NIH GUIDELINES
FOR CONDUCTING RESEARCH
IN
MINISTRY OF HEALTH INSTITUTIONS AND FACILITIES

National Institutes of Health
Ministry of Health

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NIH GUIDELINES FOR CONDUCTING RESEARCH IN MOH INSTITUTIONS AND FACILITIES

These Guidelines describe Ministry of Health (MOH) policies governing the conduct of research in MOH institutions and facilities. The policy statements in these Guidelines are based on a review of existing circulars issued by the MOH [*NIH Guidelines for Conducting Research in the MOH Institutions & Facilities Draft Version 2.1 27 August 2007*]. Where necessary, changes in the guidelines are in line with international practice on research ethics and governance. The use of information technology to facilitate the review and approval process is also included.

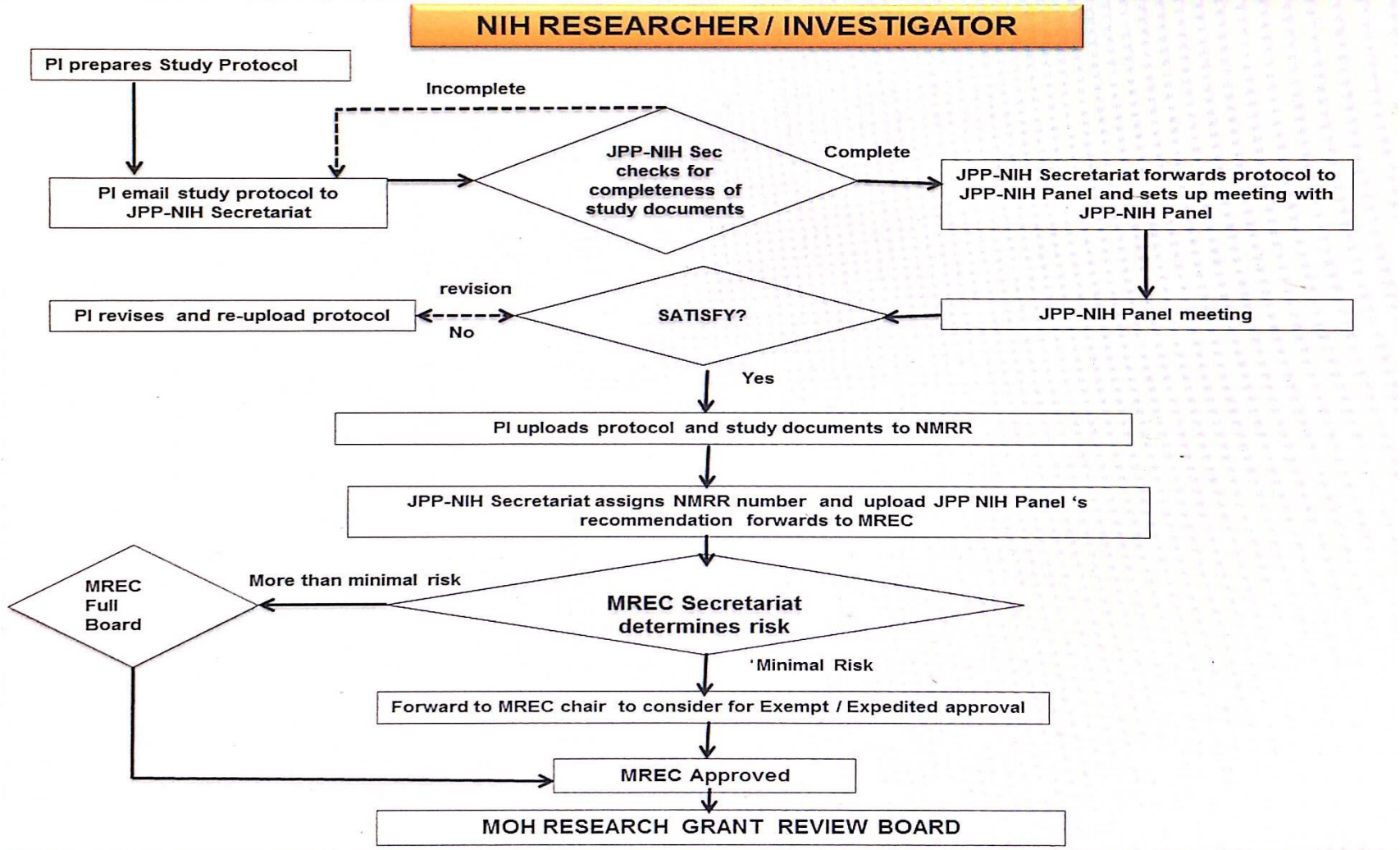
#	Policy Statements
1	**All research undertaken by Ministry of Health (MOH) personnel OR conducted in MOH facilities OR funded by an MOH research grant shall require approval according to the following categories:** i. NIH Researcher / Investigator - (Refer to **Appendix 1**) ii. Non NIH Researcher/Investigators applying for the MOH research grant - (Refer to **Appendix 2**) iii. Non NIH Researcher/Investigator, not applying for grant, using MOH facilities, data and/or MOH patients - (Refer to **Appendix 3**)
2	**Prior approval by the MOH: The researcher / investigator:** i. must sign an Investigator Agreement and obtain approval from his or her Head of Department and Organisational or Institutional Director(**IA-HOD-IA**) (Refer document 1 template in **Appendix 4**) ii. should obtain permission to conduct research at the respective facilities/ institutions (Refer document 2 template in **Appendix 5**) iii. undertaking collaborative research, where a party external to the MOH is involved, is required to obtain a formal Letter of Agreement (LoA) between the related MOH institution / division and the external party.
3	**Research involving human subjects requires prior ethics review and approval by the Medical Research and Ethics Committee (MREC)** A human subject (in the context of research) is "a living individual about whom an investigator obtains either data through intervention (eg. clinical trial) or interaction (eg questionnaire in health survey) with the individual, or identifiable private information". Submission to MREC for ethics review and approval is conducted online at www.nmrr.gov.my
4	**MOH Research Grant Approval** The MOH Research Grant Review Board, chaired by the Deputy Director General of Health (Research and Technical Support) shall convene and give final approval to research projects requesting funds that have been supported by the JPP-NIH Panel and have obtained MREC approval.

