Pengantar dan Prinsip Dasar Etik Penelitian Kesehatan serta Pertimbangan Risiko dan Manfaat dalam Penelitian

Pengenalan KEPK

Deni K Sunjaya
d.k.sunjaya@unpad.ac.id
www.deni-comhealth.org
• Sejarah
• Etik
• Prinsip Dasar Etik Penelitian
• Pertimbangan Risk Benefit
• Pengenalan KEPK FK Unpad
• Walter Reed and the yellow Fever Experiments
• The Nazi Medical experiment
• The Imperial Japanese Experiments in China
• RCT of Sreptomycin
• Salk Polio Vaccine Field Trial of 1954
• The Jewish Chronic Disease Hospital Case
• The Hepatitis Experiments at the Willowbrook School
• The Tuskegee Syphilis Experiment
• HIV Research
• Gelsinger Case
MENGELE EXPERIMENTS

• Mengele injected chemicals into the eyes of the children in an attempt to change their eye color.

• He carried out twin-to-twin transfusions, stitched twins together, castrated or sterilized twins.

• Many twins had limbs and organs removed in macabre surgical procedures, performed without using an anesthetic.

• Some survivors were kept alive because they were twins, and he wanted them for medical experiments aimed at creation of an Aryan superrace.
JEWISH TWINS KEPT ALIVE TO BE USED IN MENGELE'S MEDICAL EXPERIMENTS. THESE CHILDREN WERE LIBERATED FROM AUSCHWITZ BY THE RED ARMY IN JANUARY 1945.
PERCOBAAN PADA ANAK : KURT HEISSMEYER

• NOVEMBER 1944: 20 ANAK YAHUDI (5-10 TAHUN), 10 PRIA DAN 10 WANITA DIAMBIL DARI AUSCHWITZ DIBAWA KE KAMP KONSENIRASI NEUENGAMME, DILUAR KOTA HAMBURG.

• MEREKA DIJADIKAN “HUMAN GUINEA-PIGS” UNTUK BERBAGAI MACAM PERCOBAAN MEDIS OLEH DOKTER KURT HEISSMEYER.

• ANAK ANAK DISUNTUK DENGAN BAKTERI TBC HIDUP KEDALAM VENA DAN PARU UNTUK MELIHAT APAKAH MEREKA MEMPUNYAI IMUNITAS TERHADAP TBC

• MEREKA DIAMATI DENGAN SEKSAMA, DILAKUKAN PEMERIKASAAN, DIFOTO UNTUK MELIHAT PERJALANAN PENYAKIT.

→ KONDISI ANAK-ANAK LANGSUNG MEMBURUK DG CEPAT DAN SAKIT PARAH

• TGL 20 APRIL 1945, SEBELUM PERANG BERAKHIR, HEISSMEYER DAN ARNOLD STRIPPEL MEMUTUSKAN UNTUK MEMBUNUH ANAK-ANAK UNTUK MENYEMBUNYIKAN BUKTI KEKEJAMAN KEPADA TENTARA SEKUTU  Moh. Sudomo9
THE TUSKEGEE SYPHILIS STUDY, STUDY TTG PENYAKIT YG DILAKUKAN ANTARA 1932- 1972 DI TUSKEGEE, ALABAMA. 399 PENDERITA SIFILIS, AFRICAN-AMERICA, MISKIN, BUTA HURUF (DIBERIKAN BEBERAPA INSENTIF)
THE TUSKEGEE SYphilis STUDY, STUDY TTG PENYAKIT YG
DILAKUKAN ANTARA 1932- 1972 DI TUSKEGEE, ALABAMA.
399 PENDERITA SIFILIS, AFRICAN-AMERICA, MISKIN, BUTA
HURUF (DIBERIKAN BEBERAPA INSENTIF)

Moh. Sudomo 10
• Etik?
Ethics

• A set of philosophical beliefs and practice concerned with questions of justice, fairness, equity, rights, allocation of resources, and cost.

