Standardization of ethics review practice

Experience sharing from
Health Research Ethics Committee
Faculty of Medicine
Universitas Brawijaya

HREC/ REC/EC/ IRB/

International Guidelines

- Declaration of Helsinki,
- Belmont report
- Nuremberg code
- CIOMS International Ethical Guidelines for Epidemiological Studies
- CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects
- ICH GCP
- WHO Operational Guidelines for Ethics Committees That Review Biomedical Research
- WHO Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants
- WHO Surveying and Evaluating Ethical Review Practices

National Guidelines:

Peraturan dan Perundang-Undangan sebagai dasar pembentukan & pedoman KEPK

- Undang-Undang Nomor 39 tahun 1999 tentang Hak Asasi Manusia (Lembaran Negara Republik tahun 1999 Nomor 165, Tambahan Lembaran Negara Republik Indonesia nomor 3886);
- Undang-Undang Nomor 18 Tahun 2002 tentang Sistem Nasional Penelitian Pengembangan dan Penerapan Ilmu Pengetahuan dan Teknologi (Lembaran Negara Republik Indonesia tahun 2002 Nomor 84, Tambahan Lembaran Negara Republik Indonesia Nomor 4219);
- Undang-Undang Nomor 36 Tahun 2009 tentang Kesehatan (Lembaran Negara Republik Indonesia Tahun 2009 Nomor 144, Tambahan Lembaran Negara Republik Indonesia Nomor 5063);
- Peraturan Pemerintah Nomor 39 Tahun 1995 tentang Penelitian dan Pengembangan Kesehatan (Lembaran Negara Republik Indonesia tahun 1995 Nornor 67, Tambahan Lembaran Negara RI Nomor 3609);

National Guidelines:
Peraturan dan Perundang-Undangan sebagai dasar pembentukan & pedoman KEPK

- Keputusan Menteri Kesehatan Nomor 791/Menkes/SKNIII 1999 Tentang Koordinasi Penyelenggaraan Penelitian dan Pengembangan Kesehatan;
- Keputusan Menteri Kesehatan 1179A1Menkes/SKIXI1999 Tentang Kebijakan Penelitian dan Pengembangan Kesehatan;
- Keputusan Menteri Kesehatan 1333/Menkes/SKIXI/2001 Tentang Persetujuan Penelitian Kesehatan Terhadap Manusia;
- Keputusan Menteri Kesehatan Nomor 1031/Menkes/SKNII/2005 Tentang Pedoman Nasional Etik Penelitian Kesehatan;
- Peraturan Menteri Kesehatan Nomor 657/Menkes/PerNIII/2009 Tentang pengiriman dan penggunaan spesimen Klinik, Materi Biologik dan Muatan informasinya
- Peraturan Menteri Kesehatan Nomor 7 Tahun 2016 tentang Komisi Etik Penelitian dan Pengembangan Kesehatan Nasional

Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants

Standards for the research ethics review system

Standards and guidance for entities that establish research ethics committees

Standards and guidance for members of the research ethics committees

Standards and guidance for the secretariat, staff, and administration of the research ethics committees

Standards and guidance for researchers

Standards for the research ethics review system

Standard 1: Responsibility for establishing the research ethics review system

Standards and guidance for entities that establish research ethics committees

Standard 2: Composition of research ethics committees

Standard 3: Research ethics committee resources

Standard 4: Independence of research ethics committees

Standard 5: Training the research ethics committee

Standard 6: Transparency, accountability, and quality of the research ethics committee

Standards and guidance for members of the research ethics committees

Standard 7: Ethical basis for decision-making in research ethics committees

1. *Scientific design and conduct of the study*
2. *Risks and potential benefits*
3. *Selection of study population and recruitment of research participants*
4. *Inducements, financial benefits, and financial costs*
5. *Protection of research participants' privacy and confidentiality*
6. *Informed consent process*
7. *Community considerations*

Standard 8: Decision-making procedures for research ethics committees

Standards and guidance for the secretariat, staff, and administration of the research ethics committees

Standard 9: Written policies and procedures

1. *Membership of the committee*
2. *Committee governance*
3. *Independent consultants .*
4. *Submissions, documents required for review, review procedures, and decision-making*
5. *Communicating a decision*
6. *Follow-up reviews and monitoring of proposed research*
7. *Documentation and archiving*

