Національний технічний університет України
«КИЇВСЬКИЙ ПОЛІТЕХНІЧНИЙ ІНСТИТУТ
імені ІГОРЯ СІКОРСЬКОГО»

Department of Translational Medical Bioengineering

Fundamentals of translational medicine, regenerative and biopharmaceutical engineering

Syllabus of the academic discipline (Syllabus)

Academic discipline requirements

Level of higher education	***First (bachelor's)***
Discipline	*16 Chemical and Bioengineering*
Specialty	*163 Biomedical Engineering*
Educational program	*Medical Engineering (Medical engineering)*
Discipline status	*Elective discipline*
Form of study	*Full-time (day)*
Year of training, semester	*4th year, fall semester*
Scope of the discipline	*4 ECTS credits (120 hours)*
Semester control/control measures	*Test / essay / modular test*
Class schedule	*26 hours – lectures , 28 hours – practical , 66 hours – independent work. According to schedule on the website : https://schedule.kpi.ua/*
Language of instruction	*Ukrainian*
Information about the course leader/teachers	**Lecturer:** *Candidate of Technical Sciences , Associate Professor Lutsenko Tetiana Mykolayivna, +380976830955 , lutsenko.tetiana@lll.kpi.ua* **Practical:** *Candidate of Technical Sciences, Associate Professor Lutsenko Tetiana Mykolayivna, +380976830955 , lutsenko.tetiana@lll.kpi.ua*
Teacher profile	**Lecturer / practical:** *https://bi.fbmi.kpi.ua/uk/lutsenkoua/*
Course placement	*Link to a remote resource on Google Classroom : https://classroom.google.com/u/1/c/Nzc1MjM0NjA1NDMy*

Academic discipline program

1. Description of the academic discipline, its purpose, subject of study and learning outcomes

What will be studied?

Fundamentals of translational medicine and its development in the world and in Ukraine. Main areas of regenerative research related to the cultivation of plant and animal cell cultures, the concept of stem cells and methods of working with them. Fundamentals of tissue engineering and methods of developing biomaterials . Regulatory aspects of the market circulation of biopharmaceutical products.

Why is this interesting/needs to be studied?

The discipline is interesting to study because today translational medicine is a new and rapidly developing stage in the development of medicine and bioengineering. It is a process that involves the transfer of theoretical developments into the sphere of practical application.

Why can you learn?

Upon mastering the educational component "Fundamentals of Translational Medicine, Regenerative and Biopharmaceutical Engineering", applicants receive:

From knowledge:

- fundamental and applied foundations of development and testing biomedical products (innovative biopharmaceuticals, biosimilars , bioimplants , medical devices for diagnostics *in vitro* , other medical devices of biological origin);
- methodology for conducting biomedical and technical and economic assessment of biomedical products technologies appointment;
- basic engineering techniques for designing new and improvement of existing technologies of medical bioproducts appointment;
- a highly specialized national and international regulatory framework on the creation, evaluation and use of bioproduct technologies medical purposes.

Skill:

- analyze methods for developing and testing bioproducts medical purposes from the standpoint of their therapeutic and diagnostic, pharmacoeconomic efficiency;
- apply international and national norms legislation for the creation, evaluation and use of technologies biomedical products ;
- independently design production areas specializing in the manufacture of biomedical products .

How can you use the acquired knowledge and skills?

The acquired knowledge and skills (in general, competencies) are a tool for the implementation of the following functions by biomedical engineering specialists:

- creation and testing of new or improvement of existing technologies of bioproducts for medical purposes (scientific research and engineering and technological activities);
- assessment of compliance of biomedical product technologies with national and international standards (regulatory and certification activities).

Program competencies that must be formed after studying the discipline and that correspond to the educational program "Medical Engineering":

Integral competence:

IC - The ability to solve complex specialized tasks and practical problems in biomedical engineering or in the process of learning, which involves the application of certain theories and methods of chemical, biological and medical engineering, and is characterized by the complexity and uncertainty of the conditions.

General competencies

GC 1 – Ability to apply knowledge in practical situations;
GC 2 – Knowledge and understanding of the subject area and understanding of professional activity;
GC 5 – Ability to conduct research at the appropriate level;
GC 8 – Ability to make informed decisions;
GC 11 – Ability to evaluate and ensure the quality of work performed.

