



Kampus
Merdeka
INDONESIA JAYA

PROSEDUR OPERASIONAL BAKU (POB)

8. Telaah Dokumen Awal *(Initial Document Review)*

Komite Etik Penelitian

Universitas Pembangunan Nasional "Veteran" Jakarta



2022



UNIVERSITAS PEMBANGUNAN NASIONAL “VETERAN” JAKARTA

**PROSEDUR OPERASIONAL BAKU (POB)
KOMISI ETIK PENELITIAN UPN “VETERAN” JAKARTA**

JAKARTA, FEBRUARI 2022

URAIAN	NAMA JABATAN	TANDA TANGAN
Disusun Oleh	Tim	
Diperiksa Oleh	Sekretaris	
Menyetujui	Ka. KEPK	
Mengesahkan	Rektor	



**KEMENTERIAN RISET, TEKNOLOGI, DAN PENDIDIKAN TINGGI
UNIVERSITAS PEMBANGUNAN NASIONAL VETERAN JAKARTA
KOMITE ETIK PENELITIAN (KEP)**

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8. Telaah Dokumen Awal (*Initial Document Review*)

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JAKARTA

2022

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1. TUJUAN

Prosedur Operasional Baku (POB) bertujuan menjelaskan proses telaah awal usulan protokol penelitian, yang diajukan secara *online* oleh penelaah dan sudah diverifikasi sekretariat dan ada penugasan dari ketua KEP UPNVJ.

2. RUANG LINGKUP

POB akan digunakan sebagai acuan oleh KEP UPNVJ dalam menjalankan proses telaah usulan protokol penelitian saat pertama kali diajukan.

3. PENANGGUNG JAWAB

a. Penelaah melakukan telaah protokol penelitian secara menyeluruh, melalui formulir yang telah disesuaikan secara online.

b. Penelaah memberikan komentar pada lembar komunikasi yang ditujukan pada peneliti.

c. Penelaah menuliskan hasil telaah pada lembar komunikasi apabila ada saran perbaikan dan kesimpulan hasil penelaahan.

f. Kesimpulan hasil telaah :

1) Disetujui

Apabila Protokol penelitian termasuk kategori disetujui, selanjutnya KEP mengeluarkan surat persetujuan etik (*ethical approval*) dan diserahkan kepada peneliti.

2) Perbaikan minor

Apabila protokol ada sedikit perbaikan yang ditulis dalam lembar komunikasi secara *online*, selanjutnya peneliti melakukan perbaikan dan ditulis dalam protokol revisi, kemudian hasil perbaikannya di *upload* ke sekretariat KEP UPNVJ untuk dilakukan telaah ulang oleh penelaah sebelumnya dan diberikan keputusan hasil telaah.

3) Perbaikan mayor

Apabila protokol perlu perbaikan mendasar maka protokol tersebut termasuk kategori perlu dilakukan rapat *fullboard*.

Sekretariat akan memberi tahu kepada peneliti melalui surat atau email/WA untuk memaparkan protokol penelitiannya didalam rapat *fullboard* yang akan dilaksanakan sesuai undangan dari sekretariat KEP UPNVJ.

4) Ditolak

Apabila Protokol penelitian termasuk kategori ditolak, KEP menerbitkan surat penolakan disertai alasan penolakan, selanjutnya surat penolakan dan protokol penelitian dikembalikan ke peneliti.

- g. Kriteria kesimpulan protokol diterima, perbaikan minor, perbaikan mayor dan ditolak terlampir (lampiran 8.1)

4. ALUR KEGIATAN

No.	Aktivitas	Tanggungjawab
1.	Anggota Reviewer menerima protocol penelitian dari sekretariat	Sekretariat/ dan anggota KEP UPNVJ
3.	Penelaah awal menilai, memberikan keputusan dan kesimpulan hasil telaah protokol dan menyerahkan kepada ketua melalui sekretariat.	Penelaah awal/ Anggota KEP UPNVJ/ Sekretariat
4.	Pemberitahuan keputusan hasil telaah usulan protokol penelitian kepada peneliti.	Ketua KEP UPNVJ
5.	Penyimpanan dokumen	Sekretariat KEP UPNVJ

5. RINCIAN KEGIATAN

5.1 Penerimaan Dokumen Protokol Penelitian

- a. Sekretariat menerima dokumen yang diajukan oleh Ketua Pelaksana Penelitian beserta lampiran persyaratan secara *online*.
- b. Sekretariat melakukan pemeriksaan kelengkapan administrasi dokumen yang sudah diterima berdasarkan Formulir Pengajuan Dokumen.