#	Policy Statements
5	**Research publications Approval** All dissemination of research outputs such as abstracts for oral and poster presentation, research reports, journal articles or conference proceedings, arising from research undertaken by Ministry of Health (MOH) personnel OR conducted at MOH facilities OR funded by an MOH research grant, shall require prior review by the NIH, and subsequent approval by the Director General of Health.
6	**Roles And Responsibilities of the Research Review Panel and Secretariats (Please Refer to Appendix 6)**

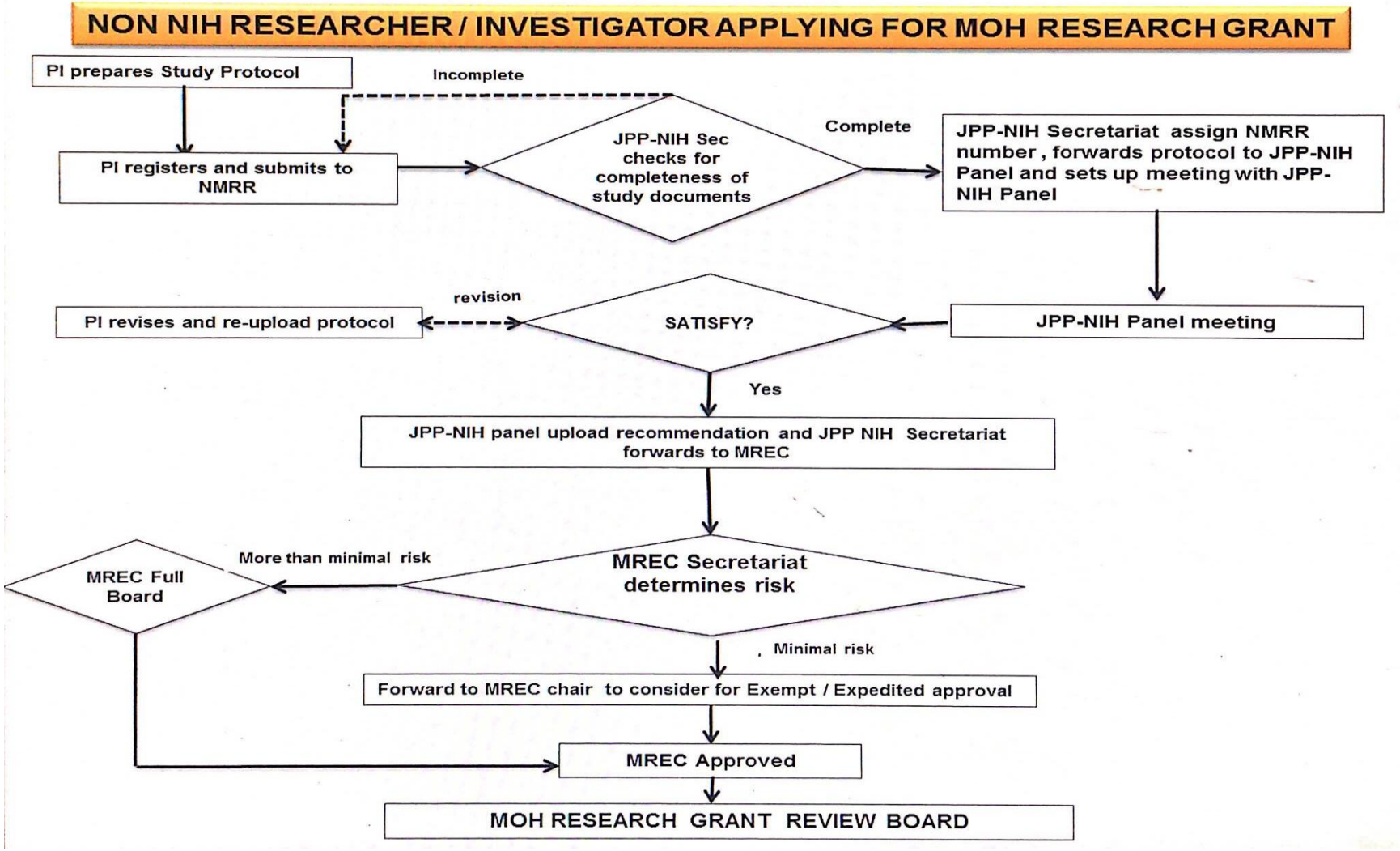
TERMINOLOGY AND DEFINITION

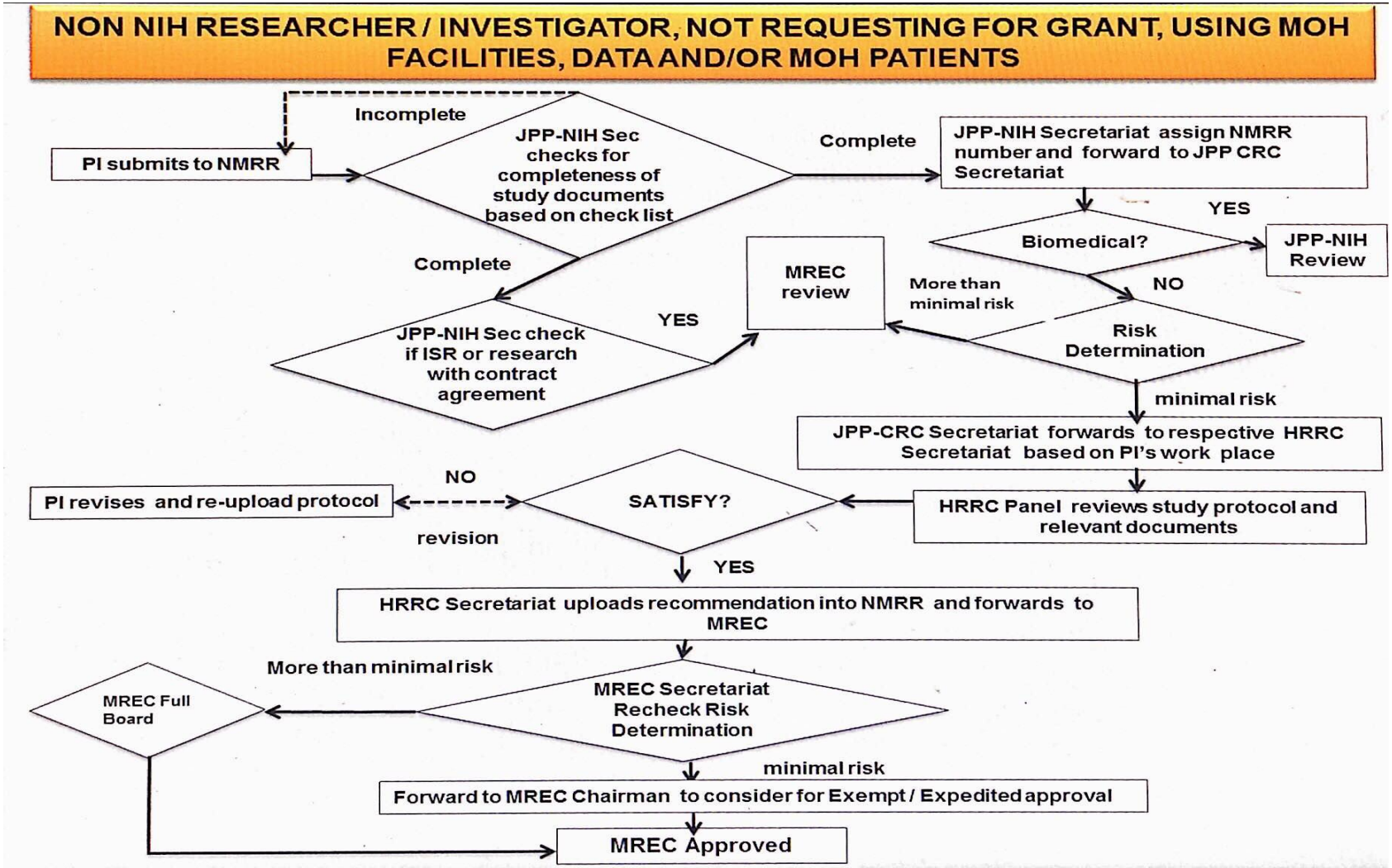
MREC	-	Medical Research and Ethics Committee
JPP-NIH	-	NIH Research Review Panel (Jawatankuasa Penilaian Penyelidikan NIH)
JPP-CRC	-	CRC Research Review Panel (Jawatankuasa Penilaian Penyelidikan CRC)
JPP-NIH Secretariat	-	Secretariat for the NIH Research Review Committee (Jawatankuasa Penilaian Penyelidikan NIH)