Professional competencies

FC 3 – Ability to learn and apply new methods and tools for analysis, modeling, design , and optimization of medical devices and systems

FC 4 – Ability to provide technical and functional characteristics of systems and devices used in medicine and biology (in prevention, diagnostics, treatment and rehabilitation);

FC 5 – Ability to apply physical, chemical, biological and mathematical methods in the analysis and modeling of the functioning of living organisms and biotechnical systems;

FC 6 – Ability to effectively use tools and methods for analysis, design , calculation, and testing in the development of biomedical products and services;

FC 8 – Ability to conduct research and observations on the interaction of biological, natural and artificial systems (prostheses, artificial organs, etc.)

FC 9 – Ability to identify, formulate, and solve engineering problems related to the interaction between living and non-living systems;

FC 11 – Ability to develop, plan and conduct experiments according to given technical and biomedical methods, applying mathematical methods in analysis, modeling the functioning of living organisms, systems and processes in biology and medicine, computer processing, analysis and synthesis of the results obtained.

FC 12 – Ability to ensure and monitor compliance with safety and biomedical ethics when working with medical equipment.

Program learning outcomes that must be achieved after studying the discipline and that correspond to the educational program "Medical Engineering":

PRN 1 – Apply knowledge of the basics of mathematics, physics and biophysics, bioengineering, chemistry, engineering graphics, mechanics, resistance and strength of materials, properties of gases and liquids, electronics, computer science, acquisition and analysis of signals and images, automatic control, systems analysis and decision-making methods at the level necessary to solve biomedical engineering problems;

PRN 2 - Formulate logical conclusions and substantiated recommendations regarding the evaluation, operation and implementation of biotechnical , medical and bioengineering tools and methods;

PRN 3 – Manage complex activities or projects , be responsible for making engineering decisions in unpredictable conditions, conduct feasibility and safety assessments of projects ;

PRN 4 – Apply the provisions of regulatory and technical documents that regulate the procedure for product certification and production certification;

PRN 5 – Be able to use databases, mathematical and software for data processing and computer modeling of biotechnical systems ;

PRN 11 – To control the quality and operating conditions of medical equipment and medical materials, artificial organs and prostheses ;

PRN 19 – Mastery of engineering methods for calculating elements of medical devices and systems, modern methods for testing the experimental integrity and operability of biotechnical systems and determining their characteristics, methods for selecting classical and modern structural materials, as well as means of designing devices, devices and systems for medical and biological purposes;

PRN 20 – Knowledge and use of methods for researching biomedical engineering objects, methods and means of systematizing and processing experimental information, methods of statistical processing for modeling and simulation of processes and systems of physical and biological nature, modern programming technologies and tools that support their use, methods for designing digital and microprocessor systems for medical purposes;

PRN 21 – Understanding and using scientific and technical principles, methods and research methods, tools for the development, planning and design of experimental and cutting-edge research in the field of biomedical engineering objects using medical, biological, biomedical devices and biotechnical systems,

biomaterials for medical purposes, as well as for quantitative assessment of the functioning of physiological systems.

2. Prerequisites and postrequisites of the discipline (place in the structural and logical scheme of study according to the relevant educational program)

Knowledge of the basics of higher mathematics, anatomy, physiology, biochemistry, biophysics, basics of biomedical engineering, laboratory analytical techniques, medical statistics. The academic discipline belongs to the cycle of elective academic disciplines, therefore its normative (mandatory) connection with other disciplines is not provided for in the structural and logical scheme of training.

3. Content of the academic discipline

Lecture topics:

1. **Introduction to translational medicine** . Concept, structure, " bench-to-bedside " principles, role of engineering.
2. **Biomedical engineering as the basis of translational technologies** . Innovative medical technologies, biotools and diagnostic platforms.
3. **Molecular foundations of regenerative medicine** . Cell signaling pathways, growth factors, microenvironment .
4. **Stem cells and their clinical applications** . ESC, iPSC , mesenchymal cells, biosafety and ethical aspects.
5. **Tissue engineering: scaffolds, matrices , biomaterials** . Natural, synthetic and composite materials, biocompatibility .
6. **Bioreactors and bioprocesses in regenerative engineering** . Scaling, environmental control, 3D cultivation.
7. **3D bioprinting and additive technologies in medicine** . Principles, types of bioinks , applications.
8. **Biopharmaceutical engineering: general principles and trends** . Biological drugs, production methods, quality control.
9. **Genetic engineering and therapy** . **Immune technologies and cellular immune therapy** . CRISPR/ Cas , vectors, safety, modern clinical approaches, CAR-T, modified immune cells, antibodies.
10. **Biosensors and biodiagnostic platforms** . Optical, electrochemical sensors, POCT systems.
11. **Clinical trials and regulatory requirements** . FDA/EMA, GMP, GLP, stages and study design.
12. **Personalized medicine and bioinformatics** . Omics technologies, big data , electronic medical systems.
13. **Commercialization of biomedical technologies and startups** . Technology transfer, patenting, ways to enter the market.