- c. Penulisan tanggal saat dokumen diterima pada Formulir Pengajuan Dokumen.
- d. Penulisan nama orang yang menerima dokumen pada Formulir Penerimaan Dokumen.
- e. Penyampaian dokumen yang telah diterima kepada Ketua KEP UPNVJ.

5.2 Proses Kaji Awal / *Initial Review*

- a. Ketua menunjuk 1-2 anggota untuk melakukan kaji etik protokol penelitian awal.
- b. Sekretariat mengirim protokol penelitian secara online kepada anggota yang ditunjuk.
- c. Penelaah melakukan telaah dalam waktu yang ditentukan dan mengembalikan kepada sekretariat secara online.
- d. Hasil kajian dapat dikategorikan : (1) disetujui. (2) perlu perbaikan minor. (3) perlu perbaikan mayor ; (4) ditolak. (lihat lampiran 8.1)
- e. Jika tidak didapat persetujuan (konsensus), Ketua berhak memutuskan melakukan telaah melalui rapat *Fullboard*.
- f. Telaah awal dilakukan dalam 14 hari.
- g. Protokol yang disepakati melalui telaah awal dan disetujui, selanjutnya KEP UPNVJ mengeluarkan persetujuan etik.

5.3 Proses komunikasi antara KEP UPNVJ dan Ketua Pelaksana Penelitian

- a. Penelaah menyampaikan saran perbaikan kepada Ketua dan Sekretariat dalam lembar komunikasi secara online untuk diperbaiki dan ditulis dalam protokol revisi..
- b. Ketua menginformasikan keputusan telaah awal dan persetujuan etik melalui sekretariat KEP UPNVJ kepada Ketua Pelaksana Penelitian.

6. SEJARAH DOKUMEN

POB Revisi III Tahun 2022	Tertulis	Rekomendasi perbaikan
Tata Urut	<ol style="list-style-type: none"> 1. Tujuan 2. Organisasi dan Tata Kerja KEP 3. Ruang Lingkup dan Kewenangan 4. Mekanisme Pengajuan <i>Ethical Approval</i> 5. Komposisi Anggota KEP UPNVJ 6. Persyaratan Keanggotaan 7. Pemberhentian dan Penggantian 8. Konsultan Profesional Independen (KI) 9. Kriteria Penetapan Konsultan Profesional Independen 10. Mekanisme Pengajuan <i>Ethical Clearance</i> 	<ol style="list-style-type: none"> 1. Tujuan 2. Ruang Lingkup 3. Tanggung Jawab 4. Alur Kegiatan 5. Rincian Kegiatan 6. Sejarah Dokumen 7. Lampiran 8. Daftar Pustaka

7. LAMPIRAN

- a. Lampiran Kriteria kesimpulan protokol diterima, perbaikan minor, perbaikan mayor dan ditolak

8. DAFTAR PUSTAKA

World Health Organization, Pedoman Operasional Untuk Komite Etik Penelitian , 2011.

Internasional Conference on Harmonization, Guidance on Good Clinical Practice. 1996

Peraturan Kepala Badan POM RI NO 21 Tahun 2015. Tentang Tata Laksana Persetujuan Uji Klinik Tahun 21 Desember 2015, Diundangkan dalam Berita Negara RI tgl 29 Desember 2015 No 1987.

Integrated Addendum to ICH E6 (R1): Guideline for Good Clinical Practice E6 (R2), 9 November 2016.

International Ethical Guidelines for Health-related Research Involving Humans. Prepared by the Council for International Organization of Medical Sciences (CIOMS) in collaboration with the World Health Organization (WHO). 2016.

