



## COURSE UNIT (MODULE) DESCRIPTION

Course unit (module) title	Code
<b>INTERNATIONAL AND EUROPEAN MEDICAL LAW</b>	

Lecturer(s)	Department(s)
<b>Coordinator:</b> Dr Aleksandra Klich <b>Other(s):</b>	Vilnius University, Faculty of Law, Department of Public Law Sauletekio av. 9, Building 1, LT-10222, Vilnius, 405 room, phone (8 5) 2366175, e-mail: <a href="mailto:vtkatedra@tf.vu.lt">vtkatedra@tf.vu.lt</a>

Study cycle	Type of the course unit (module)
Second	Optional

Mode of delivery	Course unit delivery period	Language(s) of instruction
Blended	Spring semester	English

Requirements for students	
<b>Pre-requisites:</b> none	<b>Co-requisites (if any):</b> none

Number of credits allocated	Total student's workload	Contact hours	Self-study hours
5	133	32	101

Purpose of the course unit (module): programme competences to be developed		
<p>The aim of the course is to familiarize students with the basic principles and regulations of health care in the European Union and internationally. Students will develop knowledge of the universal principles of patient rights, the responsibilities of medical professionals, procedures related to claims, and legal requirements for clinical trials and the implementation of new technologies in medicine. During the course, students will analyze patients' right to access healthcare, protection of personal data, dignity and privacy, as well as the right to file complaints and seek compensation for medical errors; students will interpret and evaluate European and international regulations and case law that shape patients' rights and mechanisms for their protection.</p>		
Learning outcomes of the course unit (module)	Teaching and learning methods	Assessment methods
Students will understand the legal and historical basis for the formation of international and European medical law and the importance of organizations such as the WHO, ONZ and EU in shaping health regulations, as well they will be able to identify key pieces of related legislation and discuss their impact on health systems.	Lectures (problem-based teaching, group discussions, comparative assessment and systemic analysis of legal norms), individual studies (analysis of the relevant legal framework, policy and case-law, reading of academic literature)	Discussion questions, single-choice tests, research paper and its presentation
Students will be able to define the universal principles of patient rights and main legal acts related to patient rights (e.g., the Oviedo Convention, the European Charter on Patients' Rights and Directive 2011/24/EU), as well as to interpret and apply these regulations in the context of cross-border healthcare and medical data protection.	Lectures (problem-based teaching, group discussions, comparative assessment and systemic analysis of legal norms), practical sessions (group discussions, comparative assessment and systemic analysis of legal norms, simulations, case studies, presentations, flipped classroom), individual studies (analysis of the relevant legal framework, policy and case-law, reading of academic literature)	Discussion questions, single-choice tests, research paper and its presentation
Students will understand the principles of cross-border health care in the EU, including patients' rights to receive treatment in other member states. They will be able to identify violations of these rights, analyze the responsibility of medical professionals and health care institutions, and apply procedures related to claims arising from such violations.	Lectures (problem-based teaching, group discussions, comparative assessment and systemic analysis of legal norms), practical sessions (group discussions, comparative assessment and systemic analysis of legal norms, simulations, case studies, presentations, flipped classroom), individual studies (analysis of the relevant legal framework, policy and case-law, reading of academic literature)	Discussion questions, single-choice tests, research paper and its presentation

Students will comprehend the rules under the GDPR and other regulations on the protection of personal data in medicine and will be able to analyze medical data protection violations and prepare legal recommendations in this regard.	Lectures (problem-based teaching, group discussions, comparative assessment and systemic analysis of legal norms), practical sessions (group discussions, comparative assessment and systemic analysis of legal norms, simulations, case studies, presentations, flipped classroom), individual studies (analysis of the relevant legal framework, policy and case-law, reading of academic literature)	Discussion questions, single-choice tests, research paper and its presentation
Students will be able to explain clinical trial regulations (e.g., EU Regulation 536/2014) and to assess the legality and ethical compliance of a clinical trial and the application of new medical technologies such as telemedicine and artificial intelligence.	Lectures (problem-based teaching, group discussions, comparative assessment and systemic analysis of legal norms), practical sessions (group discussions, comparative assessment and systemic analysis of legal norms, simulations, case studies, presentations, flipped classroom), individual studies (analysis of the relevant legal framework, policy and case-law, reading of academic literature)	Discussion questions, single-choice tests, research paper and its presentation
Students will be able to apply the procedures for pursuing patient claims arising from violations of their rights, including medical errors and violations of the right to information, as well as to prepare legal arguments in patient's rights violation sample cases involving civil law claims and identify key evidence in such cases.	Lectures (problem-based teaching, group discussions, comparative assessment and systemic analysis of legal norms), practical sessions (group discussions, comparative assessment and systemic analysis of legal norms, case studies, presentations), individual studies (analysis of the relevant legal framework, policy and case-law, reading of academic literature)	Discussion questions, research paper and its presentation
Students will communicate orally and in writing contributing to the specialist discussion, providing their own insights and reasoning their opinions.	Lectures (problem-based teaching, group discussions, comparative assessment and systemic analysis of legal norms), practical sessions (group discussions, comparative assessment and systemic analysis of legal norms, case studies, presentations), individual studies (analysis of the relevant legal framework, policy and case-law, reading of academic literature)	Discussion questions, research paper and its presentation

