Bioethics and Safety

Module designation	Provides a deep understanding of ethics in medical and health services and research as well as an understanding of ethics related to laboratory animals in medical and health research.
Module level, if applicable	Master
Code	SPSTB212207
Subtitles, if applicable	-
Courses, if applicable	-
Semester(s) in which the module is taught	Odd semester
Person responsible for the module	Dr. drh. Agustina Dwi Wijayanti, M.P.
Lecturers	Dr. drh. Agustina Dwi Wijayanti, M.P. Prof. Dr. drh. Pudji Astuti, M.P. Dyah Listyarifah, MD, MSc.,D.Med.Sci
Language	Indonesian
Relation to curriculum	Compulsory course
Type of teaching, contact hours	This course is planned to have 14 teaching weeks and 2 weeks of examination. several types of teaching conducted: - Classic tutorial, - Case-study learning, - Discussion.

Workload	This course is planned to have 13 teaching weeks, 1 week lab visit, and 2 weeks of examination. Lectures = 3 SKS x 50 minutes x 15 meetings = 2250 minutes = 37.5 hours = 37.5 hours/25 hours =1.5 ECTS Case study = 3 SKS x 60 minutes x 1 meeting = 180 minutes = 3 hours = 3/25 hours = 0.12 ECTS Assigment = 3 SKS x 60 minutes x 16 meetings = 2880 minutes = 48 hours = 48 hours/ 25 hours =1.92 ECTS Self Study = 3 SKS x 60 minutes x 16 meetings = 2880 minutes = 48 hours = 48 hours/ 25 hours =1.92 ECTS Total workload = 5.46 ECTS
Credit points	3 SKS (5.46 ECTS)
Requirements according to the examination regulations	-
Recommended prerequisites	-
Module objectives/intended learning outcomes	PLO 1: Able to use knowledge in the fields of engineering, health, and biology to analyze problems in the field of biomedical engineering globally that are relevant to public needs. PLO 3: Able to test and analyze relevant design results in biomedical engineering field. PLO 6: Able to demonstrate professionalism and adhere to principles bioethics.

Content	1. Ethics in Health and Medical Treatment and Research 2. Professional Ethics in Biomedical Engineering 3. Beneficence, Nonmaleficence, and Technological Progress 4. Ethical Issues of Animal and Human Experimentation in the 5. Development of Medical Devices 6. Regulation of Medical Device Innovation 7. Nonhuman primate in biomedical research, ethical consideration. 8. The Role of Professional Societies in Biomedical Engineering 9. Issues related ethics in health and medical treatment 10. Issues related ethics in health and medical research 11. Issues related ethics in animal experimentation 12. Informed consent 13. Role of law in clinical ethics 14. Case based ethical analysis and safety simulations → practice developing research ethics protocols and conducting risk assessments
Study and examination requirements and forms of examination	Classes are conducted with 80% classic tutorial and 20% case study/project based presentation per meeting. Exams are done by written exam and/or task-based exam.
Media employed	PowerPoint, LMS (eLok, Google Classroom, etc.), and online meeting platform (Zoom, Gmeet, etc.)
Reading list	1. Sastrowijoto, S., Ismail D., Hakimi, M., Ngatidjan, Supartinah A., Kushadiwijaya H., Hadijah S., Widyarini S., 2008, Etika Penelitian dan Publikasi Kedokteran- Kesehatan dan Modul Pelatihan WHO, diedit oleh Indriati E., Yogyakarta: Fakultas kedokteran Universitas Gadjah Mada. 2. Abee CR., Mansfield K., Tardif S., Morris T., (editor), 2012. Nonhuman Primates in Biomedical Research, Vol. 1: Biology and Management, Elsevier, London.
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