JPP-CRC Secretariat	-	Secretariat for the CRC Research Review Committee (Jawatankuasa Penilaian Penyelidikan CRC)
HRRC Secretariat	-	Secretariat for Hospital Research Review Committee
HRRC Panel	-	Hospital Research Review Committee in CRC Hospital
IA-HOD-IA	-	Investigator Agreement-Head of Department-Institutional Approval
NMRR	-	National Medical Research Registry
ACUC	-	Animal Care and Use Committee
PI	-	Principal Investigator

APPENDIX 1


NIH RESEARCHER / INVESTIGATOR
PI prepares Study Protocol
Incomplete
PI email study protocol to JPP-NIH Secretariat
JPP-NIH Sec checks for completeness of study documents
Complete
JPP-NIH Secretariat forwards protocol to JPP-NIH Panel and sets up meeting with JPP-NIH Panel
JPP-NIH Panel meeting
SATISFY?
revision
No
PI revises and re-upload protocol
Yes
PI uploads protocol and study documents to NMRR
JPP-NIH Secretariat assigns NMRR number and upload JPP NIH Panel 's recommendation forwards to MREC
MREC Secretariat determines risk
More than minimal risk
MREC Full Board
'Minimal Risk
Forward to MREC chair to consider for Exempt / Expedited approval
MREC Approved
MOH RESEARCH GRANT REVIEW BOARD

APPENDIX 2


NON NIH RESEARCHER / INVESTIGATOR APPLYING FOR MOH RESEARCH GRANT
PI prepares Study Protocol
Incomplete
PI registers and submits to NMRR
JPP-NIH Sec checks for completeness of study documents
Complete
JPP-NIH Secretariat assign NMRR number , forwards protocol to JPP-NIH Panel and sets up meeting with JPP-NIH Panel
JPP-NIH Panel meeting
SATISFY?
revision
PI revises and re-upload protocol
Yes
JPP-NIH panel upload recommendation and JPP NIH Secretariat forwards to MREC
MREC Secretariat determines risk
More than minimal risk
MREC Full Board
Minimal risk
Forward to MREC chair to consider for Exempt / Expedited approval
MREC Approved
MOH RESEARCH GRANT REVIEW BOARD


