use of no living materials or use of plants, bacteria, protozoa, or invertebrate animal species.	Biochemical, botanical, bacteriological, microbiological, or invertebrate animal studies, tissue cultures, studies on tissues obtained from autopsy or from slaughterhouse, studies on embryonated eggs, invertebrate animals have nervous systems and respond to noxious stimuli, and therefore must also be treated humanely.
Category B Experiments on vertebrate animal species that are expected to produce little or no discomfort.	Mere holding of animals captive for experimental purposes; simple procedures such as injections of relatively harmless substances and blood sampling; physical examinations; experiments on completely anesthetized animals which do not regain consciousness; food/water deprivation for short periods (a few hours); standard methods of euthanasia that induce rapid unconsciousness, such as anesthetic overdose or decapitation preceded by sedation or light anesthesia.
Category C Experiments that involve some minor stress or pain (short-duration pain) to vertebrate animal species.	Exposure of blood vessels or implantation of chronic catheters with anesthesia; behavioral experiments on awake animals that involve short-term stressful restraint; immunization employing Freud`s adjuvant; noxious stimuli from which escape is possible; surgical procedures under anesthesia that may result in some minor post-surgical discomfort. Category C procedures incur additional concern in proportion to the degree and duration of unavoidable stress or discomfort.
Category D Experiments that involve significant but unavoidable stress or pain to vertebrate animal species.	Deliberate induction of behavioral stress in order to test its effect; major surgical procedure under anesthesia that result in significant post-operative discomfort; induction of an anatomical or physiological deficit that will result in pain or distress; application of noxious stimuli from which escape is impossible; prolonged periods (up to several hours or more) of physical restraint; maternal deprivation with substitution of punitive surrogates; induction of aggression; procedures that produce pain in which anesthetics are not used, such as toxicity testing with

	death as death as end point; production of radiation sickness, certain injections, and stress and shock research that would result in pain approaching the pain tolerance threshold i.e. the point at which intense emotional reactions occur. Category D experiments present an explicit responsible on the investigator to explore alternative designs to ensure that animal distress is minimized or eliminated.
Category E Procedures that involve inflicting severe pain near, at, or above the pain tolerance threshold of unanesthetized, conscious animals.	Use of muscle relaxants or paralytic drugs such as succinyl choline or other curariform drugs used alone for surgical restraint without the use of anesthetics; severe burn or trauma infliction on unanesthetized animals; attempts to induce psychotic-like behavior; killing by use of microwave ovens designed for domestic kitchens or by strychnine; inescapably severe stress or terminal stress. Category E experiments are considered highly questionable or unacceptable irrespective of the significance of anticipated results. Many of these procedures are specifically prohibited in national policies and therefore may result in withdrawal of federal funds and/or institutional USDA registration.

AKU JANJI KETUA PROJEK

National Institutes of Health **(Institut Kesihatan Negara),**
Kementerian Kesihatan Malaysia

APPENDIX 9

Bahawasanya, saya, **[Nama Penuh]** _____ **[No Kad Pengenalan]** _____ seorang warganegara Malaysia dan kini berkhidmat di [**Nama Institut/ Hospital/ Bahagian**] _____ dengan sesungguhnya dan sebenarnya mengaku janji seperti berikut:

a. Bersetuju untuk menerima Geran Penyelidikan Kementerian Kesihatan Malaysia (KKM) berjumlah **RM**_____ bagi projek penyelidikan yang akan dijalankan oleh saya sebagai Ketua Projek bagi kajian **[NMRR ID]** _____ **[Tajuk Projek]**_____ _____ _____ _____ dari tahun _____**[mm-yyyy]** hingga _____**[mm-yyyy]**;

b. Bahawa saya akan sentiasa menjalankan projek penyelidikan dalam tempoh yang telah diluluskan dengan cermat, cekap, jujur, amanah dan bertanggungjawab;

c. Bahawa saya akan membelanjakan peruntukan dengan berhemah mengikut undang-undang dan peraturan- peraturan kewangan yang berkuat kuasa dari semasa ke semasa;

d. Mencalonkan pengganti sebagai Ketua Projek jika berpencen atau meninggalkan perkhidmatan dan akan berusaha memastikan projek berjalan dengan lancar sehingga projek tamat;

