



KEMENTERIAN RISET, TEKNOLOGI, DAN PENDIDIKAN TINGGI  
UNIVERSITAS BRAWIJAYA  
FAKULTAS KEDOKTERAN  
PROGRAM MAGISTER ILMU BIOMEDIK

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## Teaching Plan

<b>Course Title</b>	<b>: Medical Ethics and Law</b>
<b>Course Code</b>	<b>: DKF6037</b>
<b>Credits</b>	<b>: 2</b>
<b>Course Coordinator</b>	<b>: Prof. Dr. dr. Teguh Wahyu Sardjono, DTMH, MSc, SpParK (TWS) (Phone: 0811364656; email: <a href="mailto:teguhws52@yahoo.com">teguhws52@yahoo.com</a>)</b>
<b>Course Contributors</b>	<b>: Prof. Dr. dr. Moh. Istiadjid ES. SpS, SpBS(K), M.Hum. (IST) Prof. Dr. Djoko Wahono Soeatmadji, SpPD, KE (DWS) Dr. dr. I Wayan Arsana Wiyasam SpOG(K) (IWR) Dr. dr. Krisni Subandiyah, SpA(K) (KRIS)</b>

### Course Description

At the end of the study in PMIB-FKUB, every student has to conduct at least one biomedical research for their thesis. In biomedical research, there are many legal, ethical, and social aspects and implications that actually should be considered, but mostly are still unknown or even being neglected by most of the researchers. Medical Ethics and Law is a discipline with many overlapping concepts. Each of them has its forum and authority; however it needs and is needed each other, especially in the rule and regulation to conduct biomedical research. For the time being, this course is still a selected one, but in future, it may become mandatory. The key objective is to understand the ethical, social, and legal aspects and implications in the medical professional and biomedical research.

The topics in Medical Ethics and Law will discuss the principles of medical ethics, the similarities and differences between ethics and law, the values of good-bad, right-wrong, health law, medical law, and rules and ethics in health and medical services, the philosophy of medical and health ethics, as well as the use of sophisticated tools in medical services. The topics will include the medical ethics and challenges in clinical practice, religion, ethics, law and human rights in obstetric service and research, ethics and law in health and medical research; ethics and law of research involving human subjects; ethics in writing and publishing scientific paper; ethical clearance in health research; ethics in pediatrics health services; ethics in research involving children, the legal relationships between doctors and patients, as well as medical malpractice and medical risks.

### Course Learning Outcomes

On successful completion of this course students will (be):		Bloom's Taxonomy
<b>CLO1</b>	Demonstrate a comprehensive understanding of the limitations and comparisons between the legal, ethical, moral ethics, good-bad, right-wrong, and ethical principles in the field of medicine; the guidelines and procedures for medical services in accordance with ethical conducts; philosophy of medical and health ethics; ethical problems using sophisticated tools in health care; ethical challenges in medical practice, especially in emergency conditions; ethical issues in health care to pregnant women related to religion and the law, including fetomaternal problems; ethics and law in health care to children; ethics and law in the doctor-patient relationship; as well as the essence and the differences between malpractice and risk of medical procedures.	Level 2. Understanding
<b>CLO2</b>	Able to apply ethics and law in health research, from basic research using cells (in vitro) to the research using animal models (in vivo); research using human subjects, including social and observational studies; ethics and procedures for writing scientific papers that meet the rules of conduct; the need of ethical clearance in health research as well as the requirements and procedures; as well as ethics and procedures for research on the subject of children.	Level 3. Applying
<b>CLO3</b>	Able to critically appraise the medical ethics and law journal articles relevant to student's interest and communicate it through oral presentation.	Level 5. Evaluating
<b>CLO4</b>	Internalize the ethical standards regarding the intellectual and professional activities in the field of health service, health care, and health research	Affective domain: Level 5. Characterization



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**Links between CLOs and PLOs**

	PLO1.1	PLO1.2	PLO2.1	PLO2.2	PLO2.3	PLO3.1	PLO3.2	PLO3.3	PLO3.4	PLO4
<b>CLO1</b>			√	√		√	√	√		
<b>CLO2</b>			√	√		√	√	√		√
<b>CLO3</b>			√			√	√			√
<b>CLO4</b>										√