→ tell us what we ought to do

• the study of decisions or behavior that benefits or harms persons and creatures
Ethical Theory

• Virtues
• Natural Laws
• Utilitarianism
• Deontology
• Right
Principlism
Beuchamps – Childress

- Respect for autonomy → make choices and decisions for themselves
- Non-maleficence → not harming
- Beneficence → doing good
- Justice → fairness, equity, impartiality
Analysis Ethical

Utilitarianism

Communitarianism

Libertarianism
Risiko

• Minimal Risk: risk that are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examination or test
Risk Benefit Assessment

Benefit

Risk
Overview of Profile and Procedures
Health Research Ethics Committee
Faculty of Medicine - Universitas Padjadjaran
Brief History

1990
• Medical Research Ethics Team Faculty of Medicine Universitas Padjadjaran (FMUP)

1991
• Health Research Ethics Committee FMUP

1995
• Research Ethics Committee under Medical Committee dr. Hasan Sadikin Hospital (RSHS)

2009
• Health Research Ethics Joint Committee Faculty of Medicine Universitas Padjadjaran - Dr Hasan Sadikin Hospital

2012
• Health Research Ethics Committee FMUP (established January 3, Decree of Dean No. 50/UN6.C/Kep/HK/2012
• Affiliation: NHREC/KNEPK, Office for Human Research Protection-NIH-USA (IORG-IRB number: 00008626), FWA for the Protection of Human Subject: 00018324, & PRIM&R (Public Responsibility in Medicine and Research)
## Overview since 2012

<table>
<thead>
<tr>
<th>Year</th>
<th>2012</th>
<th>2013</th>
<th>2014</th>
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</thead>
<tbody>
<tr>
<td><strong>SOP</strong></td>
<td>General guidelines</td>
<td>General guidelines Sept: SOP development</td>
<td>SOP (FERCAP) Revision: April and July</td>
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<tr>
<td><strong>Members</strong></td>
<td>7</td>
<td>9</td>
<td>9 (including 1 Veterinary Med)</td>
</tr>
<tr>
<td><strong>Secretariat Staff</strong></td>
<td>1</td>
<td>September: 2</td>
<td>February: 2 March: 4 (3 new, including 1 IT)</td>
</tr>
<tr>
<td><strong>Office</strong></td>
<td>1 room at hospital</td>
<td>2 rooms at new building (admin &amp; meeting)</td>
<td>3 rooms (admin, meeting, archive), independent phone line</td>
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<tr>
<td><strong>Protocols</strong></td>
<td>??</td>
<td>??</td>
<td>1st half year: 378 (increasing)</td>
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<td><strong>Review process</strong></td>
<td>• Integrated with student proposal exam • Manual review</td>
<td>• Integrated with student proposal exam • Manual review</td>
<td>• April: separated from student proposal exam • July: online review</td>
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<tr>
<td><strong>Admin system</strong></td>
<td>Manual</td>
<td>Manual</td>
<td>April: online registration July: online protocol submission</td>
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<tr>
<td>Year</td>
<td>Guidelines</td>
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<tr>
<td>1947</td>
<td>Nuremberg Code</td>
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<tr>
<td>1978</td>
<td>Belmont Report</td>
<td></td>
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<td>1996</td>
<td>ICH Good Clinical Practice Guidelines</td>
<td></td>
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<td>2000</td>
<td>Operational Guidelines for Ethics Committees Review Biomedical Research</td>
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<td>2002</td>
<td>Surveying and Evaluating Ethical Review Practices (WHO-TDR)</td>
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<td>2004</td>
<td>SIDCER-FERCAP Recognition Program</td>
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</tbody>
</table>
National Regulation & Guidelines

- **Health Law (No. 36/2009)**
  - health protection for research participants

- **Government Regulation No. 39/1995**
  - NIHRD-MoH responsible to organize / manage the human subject protection, review and approved informed consent and compensation to those who were harmed or injured due to research

- **Decree of Ministry of Health No. 1333/2002**
  - Informed consent in research using human subject

- **Government Regulation No. 41/2005**
  - Research involving foreign institution/ researcher

- **National Committee Guidelines**
  - Research on clinical trial and archived material
Type of Review

Full Board Review
Full board review means that the research is reviewed at convened meetings at which a majority of the members of the REC/IRB are present, including at least one member whose primary concerns are in nonscientific areas. This type of review applies to studies that are greater than minimal risk, or minimal risk but do not qualify for expedited review.