Topics of practical classes:

1. Analysis of the " bench-to-bedside " translation chain . Analysis of real examples of the translation of scientific discoveries into clinical practice. Definition of the role of a biomedical engineer at different stages.

2. Engineering solutions in modern medical technologies . Analysis of innovative biomedical devices, diagnostic systems and bioinstruments (case study).

3. Modeling cell signaling pathways in regenerative medicine . Working with schemes of signaling cascades, growth factors, and cellular microenvironment .

4. Comparative analysis of stem cell types . ESC, iPSC , MSC: properties, sources, risks, clinical prospects and ethical aspects.

5. Selection and evaluation of biomaterials for tissue engineering . Assessment of biocompatibility , mechanical and biological properties of natural and synthetic matrices .

6. Design bioreactors for cell and tissue cultures . Fundamentals of bioreactor design , control of cultivation parameters, scaling of processes.

7. Practical aspects of 3D bioprinting . Analysis of types of bioinks , bioprinting methods and their application in the creation of tissue constructs.

8. Fundamentals of biopharmaceutical production . Analysis of the technological chain of creating biological drugs: from cell line to finished product.

9. Quality control of biopharmaceutical products . Introduction to methods of analytical control, validation and ensuring the stability of drugs.

10. Genetic and Cellular Engineering: Practical Cases . Analysis of the application of CRISPR/ Cas , viral vectors, CAR-T, and immune cells in therapy.

11. Design biosensors and POCT systems (Point-of-Care Testing) . Principles of operation of optical and electrochemical sensors, examples of biodiagnostic platforms.

12. Clinical trial design and regulatory requirements . Modeling the stages of clinical trials, familiarization with FDA/EMA, GMP, GLP requirements.

13. Personalized medicine and biomedical data analysis . Fundamentals of omics data, bioinformatics and the use of big data in medicine.

14. Commercialization and startup projects in biomedical engineering . Development of the concept of biomedical startup : from idea to market, patenting and technology transfer.

4. Educational materials and resources

Basic literature:

1. Pirog T.P., Penchuk Y.M. Biochemical foundations of microbial synthesis. – K.: Lira-K, 2019. – 304 p.
2. Okafor N. Modern Industrial Microbiology and Biotechnology , 2017
3. McNeil V., Harvey LM Practical Fermentation Technology , 2008 .
4. Sidorov Y.I. Processes and apparatuses of the microbiological and pharmaceutical industry: a textbook. / Y.I.Sydorov , R.Y. Vlyazlo . V.P.Novikov . – Lviv: Intellect-West, 2008. – 736 p.
5. of medicines: a textbook for students of higher education : in 2 parts / V.I. Chuyeshov , E.V. Gladukh , I.V. Saiko and others - 2nd ed., revised and supplemented - Kh.: NFAU. - 2 parts - 638 p .
6. Pharmaceutical development of biotechnological and biological products. ST-N MOZU 42-8.1:2013. – Kyiv, 2013. – 20 p.
7. Adithan C. Principles of translational science in medicine : From bench this bedside , 2nd edition . Indian J Med Res . 2017;145(3):408-409. doi:10.4103/0971-5916.211685
8. Atala , Anthony and al ., eds . Principles of Regenerative Medicine . Third edition . London , United Kingdom : Academic Press , an imprint of Elsevier , 2019.
9. Lanza R., Atala A. Essentials of Stem Cell Biology . Academic Press , 4th ed ., 2013.
10. Mallick KK, Cox SC. Biomaterial scaffolding for tissue engineering . Front Biosci (Elite) Ed). 2013 Jan 1;5(1):341-60.
11. Biopharmaceuticals : biochemistry and biotechnology . G Walsh . John Wiley & Sons , 2026. 472, 2026
12. Doudna JA, Charpentier E. The new frontier of genome engineering with CRISPR-Cas9. Science , 2014.
13. June CH, O'Connor RS, Kawalekar OU CAR T cells immunotherapy for human cancer . Science , 2018.