Content: breakdown of the topics	Contact hours							Self-study: hours and assignments	
	Lectures	Consultations	Seminars	Practical sessions	Laboratory activities	Internship/work placement	Contact hours	Self-study hours	Assignments
<b>1. Introduction to international and European medical law</b> <ol style="list-style-type: none"> <li>Basic concepts and sources of medical law [Definition of medical law in the international and European context. Characteristics of the sources of law (Oviedo Convention, EU acts, GDPR)];</li> <li>International organizations and their impact on medical law [Role of WHO, Council of Europe, European Union and others];</li> <li>Principles of bioethics and their relevance in medical law.</li> </ol>	6						6	12	Preparation for discussion: how global regulations affect national health systems
<b>2. Patients' rights in international and European law</b> <ol style="list-style-type: none"> <li>Universal principles of patient rights [Discussion of the WHO Patient Rights Charter and EU guidelines];</li> <li>Protection of patients' privacy and medical data [GDPR and medical data protection in</li> </ol>	6			4			10	25	Case study: analysis of exemplary violations of patients' rights, preparation for practical workshop on availability of treatment for people

<p>practice];</p> <p>3. Access to health services and patient mobility in the EU [Directive 2011/24/EU on cross-border healthcare];</p> <p>4. Special rights of patients of vulnerable groups [Rights of children, elderly and people with disabilities];</p> <p>5. Patient's right to information and informed consent.</p>									<p>with rare diseases;</p> <p>Preparation for simulation: assessment of hospital compliance with data protection regulations;</p> <p>Preparation for discussion: Barriers to receiving health care outside the country of residence.</p>
<p><b>3. Medical liability in international and European law</b></p> <p>1. Types of medical liability [Civil, criminal, professional and administrative liability of medical professionals];</p> <p>2. Procedure in cases of liability for medical errors [Analysis of procedures for pursuing patient claims];</p> <p>3. Standards of diligence in the medical profession;</p> <p>4. Dispute resolution in medicine [mediation, arbitration].</p>	8			2			10	30	<p>Preparation for discussion and text analysis, preparation of a patient's complaint to a rights protection institution;</p> <p>Group work: analysis of documents setting medical standards;</p> <p>Preparation for discussion: differences in standards between countries;</p> <p>Preparation for simulation: negotiations between patient and hospital representative.</p>
<p><b>4. Contemporary challenges in medical law</b></p> <p>1. New technologies in medicine and the law [Legal issues related to AI, telemedicine and genetics];</p> <p>2. Pandemics and public health [Public health regulation in the context of the COVID-19 pandemic];</p> <p>3. Bioethics in the face of contemporary challenges [Ethical and legal aspects of euthanasia, abortion, medical experiments].</p>	4						4	14	<p>Preparation for discussion: How is technology changing the approach to liability in medicine?</p>
<p><b>5. Case study: judgments of the European Court of Human Rights</b></p> <p>1. Analysis of ECHR judgments in cases concerning the right to health and protection of life.</p>	2						2	20	<p>Preparation for discussion: implications of judgments for national legal systems.</p>
<b>Total</b>	<b>26</b>			<b>6</b>			<b>32</b>	<b>101</b>	

Assessment strategy	Weight, percentage	Assessment period	Assessment criteria
Participation in the class discussions	20	During semester	<p>Students will be expected to demonstrate both the knowledge gained during the course as well as their abilities to apply it in a given situation. Active participation in the discussions and in group work. The evaluation will be based on the following: the fact that the intervention of the student is to the point, the relevance of the arguments raised, and the fact that the arguments presented are logic, coherent and persuasive. Maximum evaluation: <b>2 points</b>.</p> <p>Participation in practical sessions is mandatory (at least 2 of 3 practical sessions). If more than 1 practical session is missed, the part of practical sessions missed exceeding the permitted limit is to be settled during time arranged with the lecturer. The form of settling the missed practical sessions depends on the on the topic covered during the missed practical</p>

			session.
Test	10	During semester	One-choice test (10 closed and open-ended questions) on topics discussed during lectures and practical sessions. (0.1 points x 10 questions = 1 point). Students will be asked to select the correct answer from three options offered as a list and/or students will be asked to insert the necessary word/phrase in a sentence. Maximum evaluation: <b>1 point</b> .
Research paper and presentation of it orally	70	June	The assessment of short research paper in written of an assigned topic and presentation of it orally consists of: <b>3 points</b> for paper content (capability to critically assess the issues, to identify the most significant features, tendencies and developments related to the particular topic, proper source application, critical analytical thinking, conclusion/recommendation formulation); <b>1 point</b> for paper structure and style (clear structural parts, scientific language style, exact wording, source references, proper and ethical citation use); <b>2 points</b> for paper oral presentation (concentrated work presentation, clear arguments in support of points made in a logical, coherent and structured manner, adhesive scientific language, the use of informative visual aids); <b>1 point</b> for efficient and active participation in discussion, answering to questions, contribution to other participants' ideas Maximum evaluation: <b>7 points</b> .

Author	Year of publication	Title	Issue of a periodical or volume of a publication	Publishing place and house or web link
<b>Compulsory reading</b>				
Hervey T. K., McHale J. V.	2015	European Union Health Law: Themes and Implications		Cambridge University Press
Kennedy I.	2011	Principles of Medical Law		Oxford University Press
Yimeng W.	2023	Opportunities and Challenges in Cross-border Healthcare: A case study on the court of Justice of the European Union	International Healthcare Review	
<b>Recommended reading</b>				
Montgomery J.	2016	Health Care Law		Oxford University Press
Hall M. A., Bobinski M. J.	2018	Health Care Law and Ethics		Aspen Publishers
Harrington J.	2019	Global Health and Human Rights: Legal and Political Perspectives		Routledge
Jackson E.	2009	Medical Law. Text, cases, and materials		Oxford University Press