Expedited Review
Expedited review means that the review can be done by a qualified IRB reviewer rather than at a convened IRB meeting. Reviewers conducting an expedited review may exercise all of the authority of the REC/IRB except that they may not disapprove a study. When reviewers cannot approve the research under expedited review, the study is referred for full board review.

Exempt Review
The categories of research which are exempt from the regulations. Although the category is called "exempt," the determination of exemption must be made by the REC/IRB Office. Exempt projects are different from Expedited or Full Board review in that they are not assigned an expiration date, do not have to undergo continuing review and are able to undergo alteration without REC/IRB approval.
Research Ethics Committees (RECs) INDOMESIA
Reciprocal Review
Under a reciprocal agreement between REC/IRB to accept the review each institution reserves the right to have its own REC/IRB review the research.

Umbrella Grant Review
Umbrella review should be requested if REC/IRB approval letter is needed to the funding agency for a training grant, center grant, or program project grant that will support multiple research projects involving human subjects. REC/IRB approval represents approval of the grant in concept only. Separate REC/IRB approval must be obtained for each human subjects research project that receives funds from the grant.

Development Grant Review
Development grant review should be requested if REC/IRB approval letter is needed for a grant application but are not yet ready to begin research with human subjects. "Development-only" approval shows that the IRB has approved the study in concept. When you are ready to begin your research with human subjects, submit a new study to receive the final approval.
BASIC PRINCIPLE FOR ALL MEDICAL RESEARCH

- Appropriate caution must be exercised in the conduct of research which may affect the environment, and

- the welfare of animals used for research must be respected
Reduction: alternative models to have minimal number of animal as subject of study

Replacement: alternative of changing animal to invertebrata or cell lines (tissue culture)

Refinement: minimize severity of pain and stress
• **Replacement**: Methods that avoid using animals.
  - Relatif: - use animal organs/tissues from slaughter house.
    - use animal of lower ordo
  - Absolut: - replace the use of animal with tissue culture/computer program.
    (mengganti hewan coba dengan alternatif lain seperti hewan invertebrata/kultur jaringan/program kompter)

• **Reduction**: Strategies for obtaining comparable levels of information from the use of fewer animals or for maximizing the information obtained from a given number of animal without increasing pain or distress → viewer animals are needed to aquire the same scientific information.
  (model alternatif agar dapat mengurangi jumlah hewan coba)

• **Refinement**: Modification of husbandry or experimental procedures to enhance animal well-being or eliminate pain and distress → use of analgesics, anesthetics.
  (mengurangi/menghindari penederitaan dan rasa nyeri ataupun stresseperti pemberian analgesika dan obat anestesi)
5 Freedoms from

- Hunger and thirst
- Pain, injury and disease
- Discomfort
- Fear and distress
- Express natural behavior
Free from hunger and thirst
“The love for all living creatures is the most noble attribute of man”

(Charles Darwin)
THE INTERNATIONAL CONFERENCE ON HARMONISATION (ICH)

- Collaborating the European Union, the United States, and Japan (since 1991)

↓

Technical Requirement for Registration of Pharmaceuticals for Human Use

Principles of International Conference on Harmonisation (ICH) Good Clinical Practice (GCP) (clinical trial-human as subject)

Objective:
- To define the ICH and its origin
- To list the universal principles that form the basis of GCP
- To identify those who benefit from GCP
RESEARCH MISCONDUCT

- **Fabrication**: menggandakan data, hasil penelitian dalam catatan data dalam pelaporan hasil penelitian.
- **Falsification**: memalsukan/memempilulası bahan penelitian, alat, proses, merubah atau menghilangkan data atau hasil sehingga mengubah hasil pencatatan data.
- **Plagiarism**: mengambil data penelitian orang lain; ide, proses, hasil atau kata-kata tanpa menyebutkan sumbernya.
Conflict of Interest (COI)

- COI is a set of conditions in which professional judgment concerning a primary interest (such as patient’s welfare or validity of research) tends to be unduly influenced by a secondary interest (such as financial gain). COI rules, formal and informal, regulate the disclosure and avoidance of these conditions.

(Dennis F. Thompson)
What is wrong with COI?

