



KEMENTERIAN PENDIDIKAN, KEBUDAYAAN,  
FAKULTAS KEDOKTERAN UNIVERSITAS BRAWIJAYA  
KOMISI ETIK PENELITIAN KESEHATAN

Jalan Veteran Malang – 65145, Jawa Timur - Indonesia

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**GUIDELINES**

**HEALTH RESEARCH ETHICS COMMITTEE (HREC)**

**FACULTY OF MEDICINE UNIVERSITAS BRAWIJAYA (FoM UB)**

1. The Belmont Report 1979
2. World Medical Association, 2013. *WMA Declaration of Helsinki*.
3. Council for International Organizations of Medical Sciences (CIOMS)-WHO, 2016. *International Ethical Guidelines for Health related Research Involving Humans*. CIOMS, Geneva.
4. Council for International Organizations of Medical Sciences (CIOMS)-WHO, 2009. *International Ethical Guidelines for Epidemiological Studies*. Geneva.
5. International Conference on Harmonization, 2016. *Guideline for Good Clinical Practice (ICH GCP)*.
6. World Health Organization (WHO), 2000. *Operational Guidelines for Ethics Committees that Review Biomedical Research*. Geneva.
7. World Health Organization (WHO), 2002. *Surveying and Evaluating Ethical Review Practices*. Geneva.
8. World Health Organization (WHO), 2011. *Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants*.
9. World Health Organization (WHO). 2020. *Guidance for Research Ethics Committees for Rapid Review of Research During Public Health Emergencies*
10. World Health Organization (WHO). 2020. *Key Criteria for the Ethical Acceptability of Covid-19 Human Challenge Studies*.
11. Peraturan Badan Pengawas Obat dan Makanan No 21 Tahun 2015 Tentang Tata Laksana Persetujuan Uji Klinik
12. Keputusan MenKes RI No 1179 A/Menkes/SK/1999 Tentang Kebijakan Nasional Penelitian dan Pengembangan Kesehatan
13. Peraturan Pemerintah Nomor 39 Tahun 1995 tentang Penelitian dan Pengembangan Kesehatan
14. Peraturan Menteri Kesehatan Nomor 657/Menkes/PerNIII/2009 Tentang pengiriman dan penggunaan spesimen Klinik, Materi Biologik dan Muatan informasinya
15. Peraturan Pemerintah RI no 41 Tahun 2006 tentang Perijinan Melakukan Kegiatan Penelitian dan Pengembangan bagi Perguruan Tinggi Asing, Lembaga Penelitian dan Pengembangan Asing, Badan Usaha Asing, dan Orang Asing



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**LIST of STANDARD OPERATING PROCEDURE HREC FoM UB**

- SOP 001: Writing, Reviewing, Distributing and Amending Standard Operating Procedures for Ethics Committees
- SOP 002: Preparation of Operational Guidelines
- SOP 003: Establishment of HREC FM-UB
- SOP 004: Confidentiality and Conflict of Interest Agreements
- SOP 005: Training of Staff and Ethics Committee Members
- SOP 006: Independent Consultants Selection
- SOP 007: Management of Protocol Submissions
- SOP 008: Initial Review of Submitted Protocol
- SOP 009: Expedited review
- SOP 010: Protocol review in full board
- SOP 011: Use of Protocol Assessment Forms
- SOP 012: Review of Medical Device Study
- SOP 013: Review of Resubmitted Protocols
- SOP 014: Review of Protocol Amendments
- SOP 015: Continuing Review of Study Protocols
- SOP 016: Review of Final Reports
- SOP 017: Intervention in Protocol Deviation/ Non-compliance/ Violation
- SOP 018: Response to Participants' Requests
- SOP 019: Management of Study Termination
- SOP 020: Review of Serious Adverse Events (SAE) Reports
- SOP 021: Site Monitoring Visit
- SOP 022: Agenda Preparation, Meeting Procedures and Minutes
- SOP 023: Emergency Meeting
- SOP 024: Communication Records
- SOP 025: Maintenance of Active Study Files
- SOP 026: Archive and Retrieval of Documents
- SOP 027: Maintaining Confidentiality of HREC FM-UB Documents
- SOP 028: Audit and Inspection of the HREC FM-UB