NON NIH RESEARCHER / INVESTIGATOR, NOT REQUESTING FOR GRANT, USING MOH FACILITIES, DATA AND/OR MOH PATIENTS
PI submits to NMRR
Incomplete
JPP-NIH Sec checks for completeness of study documents based on check list
Complete
JPP-NIH Secretariat assign NMRR number and forward to JPP CRC Secretariat
YES
Biomedical?
JPP-NIH Review
NO
Risk Determination
More than minimal risk
MREC review
Complete
YES
JPP-NIH Sec check if ISR or research with contract agreement
minimal risk
JPP-CRC Secretariat forwards to respective HRRC Secretariat based on PI's work place
HRRC Panel reviews study protocol and relevant documents
SATISFY?
NO
PI revises and re-upload protocol
revision
YES
HRRC Secretariat uploads recommendation into NMRR and forwards to MREC
More than minimal risk
MREC Secretariat Recheck Risk Determination
MREC Full Board
minimal risk
Forward to MREC Chairman to consider for Exempt / Expedited approval
MREC Approved

APPENDIX 4

Document Template 1 - Investigator Agreement, Head of Department and Institutional Approval Form (IA-HOD-IA)

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 **Approval from investigator's Head of Department and Instituition Director** . Please upload this document in the required section in NMRR upon completion together with the protocol..
***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 K**etua Jabatan dan Pengarah Institusi 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]*			
Research ID *[Nombor Pendaftaran]*		**Protocol number (if available)** *[No. Protocol (jika ada)]*	

INVESTIGATOR'S AGREEMENT ***PERSETUJUAN PENYELIDIK***	
I am the investigator for the above research and am responsible to the conduct the research. *Saya adalah penyelidik penyelidikan yang tersebut d iatas dan akan bertanggungjawab untuk melaksanakan penyelidikan tersebut.*	
Name *[Nama]*	
IC number *[No. K/P]*	
Institute *[Institusi]*	
Signature and Official Stamp *[Tandatangan dan Cop Rasmi]*	
Date *[Tarikh]*	

HEAD OF DEPARTMENT'S APPROVAL ***PERSETUJUAN KETUA JABATAN***	
I agree to allow the above named officer to conduct the research. *Saya bersetuju dan membenarkan pegawai di atas menjalankan projek penyelidikan tersebut di atas.*	
Name of Head of Department *[Nama Ketua Jabatan]*	
Signature and Official Stamp *[Tandatangan dan Cop Rasmi]*	
Date *[Tarikh]*	

ORGANISATIONAL / INSTITUTIONAL DIRECTOR'S APPROVAL ***KEBENARAN ORGANISASI / INSTITUSI***	
I acknowledge and approve the named officer to conduct the research. Saya mengesahkan dan membenarkan pegawai *di atas menjalankan projek penyelidikan tersebut di atas*	
Name of Director *[Nama Pengarah]*	
Signature and Official Stamp *[Tandatangan dan Cop Rasmi]*	
Date *[Tarikh]*	

APPENDIX 5
Document Template 2

Rujukan kami:
Tarikh:

Pengarah [*Institusi / Hospital*]
[*Alamat institusi / hospital*]

YBhg Dato' / Tuan / Puan,

PERMOHONAN KEBENARAN PENGGUNAAN [*nama fasiliti*] UNTUK MENJALANKAN PENYELIDIKAN

Dengan hormatnya saya merujuk kepada perkara tersebut di atas.
2. Saya perlu menggunakan fasiliti YBhg Dato'/Tuan/Puan untuk aktiviti penyelidikan bertajuk, "[*nombor pendaftaran NMRR - Tajuk Penyelidikan*]". Penyelidikan ini telah diluluskan oleh Jawatankuasa Etika Penyelidikan Perubatan JEPP (*Medical Research Ethics Committee MREC*). Bersama-sama ini disertakan surat kebenaran MREC (Lampiran 1) dan kertas kajian (*protocol)* / makluman ringkas projek (Lampiran 2).

