

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

Pengenalan KEPK

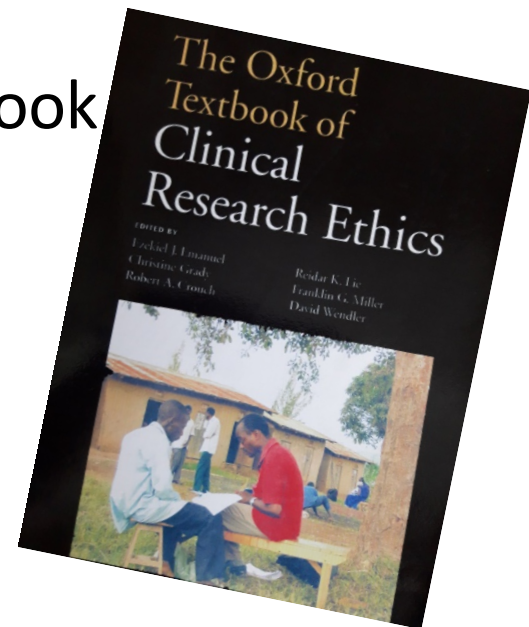
Deni K Sunjaya

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 Streptomycin
- 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 KONSENTRASI *NEUENGAMME*, DI LUAR KOTA *HAMBURG*.**
- MEREKA DIJADIKAN “***HUMAN GUINEA-PIGS***” UNTUK BERBAGAI MACAM PERCOBAAN MEDIS OLEH DOKTER ***KURT HEISSMEYER***.
- **ANAK ANAK DISUNTIK 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