14. Mehrotra P. Biosensors and their applications – A review . Journal of Oral Biology and Craniofacial Research , 2016.

15. Vashist SK et al . Point-of-care diagnostics : recent advances . Biosensors and Bioelectronics , 2015.

16. Groll J, Boland T, Blunk T, Burdick JA, Cho DW, Dalton PD, Derby B, Forgacs G, Li Q, Mironov VA, Moroni L, Nakamura M, Shu W, Takeuchi S, Vozzi G, Woodfield TB, Xu T, Yoo JJ, Malda J. Biofabrication : reappraising the definition of an evolving field . Biofabrication . 2016 Jan 8;8(1)

17. Regulation (EC) No. 1394/2007 of the European parliament and of the council of 13 November

2007 advanced therapy medicinal products and amending Directive 2001/83/EC and Regulation (EC) No. 726/2004. Available at : http://ec.europa.eu/health/sites/health/files/files/eudralex/vol1/reg_2007_1394/reg_2007_1394_en.pdf

18. Biotechnology: Textbook / V.G. Gerasimenko, M.O. Gerasimenko, M.I. Tsvilikhovsky and others; Edited by V.G. Gerasimenko. — K.: «INKOS», 2006. — 647 p.

19. Pharmaceutical Encyclopedia / Chairman of the Editorial Board and author of the foreword V.P. Chernykh . – 3rd ed. – K.: "MORION", 2016. – 1952 p.

20. Pharmaceutical and medical-biological aspects of drugs. Textbook / Edited by I.M. Pertsev . - Second edition. - Vinnytsia: NOVA KNYGA, 2007. - 728 p.

21. Cheng , C.W., Solorio , L.D., and Alsberg , E. (2014) Decellularized tissue and cell-derived extracellular matrices as scaffolding for orthopedic tissue engineering . Biotechnol . Adv ., 32 (2), 462–484.

22. Bajaj , P., Schweller , RM, Khademhosseini , A., West , JL, and Bashir , R. (2014) 3D biofabrication strategies for tissue engineering and regenerative medicine Ann . Rev. Biomed . Eng ., 16 (1), 247–276.

23. Janicki S., Sznitowska M., Zielinski W. Dostepnosc pharmaceutical and accessibility biology Lekow . - Warsaw , 2001.-242 p.

24. Biopharmaceuticals : Biochemistry and Biotechnology , 2nd Edition . - 2013. - 544

25. Encyclopedia of pharmaceutical technology . Third Edition . / Edited by J. Swarbick . – New York , London : Informa healthcare , 2007 - 1171

26. Guideline on immunogenicity assessment of biotechnology-derived therapeutic proteins , EMEA/CHMP/BMWP/14327/2006.

27. Rothaermel FT Strategic Management of Technology and Innovation . McGraw-Hill , 5th ed., 2017.

Additional literature:

28. Dincer , Z, Jones S, and R Haworth . 2006. " Preclinical safety assessment of a DNA vaccine using particle-mediated epidermal delivery in domestic pig , minipig and mouse ." Experimental and Toxicology Pathology 57 (5):351–357.

29. Cavagnaro , Joy & Cosenza , Mary . (2021). Translational Medicine : Optimizing Preclinical Safety Evaluation of Biopharmaceuticals . 10.1201/9781003124542.

30. Cauvin A, Peters C, Brennan FR. Advantages and limitations of usually used nonhuman primate species in research and development of biopharmaceuticals . In : Bluemel J, Korte S, Schenck E, Weinbauer G, editors . *The Non-Human Primate in Nonclinical Drug Development and Safety Assessment* . Academic Press . Elsevier , 125 London Wall , London , EC2Y 5AS, UK; 2015. Chapter 19; pp . 379–95.

31. FDA. Guidance for industry : Non-clinical safety evaluation of pediatric drug products . 2006; Available at : http:// www.fda.gov/downloads/Drugs/GuidanceCompliance RegulatoryInformation / Guidances /ucm079247.pdf

32. EMEA.Guideline on the need for non-clinical testing in juvenile animals of pharmaceuticals for pediatric indica-tions . 2008; Available at : http://www.ema.europa.eu/docs/en_GB/ document_library / Scientific _ guideline / 2009/09/WC500003305.pdf

33. EMEA.Guideline on strategies this identify and mitigate risks for first-in-human clinical trials with investigative medicinal products . 2007; Available at : http://www.ema.europa.eu/docs/en_ GB/ document _ library / Scientific _ guideline /2009/09/WC500002988.pdf