Declaration of Helsinki, World Medical Association Declaration of Helsinki, Ethical Principles for Medical Research Involving Human Subjects (1962-2008)

Lampiran 8.1 Kriteria kesimpulan hasil telaah protokol penelitian
diterima, perbaikan minor, perbaikan mayor dan ditolak

1. Abstract

Reject

Originality/Impact, No

- Missing; poorly written;
- Content doesn't match text;
- Stated objective/methods/ results/conclusions missing or incomprehensible
- Subject matter is not fresh, new; content is not original; material is of marginal general interest

Major Revision

Originality/Impact, Yes

- Errors in data (compared with text, tables, figures);
- Poorly written (incomplete sentences, needs major rewriting for sense and flow);
- Components (objective/ methods/results/conclusion s) missing or unclear
- Subject matter is of specialized or moderate interest, or of major interest only if paper is substantially revised

Minor Revision

Originality/Impact, Yes

- Minor data errors (rounding errors; minor mismatch with text/tables/figures);
- Components present but may need minor writing for readability
- Subject matter is original and important

Accept

Originality/Impact, Yes

- All components present;
- Data are accurate and match text;
- Well-written, concise, clear
- Subject matter is original, pressworthy, of major general interest

2. Introduction

- Missing; poorly written (would require major rewriting for sense;
- No clear statement of why study was performed);
- Hypothesis missing, weak, or unclear;
- Intro text doesn't match/support body text;
- Multiple data errors
- Needs major rewriting for sense and flow; data errors (data do don't match text/tables/figures);
- Hypothesis and objective not clearly stated;

- Inadequate references (but could be fixed via lit review)
 - IRB/HIPAA documentation missing
 - Minor data errors (e.g., rounding errors);
 - Minor rewriting; hypothesis is clearly presented and is supported by text
 - References are adequate
 - Well-written, concise;
 - Hypothesis and purpose of study are clearly and concisely presented
 - Data are accurate; hypotheses are correctly presented and fully supported by text
 - Current references that will be of or data are questionable;
 - Inadequate or outdated references or too many references (and little chance of this flaw being fixed)
 - IRB/HIPAA documentation missing
- Needs major rewriting for sense and flow; data errors (data do don't match text/tables/figures);
 - Hypothesis and objective not clearly stated;
 - Inadequate references (but could be fixed via lit review)
 - IRB/HIPAA documentation missing
- Minor data errors (e.g., rounding errors);
 - Minor rewriting; hypothesis is clearly presented and is supported by text
 - References are adequate
- Well-written, concise;
 - Hypothesis and purpose of study are clearly and concisely presented
 - Data are accurate; hypotheses are correctly presented and fully supported by text
 - Current references that will be of

3. Materials and Methods

- Unfixable flaws in data/research (number/selection of subjects; instruments/drugs used; blinded/unblinded; independent vs consensus readings)
- Description of procedures missing or so unclear that others couldn't reproduce study, with little likelihood that deficit could be fixed;
- IRB/HIPAA compliance statements missing
- Questionable data
- Flaws in data and/or numerous errors/mismatches in data that potentially can be fixed;
- Poorly written (incomplete sentences, needs major rewriting for sense and flow); grammar/punctuation/ spelling errors that detract from readability;

- Description of procedures unclear; would be difficult for others to reproduce study by reading article, although with major rewriting, deficit could be remedied
 - Tables/figures need major work
 - Minor data errors that are easily fixed
 - Adequately written, although writing could be polished; minor typos/grammar/punctuation errors
 - Description of procedures needs minor clarification (clearly remediable)
 - Too many/too few figures/tables (easily remediable)
 - Data are accurate
 - All research components are present, clearly stated
 - Procedures are clear, concise, and easily replicable; article advances knowledge
 - All compliance guidelines are met
 - Tables/figures contribute substantially to content and/or major errors in data/statistical methods;
 - No new information is imparted; poorly written/hard to understand;
 - Inadequate/missing figures/tables
 - Multiple grammar/ punctuation/spelling errors and language grasp
-
- Flaws in data and/or numerous errors/mismatches in data that potentially can be fixed;
 - Poorly written (incomplete sentences, needs major rewriting for sense and flow); grammar/punctuation/ spelling errors that detract from readability;
 - Description of procedures unclear; would be difficult for others to reproduce study by reading article, although with major rewriting, deficit could be remedied
 - Tables/figures need major work
-
- Minor data errors that are easily fixed
 - Adequately written, although writing could be polished; minor typos/grammar/punctuation errors
 - Description of procedures needs minor clarification (clearly remediable)
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- Data are accurate
 - All research components are present, clearly stated
 - Procedures are clear, concise, and easily replicable; article advances knowledge
 - All compliance guidelines are met
 - Tables/figures contribute substantially to content