**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)**

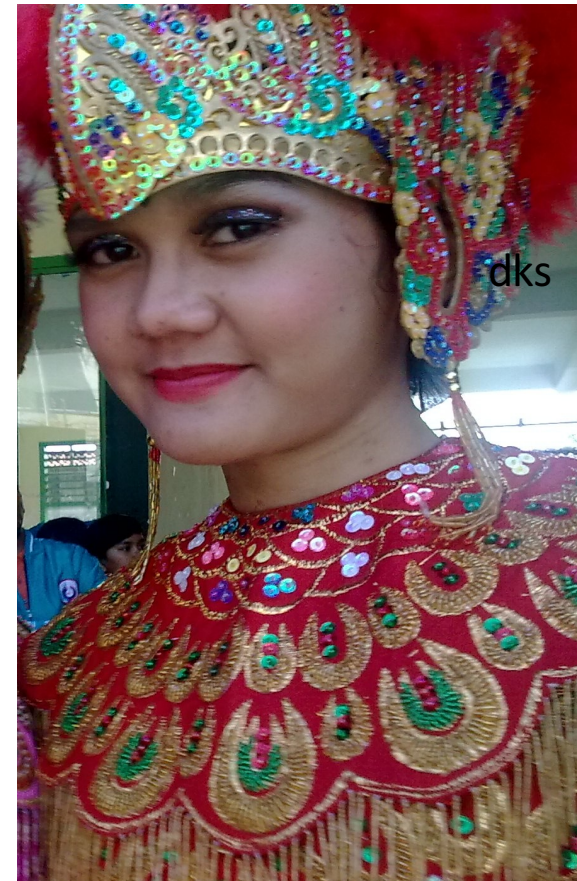
- **Etik?**

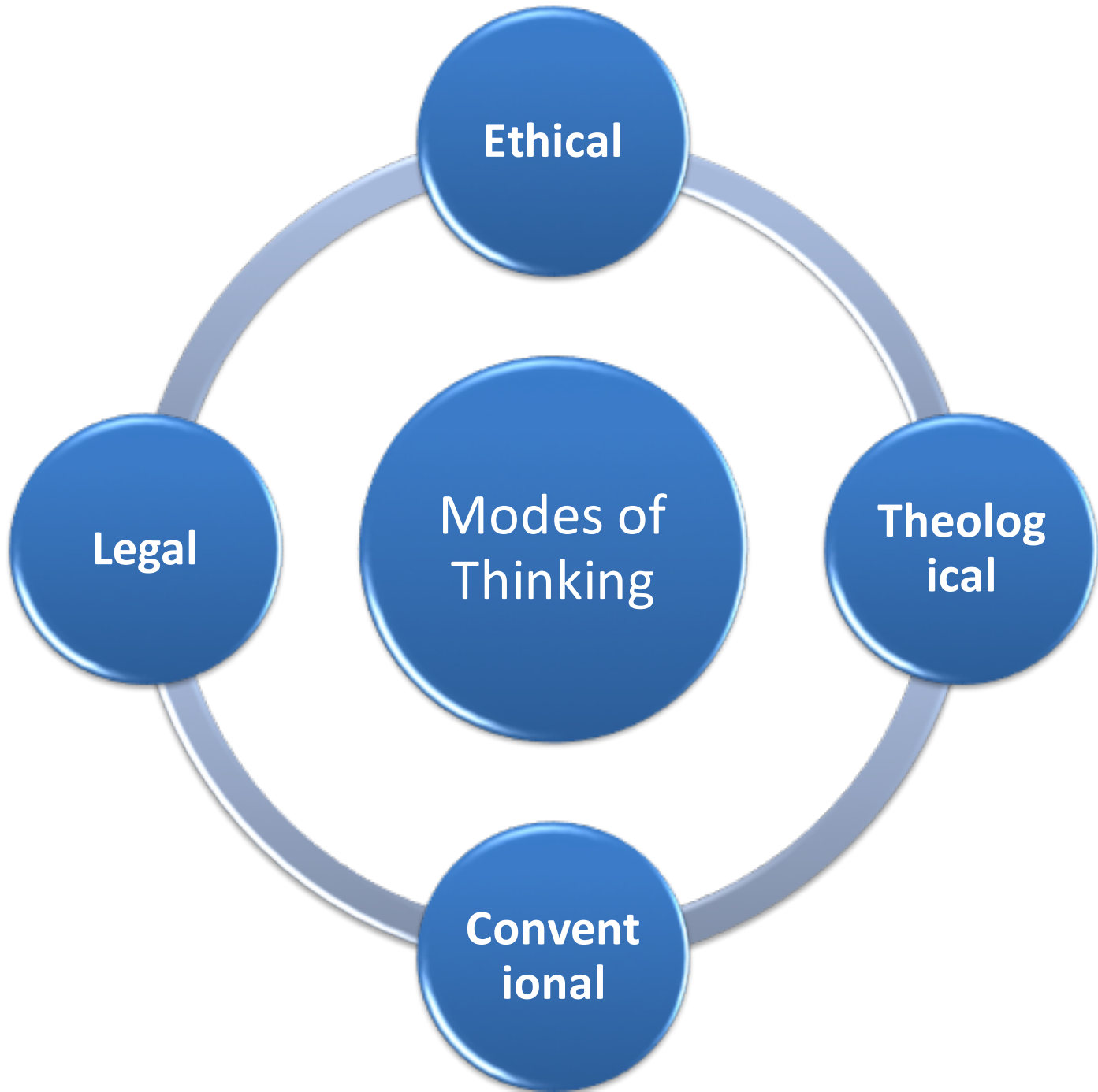




Ethics

- 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

Legal

**Modes of
Thinking**

**Theolog
ical**

**Convent
ional**

Ethical Theory

- **Virtues**
- **Natural Laws**

- **Utilitarianism**
- **Deontology**
- **Right**

Principlism

Beuchamps – Childress



Respect for autonomy → make choices and decisions for themselves



Non- maleficence → not harming

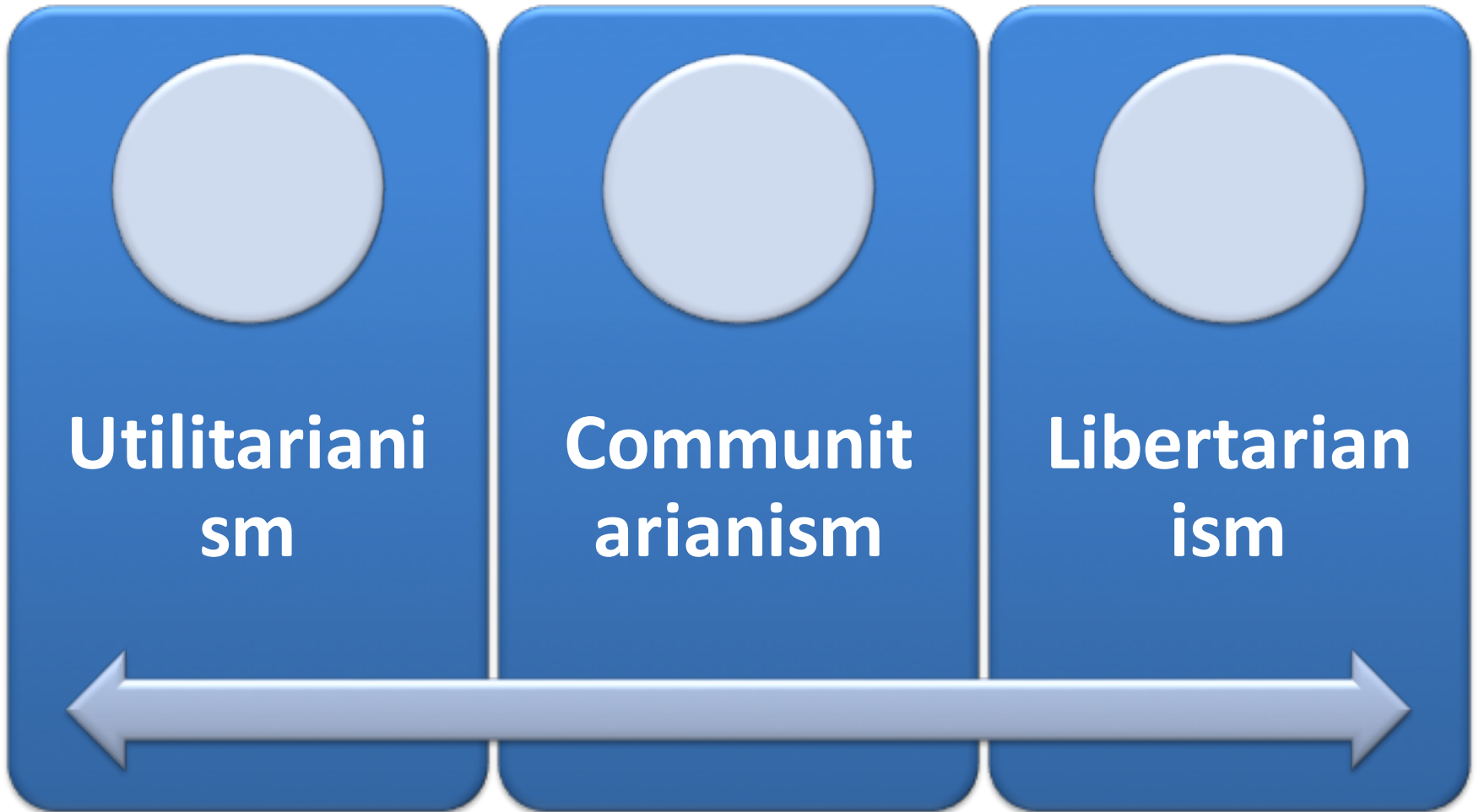


Beneficence → doing good



**Justice → fairness, equity,
impartiality**

Analysis Ethical



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

Year	2012	2013	2014
SOP	General guidelines	General guidelines Sept: SOP development	SOP (FERCAP) Revision: April and July
Members	7	9	9 (including 1 Veterinary Med)
Secretariat Staff	1	September: 2	February: 2 March: 4 (3 new, including 1 IT)
Office	1 room at hospital	2 rooms at new building (admin & meeting)	3 rooms (admin, meeting, archive), independent phone line
Protocols	??	??	1 st half year: 378 (increasing)
Review process	<ul style="list-style-type: none"> Integrated with student proposal exam Manual review 	<ul style="list-style-type: none"> Integrated with student proposal exam Manual review 	<ul style="list-style-type: none"> April: separated from student proposal exam July: online review
Admin system	Manual	Manual	April: online registration July: online protocol submission

Basic International Guidelines Research in Human Being

1947

- Nuremberg Code

1964

- Declaration of Helsinki (revised 2002, 2008, 2013)

1978

- Belmont Report

1991

- CIOMS/WHO (1993)

1996

- ICH Good Clinical Practice Guidelines

2000

- Operational Guidelines for Ethics Committees Review Biomedical Research

2002

- Surveying and Evaluating Ethical Review Practices (WHO-TDR)

2004

- SIDCER-FERCAP Recognition Program

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.