- COI is not an evidence of wrongdoing
- For many professionals, it is almost impossible to avoid having COIs from time to time
- A COI can, however, become an ethical or legal issue if an individual tries or succeeds in influencing the outcome of a decision, for personal benefit
Rules for control of COI

• To maintain integrity of professional judgment

• To prevent secondary interests from dominating the primary interests in the making of professional decisions

• To maintain public trust in the profession
Authorship

• Each author should have participated sufficiently in the work to take public responsibility for appropriate portions of the content
• One or more authors should take responsibility for the integrity of the work as a whole
• Authorship credit should be based only on (1) substantial contributions to conception and design, or acquisition of data, or analysis and interpretation; (2) drafting the article or revising it critically for important intellectual content; (3) final approval of the version to be published

(“Vancouver Group”)
Member Appointment

- Voluntary and independent
- Proposed by Committee ➔ Decree of Dean
- 9 members from multidiscipline
- At least 1 from medicine, 1 non affiliated (currently: 4 MD, 4 non affiliated)
- 6 male, 3 female
- 4 years appointment, decree annually renewed (University regulation)
- Possible to withdraw
- Subject to be replaced or disqualified
Independent Consultant Appointment

- To be consulted in certain field of expertise
- Proposed by Committee → Decree of Dean
- 41 consultants from 24 field of expertise
- 8 non affiliated

