DESCRIPTION OF COURSE UNIT FOR DOCTORAL STUDIES AT VILNIUS UNIVERSITY

Scientific Area/eas, Field/ds of Science	Medical and Health Sciences (M 000): Medicine (M 001); Dentistry (M 002); Public Health (M 004); Nursing (M 005)			
Faculty, Institute, Department/Clinic	Faculty of Medicine Institute of Health Sciences Centre for Health Ethics, Law and History			
Course unit title (ECTS credits, hours)	**Health Research Ethics** 9 credits (216 hours)			
Study method	**Lectures**	**Seminars**	**Consultations**	**Self-study**
Number of ECTS credits	0.5	-	0.5	8
Method of the assessment (in 10 point system)	The oral exam. PhD students have to answer 2 questions. Grading scale: 10 (Excellent): Excellent performance, outstanding knowledge and skills 9 (Very good): Strong performance, good knowledge and skills 8 (Good): Above the average performance, knowledge and skills 7 (Highly satisfactory): Average performance, knowledge and skills with unessential shortcomings 6 (Satisfactory): Below average performance, knowledge and skills with substantial shortcomings 5 (Sufficient): Knowledge and skills meet minimum criteria 4, 3, 2, 1 (Insufficient): Knowledge and skills do not meet minimum criteria/below minimum criteria			

PURPOSE OF THE COURSE UNIT

1. To introduce students to the history of health-related research, its problems and ethical requirements.
2. To provide information about the main national and international legal and ethical documents relevant to health-related research.
3. To develop an ability to critically evaluate acquired knowledge and apply it in analysing ethically problematic cases in practice.

MAIN TOPICS OF THE COURSE UNIT

1. **Historical developments of health research ethics.** Human experimentation that had impact on research ethics. The main international research ethics documents and guidelines. Ethical principles of health research ethics and ethical theories.
2. **The concept and types of health research.** Interventional and non interventional studies. Distinction between biomedical research, clinical practice and "experimental" treatment.
3. **Clinical trials design and its ethical implications.** Ethical issues related to randomisation, choice of control group, and blind/double blind research method. Concept of clinical equipoise. Ethical issues relevant to different phases of clinical trials. Ethical implications of the EU clinical trial Regulation.
4. **Risks and benefits of research**. Problem of acceptable risk and the balance between individual and societal benefits. Concept of "minimal risk". Ethical

issues in research with healthy volunteers. Compensation for research-related harms and reimbursment for possible risk and inconvenience.

5. **Informed consent.** Principle of informed consent and problems of its practical application. Therapeutic misconception. Conflicts of interests and their impact on voluntary participation in health research and understanding of health research related information.
6. **Modifications of informed consent and protection of privacy.** The use of biological materials and health data in research. Broad consent and other ethical issues related to biobanks. Health research using online environment and digital tools. Incomplete disclosure of research related information and deception of research participants in behavioral studies. Relevance of the General Data Protection Regulation in health research.
7. **Principle of justice and health research with vulnerable persons.** Concept of vulnerable individuals and groups. Health research with institutionalized persons and persons incapable of giving informed consent. Ethical issues in research involving participants with mental disorders and children. Ethical issues of health research conducted in developing countries.
8. **Ethical issues in genetic research and research with embryos**. "Reproductive" and "therapeutic" cloning. Ethical considerations of somatic and germline genome editing. Ethical and legal assessment of embryo and fetal research.
9. **Ethics review and regulation of health related research.** Principles of composition and functioning of health research ethics committees. The system of research ethics review in Lithuania. Ethical and legal regulation of health research in Lithuania: relevant legal documents and recommendations.

RECOMMENDED LITERATURE SOURSES

1. European Textbook on Ethics in Research. European Commission, 2010. Internet access: https://www.smi.mf.vu.lt/application/files/2316/4975/0114/European_Textbook_on_Ethics_in_Research-Lithuanian.pdf
2. International Ethical Guidelines for Biomedical Research Involving Human Subjects (CIOMS). 2016. https://cioms.ch/wp-content/uploads/2017/01/WEB-CIOMS-EthicalGuidelines.pdf
3. European Group on Ethics in Science and New Technologies. Ethics of genome editing. 2021. Internet access: https://ec.europa.eu/info/sites/default/files/research_and_innovation/ege/ege_ethics_of_genome_editing-opinion_publication.pdf
4. *Encyclopedia of Global Bioethics*, Springer Science+Business Media Dordrecht, 2015. Internet access: https://link.springer.com/referencework/10.1007/978-3-319-05544-2
5. Gefenas, E; Dranseika, V; Čekanauskaitė, A; Hug, K; Mezinska, S; Peičius, E; et al. Non-equivalent stringency of ethical review in the Baltic States: a sign of a systematic problem in Europe? *J Med Ethics*, 2010, p. 435-439. DOI: 10.1136/jme.2009.035030 https://jme.bmj.com/content/36/7/435
6. Johan PE Karlberg and Marjorie A Speers (eds.) (2010) Reviewing Clinical Trials: A Guide for the Ethics Committee. Ch. 2, pp. 29-58.
7. Lukaševičienė, V; Hasford, J; Lanzerath, D; Gefenas, E. Implementation of the EU clinical trial regulation transforms the ethics committee systems and endangers ethical standards. *J Med Ethics*. 2021, *47(12)*, e 82, p. [1-6]. DOI: 10.1136/medethics-2020-106757.
8. The Norwegian National Research Ethics Committees. A guide to internet research ethics. 2nd edition in English May 2019. Internet access: https://www.forskningsetikk.no/en/guidelines/social-sciences-humanities-law-and-theology/a-guide-to-internet-research-ethics/

9. Lekstutienė, Jūratė; Holm, Soren; Gefenas, Eugenijus. Biobanks and individual health related findings: from an obstacle to an incentive // Science and engineering ethics. Dordrecht : Springer. 2021, vol. 27, iss. 4, art. no. 55, p. [1-16]. DOI: 10.1007/s11948-021-00330-9. https://link.springer.com/article/10.1007/s11948-021-00330-9
10. Gefenas, E; Lekstutienė, J; Lukaševičienė, V; Hartlev, M; Mourby, M; Ó Cathaoir, K. Controversies between regulations of research ethics and protection of personal data: informed consent at a cross-road. Med Health Care and Philos 2022, 25(1), DOI: 10.1007/s11019-021-10060-1. https://link.springer.com/article/10.1007/s11019-021-10060-1#citeas
11. Utrecht University. Informed consent for data sharing. Internet access: https://www.uu.nl/en/research/research-data-management/guides/informed-consent-for-data-sharing

Legal documents and recommendations

12. World Medical Association. Declaration of Helsinki. 2013. https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/
13. Council of Europe. Additional protocol to the Convention on human rights and biomedicine, concerning biomedical research. 2005. https://rm.coe.int/168008371a
14. Biomedicininių tyrimų etikos įstatymas https://www.e-tar.lt/portal/lt/legalAct/TAR.234B15954C2F/asr
15. Lietuvos bioetikos komitetas. Biomedicininių tyrimų etikos sistema http://bioetika.sam.lt/index.php?1370518321

CONSULTING LECTURERS

1. Coordinating lecturer: Eugenijus Gefenas (Prof. Dr.).
2. Aistė Bartkienė (Dr.).
3. Asta Čekanauskaitė (Dr.).
4. Margarita Poškutė (Dr.).

APPROVED:

By Council of Doctoral School of Medicine and Health Sciences at Vilnius University: 29th of September 2022

Chairperson of the Board: Prof. Janina Tutkuvienė