34. EMA.Guideline on strategies this identify and mitigate risks for first-in-human and early clinical trials with investigative medicinal products . 2017; Available at : https://www.ema.europa.eu/en/documents/scientific-guideline/guide-line-strategies-identify-mitigate-risks-first-human-early-clinical-trials-investigative_en.pdf

Educational content

5. Methodology for mastering the academic discipline (educational component)

Lectures are held according to the classic scheme: in a visual form, the lecturer presents the relevant topic. During the lecture and after it, applicants have the opportunity to ask questions. A discussion between the lecturer and applicants can be held on individual issues of the lecture course - or to focus on important, fundamental and problematic points. Applicants can take notes during the lectures, and the presentation and/or lecture notes or its fragments are presented with the possibility of downloading on the Sikorsky distance learning platform.

Practical classes are aimed at acquiring deeper knowledge and skills on topics covered in the lecture course and independently mastered by applicants. The algorithm for conducting a practical class provides for the following: the teacher presents basic (strategic) theses within the framework of the relevant topic, applicants present mini-reports with pre-formed problem questions within the framework of the relevant topic, a discussion takes place between the speaker, other applicants and the teacher, which aims to clarify all the fundamental and applied issues of obtaining biomedical products using microbial synthesis. Applicants' reports involve the preparation of a corresponding analytical note in the form of a small review of literature in Ukrainian, as well as a visual presentation, which allows you to deepen your skills in written and oral scientific Ukrainian. If necessary, during practical classes, regulatory documents, methodological recommendations, etc., are studied (familiarized), as well as solving situational problems. At the last practical session, candidates complete a modular test (MCR) in the form of a test. Material that is useful for preparing for practical sessions is provided with the possibility of downloading on the Sikorsky distance learning platform.

Lectures and practical classes are held according to the schedule of classes http://rozklad.kpi.ua/ according to the following scheme: on each topic, lectures are held first, and after their completion - practical classes. Detailed information is provided to applicants through appropriate communication channels, in particular through the platforms "Sikorsky" and " Campus ".

No. of the company	*Topic*	*Program learning outcomes*	*Main tasks*	
			Control West	*Term implementation*
1.	*Introduction to translational medicine. Concept, structure, bench-to-bedside principles , role of engineering*	*PRN -01, PRN-21*	*Practical work 1*	*1st week*
2.	*Biomedical engineering as the basis of*	*PRN -01, PRN-*	*Practical work 2*	*2nd week*

No. of the company	Topic	Program learning outcomes	Main tasks	
			Control West	Term implementation
	translational technologies. Innovative medical technologies, biotools and diagnostic platforms.	19		
3.	Molecular foundations of regenerative medicine. Cell signaling pathways, growth factors, microenvironment .	PRN -01, PRN-02	Practical work 3	3rd week
4.	Stem cells and their clinical applications. ESC, iPSC , mesenchymal cells, biosafety and ethical aspects.	PRN-01, PRN-02, PRN-20	Practical work 4	4th week day
5.	Tissue engineering: scaffolds, matrices , biomaterials . Natural, synthetic and composite materials, biocompatibility .	PRN -01, PRN-03	Practical work 5	Week 5
6.	Bioreactors and bioprocesses in regenerative engineering. Scaling, environmental control, 3D cultivation.	PRN -02, PRN-05	Practical work 6	Week 6
7.	3D bioprinting and additive technologies in medicine. Principles, types of bioinks , applications.	PRN -05, PRN-20	Practical work 7	Week 7
8.	Biopharmaceutical engineering: general principles and trends. Biological drugs, production methods, quality control.	PRN -01, PRN-02	Practical work 8	Week 8
9.	Genetic engineering and therapy. Immune technologies and cellular immune therapy. CRISPR/ Cas , vectors, safety, modern clinical approaches, CAR-T, modified immune cells, antibodies.	PRN -02, PRN-11	Practical work 9	Week 9
10.	Biosensors and biodiagnostic platforms. Optical, electrochemical sensors, POCT systems.	PRN -02, PRN-11	Practical work 10	Week 10
11.	Clinical trials and regulatory requirements. FDA/EMA, GMP, GLP, phases and study design.	PRN-11, PRN-20	Practical work 11	Week 11
12.	Personalized medicine and bioinformatics . Omics technologies, big data , electronic medical systems.	PRN-04, PRN-11, PRN-20	Practical work 12	12th week
13.	Commercialization of biomedical technologies and startups . Technology transfer, patenting, ways to enter the market.	PRN-01, PRN-02, PRN-20	Practical work 13	Week 13
14.	Modular test work		Practical work 14	
15.	Abstract	PRN-02 PRN-05 PRN-18	Designing and sending work	Week 14