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**Daftar Isi Standard Operating Procedure (SOP) KEPK FKUB**

Topik No.	Topik/Prosedur Operasional Baku (SOP)	Kode SOP
<b>1.</b>	<b>Menyiapkan Prosedur Operasional Baku (SOP) dan Pedoman Operasional untuk KEPK</b>	
1.1.	Penulisan, Telaah ( <i>Review</i> ), Distribusi dan Perbaikan Prosedur Operasional Baku (SOP)	SOP/001/01.1
1.2.	Persiapan Penyusunan Pedoman Operasional	SOP/002/01.2
<b>2</b>	<b>Pembentukan Komisi Etik</b>	
2.1.	Pembentukan Komisi Etik Penelitian Kesehatan FKUB	SOP/003/01.3
2.2.	Pernyataan Kerahasiaan dan Pernyataan ' <i>Conflict of Interest</i> '	SOP/004/01.1
2.3.	Pelatihan Staf dan Anggota Komisi Etik Penelitian Kesehatan	SOP/005/01.1
2.4.	Pemilihan Konsultan Independen	SOP/006/01.1
<b>3.</b>	<b>Prosedur Telaah Awal</b>	
3.1.	Manajemen Penerimaan Protokol	SOP/007/01.2
3.2.	Pengajuan Protokol untuk Telaah Awal	SOP/008/01.2
3.3.	<i>Expedited Review</i>	SOP/009/01.2
3.4.	Telaah Protokol dalam rapat Full Board	SOP/010/01.2
3.5.	Penggunaan formulir Penilaian Protokol	SOP/011/01.3
3.6.	Penelaahan protokol penelitian peralatan kesehatan	SOP/012/01.1
<b>4.</b>	<b>Amandemen Protokol, Telaah Lanjutan dan Telaah Laporan Akhir</b>	
4.1.	Telaah protokol yang diajukan kembali	SOP/013/01.2
4.2.	Telaah Amandemen Protokol	SOP/014/01.1
4.3.	Telaah Lanjutan terhadap Protokol yang sedang dilaksanakan	SOP/015/01.1
4.4.	Telaah Laporan akhir	SOP/016/01.1



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Topik No.	Topik/Prosedur Operasional Baku (SOP)	Kode SOP
<b>5.</b>	<b>Pemantauan/ Monitoring Pelaksanaan Protokol</b>	
5.1.	Intervensi terhadap Kesalahan/ Penyimpangan Protokol/ <i>Non-Compliance</i>	SOP/017/01.1
5.2.	Menanggapi keinginan subjek penelitian	SOP/018/01.1
5.3.	Manajemen Terminasi Penelitian	SOP/019/01.1
<b>6.</b>	<b>Pemantauan/ Monitoring dan Evaluasi <i>Adverse Events</i></b>	
6.1.	Telaah laporan <i>Serious Adverse Events (SAE)</i>	SOP/020/01.1
<b>7.</b>	<b>Pemantauan/ Monitoring ke Lokasi Penelitian</b>	
7.1.	Kunjungan pemantauan ke lokasi penelitian	SOP/021/01.1
<b>8.</b>	<b>Persiapan Agenda Pertemuan dan Rekaman Komunikasi</b>	
8.1.	Persiapan Agenda, Prosedur dan Notulen rapat	SOP/022/01.1
8.2.	Pertemuan Luar Biasa	SOP/023/01.1
8.3.	Rekaman Komunikasi	SOP/024/01.1
<b>9.</b>	<b>Manajemen Dokumen Penelitian</b>	
9.1.	Mengelola Dokumen Penelitian yang masih berlaku	SOP/025/01.1
9.2.	Pengarsipan dan Pencarian Dokumen	SOP/026/01.1
9.3.	Menjaga Kerahasiaan Dokumen KEPK-FKUB	SOP/ 027/01.1
<b>10.</b>	<b>Evaluasi KEPK</b>	
10.1	Audit dan Pemeriksaan KEPK-FKUB	SOP/028/01.1