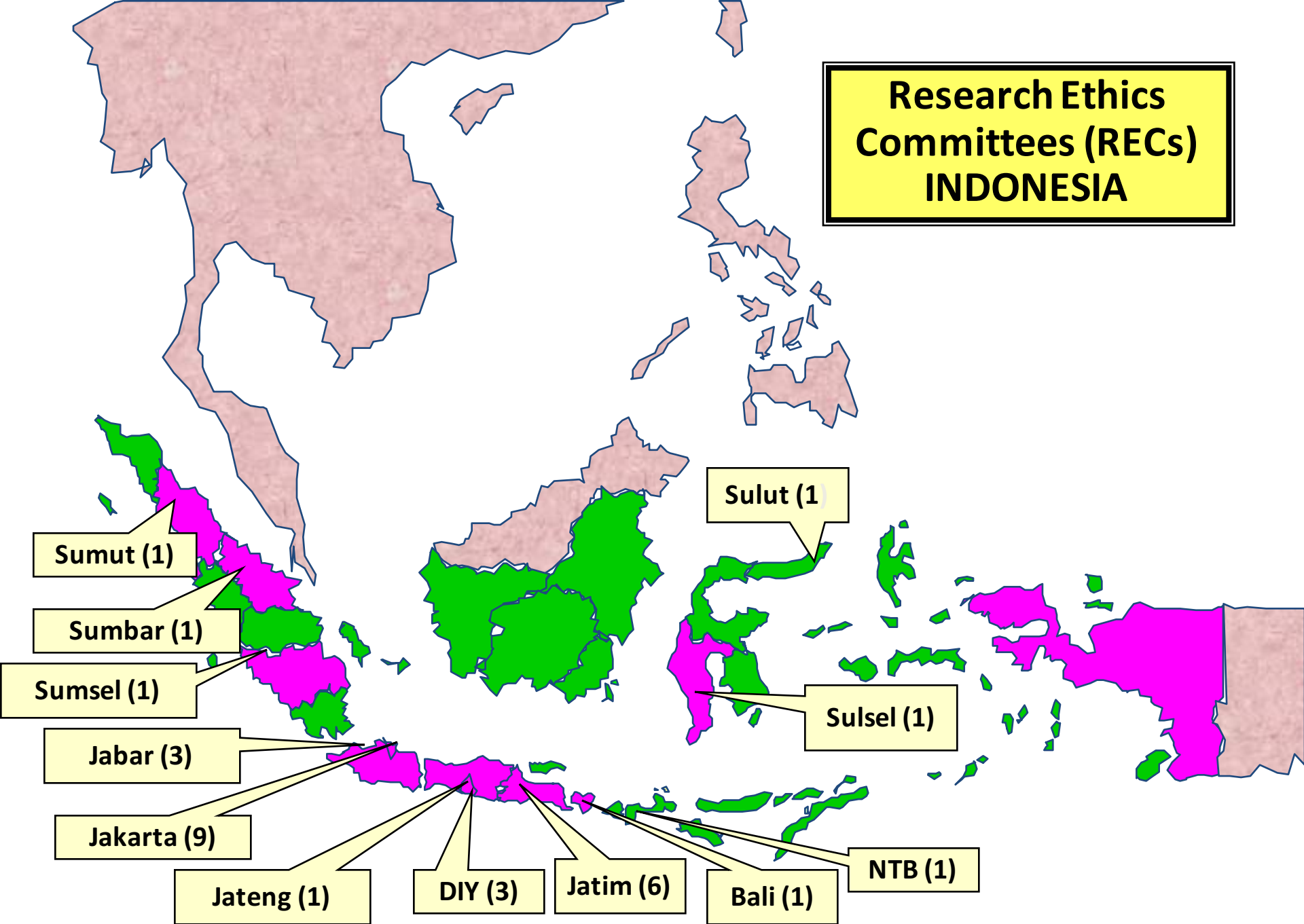
Expedited Review

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) INDONESIA



Type of Review ... continue....

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.