3. Pegawai dari fasiliti YBhg Dato'/Tuan/Puan yang terlibat dalam penyelidikan ini adalah seperti berikut: (jika berkenaan)
   i. [nama pegawai #1]
   ii. [nama pegawai #2]

4. Fasiliti/Jabatan di tempat YBhg Dato'/Tuan/Puan yang diperlukan adalah seperti berikut:
   i. [Fasiliti/Jabatan #1]
   ii. [Fasilit/Jabatani #2]

5. Aktiviti penyelidikan yang akan dijalankan di fasiliti YBhg Dato' / Tuan / Puan adalah seperti berikut:
   i. [aktiviti #1]
   ii. [aktiviti #2]

Kami berharap mendapat kebenaran YBhg Dato' / Tuan / Puan.

Sekian, terima kasih.

Saya yang menurut perintah,
…….
(Nama Ketua Penyelidik)
s.k.
<Ketua Jabatan Ketua Penyelidik>
< Ketua Jabatan Tapak Penyelidikan
<Nama Penyelidik bersama (Co-Invesigator) di lokasi berkaitan>

APPENDIX 5(a)

Surat Kebenaran MREC

LAMPIRAN 2

Protokol (*full protocol)*

Ringkasan Projek Penyelidikan

Tajuk Penyelidikan:

Nama dan Jabatan Ketua Penyelidik:

Nombor pendaftaran NMRR:

Rujukan kelulusan MREC:

Tarikh mula penyelidikan:

Tarikh tamat penyelidikan:

Objektif penyelidikan:

Ringkasan metodologi penyelidikan:

APPENDIX 5 (b)

MAKLUMBALAS PERMOHONAN KEBENARAN PENGGUNAAN < nama fasiliti> UNTUK MENJALANKAN PENYELIDIKAN

Tajuk Penyelidikan :
Nama dan Jabatan Ketua Penyelidik :

Pihak hospital/institusi dengan ini membuat keputusan seperti berikut : -

☐ Membenarkan projek penyelidikan dijalankan

☐ Tidak membenarkan projek penyelidikan dijalankan

"BERKHIDMAT UNTUK NEGARA"

Saya yang menurut perintah

…… .....
(<Ketua Jabatan di mana penyelidikan akan dijalankan>) (<Nama Pengarah >)

S.K.
<Ketua CRC hospital >
<Nama penyelidik bersama (co- investigators) di fasiliti berkaitan (jika berkaitan)

APPENDIX 6

ROLES AND RESPONSIBILITIES OF REVIEW PANELS AND SECRETARIATS

1. JPP-NIH Secretariat

a. Examine all documents for data and document completeness
b. Distribute documents for further action to the JPP-NIH Panel,
c. Distribute documents to the JPP-CRC Secretariat (for distribution to Hospital CRC Secretariat)
d. Forward supported protocols to MREC for further action.
(Please refer to Appendix 1, 2 and 3)

2. JPP-NIH Review Panel

a. Review the scientific merit of submitted protocols
b. Support or reject research applications from NIH researchers/investigators and Non NIH researchers applying for grants
c. Approve protocols with non-human subjects and forward for further action by the MOH Research Grant Panel (if applicable).
(Please refer to Appendix 1 and 2)
d. Review protocol of biomedical in nature from any investigator.

3. JPP-CRC Secretariat

a. Receive protocols forwarded by the JPP-NIH Secretariat.
b. Determine risk
c. Distribute protocols and study documents of minimal risk to the Hospital Research Review Committee (HRRC) Secretariat
d. Redirect biomedical research protocols to JPP-NIH
(Please refer to Appendix 3)

4. HRRC Secretariat

a. Distribute protocols received from JPP-CRC Secretariat to HRRC Panel for review.
b. Upload recommendations from HRRC Panel into NMRR and forward to MREC
(Please refer to Appendix 3)

5. HRRC Review Panel

a. Review protocols based on scientific merit forwarded by the CRC Hospital Secretariat
b. Support or reject research applications from Non NIH researchers
(Please refer to Appendix 3)

Note:

i. For Industry Sponsored Research (ISR) and protocols involving research agreements, the JPP-NIH Secretariat shall forward the protocols and study documents directly to MREC for approval.
ii. Studies involving collaboration with international agencies or Institution will be directed to MREC for further action.
iii. For ACUC, herbal studies, stem cell approval etc, please submit to the various committees before submitting to JPP-NIH Secretariat.