e. Memastikan semua Laporan Kewangan, Laporan Kemajuan Projek dan laporan yang diperlukan dan ditetapkan oleh Institut Kesihatan Negara (*National Institutes of Health*) dikemukakan pada masa dan tarikh yang ditetapkan berdasarkan garis panduan yang berkuat kuasa;

f. Mendapatkan kelulusan daripada Ketua Pengarah Kesihatan sebelum menerbitkan sebarang diseminasi atau sebaran hasil penyelidikan melalui penulisan, pengiklanan, pembentangan atau untuk disiarkan di media massa/ media sosial; dan

g. Memastikan semua hak cipta dan harta intelek milik serta rahsia Kerajaan terpelihara walaupun selepas Projek tamat..

Diperakukan oleh;

Nama Ketua Projek:
No KP:
Tandatangan:
Tarikh:

Di hadapan saya, [Pengarah Institut / Hospital / Bahagian]

Nama:
No KP:
Tandatangan:
Tarikh:

Versi 3.0/ 5 Mei 2017

APPENDIX 12: **LAPORAN PRESTASI**

A. NMRR ID : ……

TAJUK PROJEK : ……
……
……

NAMA KETUA PROJEK : ……

NO TELEFON : …… NO FAKS : ……

E-MAIL :

TARIKH : …… TANDATANGAN : ……

B. KEMAJUAN PROJEK

Nyatakan kemajuan setiap aktiviti penyelidikan (merujuk kepada jadual projek asal).

*Kemajuan hendaklah dilaporkan di dalam terma yang boleh diukur,; seperti bilangan sampel yang telah dikumpulkan, bilangan analisis yang telah dilakukan, dsb.

Tahun:…… Tempoh: ☐ Jan-Jun ☐ Jul-Dis

Nyatakan status terkini projek:

☐ Berjalan (Ongoing)

☐ Ditamatkan (Terminated)

☐ Terbengkalai (Abandoned)

☐ Digantung (Suspended)

☐ Selesai (Completed)

Sekiranya projek ditamatkan/terbengkalai/digantung, sila nyatakan sebab

_____

Tajuk aktiviti:

Kemajuan (*sila nyatakan sebab sebarang kelewatan)

Nota: *ulang ruangan ini bagi setiap aktiviti yang dijadulakan bagi tempoh di atas.*
Sila lampirkan jadual projek yang telah dikemaskini sekiranya terdapat perubahan berbanding jadual asal

C. PENCAPAIAN MILESTONE

Tajuk milestone : ……..……..……

……..……

Status : ☐ **TERCAPAI** ☐ **TIDAK TERCAPAI** (sila lengkapkan ruangan C1, C2, C3 and C4)

C1. Faktor ketidakcapaian (sila nyataka sebab)

C2. Cadangan pelarasan (sila nyatakan pelarasan yang dilakukan)

C3. Impak kepada jadual projek (sila lampirkan jadual projek yang dikemaskini, jika berkenaan)

C1. Faktor ketidakcapaian (sila nyataka sebab)

Tarikh kemaskini milestone : ……..……

Tarikh baru projek selesai : ……..…… Tarikh asal : ……..……

Impak kepada peruntuka projek (sila lampirkan peruntukan yang telah disemak semula jika berkenaan)

Peruntukan yang diluluskan : RM ……..……

Peruntukan selepas semakan semula : RM ……..……

Tarikh : ……..…… **Tandatangan :** ……..……

APPENDIX 13: **LAPORAN KEWANGAN**

A. NMRR ID : ……

TAJUK PROJEK : ……
……
……

NAMA KETUA PROJEK : ……

NO TELEFON : …… NO FAKS : ……

E-MAIL :

TARIKH : …… TANDATANGAN : ……

B. PERBELANJAAN TERKUMPUL BERAKHIR

TAHUN: ……

BULAN (sila / pada yang berkenaan):

☐ Januari	☐ Februari	☐ Mac	☐ April
☐ Mei	☐ Jun	☐ Julai	☐ Ogos
☐ September	☐ Oktober	☐ November	☐ Disember

Kategori	Peruntukan (RM)	Perbelanjaan Terkumpul (RM)
Perjalanan dan Pengangkutan		
Perhubungan Dan Utiliti		
Sewaan		
Bahan-bahan Makanan dan Minuman		
Bekalan Bahan Mentah dan Bahan-bahan Untuk Penyelenggaraan dan Pembaikan		
Bekalan dan Bahan Penyelidikan		
Selenggaraan Dan Pembaikan Kecil		
Khidmat Ikhtisas		
Pegawai Sambilan Harian (PSH) / Research Assistant (RA)		
Harta Modal		
JUMLAH		

APPENDIX 14: **PINDAAN AGIHAN**

(A) MAKLUMAT PERMOHONAN			
TAHUN KEWANGAN :			
Ketua Projek:			
Institut/Jabatan:			
Emel:		No. Telefon:	
NMRR ID:		Kod Projek JPP-NIH:	
Jumlah Peruntukan Tahun Semasa (RM)		Baki Peruntukan Semasa (RM)	

Kategori	**(B) PINDAHAN PERUNTUKAN**			
	Pecahan Asal (RM)	**Pengurangan (RM)**	**Penambahan (RM)**	**Pecahan Terkini (RM)**
Perjalanan & Sara Hidup				
Perhubungan dan Utiliti				
Sewaan				
Bahan Makanan & Minuman				
Bekalan Bahan Mentah				
Bekalan & Bahan Penyelidikan				
Penyelenggaraan & Pembaikan				
Perkhidmatan				
Pekerja Sambilan Harian (PSH)				
Harta Modal/Aset				
Lain-lain (sila nyatakan)				
JUMLAH				

(C) JUSTIFIKASI PERMOHONAN

PERAKUAN KETUA PROJEK

Tarikh ……..... ……..…..…….
(Tandatangan & Cop Rasmi)

PERAKUAN PENGARAH INSITUT/ HOSPITAL / BAHAGIAN

Permohonan ini disokong / tidak disokong

Tarikh ……..... ……..…..…….
(Tandatangan & Cop Rasmi)

PERAKUAN NIH

Permohonan ini disokong / tidak disokong

Tarikh ……..... ……..…..…….
(Tandatangan & Cop Rasmi)

(F) KELULUSAN TIMBALAN KETUA PENGARAH KESIHATAN (PENYELIDIKAN DAN SOKONGAN TEKNI-KAL)

Permohonan ini disokong / tidak disokong

Tarikh ……..... ……..…..…….
(Tandatangan & Cop Rasmi)

APPENDIX 15: **LAPORAN PEMANTAUAN**

ARAHAN

1. Laporan ini bertujuan untuk memantau hasil penyelidikan setiap projek bermula sehingga projek tamat.
2. Laporan ini hendaklah dihantar setiap suku keempat iaitu **sebelum 15 Januari tahun berikutnya**.

MAKLUMAT PROJEK PENYELIDIKAN

Kod JPP-NIH : _____ NMRR : _____

Tajuk Projek : _____

_____

_____

Ketua Penyelidik : _____

Tarikh Mula (mmm-yy) : _____ Tarikh Tamat (mmm-yy) : _____

Jumlah Peruntukan (RM) : _____

HASIL-HASIL PENYELIDIKAN

1. PENERBITAN : _____

You CH, Lee KY, Chev RY, Menguy R (1980). Electrogastrographic study of patients with unexplained masses, bloating and vomiting. Gastroenterology 79(2):311-314.

No	Tajuk	Status
1.		
2.		
3.		

Status:
DGA : DG Approval :setelah mendapat kelulusan Ketua Pengarah Kesihatan
SUB : Submitted to Journal Editor
ACC : Accepted / In-Press
PUB : Published

2. LAPORAN TEKNIKAL : _____

Public Health Institute, Ministry of Health. National Health and Morbidity Survey (1986-1987): Purpose, scope and methodology. Malaysia, Kuala Lumpur, 1987. (ISBN No)

No.	**Tajuk**
1.	
2.	
3.	

3. PEMBENTANGAN LISAN : _____

Mazlan AB, Kamal A, Susila R. Contribution of Health Research Towards National Health Development. Paper presented at the 2nd Health Research Seminar. Kuala Lumpur, 12- 14 July 2005.

No.	Tajuk
1.	
2.	

4. PEMBENTANGAN POSTER : _____

Noraznawati I, Ho TM, Nathan S, Wan KL. Identification of recombinant clones of house dust mites, S. pontifica. Poster presented at 11th National Biotechnology Seminar, Malacca, 10 – 12 November 2005.

No.	Tajuk
1.	
2.	

5. LAIN-LAIN; nyatakan : _____

No.	Tajuk
1.	
2.	

Disediakan oleh:

Tandatangan dan Cop Rasmi Ketua Projek:

_____

( ) Tarikh:

APPENDIX 16: **LAPORAN TAMAT PROJEK**

A. NMRR ID: .....

TAJUK PROJEK: .....
.....
.....

NAMA KETUA PROJEK: .....
NO TELEFON.: ..... NO FAKS: .....
E-MAIL: .....

TARIKH: ..... TANDATANGAN: .....

B. RINGKASAN LAPORAN AKTIVITI PENYELIDIKAN
(sila nyatakan objektif projek, keputusan, penemuan dan impak projek)

C. PERUNTUKAN YANG DITERIMA

(sila senaraikan peruntukan yang diterima beserta sumber)

SUMBER PERUNTUKAN	JUMLAH (RM)

D. PENCAPAIAN OBJEKTIF

- Objektif projek asal
  (sila nyatakan objektif umum dan spesifik seperti yang dinyatakan di dalam proposal asal)

- Objektif yang tercapai
  (sila nyatakan sejauh mana objektif projek telah dicapai dan dinyatakan di dalam terma yang boleh diukur)

- Objektif yang tidak tercapai
  (sila nyatakan objektif yang tidak tercapai dan sebab-sebab ketidakcapaian)

E. PENGGUNAAN DAN IMPAK HASIL PENYELIDIKAN

Sila nyatakan penggunaan hasil penyelidikan *(bagaimana,di mana, bila, siapa, dsb.)*

F. Output

1. Bilangan Penerbitan: ……
(sila senaraikan mengikut format seperti di bawah.)

You CH, Lee KY, Chev RY, Menguy R (1980). Electrogastrographic study of patients with unexplained masses, bloating and vomiting. *Gastroenterology* 79(2):311-314.

Bil.	Tajuk

2. Bilangan Laporan: ……..
(sila senaraikan mengikut format seperti di bawah.)

Public Health Institute, Ministry of Health. National Health and Morbidity Survey (1986-1987): Purpose, scope and methodology. Malaysia, Kuala Lumpur, 1987.

Bil.	Tajuk

3. Bilangan Pembentangan (Oral): ……..
(sila senaraikan mengikut format seperti di bawah.)

Mazlan AB, Kamal A, Susila R. Contribution of Health Research Towards National Health Development. Paper presented at the Health Research Seminar. Malaysia, Kuala Lumpur, July.

Bil.	Tajuk

4. Bilangan Pembentangan (Poster):……..
(sila senaraikan mengikut format seperti di bawah.)

Noraznawati I, Ho TM, Nathan S, Wan KL. Identification of recombinant clones of house dust mites, *S. pontifica*. Poster presented at 11th National Biotechnology Seminar, Malacca, November.

Bil.	Tajuk

5. Latihan
(sila nyatakan bilangan pegawai yang dilatih bagi setiap kategori di bawah.)

Kategori	Bilangan Pegawai
B.Sc atau setara	
M.Sc atau setara	
PhD atau setara	
Kursus pendek (Senaraikan nama kursus: ……)	
Attachment training	
Lain-lain (sila nyatakan)	

6. Harta Intelek

Kategori	Bilangan
Paten telah diperolehi	
Paten belum selesai	
Permohonan paten untuk diisi	
Hak Cipta	

7. Kerjasama Penyelidikan

Kategori	Nama
Kerjasama dengan Institusi Penyelidikan Tempatan	1. 2.
Kerjasama dengan Institusi Penyelidikan Antarabangsa	1. 2.
Kerjasama dengan Industri Tempatan	1. 2.
Kerjasama dengan Industri Antarabangsa	1. 2.

8. Pengkomersilan (sila nyatakan jika hasil penyelidikan berpotensi untuk dikomersilkan. Jika pengkomersilan telah bermula, sila nyatakan aktiviti pengkomersilan yang telah dijalankan)

APPENDIX 17: **PELANJUTAN TEMPOH**

MAKLUMAT KETUA PROJEK DAN PROJEK PENYELIDIKAN			
Ketua Projek:			
Institut/Jabatan:			
Emel:		No. Telefon:	
NMRR ID:		Kod Projek JPP-NIH:	
Tajuk Projek:			
Jumlah Peruntukan Keseluruhan (RM)		Baki Peruntukan (RM)	

PERMOHONAN PELANJUTAN TEMPOH PROJEK PENYELIDIKAN			
1) Maksimum tempoh pelanjutan adalah 12 bulan sahaja 2) Permohonan hendaklah dikemukakan kepada Bahagian Pengurusan Penyelidikan dan Geran, NIH tiga (3) bulan sebelum tamat projek 3) Permohonan mestilah disertakan sekali dengan Laporan Kemajuan Projek Penyelidikan dan Gantt Chart asal dan terkini.			
Tarikh Mula Projek:		Tarikh Tamat Asal:	
Tarikh Tamat Dipohon:		Berapa Bulan:	

JUSTIFIKASI PERMOHONAN
PERAKUAN KETUA PROJEK

Tarikh: _____ _____

(Tandatangan & Cop Rasmi)

PERAKUAN PENGARAH INSITUT/ HOSPITAL / BAHAGIAN

Permohonan ini disokong / tidak disokong

Tarikh: _____ _____

(Tandatangan & Cop Rasmi)

PERAKUAN BAHAGIAN PENGURUSAN PENYELIDIKAN DAN GERAN

Permohonan ini disokong / tidak disokong

Tarikh: _____ _____

(Tandatangan & Cop Rasmi)

KELULUSAN TIMBALAN KETUA PENGARAH KESIHATAN (PENYELIDIKAN DAN SOKONGAN TEKNIKAL)

Permohonan ini diluluskan / tidak diluluskan

Tarikh: _____ _____

(Tandatangan & Cop Rasmi)

NIH INSTITUT KESIHATAN NEGARA NATIONAL INSTITUTES OF HEALTH	**APPENDIX 18: INVENTION DISCLOSURE EVALUATION FORM** **INNOVATION AND COLLABORATION UNIT,** **NATIONAL INSTITUTES OF HEALTH (NIH)** **Setia Alam, 40170 Selangor.** **Tel: 03-3362 8089; Fax: 03-3362**

1. Invention Title:

2. Inventor/s:

3. Name of Reviewer:

4. Date of Review:

Reviewer's Scale of Review (1 – 10)

1 - 3 : adequate	**4 - 5 : moderate**	**6 - 8 : acceptable**	**9 - 10 very good**	
No.	**Aspects** **Justification**	**To be filled by REVIEWER**		
		Score	**Reviewer's Comments**	
1.	Novelty of Invention (e.g novelty search, invention has not carried out elsewhere previously)			
2.	Level of technology and stage of development (prototype development stage, commercialisable stage etc.)			
3.	Patentability of Invention Yes/No			
4.	Value of technology			
5.	Is the level of technology fit with industry requirement?			
6.	Commercial potential of prospective patent?			

7.	Can the industry develop the invention into useful products?		
8.	Marketability of prospective patent		
9.	Is the invention required considerable investment to transform it into marketable product?		
10.	What is the size of potential market for prospective patent? **(1 very high, 10 very low)**		

Please return the completed form to:

INNOVATION AND COLLABORATION UNIT,
MANAGER OFFICE
NATIONAL INSTITUTES OF HEALTH (NIH)
Setia Alam, 40170 Selangor.
Tel: 03-3362 8089; Fax: 03-3362

National Institutes of Health,
Ministry of Health Malaysia
1, Jalan Setia Murni U13/52,
Section U13, Setia Alam,
40170 Shah Alam,
Selangor, MALAYSIA.

Tel : +603-3362 8403/ 8316
Fax : +603-3362 8001

www.nih.gov.my

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