GDAŃSK UNIVERSITY OF TECHNOLOGY

Subject card

Subject name and code	Legal and Ethical Aspects of Biomedical Engineering, PG_00068167		
Field of study	Biomedical Engineering, Biomedical Engineering, Biomedical Engineering		
Date of commencement of studies	October 2026	Academic year of realisation of subject	2026/2027
Education level	first-cycle studies	Subject group	Obligatory subject group in the field of study Humanistic-social subject group
Mode of study	Full-time studies	Mode of delivery	at the university
Year of study	1	Language of instruction	Polish
Semester of study	1	ECTS credits	1.0
Learning profile	general academic profile	Assessment form	assessment
Conducting unit	Department of Biomedical Engineering -> Faculty of Electronics Telecommunications and Informatics -> Faculties of Gdańsk University of Technology		
Name and surname of lecturer (lecturers)	Subject supervisor	dr Wojciech Zieliński	
	Teachers	dr Wojciech Zieliński dr Justyna Pawłowska-Bajerska dr inż. Adam Bujnowski	

Lesson types	Lesson type	Lecture	Tutorial	Laboratory	Project	Seminar	SUM
	Number of study hours	15.0	0.0	0.0	0.0	0.0	15
	E-learning hours included: 0.0						

Learning activity and number of study hours	Learning activity	Participation in didactic classes included in study plan	Participation in consultation hours	Self-study	SUM
	Number of study hours	15	2.0	8.0	25

Subject objectives	Introduction to ethical problems in medicine and in medical engineering; also to certification of medical products and instruments as well as with intellectual rights protection.

Learning outcomes

Course outcome	Subject outcome	Method of verification
[K6_W11] knows and understands, to an advanced extent, the general principles of setting up and development of business entities, forms of individual entrepreneurship and running ventures and the fundamental dilemmas of modern civilization and basic economic, legal and other conditions of various types of activities related to the field of study, including the basic concepts and principles in the field of industrial property and copyright protection	The student knows and understands the basic legal and ethical aspects of activities in the field of biomedical engineering, including the principles of intellectual property protection, and recognizes fundamental moral dilemmas associated with the development and application of biomedical technologies.	[SW2] Assessment of knowledge contained in presentation
[K6_K01] is ready to cultivate and disseminate models of proper behaviour in and outside the work environment; make independent decisions; critically evaluate actions of their own, teams they lead and organisations they are part of; take responsibility for results of these actions; responsibly perform professional roles, including:n - observing rules of professional ethics and require it from others,n - care for the achievements and traditions of the professionn	Adheres to the principles of professional ethics. Knows and understands the certification process of medical products.	[SK2] Assessment of progress of work
[K6_K03] is ready to meet social obligations, co-organise activities for the social environment, initiate actions for the public interest, think and act in an entrepreneurial way	It is ready to act in the public interest and to act in an entrepreneurial manner in the field of biomedical technologies.	[SK3] Assessment of ability to organize work

Subject contents

Course content – lecture

Basic concepts in ethics. Ethics in business, work, corruption etc.

Conflict situations in healthcare. Human rights and bioethics, problems in procreation and other.

Ethics in science; clinical trials; transplantology, genetics, cloning,

Ethics in management and healthcare.

Intellectual property rights and patent regulations.

Certification of medical products and instruments. Duties and rights of medical producers.

Accreditation and quality in medical engineering.

Prerequisites and co-requisites

Assessment methods and criteria

Subject passing criteria	Passing threshold	Percentage of the final grade
participation in lectures	75.0%	50.0%
competent test	75.0%	50.0%

Recommended reading

Basic literature	Digital material of the subject
Supplementary literature	Materials concerning certification of medical products

	eResources addresses	Basic https://www.unesco.org/en/legal-affairs/universal-declaration-bioethics-and-human-rights - UNESCO – Bioethics Declaration https://eli.gov.pl/eli/DU/2024/581/ - Act on Patient Rights and the Patient Ombudsman https://eur-lex.europa.eu/eli/reg/2017/745/oj/pol - EU Regulation 2017/745 (MDR) https://eur-lex.europa.eu/eli/reg/2016/679/oj?locale=PL - GDPR – EU Regulation 2016/679 Supplementary https://www.who.int/publications/i/item/9789240029200 - WHO – Ethics and Governance of Artificial Intelligence for Health (2021) https://eur-lex.europa.eu/legal-content/PL/TXT/?uri=CELEX:32024R1689 - EU Regulation 2024/1689 (AI Act) https://www.wipo.int/en/web/about-ip - resources of the World Intellectual Property Organization (WIPO)
Example issues/ example questions/ tasks being completed	1. What are the fundamental differences and relationships between law, morality, and ethics in the context of biomedical engineering? 2. What ethical dilemmas arise from the development and application of modern biomedical technologies? 3. What does respect for human dignity, patient autonomy, and patients' rights entail in medical practice and biomedical engineering? 4. What legal and ethical principles should govern scientific research and the design and implementation of medical devices? 5. What is the significance of intellectual property protection and professional responsibility in the work of a biomedical engineer?	
Practical activites within the subject	Not applicable	

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