WORLD MEDICAL ASSOCIATION DECLARATION OF HELSINKI (1964 - 2013)

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

ANIMAL RESEARCH

- **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 komputer)
- **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 acquire 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 penderitaan dan rasa nyeri ataupun stres seperti pemberian analgesika dan obat anestesi)

5 Freedoms from



Hunger and
thirst



Discomfort



Pain, injury and
disease



Fear and distress



Express natural
behavior

Free from hunger and thirst





**LABORATORIUM
FARMAKOLOGI
PASCA SARJANA
FK UNPAD/RSHS**



“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

- **ICH Harmonised Tripartite Guidelines for Good Clinical Practise (1996) -> GCP**

**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/memanipulasi 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**

Anesthesiologist 2	Biochemistry 2	Radiologist 2
Pharmacist/ Pharmacologist 3	Cell Biology/ Molecular Biologist 3	Dermatology/ Venerealogist 1
Surgeon 2	Epidemiology 2	Nutritionist 1
Obgyn 3	Internist 2	Physiologist 1
Psychiatry 1	Sociologist 1	Neurologist 1
Paeditrician 2	Dentist 3	Ortophaedics 2
ENT 1	Public Health 1	Pathologist 1
Ophthalmologist 2	Microbiologist 1	Clinical Pathologist 1

Independent Consultants

No	Name	Specialty	Affiliation
1	Dr. Ike Sri Redjeki, dr., SpAn-KIC, KMN,M.Kes	Anesthesiology	FMUP
2	Prof. Dr. Tatang Bisri, dr., SpAn-KNA	Aneshtesiology	FMUP
3	Dr. Diah Dhianawaty, Dra., M.Si	Biochemistry	FMUP
4	Prof. Dr. M. Nurhalim Shahib, dr	Biochemistry	FMUP
5	Dr. Achadiyani, dr., M.Kes	Cell Biology	FMUP
6	Dr. Hadyana Sukandar, Drs., M.Sc	Epidemiology	FMUP
7	Dr. Rd. Tina Dewi Judistiani, dr., SpOG	Epidemiology	FMUP
8	Dr. Ahmad Muhtadi, MS., Apt	Pharmacy	Pharmacy Unpad
9	Prof. Dr. Anas Subarnas, M.Sc., Apt	Pharmacy	Pharmacy Unpad
10	Dr. Eriska Riyanti, drg., SpKGA	Dentist	Dentistry Unpad
11	Dr. Mieke Hemiawati Satari, drg., MS	Dentist	Dentistry Unpad
12	Prof. Dr. Herri S. Sastramihardja, dr., SpFK(K)	Pharmacology	FMUP
13	Prihatini Ambaretnani, Dra., MA., Ph.D	Sociology	Social & Political Science
14	Dr. Hermawan N. Rasyid, dr., SpOT-K., MT(BME)., FICS	Orthopaedics	Dr. Hasan Sadikin Hospital
15	Prof. Dr. Fachry Ambia Tandjung, dr., SpB., SpOT-K, M.Phil(Orth)., FICS	Orthopaedics	Dr. Hasan Sadikin Hospital

No	Name	Background	Affiliation
17	Dr. Bambang S. Noegroho, dr., SpB., SpU	Surgeon	Dr. Hasan Sadikin Hospital
18	Prof. Dr. Hendro Sudjono Yuwono, dr., Sp.B-KBV	Surgeon	FMUP
19	Dr. R. Reni Farenia Soedjana Ningrat, dr., M.Kes., AIF	Physiology	FMUP
20	Dr. Vita Murniati Tarawan, dr., SpOG., AIFO., M.Kes., SH	Obstetrics & Gynaecology	FMUP
21	Dr. Dewi Marhaeni Diah Herawati, drg., M.Si	Nutrition	FMUP
22	Dr. Hadi Susiarso, dr., SpOG., M.Kes., MH.Kes	Obstetrics & Gynaecology	FMUP
23	Prof. Dr. Johanes C.Mose, dr., SpOG-K	Obstetrics & Gynaecology	FMUP
24	Prof. Dr. Tuti Wahmurti Arie Sapiie, dr., SpKJK	Psychiatry	FMUP
25	Dr. Meita Dhamayanti, dr., SpA(K)., M.Kes	Paediatrician	FMUP
26	Prof. H. Herry Garna, dr., SpA-K., Ph.D	Paediatrician	FMUP
27	Dr. Oki Suwarsa, dr., SpKK (K)., M.Kes	Dermatology & Venereal Dis	FMUP
28	Dr. Elsa Pudji Setiawati, dr., MM	Public Health	FMUP
29	Dr. Arief Syamsulaksana K, dr., SpM(KVR)., MM., M.Kes	Ophtalmology	FMUP
30	Dr. Sutarya Enus., dr., SpM-K	Ophtalmology	FMUP
31	Dr. Ratna Anggraeni Agustian., dr., M.Kes., SpTHT-KL(K)	ENT	FMUP
32	Dr. Arto Yuwono Soeroto, dr., SpPD-KP	Internal Medicine	FMUP
33	Prof. Dr. H. M. Rachmat Soelaeman, dr., SpPD-KGH	Internal Medicine	FMUP
34	Dr. Anam, dr., SpS	Neurology	FMUP
35	Dr. Sadeli Masria, dr., DMM., MS., SpMK	Microbiology	FMUP
36	Herry Herman, dr., PhD., SpOT	Molecular Biology	FMUP
37	Bethy Suryawathy Hernowo, dr., SpPA(K), Ph.D	Pathology	FMUP
38	Prof. Dr. Ida Parwati, dr., SpPK-K, Ph.D	Clinical Pathology	FMUP
39	Dr. Ristianah D. Soetikno, dr., SpRad(K)., M.Kes	Radiology	FMUP
40	Dr. Setiawan Sutopo, dr., SpRad.	Radiology	FMUP
41	Dr. Ani Melani M., drg., M.Kes	Dentist	FMUP