<table>
<thead>
<tr>
<th>Anesthesiologist 2</th>
<th>Biochemistry 2</th>
<th>Radiologist 2</th>
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<tbody>
<tr>
<td>Pharmacist/Pharmacologist 3</td>
<td>Cell Biology/Molecular Biologist 3</td>
<td>Dermatology/Venerealogist 1</td>
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<td>Surgeon 2</td>
<td>Epidemiology 2</td>
<td>Nutritionist 1</td>
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<td>Obgyn 3</td>
<td>Internist 2</td>
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<td>Sociologist 1</td>
<td>Neurologist 1</td>
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<td>Dentist 3</td>
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<td>Public Health 1</td>
<td>Pathologist 1</td>
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<td>Clinical Pathologist 1</td>
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<tr>
<td>1</td>
<td>Dr. Ike Sri Redjeki, dr., SpAn-KIC, KMN, M.Kes</td>
<td>Anesthesiology</td>
</tr>
<tr>
<td>2</td>
<td>Prof. Dr. Tatang Bisri, dr., SpAn-KNA</td>
<td>Anesthesiology</td>
</tr>
<tr>
<td>3</td>
<td>Dr. Diah Dhianawaty, Dra., M.Si</td>
<td>Biochemistry</td>
</tr>
<tr>
<td>4</td>
<td>Prof. Dr. M. Nurhalim Shahib, dr</td>
<td>Biochemistry</td>
</tr>
<tr>
<td>5</td>
<td>Dr. Achadiyani, dr., M.Kes</td>
<td>Cell Biology</td>
</tr>
<tr>
<td>6</td>
<td>Dr. Hadyana Sukandar, Drs., M.Sc</td>
<td>Epidemiology</td>
</tr>
<tr>
<td>7</td>
<td>Dr. Rd. Tina Dewi Judistiani, dr., SpOG</td>
<td>Epidemiology</td>
</tr>
<tr>
<td>8</td>
<td>Dr. Ahmad Muhtadi, MS., Apt</td>
<td>Pharmacy</td>
</tr>
<tr>
<td>9</td>
<td>Prof. Dr. Anas Subarnas, M.Sc., Apt</td>
<td>Pharmacy</td>
</tr>
<tr>
<td>10</td>
<td>Dr. Eriska Riyanti, drg., SpKGA</td>
<td>Dentist</td>
</tr>
<tr>
<td>11</td>
<td>Dr. Mieke Hemiawati Satari, drg., MS</td>
<td>Dentist</td>
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<tr>
<td>12</td>
<td>Prof. Dr. Herri S. Sastramihardja, dr., SpFK(K)</td>
<td>Pharmacology</td>
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<tr>
<td>13</td>
<td>Prihatini Ambarettnani, Dra., MA., Ph.D</td>
<td>Sociology</td>
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<td>14</td>
<td>Dr. Hermawan N. Rasyid, dr., SpOT-K., MT(BME)., FICS</td>
<td>Orthopaedics</td>
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<tr>
<td>15</td>
<td>Prof. Dr. Fachry Ambia Tandjung, dr., SpB., SpOT-K, M.Phil(Orth)., FICS</td>
<td>Orthopaedics</td>
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<tr>
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<tr>
<td>17</td>
<td>Dr. Bambang S. Noegroho, dr., SpB., SpU</td>
<td>Surgeon</td>
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<tr>
<td>18</td>
<td>Prof. Dr. Hendro Sudjono Yuwono, dr., Sp.B-KBV</td>
<td>Surgeon</td>
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<tr>
<td>19</td>
<td>Dr. R. Reni Farence Soedoja Ningrat, dr., M.Kes., AIF</td>
<td>Physiology</td>
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<td>20</td>
<td>Dr. Vita Murniati Tarawan, dr., SpOG., AIFO., M.Kes., SH</td>
<td>Obstetrics &amp; Gynaecology</td>
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<tr>
<td>21</td>
<td>Dr. Dewi Marhaeni Diah Herawati, drg., M.Si</td>
<td>Nutrition</td>
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<td>22</td>
<td>Dr. Hadi Susiamono, dr., SpOG., M.Kes., MH.Kes</td>
<td>Obstetrics &amp; Gynaecology</td>
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<tr>
<td>23</td>
<td>Prof. Dr. Johannes C. Mose, dr., SpOG-K</td>
<td>Obstetrics &amp; Gynaecology</td>
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<td>24</td>
<td>Prof. Dr. Tuti Wahnurtdi Arie Sapiie, dr., SpKJK</td>
<td>Psychiatry</td>
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<td>25</td>
<td>Dr. Meita Dhamayanti, dr., SpA(K)., M.Kes</td>
<td>Paediatrician</td>
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<td>Prof. H. Herry Garna, dr., SpA-K., Ph.D</td>
<td>Paediatrician</td>
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<td>Dr. Oki Suwarsa, dr., SpKK (K)., M.Kes</td>
<td>Dermatology &amp; Venereal Dis</td>
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<td>28</td>
<td>Dr. Elsa Pudji Setiawati, dr., MM</td>
<td>Public Health</td>
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<td>Dr. Arief Syamsulaksana K, dr., SpM(KVR)., MM., M.Kes</td>
<td>Ophtalmology</td>
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<td>30</td>
<td>Dr. Sutarya Enus., dr., SpM-K</td>
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<td>31</td>
<td>Dr. Ratna Anggraeni Agustian., dr., M.Kes., SpTHT-KL(K)</td>
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<tr>
<td>32</td>
<td>Dr. Arto Yuwono Soeroto, dr., SpPD-KP</td>
<td>Internal Medicine</td>
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<tr>
<td>33</td>
<td>Prof. Dr. H. M. Rachmat Soelaeman, dr., SpPD-KGH</td>
<td>Internal Medicine</td>
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<td>34</td>
<td>Dr. Anam, dr., SpS</td>
<td>Neurology</td>
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<td>35</td>
<td>Dr. Sadeli Masria, dr., DMM., MS., SpMK</td>
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<td>36</td>
<td>Herry Herman, dr., PhD., SpOT</td>
<td>Molecular Biology</td>
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<td>37</td>
<td>Bethy Suryawathy Hernowo, dr., SpPA(K), Ph.D</td>
<td>Pathology</td>
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<td>38</td>
<td>Prof. Dr. Ida Parwati, dr., SpPK-K, Ph.D</td>
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<td>Dr. Ristantiah D. Soetikno, dr., SpRad(K)., M.Kes</td>
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<td>Dr. Setiawan Sutopo, dr., SpRad.</td>
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<td>41</td>
<td>Dr. Ani Melani M., drg., M.Kes</td>
<td>Dentist</td>
</tr>
</tbody>
</table>
Appointment of Secretariat Staffs

• Decree of Dean
• Employment status is integrated within the State University employment system
  • Statement of Confidentiality
• **Head of Secretariat:**
  – Ipur Purwatiningingsih (September, 2013)