**Topic and Schedule**

Week/Topics	Content	Competencies	Lecturer
I. Introduction to Medical Ethics and Law	<ul style="list-style-type: none"> <li>▪ The differences and similarities between law and ethics</li> <li>▪ The values of good-bad, right-wrong</li> <li>▪ The principles of medical ethics</li> </ul>	Able to explain: <ul style="list-style-type: none"> <li>▪ Ethics and moral in medical and health practice, basic principles of medical ethics</li> <li>▪ Ethics: 4 W and 1 H → social norms, ethics system, principles of ethics, urgency of ethics on health professionalism</li> <li>▪ Ethical problems</li> <li>▪ The differences of sanction in violence of ethics and law</li> </ul>	IST
II. Health Law, Medical Law, and Rules and Ethics in Health and Medical Service	<ul style="list-style-type: none"> <li>▪ Health law and medical law</li> <li>▪ The procedures and ethics in medical practices ad services</li> <li>▪ Informed consent in medical services</li> </ul>	Able to explain: <ul style="list-style-type: none"> <li>▪ The meaning of law, the kinds of law, health law, and medical law</li> <li>▪ The application and of the medical rules and ethics in daily practice</li> <li>▪ The kinds of medical aids and the role of informed consent in medical aid and health service</li> </ul>	IST
III. The Legal Relationships between Doctors and Patients, Medical Malpractice and Medical Risks	<ul style="list-style-type: none"> <li>▪ Pattern of legal doctor-patient relationship</li> <li>▪ Medical aid transaction</li> <li>▪ Legal, civil law and ethical responsibilities</li> <li>▪ Distinction between medical malpractice and medical risks</li> <li>▪ The true medical violence and ethicolegal</li> </ul>	Able to explain: <ul style="list-style-type: none"> <li>▪ Legal regulation of the physician–patient relationship</li> <li>▪ Legislative constraints and consent and capacity legislation</li> <li>▪ Rules of professional competence and conduct</li> <li>▪ The law–responsibilities of doctor, nurse, midwife, and hospital in doing health services</li> <li>▪ The meaning and kinds of malpractice and how to avoid and solve it</li> </ul>	IST
IV Deepening the Philosophy of Medical Ethics and Health	<ul style="list-style-type: none"> <li>▪ The philosophy of medical ethics and its development related to the culture and society</li> <li>▪ The changes ethical values in health and society</li> </ul>	Able to explain: <ul style="list-style-type: none"> <li>▪ Paradigms and personhood the dilemmas in ethics and medical ethics</li> <li>▪ The importance of values and culture in ethical decision-making</li> </ul>	DWH
V The Use of Sophisticated Tools in Medical Services	<ul style="list-style-type: none"> <li>▪ Ethical aspects of using sophisticated tools in medical services</li> <li>▪ Transfusion and Organ Transplantation</li> <li>▪ Cloning</li> <li>▪ Euthanasia</li> </ul>	Able to explain: <ul style="list-style-type: none"> <li>▪ The ethical aspects of doing medical profession relevance to the grow of medical technology</li> <li>▪ The rules of using sophisticated medical equipment, and application of modern medical technology and result of medical research</li> </ul>	DWH
VI Medical Ethics and Challenges in Clinical Practice	<ul style="list-style-type: none"> <li>▪ Ethical aspects in Professional clinical practice</li> <li>▪ Ethical aspects in emergency cases</li> </ul>	<ul style="list-style-type: none"> <li>▪ Students consider that sick persons ask physicians to help them get better</li> <li>▪ Physicians profess to be morally committed and technically competent to help the sick</li> </ul>	IWR
VII. Religion, Ethics, Law and Human Rights in	<ul style="list-style-type: none"> <li>▪ Subject is a woman</li> <li>▪ Fetus is a human life</li> <li>▪ The beginning and the end of life</li> <li>▪ Fetomaternal conflicts</li> </ul>	Students respect women’s right and obligation. Able to explain: <ul style="list-style-type: none"> <li>▪ When does a fetus become a person?</li> <li>▪ Does a fetus have rights?</li> </ul>	IWR