6. Independent work of the applicant

The total amount of independent work within the discipline is 66 hours, including:

- Studying lecture material – 7 hours;
- preparation for practical classes – 13 hours;
- preparation for the modular test (MCR) – 4 hours;
- writing an essay – 10 hours;
- preparation for the test – 6 hours;
- independent study of topics – 26 hours.

No. salary	the topics and issues that is taken out on its own processing and reference to the educational literature	Number hours of SRS
1	**Topic 1. The history of translational medicine: key cases of successful translations** ***List of questions for independent study:*** Analysis of examples of the transition of fundamental discoveries into clinical practice (vaccines, monoclonal antibodies, cell products). Success factors and typical barriers to translation. [7, 8 , 12].	**4**
2	**Topic 2. The role of academic, clinical, and industrial partnerships in translational medicine.** ***List of issues submitted for independent study:*** Models of interaction between universities, hospitals and biotechnology companies. Consortia, translational hubs , examples from the EU and Ukraine. [7, 29].	**6**
3	**Topic 3. Ethical , social and legal challenges regenerative and biopharmaceutical engineering .** ***List of issues submitted for independent study:*** Bioethics of cell and tissue technologies, accessibility of innovative therapies, informed consent, public perception of new medical technologies. [9, 10, 21, 30].	**8**
4	**Topic 4. Preclinical models in translational and regenerative medicine.** ***List of questions submitted for independent study:*** *In in vitro* and *in In vivo* models, organoids, organ-on-chip as alternatives to animal models. Their role in preclinical safety and efficacy assessment. [9, 21].	**4**
5	**Topic 5. Broadcasting aspects production cellular and tissue products .** ***List questions What is taken out on its own processing :*** Features of the transition from a laboratory protocol to a standardized product: reproducibility , stability , control of critical parameters process . [10, 30].	**2**
6	**Topic 6. Regulatory environment for regenerative and biopharmaceutical products in Ukraine.** ***List of issues submitted for independent consideration:*** National regulatory authorities, harmonization with EU requirements, prospects for ATMP implementation, challenges and opportunities for Ukrainian developers. [17, 26, 31, 32, 33, 34].	**2**
Total		26

Policy and control

7. Academic discipline policy (educational component)

Violation of task deadlines and incentive points

Applicants may be awarded incentive points. The total amount of incentive points cannot exceed 10 points.

Incentive points are awarded for the following activities:

- participation in international or all-Ukrainian scientific conferences, congresses, etc. (on the subject of the academic discipline) (subject to publication of abstracts of reports) (5 points);
- preparation of a manuscript of a review or experimental article or participation in competitions (subject to taking a prize place) on the topic of the academic discipline (10 points).

Attending classes

No penalty points are awarded for absence from classes. However, applicants are encouraged to attend classes, as they teach theoretical material and develop practical skills necessary for the thorough formation of relevant competencies .

The assessment system is focused on receiving points for student activity, as well as completing tasks that can develop practical skills and abilities.

Missed assessment controls

Assessment tests scheduled to be administered during class are conducted on a pre-determined day, which is announced to students during the first week of the educational process. Conducting such assessment tests on another day is permitted in case of serious and/or force majeure circumstances.

In the event of the applicant's absence from a practical session where he is expected to give a presentation, such a presentation is either postponed to another practical session or replaced by the preparation of an analytical note on the relevant topic of 5-10 pages (in the case of special force majeure circumstances).

The result of the module test for an applicant who did not appear for the test is zero. In this case, the applicant has the opportunity to complete the module test at another time in agreement with the teacher. Postponement of the test date is possible only for good reasons (force majeure circumstances).

Re-testing is not provided within the framework of the modular test.

Ensuring objectivity in assessing applicants

The objectivity of the assessment of applicants at all stages of mastering the discipline is ensured through the following mechanisms. First, the use of test forms for assessing knowledge. Second, detailed recommendations on the rating system for assessing learning outcomes (Section 8 of the Syllabus). Third, the use by applicants and teachers of all possible communication tools that ensure the preservation of the history of communications (e-mail, social networks, messengers , etc.). