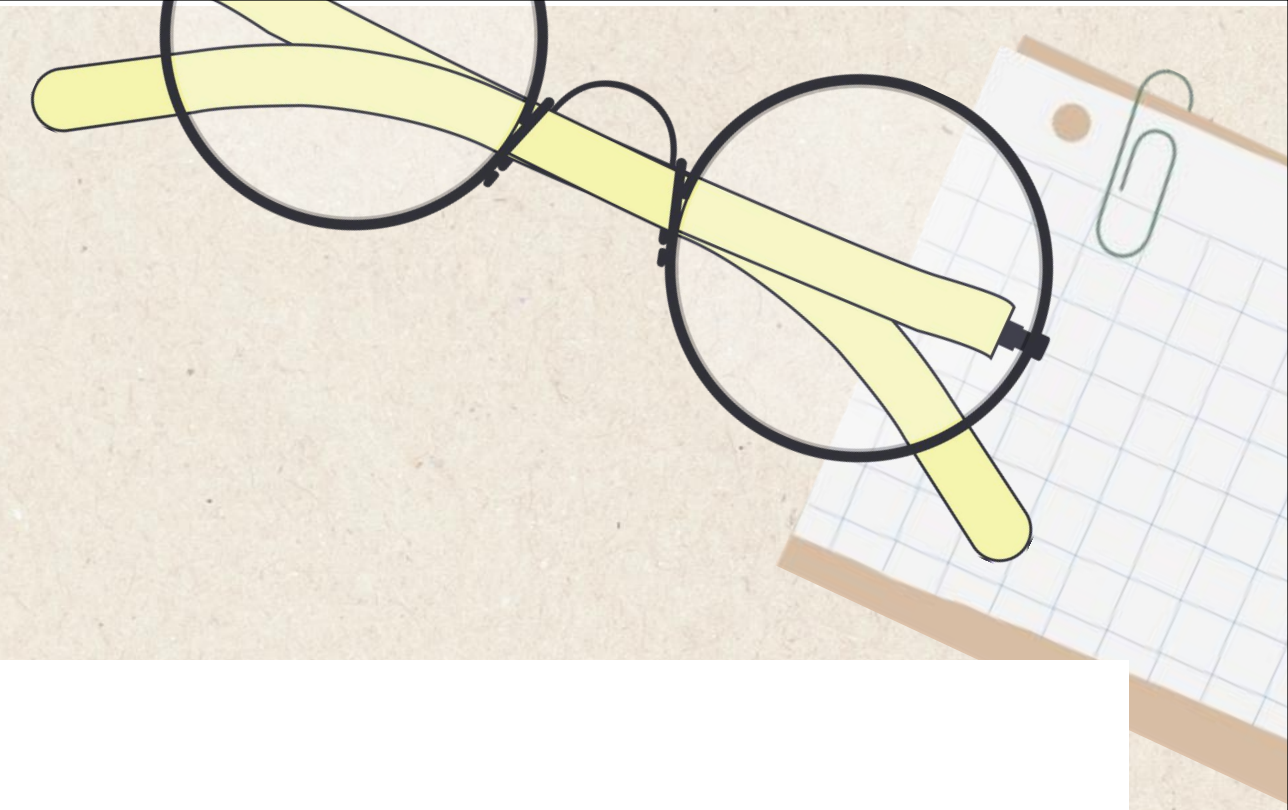
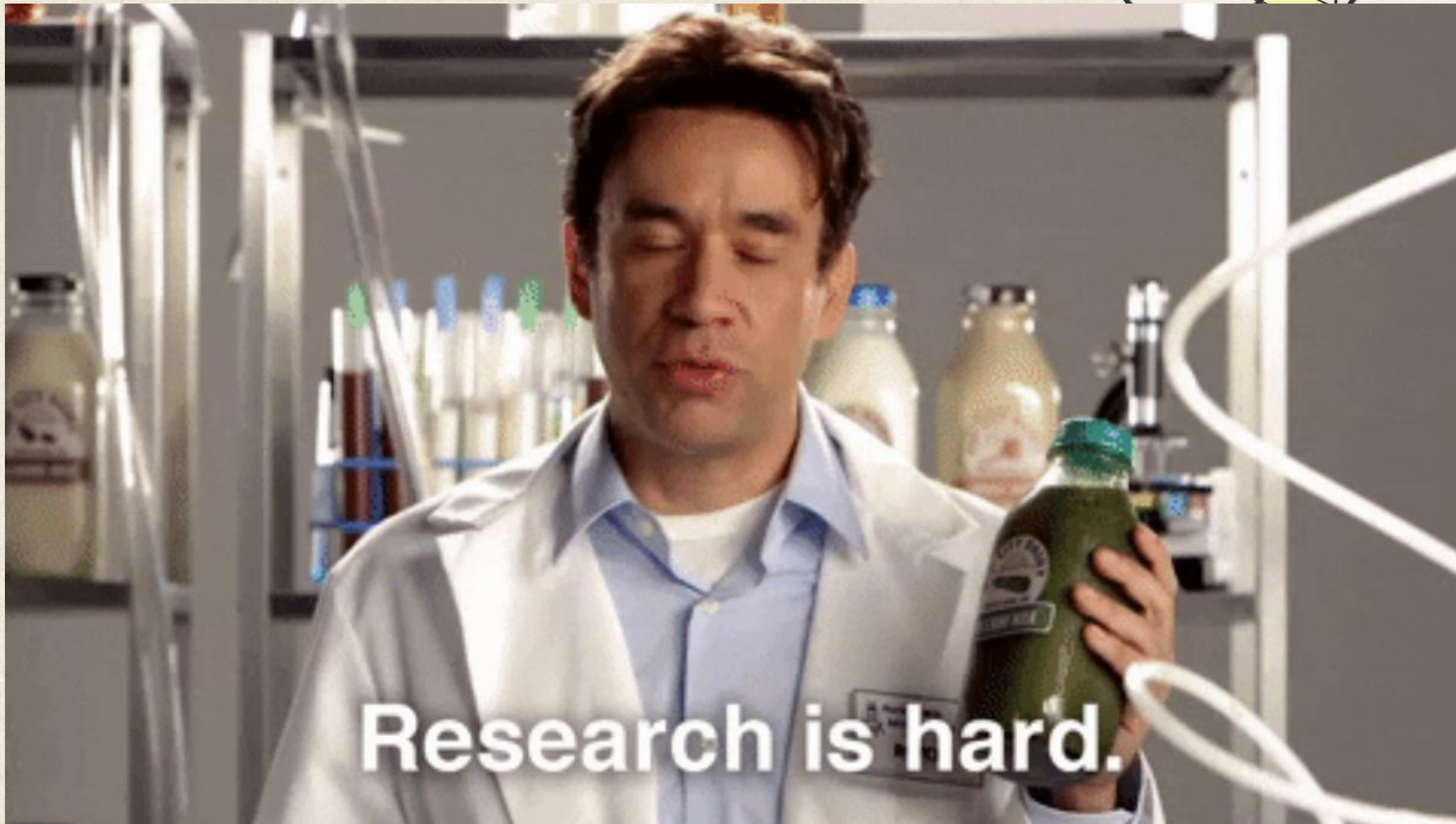




APPLICATION FOR CONDUCT OF RESEARCH IN MINISTRY OF HEALTH MALAYSIA

CAWANGAN EPIDEMIOLOGI & PENYELIDIKAN KESIHATAN PERGIGIAN
PROGRAM KESIHATAN PERGIGIAN, KKM





Research is hard.



DEFINITION

The background of the slide is a light brown, textured surface resembling a desk or a piece of paper. In the top left corner, there is a red-bordered box with a dashed orange outline containing the word 'DEFINITION' in a bold, black, serif font. In the top right corner, there is a pair of yellow-rimmed glasses with black frames, resting on a piece of white paper with a blue grid pattern. A silver paperclip is attached to the top right corner of the grid paper. In the center, a brown paperclip is attached to the top edge of a white rectangular box that contains the definition text. On the left side, there is a brown clipboard with a black strap, and a gold watch with a brown leather strap is visible in the bottom left corner.