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Obstetric Service and Research	<ul style="list-style-type: none"> <li>▪ Patient's safety in Obstetric Gynecology</li> </ul>	<ul style="list-style-type: none"> <li>▪ Complication of pregnancy, abortion, family planning, infertility, well-born baby and well health mother.</li> </ul>
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VIII	MID-TERM EXAM / TOPIC EXAM	TEAM/related lecturer	
IX Ethics and Law in Health and Medical Research	<ul style="list-style-type: none"> <li>▪ What is a medical research</li> <li>▪ In vitro, ex-vivo, and in vivo studies</li> <li>▪ In vivo study using animal models</li> </ul>	Able to explain: <ul style="list-style-type: none"> <li>▪ The differences of in vivo and in-vitro research</li> <li>▪ The rules of using animal models in research</li> </ul> Able to apply: <ul style="list-style-type: none"> <li>▪ The ethical aspects of medical research</li> </ul>	TWS
X Ethics and Law of Research Involving Human Subjects	<ul style="list-style-type: none"> <li>▪ Research involving human subjects</li> <li>▪ The use vulnerable subjects</li> <li>▪ Observational and social studies</li> <li>▪ Clinical research,</li> </ul>	Able to apply: <ul style="list-style-type: none"> <li>▪ The obligation of subjects (Three Belmont's principles)</li> <li>▪ Right, roles, and responsibility of health researchers</li> <li>▪ The requirements and procedures and risks of clinical research</li> </ul>	TWS
XI Ethics in Writing and Publishing Scientific Paper	<ul style="list-style-type: none"> <li>▪ Writing ethical scientific paper</li> <li>▪ Ethics of publishing paper</li> <li>▪ Integrity of authors</li> <li>▪ Scientific misconducts</li> </ul>	Able to apply: <ul style="list-style-type: none"> <li>▪ The integrity of the researcher</li> <li>▪ The rules of writing and publishing scientific paper</li> <li>▪ Prevention of scientific misconducts and plagiarism</li> </ul>	TWS
XII. Ethical Clearance In Health Research	<ul style="list-style-type: none"> <li>▪ What Ethical Clearance</li> <li>▪ Informed consent in research</li> <li>▪ The kind of research that need ethical clearance</li> <li>▪ Ethical Research Committee</li> <li>▪ Manual procedure of EC</li> </ul>	Able to apply: <ul style="list-style-type: none"> <li>▪ The main ethical issues in research using human subjects</li> <li>▪ The importance of ethical clearance in medical research</li> </ul>	TWS
XIII. Ethics in Pediatrics Health Services	<ul style="list-style-type: none"> <li>▪ Children are special individuals</li> <li>▪ Children are not adult miniatures</li> <li>▪ Ethics and rules in pediatric services</li> </ul>	Able to explain: <ul style="list-style-type: none"> <li>▪ Professionalism in Pediatrics</li> <li>▪ Ethical problems in pediatrics</li> <li>▪ Ethics challenges of transition from pediatric to adult health care service</li> </ul>	KRIS
XIV. Ethics in Research Involving Children	<ul style="list-style-type: none"> <li>▪ Clinical observational study</li> <li>▪ Growth and development studies</li> <li>▪ Medical decision and medical treatment</li> </ul>	Able to apply: <ul style="list-style-type: none"> <li>▪ Ethical consideration in pediatric research</li> <li>▪ Ethical issues in neonatal and pediatric clinical trials</li> </ul>	KRIS
XV	Journal reading, critical appraisal, and oral presentation	Able to: <ul style="list-style-type: none"> <li>• Select and choose the journal that fulfills ethical requirements</li> <li>• Orally present scientific paper</li> <li>• Criticize the journal structure, the way of writing, and the ethical issues in health care and practice</li> </ul>	TEAM
XVI.	FINAL EXAM	TEAM/related lecturer	

**Teaching and Learning Strategy**

Core material will be delivered through lectures, completed with an oral presentation of journal reading and critical appraisal.



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### Assessment Methods

Type	Weighting	CLO Assessed	Description
Journal reading and critical appraisal and oral presentation	20%	1, 2, 3, 4	Journal reading and critical appraisal are basically for the students to read articles from recent journals, and then appraise them critically in written form. This assessment includes a 15 minutes presentation on the highlights of the journal followed by 10 minutes of discussion.
Written exam (mid)	30%	1, 2	The examination will be close book or open book exam with questions on theoretical and application aspects of the medical ethics and law.
Written exam (final)	50%	1, 2, 4	

### Learning Sources

<b>Essential reading/resources</b>	<ol style="list-style-type: none"><li>1. Brock LV and Mastroianni A. Ethics in Medicine – University of Washington</li><li>2. Declaration of Helsinki-Ethical Principles for Medical Research Involving Human Subjects (World Medical Association).</li><li>3. Good clinical practice (International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use – ICH).</li><li>4. International Guiding Principles for Biomedical Research Involving Animals (CIOMS).</li><li>5. Mason and McCall Smith's Law and Medical Ethics</li><li>6. Medical Law, Cases and Materials</li><li>7. National Guidelines for Health Research Ethics. National Health Research Ethics Commission, the Ministry of Health. Jakarta.</li><li>8. Principles of Biomedical Ethics</li><li>9. The Guide for the Care and Use of Laboratory Animals (National Research Council, National Academy of Sciences, 2010).</li></ol>
<b>Further reading/resources</b>	Related journals <ol style="list-style-type: none"><li>1. AMA Journal of Medical Ethics - JAMA group</li><li>2. American Journal of Law &amp; Medicine (AJLM)</li><li>3. Journal of Medical Ethics (JME) – BMJ group</li><li>4. Journal of Medical Law and Ethics (JMLE) – Paris Legal Publishers</li><li>5. <a href="#">Oxford Journals Medicine &amp; Health - BJA</a></li><li>6. The Journal of Law, Medicine &amp; Ethics (JLME)</li><li>7. Etc</li></ol>

**Course Coordinator,**

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