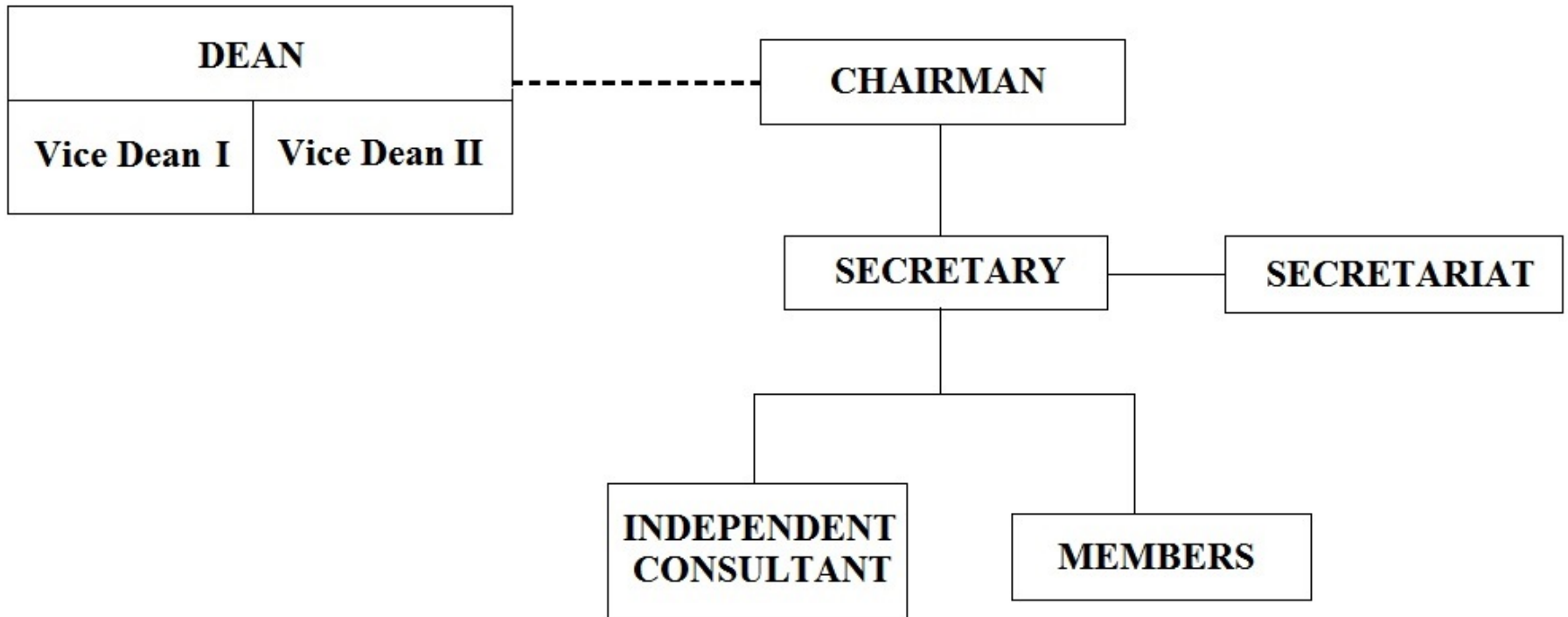
Appointment of Secretariat Staffs

- **Decree of Dean**
- **Employment status is integrated within the State University employment system**
 - **Statement of Confidentiality**

Secretariat

- **Head of Secretariat:**
 - **Ipur Purwatiningsih** (September, 2013)
- **Staffs:**
 - **Sita Purnadewi** (IT staff) (March, 2014)
 - **Lilik** (August, 2016)

Structure of Organization



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 Djuwantono

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

Secretariat

- 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

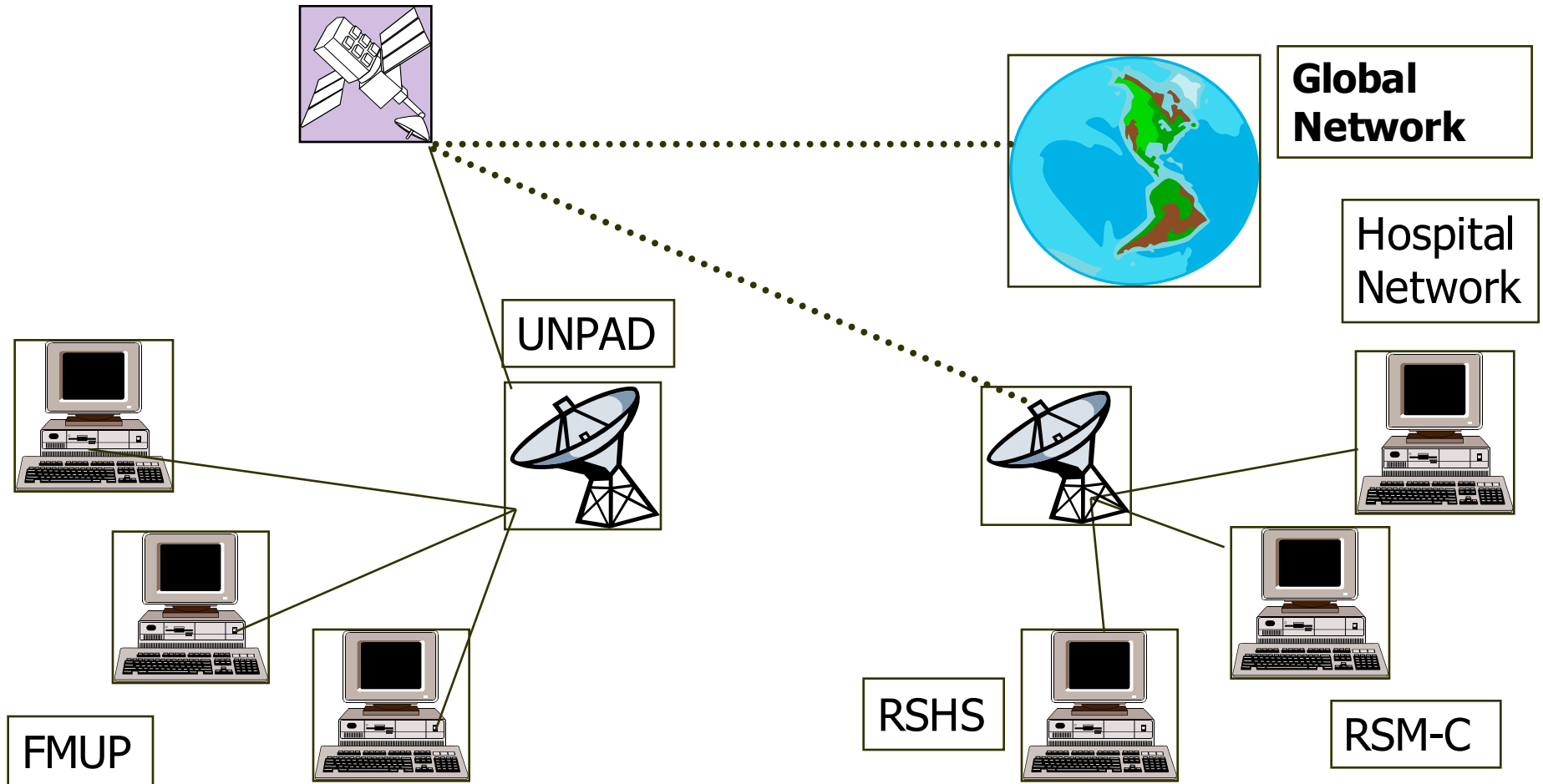
Information system (URL):