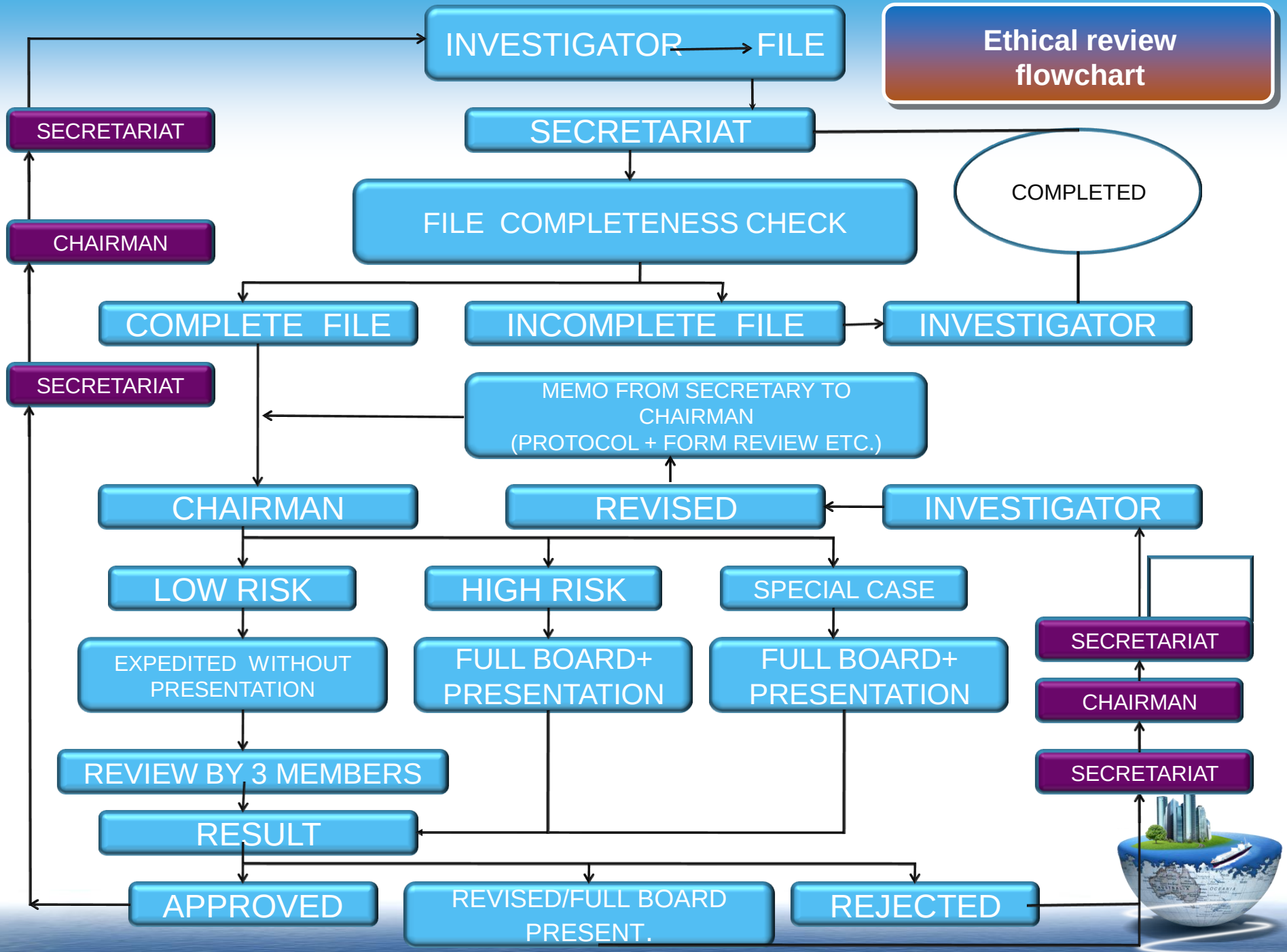
Standards and guidance for researchers

Standard 10: Researchers' responsibilities

1. *Submitting an application for review*
2. *Conduct of research*
3. *Safety reporting*
4. *Ongoing reporting and follow-up*
5. *Information to research participants*

Practices in Indonesia (HREC FM-UB)

Ethical review flowchart



Standards and guidance for members of the research ethics committees

Assessment forms for ethical reviews

HREC - National Institute for Health Research and Development (NIHRD)

1. Assessment forms for clinical trials

2. Assessment forms for health research (Survey/medical record/Surveilans-Epidemiologi-Humaniora, research on stored samples, and other non clinical research)

3. Assessment forms for studies using animal model

HREC FM-UB:

Assessment forms for

1. Social science research
2. Epidemiological research
3. Clinical trials
4. Studies using animal model
5. research on stored samples
6. Research on Genetics
7. Research on stem cell
8. Research on medical records

Standard 7: Ethical basis for decision-making in research ethics committees

Essential Component on Reviewing studies with human participants

1. Scientific issues

(Methodology: design, sample, Selection of study population and recruitment of research participants, data analysis, competence of PI)

2. Ethical issues

- ✓ *Recognizing vulnerability*
- ✓ *Risks and potential benefits, Risk : benefits Ratio*
- ✓ *Protection of research participants' privacy, confidentiality, voluntary participation*
- ✓ *Informed consent/ assent process, language & content*
- ✓ *Inducements, compensation, financial benefits, and financial costs*
- ✓ *Medical care*
- ✓ *Community considerations*

Challenges

- PI questioning about why HREC assess the scientific issue
- Timeline review process
- Protocols : EC members ratio
- Incomplete Information provided by PI in the protocol
- PI gather data before getting ethical approval from the EC
- Different opinion/perception between PI & EC members
- Ethical approval for a research group

Strategies

- Socializing and providing training regarding research ethics principles to EC members and researchers
- Updating information, sharing & discussion
- Strict to the timeline review process

Quality control, Ensuring the EC meet the standard 1-10

National HREC & Health Development

Komisi Etik Penelitian dan Pengembangan Kesehatan Nasional (KEPPKN)

Jaringan Komunikasi KEPK

1. Pokja Pedoman (Guidelines)
2. Pokja SOP (Standard of procedures)
3. Pokja Pembinaan (Assistance)
4. Pokja Akreditasi (Acreditation)

Forum for Ethical Review Committees in the Asian & Western Pacific REgion (FERCAP)

Survey for ethical review practices/ Recognizion

FERCAP Survey standard:

1. Structure and composition
2. Adherence to specific policies
3. Completeness of the review process
4. After review process
5. Documentation & archiving

Includes the assessment of:

1. Office visit
2. Membership review
3. SOP review
4. Protocol file review
5. Quality of protocol review
6. Meeting minutes
7. SAE Review
8. Board meeting observation
9. Interviewing Head & secretary, EC members, and staff

INTERNATIONAL RECOGNITION FROM FERCAP TO HREC FM-UB in 2013

Thank you