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

Circulars For The Conduct of Research IN MOH



KETUA PENGARAH KESIHATAN MALAYSIA
DIRECTOR GENERAL OF HEALTH MALAYSIA

Kementerian Kesihatan Malaysia,
Ara 12, Blok E7, Parcel E,
Pusat Pentadbiran Kerajaan Persekutuan
62590 Putrajaya.

Tel : 603-88832545
Faks : 603-88895542
E-mail : ismailmerican@moh.gov.my

Ruj Kami : (1) dlm KKM/NIHSEC/03/0301-01
Tarikh : 5 September 2007

Senarai Edaran Seperti Di Lampiran

Y Bhg Datuk / Dato' / Datin / Tuan / Puan

SURAT PEKELILING KETUA PENGARAH KESIHATAN MALAYSIA BIL.9/2007

GARISPANDUAN INSTITUT KESIHATAN NEGARA MENGENAI PENYELIDIKAN YANG
DIJALANKAN DI INSTITUSI DAN FASILITI KEMENTERIAN KESIHATAN MALAYSIA

1. TUJUAN

Pekeliling ini bertujuan untuk memaklumkan garispanduan yang mesti digunakan untuk maksud penyelidikan yang dilaksanakan di Jabatan / Institusi dan fasiliti Kementerian Kesihatan Malaysia (KKM).

Garispanduan yang bertajuk "*National Institutes of Health (NIH) Guidelines for Conducting Research in the Ministry of Health (MOH) Institutions and Facilities*" ini disediakan sebagai satu pengemaskinian dan penyeragaman polisi dan prosedur penyelidikan KKM.

2. ASPEK PENTING GARISPANDUAN


Berikut adalah aspek-aspek penting di dalam garispanduan yang mesti diberikan perhatian dan penekanan :


- 2.1 Semua penyelidikan mesti memperolehi kelulusan Kementerian Kesihatan Malaysia melalui tatacara yang ditetapkan.
- 2.2 Semua penyelidikan KKM mesti didaftarkan secara *online* di *National Medical Research Register* (www.nmrr.gov.my).
- 2.3 Penyelidikan yang mempunyai aspek etika mesti memperolehi kelulusan dari Jawatankuasa Etika dan Penyelidikan Perubatan (JEPP), KKM.

keliling Ketua Pengarah Kesihatan Malaysia Bil.
ruj. (1) dlm KKM/NIHSEC/03/0301-01 bertarikh
[5 September 2007]

duan Institut Kesihatan Negara Mengenai
kan yang Dijalankan di Institusi dan Fasiliti KKM

Circulars For The Conduct of Research IN MOH

 **KETUA PENGARAH KESIHATAN MALAYSIA**
DIRECTOR GENERAL OF HEALTH MALAYSIA
Kementerian Kesihatan Malaysia
Aras 12, Blok E7, Kompleks E
Pusat Pentadbiran Kerajaan Persekutuan
62590 PUTRAJAYA



Tel : 03-8883 2545
Faks : 03-8889 5542
Web : ansham@moh.gov.my

Ruj. Kami: (17)KKM/NIHSEC/100-1/1/1 Jld 2
Tarikh: 21 Oktober 2015

SEPERTI SENARAI EDARAN

YBhg Datuk/Dato'/Datin/Tuan/Puan,

SURAT PEKELILING KETUA PENGARAH KESIHATAN MALAYSIA BIL. 10 /2015

GARISPANDUAN INSTITUT KESIHATAN NEGARA MENGENAI PENYELIDIKAN DI INSTITUSI DAN FASILITI KEMENTERIAN KESIHATAN MALAYSIA (PINDAAN 01/2015)

1. TUJUAN

Pekeliling ini bertujuan untuk memaklumkan pindaan garispanduan yang digunakan untuk maksud Penyelidikan di Institusi dan fasiliti Kementerian Kesihatan Malaysia (KKM).

Pindaan garispanduan yang bertajuk **"NIH GUIDELINES FOR CONDUCTING RESEARCH IN MOH INSTITUTIONS AND FACILITIES"** ini disediakan untuk mempertingkatkan kualiti proposal / protokol Penyelidikan seterusnya mempercepatkan proses kelulusan melaksanakan Penyelidikan.

2. ASPEK PENTING GARISPANDUAN

Berikut adalah aspek – aspek penting di dalam garis panduan ini:

2.1 Semua Penyelidikan mesti memperolehi kelulusan Kementerian Kesihatan Malaysia melalui tatacara yang telah ditetapkan mengikut kategori seperti berikut:-

- (i) Penyelidik Institut Kesihatan Negara (*NIH Researcher/Investigator*)
- (ii) Penyelidik selain Institut Kesihatan Negara yang memohon Geran Penyelidikan (*Non NIH Researcher / Investigators applying for grant*)
- (iii) Penyelidik selain Institut Kesihatan Negara yang tidak memohon Geran Penyelidikan, tetapi menggunakan fasiliti, data dan/atau pesakit fasiliti KKM (*Non NIH Researcher / Investigator, not requesting for Grant, using MOH facilities, Data and/or MOH Patients*)

2.2 Semua penyelidikan yang dilaksanakan di Institusi dan fasiliti Kementerian Kesihatan Malaysia (KKM) mesti didaftarkan secara online di *National Medical Research Register (NMRR)* – <https://www.nmrr.gov.my>

Pekeliling Ketua Pengarah Kesihatan Malaysia Bil. 10/2015 [ruj. (17) dlm KKM/NIHSEC/100-1/1/1 Jld 2 tarikh 21 Okt. 2015]

garispanduan Institut Kesihatan Negara Mengenai Penyelidikan di Institusi dan Fasiliti KKM (Pindaan 01/2015)

OVERVIEW OF MOH RESEARCH GUIDELINES

MRG Guidelines

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

Research Dissemination

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

3rd Edition

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

Circulars For The Conduct of Research IN MOH



KETUA PENGARAH KESIHATAN MALAYSIA

Kementerian Kesihatan Malaysia
Aras 12, Blok E7, Kompleks E
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Tel.: 03-8000 8000
Faks: 03-8889 5542
Email: anhisham@moh.gov.my

Ruj. Kami : NIH.800-3/2/3 Jld.4 (63)
Tarikh : 31 Januari 2022

SEPERTI SENARAI EDARAN

YBhg Dato' Indera/ Dato' Seri/Datuk/Dato'/Datin/Tuan/Puan,

SURAT PEKELILING KETUA PENGARAH KESIHATAN MALAYSIA BIL. 4 /2022
GARIS PANDUAN PENYELIDIKAN DI KEMENTERIAN KESIHATAN MALAYSIA
BERTAJUK "NATIONAL INSTITUTES OF HEALTH (NIH) GUIDELINES FOR
CONDUCTING RESEARCH IN MINISTRY OF HEALTH (MOH) INSTITUTIONS &
FACILITIES, 3RD EDITION, 2021"

1. TUJUAN

Pekeliling ini bertujuan untuk memaklumkan kemaskini garis panduan Institut Kesihatan Negara (NIH) berkaitan tatacara menjalankan penyelidikan di institusi dan fasiliti di bawah Kementerian Kesihatan Malaysia (KKM).

Garis panduan yang bertajuk "NATIONAL INSTITUTES OF HEALTH (NIH) GUIDELINES FOR CONDUCTING RESEARCH IN MINISTRY OF HEALTH (MOH) INSTITUTIONS & FACILITIES, 3RD EDITION, 2021" menggabungkan garis panduan sedia ada berkaitan tatacara menjalankan penyelidikan bermula daripada pendaftaran penyelidikan, kelulusan etika, permohonan geran penyelidikan sehingga ke sebaran hasil saintifik secara lebih komprehensif dan sistematik.