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

Sistem Informasi Komite Etik Penelitian Kesehatan
Fakultas Kedokteran UNPAD

Rabu, 08 Oktober 2014 | 13:23:57

Halaman Utama

REGISTRASI BARU

Log in

Nama Pengguna

Kata Sandi

Kalender

Oktober 2014

M	S	S	R	K	J	S
			1	2	3	4
5	6	7	8	9	10	11
12	13	14	15	16	17	18
19	20	21	22	23	24	25
26	27	28	29	30	31	

Petunjuk Untuk Peneliti

[Prosedur untuk Memperoleh Ethical Approval.docx](#) **HARUS DIBACA**
[Pedoman Pembuatan Lembar Informasi untuk Informed Consent.docx](#) **HARUS DIBACA**

Download Formulir Pengajuan Persetujuan Penelitian Kesehatan Versi BARU

[FORM ETIK NON UJI KLINIK.rar](#)
[FORM ETIK UJI KLINIK.rar](#)
[FORM ETIK UJI HEWAN.rar](#)

[Formulir Telaah Yang Diajukan Kembali \(setelah perbaikan protokol\) - Rev Juli 2014.doc](#)
[Formulir Telaah Amandemen Rev Juli 2014.doc](#)
[FORMULIR-PENGAJUAN-PERPANJANGAN.doc](#)
[Formulir-Laporan-KTD-SAE.doc](#)

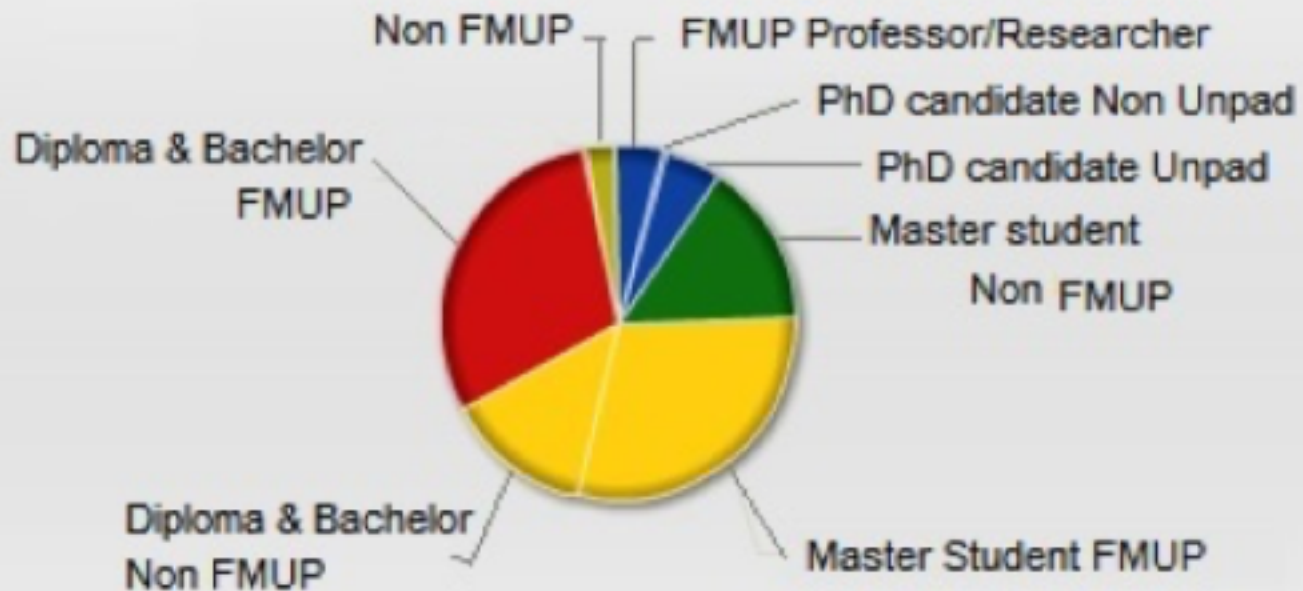
Daftar Judul Penelitian

Judul :

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Submission 2014

Based on Status of PI





THANK YOU