• **Staffs:**
  – Sita Purnadewi (IT staff) (March, 2014)
  – Lilik (August, 2016)
Structure of Organization

DEAN
- Vice Dean I
- Vice Dean II

CHAIRMAN

SECRETARY

SECRETARIAT

INDEPENDENT CONSULTANT

MEMBERS
Review Policy

• Independent review
• Confidential
• Reviewers: Committee members and/or independent consultants
• Conflict of Interest management
  – Reviewer cannot review his/her own research project
  – Reviewer cannot involve in full-board meeting discussing his/her own research project
• Category of Decision:
  – Exemption (Chair/Secretary)
  – Expedited (2 reviewers, 1 from related expertise)
  – Full board (initial reviewers 2, distributed to all members)
• Full board decision requires quorum: 50%+1
Review Process

- FERCAP based SOP - January 2, 2014
- First revision for certain SOPs - April and July, 2014
- Online protocol registration - April 15, 2014
- Online review since - July 17, 2014
- Manual system for Revision, Amendment, Continuous (IT system under development)
Funding

Before 2012

• Independent funding
• Fee per review
• Researcher pays application fee per proposal

After 2012

• Free application for researcher
• Monthly salary for committee members only
• No fee per review for members and consultants
• Secretariat is facilitated fully by Faculty of Medicine
• Budgeting and remuneration system have been proposed through University, waiting for decision from Ministry of Finance
Trainings

Basic Research Ethics

- Required for all members (each had received different trainings and period)
- In house training is obligatory for each Secretariat Staffs

Research Ethics Training

- January, 2013 – in house, for consultants, researchers, refreshing for members
- July, 2013 – trainees in FERCAP survey at Unud, Bali
- November, 2013 – seminar attendance, FERCAP conference, Bali
- April 2014 – refreshing for consultants and members, SOPs introduction
- May 2014 – study at EC Litbangkes, Jakarta
- May 2014 – trainees in FERCAP Survey at MRIN, Jakarta
- May 2014 – study at EC Unhas, Makassar
- July 2014 – training for all researchers in Unpad, refreshing for members
- July 2014 – training of online review system for members and consultants
Current Committee Members

Chair: Prof. Dr. Firman F. Wirakusumah

Secretary: Dr. Meita Damayanti

**Clinical Trial**
Chair: Prof. Dr. Diah Dhianawaty
Secretary: Nur Atik PhD.
Members:
Prof. Dr. Anas Subarnas, M.Sc., Apt,
Prof. Dr. Efa Laela Fakhriah Rovina, PhD
Dr. Tono Djuwantonono
Ihsan Hikmawan, S, Pd

**Basic Medical Science**
Chair: Prof. Dr. Ramdan Panigoro
Secretary: Dr. Agnes Rengga Indrati
Members:
Prof. Dr. Dany Hilmanto
Dr. Bambang Setiohaji
Dr. Eriska Riyanti
Drh. Yusni
Asri Wijayanti, S.Si

**Community Health Sciences**
Chair: Dr. Deni K Sunjaya
Secretary: Shelly Iskandar, PhD
Members:
Prof. Dr. Tuti Wahmurti Sapiie
Prof. Dr. Haryo S. Martodirdjo
Dr. Eddy Fadlyana
Dr. Hadi Susiarno
Dr. Yanti Hermayanti
Dr. R. Tina Dewi Judistiani
• Address:
  Gedung RS Pendidikan 3rd floor
  Jl. Eijkman No. 38,
  Bandung 40161
  INDONESIA
  Tel/Fax (direct): +62-22-2038697
  email: kepk.fk.unpad@gmail.com
  Information system (URL):
  kepk.fk.unpad.ac.id
INFRASTRUCTURE : Program/activities ICT system

Development of Networking System → provide complex infrastructure network between FMUP; departments, libraries and administration inside into global network
Contoh: e-government online service kepk_fk.unpad.ac.id
Submission 2014

Based on Status of PI

- Non FMUP
- FMUP Professor/Researcher
- PhD candidate Non Unpad
- PhD candidate Unpad
- Master student
- Non FMUP
- Diploma & Bachelor
- FMUP
- Non FMUP
- Master Student FMUP