2. ASPEK PENTING GARIS PANDUAN

Berikut adalah aspek – aspek penting di dalam garis panduan ini:

ekeliling Ketua Pengarah Kesihatan Malaysia Bil.
[NIH.800-3/2/3 Jld.4 (63) bertarikh 31 Jan. 2022]
anduan Penyelidikan di KKM Bertajuk "NATIONAL
ITE OF HEALTH (NIH) GUIDELINES FOR CONDUCTING
RCH IN MOH INSTITUTIONS & FACILITIES, 3RD EDITION"



KETUA PENGARAH KESIHATAN MALAYSIA

Kementerian Kesihatan Malaysia
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Ruj. Kami : NIH.800-3/2/3 Jld.4 (63)
Tarikh : 31 Januari 2022

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YBhg Dato' Indera/ Dato' Seri/Datuk/Dato'/Datin/Tuan/Puan,

SURAT PEKELILING KETUA PENGARAH KESIHATAN MALAYSIA BIL. 4 /2022
GARIS PANDUAN PENYELIDIKAN DI KEMENTERIAN KESIHATAN MALAYSIA
BERTAJUK "*NATIONAL INSTITUTES OF HEALTH (NIH) GUIDELINES FOR
CONDUCTING RESEARCH IN MINISTRY OF HEALTH (MOH) INSTITUTIONS &
FACILITIES, 3RD EDITION, 2021*"

1. TUJUAN

Pekeliling ini bertujuan untuk memaklumkan kemaskini garis panduan Institut Kesihatan Negara (NIH) berkaitan tatacara menjalankan penyelidikan di institusi dan fasiliti di bawah Kementerian Kesihatan Malaysia (KKM).

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2. ASPEK PENTING GARIS PANDUAN

Berikut adalah aspek – aspek penting di dalam garis panduan ini:

MOH/S/NIH/10.21(G)

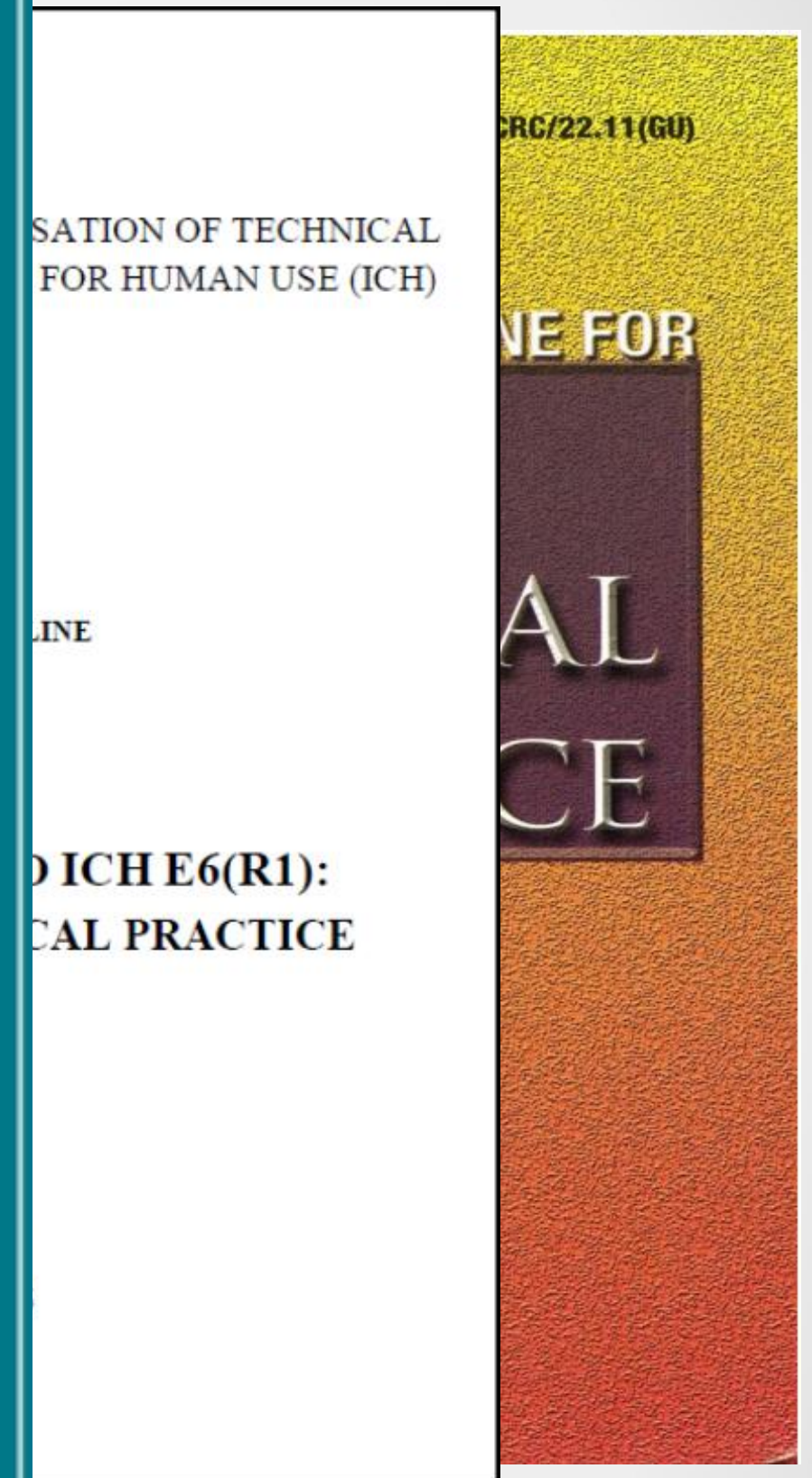
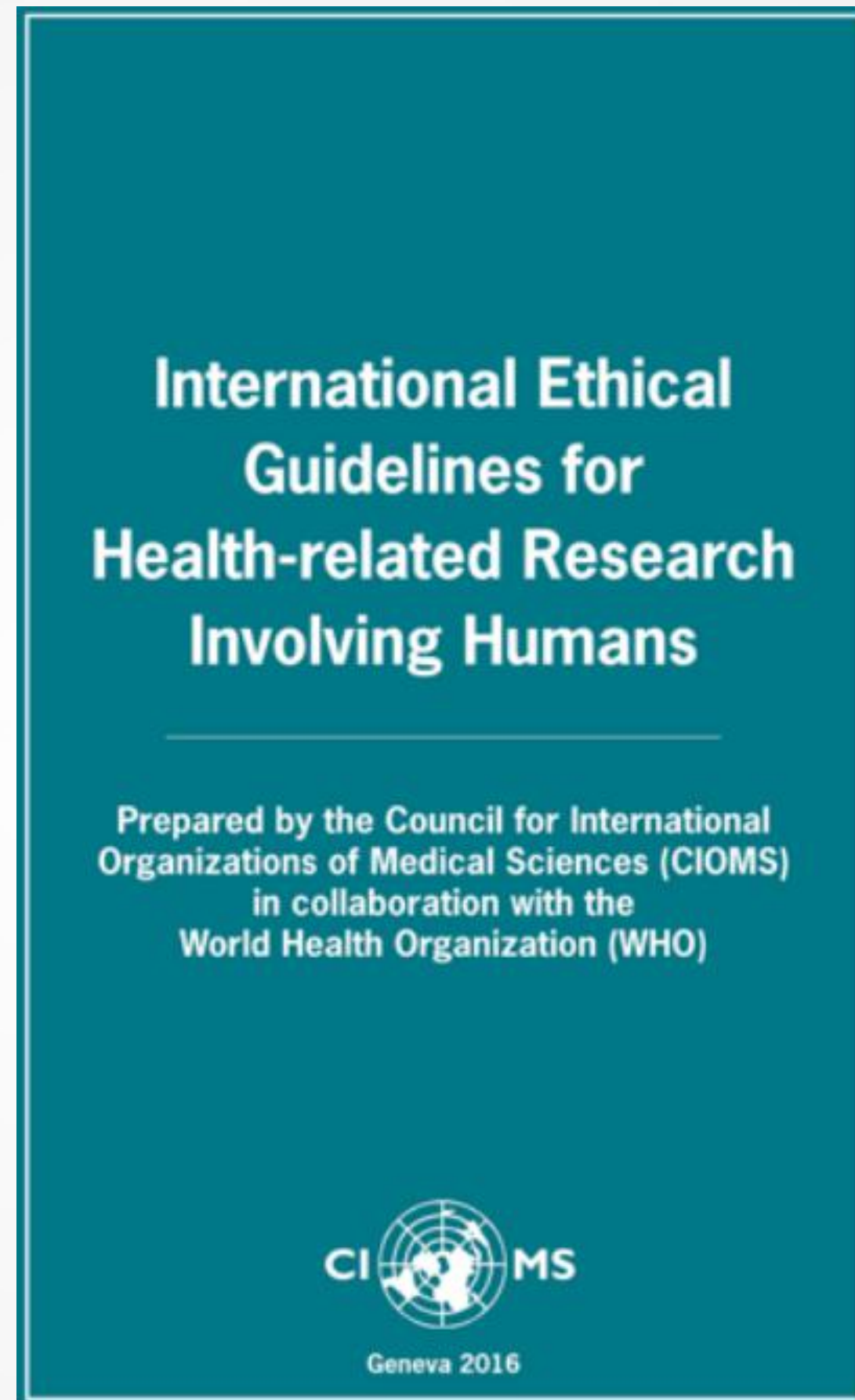


MINISTRY OF HEALTH MALAYSIA
NATIONAL INSTITUTES OF HEALTH (NIH)

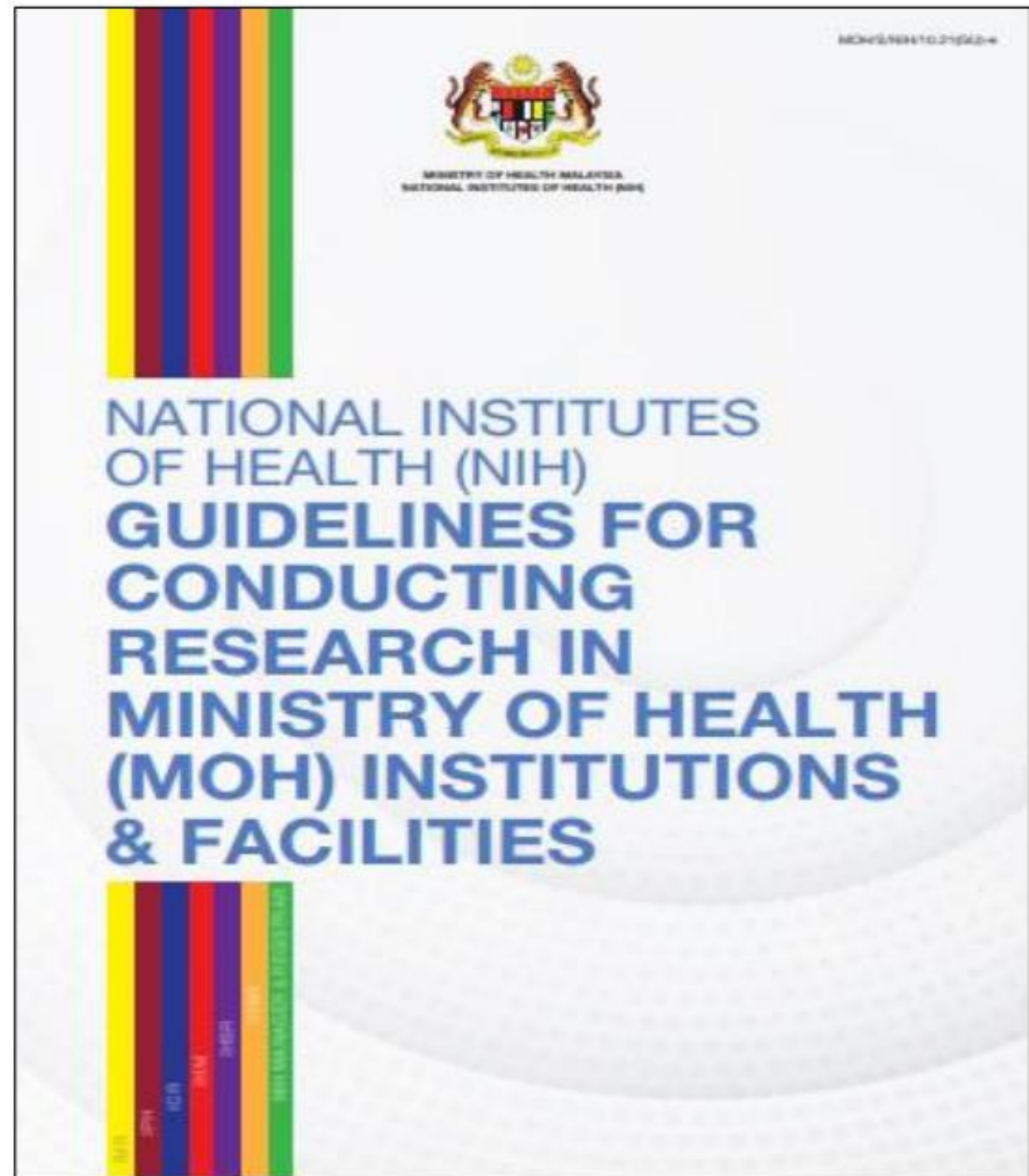
NATIONAL INSTITUTES OF HEALTH (NIH) GUIDELINES FOR CONDUCTING RESEARCH IN MINISTRY OF HEALTH (MOH) INSTITUTIONS & FACILITIES

General Policy of Research Conduct

- 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.**



RESEARCH GUIDELINES



1. NIH Guidelines For Conducting Research In Ministry Of Health Institutions And Facilities 2021, 3rd Edition 2021.
2. Malaysian Guideline For Good Clinical Practice (4th Edition 2018)
3. Guidelines For The Conduct Of Bioavailability And Bioequivalence Studies In Malaysia
4. Guidelines On The Use Of Human Tissue In Clinical Research
5. Guidelines For Application Of Clinical Trial Import Licence And Clinical Trial Exemption In Malaysia



RESEARCH GUIDELINES

7. Pharmacogenomics/Genetics Studies
8. Research On Stem Cell & Cell-based Therapies
9. Guidelines On The Use Of Human Tissue In Clinical Research.
10. Malaysian Medical Council Guideline Clinical Trials and Biomedical Research
11. Malaysian Medical Council Guideline Clinical Trials and Biomedical Research (2016)
12. The Malaysia Code of Responsible Conduct in Malaysia (2017)
13. Others...

RESEARCH GUIDELINES



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Ruj. Kami : NIH.800-3/2/3 Jld 4 (63)
Tarikh : 31 Januari 2022

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YBhg Dato' Indera/ Dato' Seri/Datuk/Dato'/Datin/Tuan/Puan,

SURAT PEKELILING KETUA PENGARAH KESIHATAN MALAYSIA BIL. 4 /2022
GARIS PANDUAN PENYELIDIKAN DI KEMENTERIAN KESIHATAN MALAYSIA
BERTAJUK "NATIONAL INSTITUTES OF HEALTH (NIH) GUIDELINES FOR
CONDUCTING RESEARCH IN MINISTRY OF HEALTH (MOH) INSTITUTIONS &
FACILITIES, 3RD EDITION, 2021"

1. TUJUAN

Pekeliling ini bertujuan untuk memaklumkan kemaskini garis panduan Institut Kesihatan Negara (NIH) berkaitan tatacara menjalankan penyelidikan di institusi dan fasiliti di bawah Kementerian Kesihatan Malaysia (KKM).

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2. ASPEK PENTING GARIS PANDUAN

Berikut adalah aspek – aspek penting di dalam garis panduan ini:

2.1 Pendaftaran penyelidikan di *National Medical Research Register (NMRR)*.

Semua penyelidikan yang dijalankan oleh warga KKM atau dilaksanakan di institusi / fasiliti KKM atau menggunakan data/pesakit/sampel/personel KKM sebagai subjek atau menggunakan geran penyelidikan KKM hendaklah didaftarkan dengan NMRR sebelum penyelidikan dijalankan.

2.2 Penilaian saintifik dan kelulusan etika.

Penyelidikan yang melibatkan KKM (terutamanya penyelidikan melibatkan manusia) perlu menjalani proses penilaian oleh Jawatankuasa Penilaian Penyelidikan (JPP) dan seterusnya penilaian serta kelulusan etika daripada Jawatankuasa Etika Penyelidikan dan Perubatan (JEPP), KKM.

2.3 Permohonan geran penyelidikan.

Permohonan geran penyelidikan adalah terbuka kepada warga penyelidik KKM sahaja. Permohonan geran hendaklah melalui proses penilaian dan sokongan daripada Jawatankuasa Penilaian Penyelidikan - NIH (JPP-NIH), kelulusan etika daripada JEPP, KKM dan dimuktamadkan kelulusan agihan oleh Panel Penilaian Geran Penyelidikan, KKM. Tatacara perolehan adalah tertakluk kepada garis panduan dan peraturan kewangan sedia ada yang berkuatkuasa dari semasa ke semasa.

2.4 Sebaran (pembentangan & penerbitan) saintifik.

Hasil sebaran saintifik seperti abstrak, poster, laporan penyelidikan, jurnal dan lain-lain yang dihasilkan oleh penyelidik KKM atau menggunakan data pesakit/ sampel/personel KKM sebagai subjek atau dibiayai oleh geran penyelidikan KKM perlu mendapat kelulusan Ketua Pengarah Kesihatan sebelum diterbitkan atau dibentangkan.

Bersama-sama dengan Surat Pekeliling ini, disertakan Garis Panduan "National Institutes of Health (NIH) Guidelines for Conducting Research in Ministry of Health (MOH) Institutions & Facilities, 3rd Edition, 2021". Garis panduan ini juga boleh dimuat turun daripada laman sesawang www.nih.gov.my / www.nmrr.gov.my.

3. TARIKH PERLAKSANAAN

Surat pekeliling dengan garis panduan ini berkuatkuasa mulai tarikh pekeliling ini dikeluarkan. Surat pekeliling berkaitan terdahulu adalah dengan sendirinya terbatal.

4. PERTANYAAN

Dr Asyraf Syahmi Mohd Noor
Ketua Unit Registri Penyelidikan & Koordinasi Data,
Sektor Etika & Pengawasan Penyelidikan,
Pejabat Pengurus NIH,
Institut Kesihatan Negara (NIH)
Tel: 03-3362 8403 Email: asyraf.nih@moh.gov.my

Puan Nurul Syarhani Elana Musa
Unit Pengurusan Penyelidikan & Dana Penyelidikan,
Pejabat Pengurus NIH,
Institut Kesihatan Negara (NIH)
Tel: 03-3362 8316 Email: elana@moh.gov.my

Sekian,

"WAWASAN KEMAKMURAN BERSAMA 2030"

"BERKHIDMAT UNTUK NEGARA"

Saya yang menjalankan amanah,

(TAN SRI DATO' SERI DR. NOOR HISHAM BIN ABDULLAH)

Category of Investigator

- All research related to MOH



**Undertaken
by MOH
personnel**



**Conducted
In MOH
Institutions /
facilities**



**Using MOH
data/patient
/sample/
personnel as
subject**



**Funded
by MOH
Research
Grant**

- 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)



National Medical Research Register

Advancing Medical Research in Malaysia

PRIOR to data collection and/or subject requirement

NEW

The Conduct of the Research

Registration of Retrospective Study

- 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.
- Case study, systematic review, scoping review, and research involving non-human subjects.



EMPOWERING RESEARCH FOR A HEALTHY & EQUITABLE MALAYSIA

NMRR serve as platform where information, progress and conduct of clinical trial, medical & health related research can be shared publicly

[Learn more](#)

National Medical Research Register (NMRR)
nmrr.gov.my

The Conduct of Research Involving MOH facilities & Institutions

@work & visualisation by:
Research Registry & Data Coordination, Sector for Ethics & Research Surveillance, NIH, MOH



Types of Submission in NMRR

- Submissions without the requirement of ethical approval (e.g., research that is exempted from MREC review)
- Submissions with Grant Application (MRG)
- Submission requiring Ethical Review & Approval from MREC (involves human subject)

Research activity starts

Site Approval Form

NMRR ID issued

JPP-NIH Board Review

with recommendation

Research Registration

NMRR ID issued

MREC Ethical Review & Approval

Research Planning & Development

GCP cert
IAHODIA form
NMRR Submission

Special Committee Approval/Regulatory Notification Submission**

data analysis, result reporting
research completion

any types of publication & presentation

DG Approval for Scientific Dissemination

MREC Post Ethical Approval Activity

any update, reporting, notification

Research activity starts

Research activity starts

post grant approval

Site Approval Form

approval & disbursement

MRG Panel Review

MRG Post Approval Activity

Research Conduct Phases*

- Before research initiation
- During subject recruitment/data collection
- After subject recruitment /data collection (during data analysis and result reporting & dissemination)

*Application during the conduct of research at phase 1,2,3 is done using the National Medical Research Register (NMRR) system while Submission at phase 4 is made through the system as mentioned

**Committee established on national or institutional level aims to steer development and govern specific research-type in Malaysia (e.g: NSCERT, NRDHM, ACUC, IBBC, FIH) Regulatory notification are specific for medical device involvement and usage in clinical and health relevant research to Medical Device Authority (MDA)

NIH

CRITERIA TO APPLY NMRR

(any **one** of the following)

1. Plan to conduct research involving Ministry of Health
(MOH patient/ data/ sample/personnel as subject OR conduct in MOH facilities OR using grant MOH)
2. Submission to Medical Research & Ethic Committee (MREC), MOH for ethical review & approval
3. Plan to conduct research using MOH Medical Research Grant (MRG)
4. Publication or Presentation Approval for Study Results involving Ministry of Health
5. All clinical trial conducted in Malaysia : following the requirement of CTIL, CTX by National Pharmaceutical Regulatory Agency(NPRA)

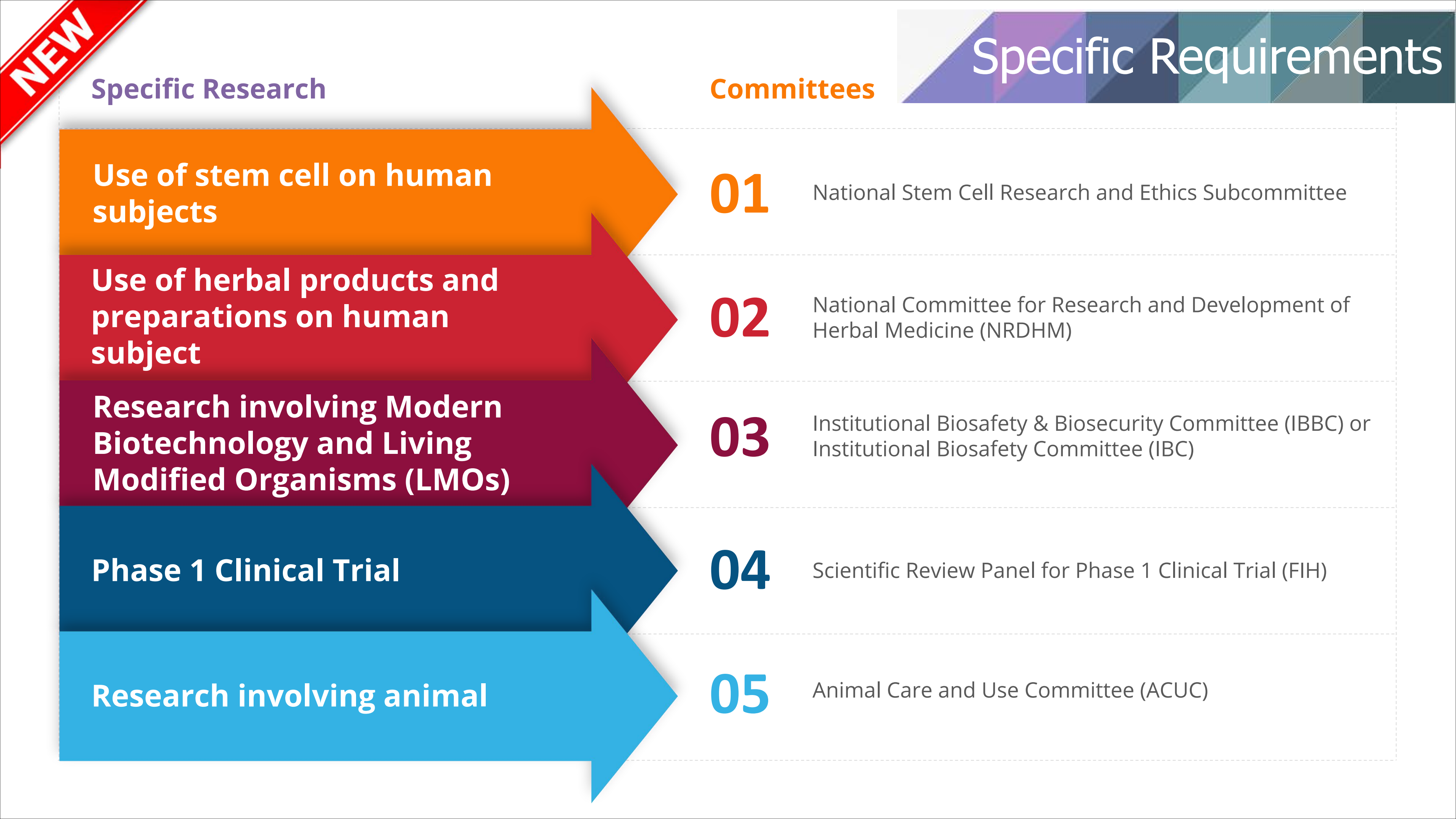
Documents required for NMRR & CRC Submission (Observational study)

1. *Research Application Letter From Researcher/ University (up to the sites)
2. Research Protocol
3. Case Report From/ Data Collection form
- all research e.g using secondary data
4. Questionnaire (if research involve questionnaire e.g Quality of Life)
5. Patient Information Sheets & Consent
Malay & English ± Others (Tamil, Mandarin)
6. IAHOD FORM (download from NMRR)
7. CV (Principal Investigator & Study team)
8. Declaration of Conflict of Interest (download from NMRR)
9. MREC Cover letter
10. MOU, MOA or LOA (if study involves multiple collaboration)
11. Advertisement (if applicable)

Documents required for NMRR (Interventional study)

1. *Research Application Letter From Researcher/ University (up to the site)
2. Research Protocol
3. Case Report Form/ Data Collection Form
 - all research except research involve questionnaire
4. Questionnaire (if research involve questionnaire e.g Quality of Life)
5. Patient Information Sheets & Consent
 - Malay & English ± Others (Tamil, Mandarin)
6. IAHOD FORM (download from NMRR)
8. CV (Principal Investigator & Study team)
9. Clinical Trial Agreement / MOU, MOA or LOA (if study involves multiple collaboration)
10. Clinical Trial Insurance
11. Professional Indemnity (Highly recommended for Researcher to have)
12. Conflict of Interest (download from NMRR)
13. MREC Cover letter
14. Investigator Brochure (if applicable)
15. Advertisement (if Applicable)





NEW

Specific Research

Research involving Orang Asli (Aborigines)

Research involving Ministry of Education (MOE) facilities

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

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

Committees

06

Jabatan Kemajuan Orang Asli (JAKOA)

07

eRas system at www.eras.moe.gov.my (*Sistem Permohonan Menjalankan Penyelidikan Pendidikan Dalam Talian*)

08

Economic Planning Unit (EPU)

09

Clinical Research Malaysia (CRM)

Specific Requirements

RESEARCH : POLICY STATEMENT

3.3 The Conduct of Research	Policy Statements
<ul style="list-style-type: none"> i. Prior Approval by the MOH. <ul style="list-style-type: none"> 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 superior using the IA-HOD-IA Form. c. Investigator is advised to engage with relevant stakeholder prior to selecting the research sites; and d. For collaborative research, a Memorandum of Understanding (MOU) 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, <ul style="list-style-type: none"> 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. 	<ul style="list-style-type: none"> iii. During the conduct of the research (recruitment of subjects and/or data collection). <ul style="list-style-type: none"> 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 include changes to research protocol and methodology, ii) changes to research objectives, iii) changes to research documents. Changes should be made on a yearly basis and require 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.

RESEARCH : POLICY STATEMENT

3.3 The Conduct of Research	Policy Statements
<p>i. Prior Approval by the MOH</p> <ul style="list-style-type: none"> a. All research must be approved by the NMRR; b. Principal Investigator (PI) must obtain approval from the MOH at each research site without using the IA-HOD-IA Form; c. Investigator is advised to obtain approval from the research sites; and d. For collaborative research, a Memorandum of Understanding (MOU) and Research Agreement (RA) must be signed by the PI and the external party. <p>ii. After obtaining ethical approval for research subjects and/or data collection,</p> <ul style="list-style-type: none"> 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. 	<p>that has received prior ethical approval must be submitted, reviewed, and approved by the NMRR before being implemented. These changes to the research protocol and methodology, ii) must be made on a yearly basis and must be updated in the NMRR. The PI should be notified to MREC (for research receiving MRG approval from MREC).</p> <p>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.</p>

Important note:

- a. Site without a signed IA-HOD, 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
- b. Application of renewal of ethical approval should be made yearly basis.

**INVESTIGATOR'S AGREEMENT, HEAD OF DEPARTMENT'S AND INSTITUTIONAL APPROVAL
PERSETUJUAN PENYELIDIK DAN KETUA JABATAN, DAN PENGESAHAN 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 Institutional Acknowledgement. Please upload this document in required section in NIMRR upon completion.

Note: This form is NOT used for obtaining permission to conduct the research at the named / selected study site(s).

Dokumen ini adalah untuk pendaftaran online mengikut prosedur rasmi pendaftaran penyelidik. Borang ini dikeluarkan sebagai pengakuan penyelidik untuk menjalankan penyelidikan dan persetujuan serta kesetiaan daripada Ketua Jabatan dan Pengarah Institut masing-masing. Sila lampirkan borang ini dan muat naik ke dalam sistem NIMRR di seksyen yang telah ditetapkan.

Note: Borang ini digunakan BUKAN untuk tujuan mendapatkan kebenaran untuk menjalankan penyelidikan di lokasi kajian yang dipilih.

Research Title <i>[Tajuk Penyelidikan]</i>			
Research ID <i>[Nombor Pendaftaran]</i>		Protocol number (if available) <i>[No. Protokol (jika ada)]</i>	

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. <i>Saya faham atas cadangan penyelidikan di atas dan bersetuju untuk mengambil bahagian serta bertanggungjawab untuk melaksanakan penyelidikan tersebut.</i>	
Name <i>[Nama]</i>	
IC number <i>[No. KP]</i>	
Institute <i>[Institut]</i>	
Signature and Official Stamp <i>[Tandatangan dan Cop Rasmi]</i>	
Date <i>[Tarikh]</i>	

HEAD OF DEPARTMENT AGREEMENT PERSETUJUAN KETUA JABATAN	
I agree to allow the above named investigator to conduct the above titled research. <i>Saya bersetuju dan membenarkan pegawai seperti bernama di atas untuk menjadi penyelidik di dalam projek penyelidikan tersebut di atas.</i>	
Name of Head <i>[Nama Ketua Jabatan]</i>	
Signature and Official Stamp <i>[Tandatangan dan Cop Rasmi]</i>	
Date <i>[Tarikh]</i>	

INSTITUTIONAL APPROVAL PENGESAHAN INSTITUSI	
I acknowledge and approve the named officer to conduct the above titled research. <i>Saya mengesahkan dan mengambil maklum penglibatan pegawai ini di dalam penyelidikan tersebut.</i>	
Name of Director <i>[Nama Pengarah]</i>	
Signature and Official Stamp <i>[Tandatangan dan Cop Rasmi]</i>	
Date <i>[Tarikh]</i>	

INVESTIGATOR (PI and PI
at the site)

HEAD OF DEPARTMENT /
PYM
(where work/ study)

INSTITUTIONAL APPROVAL
(DIRECTOR/ PKD)

Scientific / Technical Evaluation

Scientific evaluation must always precede ethical review

- In-MOH vetting for all MOH research:
 - Preliminary scientific and funding evaluation by relevant NIH institute (and HCRCs)
 - Ethical evaluation by MREC
 - NIH grant application assessed by NIH Committee
 - Use of lab animals evaluated by ACUC IMR

Semua kaji selidik perlu:

- i. Didaftarkan dengan pihak *national medical research registry (NMRR)* di kementerian kesihatan malaysia (www.nmrr.gov.my).
- ii. Diluluskan oleh jawatankuasa etika dan penyelidikan perubatan, kementerian kesihatan malaysia.
- iii. Dijalankan secara berintegriti mengikut tatacara yang telah ditetapkan oleh HSR negeri dan Kementerian Kesihatan Malaysia.
- iv. Dipantau oleh PPYM/ pegawai pergigian daerah/ penyelarass HSR negeri/ unit CRC (sekiranya ada) dari semasa ke semasa bagi memastikan kajian yang dijalankan oleh personel pergigian KKM/ pasca siswazah atau bukan personel KKM berpandukan garis panduan dan pekeliling sedia ada.

Lain-lain pemakluman

- i. Tiada data individu pesakit dari mana-mana fasiliti KKM/ fasiliti yang dilawat/ dirawat oleh anggota KKM dibenarkan untuk dibawa keluar dalam sebarang bentuk salinan *hard copy/ soft copy/ scan copy* oleh penyelidik utama/ ahli kumpulan penyelidik.
- ii. Penyelidikan yang dijalankan hendaklah tidak bercanggah dengan Dasar KKM dan Dasar Perkhidmatan Kesihatan Pergigian yang sedia ada.
- iii. Senaskhah laporan perlu dihantar ke PKP KKM setelah projek selesai.
- iv. Semua pembentangan/ penerbitan kajian / teknikal yang melibatkan fasiliti/ data/ personel KKM termasuk pelajar pasca siswazah tajaan KKM perlulah mendapat kebenaran daripada Ketua Pengarah Kesihatan, KKM.



Permohonan Data Kesehatan Pergigian

APPLICATION FOR MOH DATA

1

Either at state
or national
level by the
Oral Health
personnel.

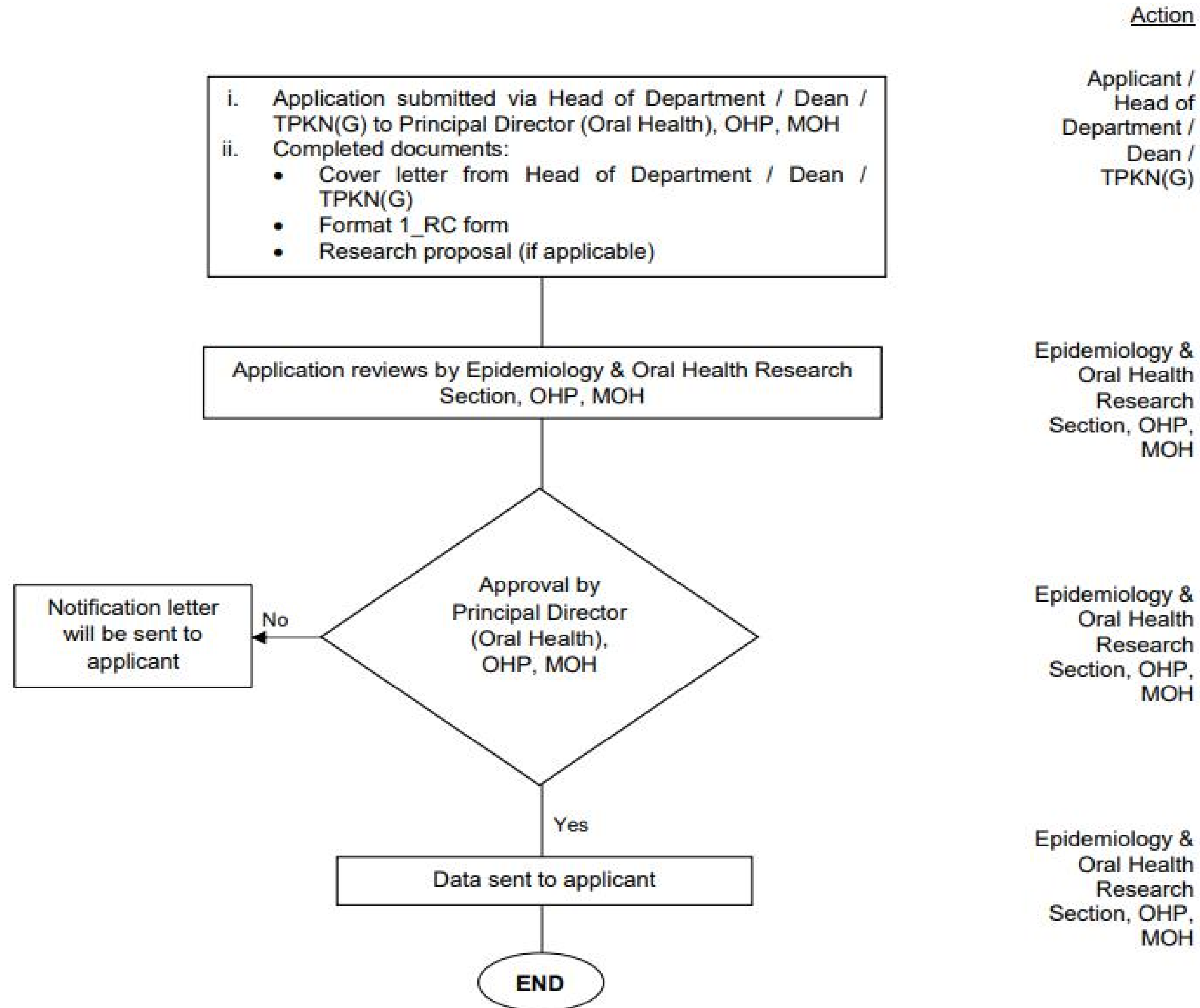
2

MOH, post-
graduates
students (MOH
personnel) at
local or overseas
universities.

3

Non-MOH
applicants.

i. Procedure for applying data of Oral Health, OHP, MOH



BORANG
PERMOHONAN
DATA



FORMAT 1_RC

PROGRAM KESIHATAN PERGIGIAN
KEMENTERIAN KESEHATAN MALAYSIA

PERMOHONAN MENGGUNAKAN DATA _____ BAGI PROJEK/PENERBITAN/POSTER/ORAL

Sila Lengkapkan Maklumat Berkaitan Penerbitan, Artikel atau Poster Anda Yang Akan Diterbitkan

Tajuk Penerbitan/Projek : _____
/Poster/Oral _____

Title Article/Project
/Poster/Oral _____

Objektif : _____
Objective _____

Penulis Pertama : _____
First Author _____

Penulis-Penulis Lain : _____
Other Authors _____

Variable Yang : _____
Diperlukan _____

Variables
Needed _____

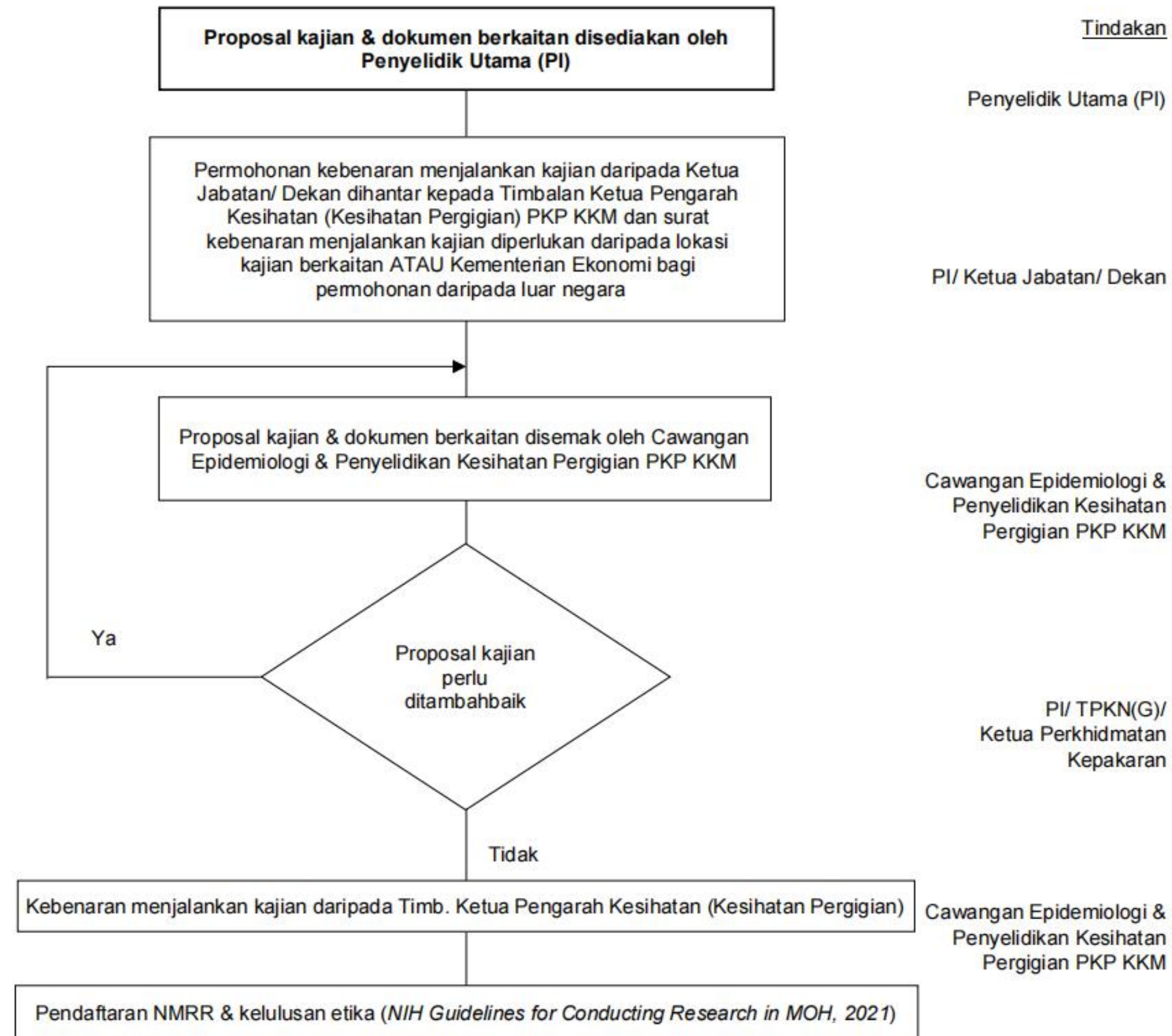
Sila gunakan lampiran berasingan sekiranya ruang tidak mencukupi - Please attach appendix if the space is not enough

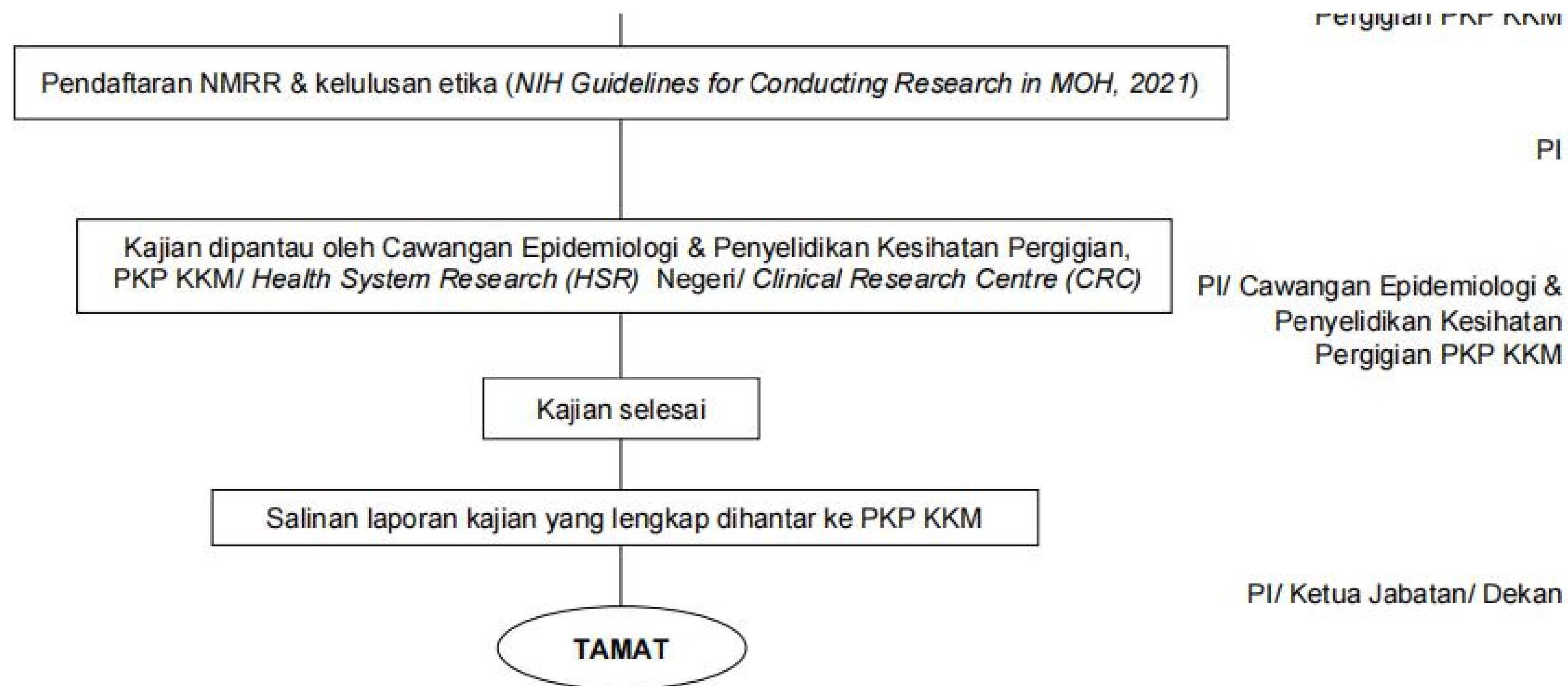
Nama dan : _____
Tandatangan Penulis Pertama
Name & Signature First Author



Permohonan Menjalankan Kajian

iii. Permohonan Daripada Pelajar Pascasiswazah/ Termasuk Dari Universiti Atau Agensi-Agensi
BUKAN Anggota KKM Tempatan/ Luar Negara Selain KKM







Sebaran Saintifik (Penerbitan & Pembentangan)

Publication & Presentation

Processing

Requirement

- Full NMRR registration number (for any research that has not previously registered with NMRR),
- State the following:
 - Ethical clearance and approval (if applicable)
 - Source of funding (if applicable)
 - Conflict of interest amongst the authors



Publication

- Processing period of **minimum of 14 working days** is required for each application



Presentation

- 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.**

P1 Form (BM)
Penerbitan / publish article

BORANG P1/20150608/Ver 2.0

PERMOHONAN KELULUSAN PENERBITAN HASIL PENYELIDIKAN / KAJIAN		
MAKLUMAT PEMOHON		
Nama Pengarang:		
Jawatan:		
Alamat Jabatan:		
Bandar:	Poskod:	
Negeri:		
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E-mail:		
MAKLUMAT ARTIKEL		
Alamat surat menyurat (jika berbeza dengan alamat jabatan):		
Tajuk:		
Nama jurnal:		
Impact factor:		
DG Acknowledgement: <input type="checkbox"/> Ada <input type="checkbox"/> Tiada		
"We would like to thank the Director General of Health Malaysia for his permission to publish this article"		
Artikel penerbitan: Dikepilkkan di helaian berasingan		
Tandatangan Ketua Pengarang: dan cop rasmi	Tarikh:	

PERHATIAN:
Pastikan artikel mempunyai DG acknowledgement dan mengikut format jurnal yang berkaitan.
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 Faks : 03-2282 8072
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P2 Form (BM/BI)
Pembentangan Saintifik /
Scientific Presentation

BORANG P2/20140923/Ver 2.0

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Type of presentation: <input type="checkbox"/> Poster <input type="checkbox"/> Oral	
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Venue:	
Date of meeting/conference:	
Abstract: Attached on a separated page	
Author's signature: and official stamp	Date:

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2



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you!

dr.aira@moh.gov.my

03-8883 3811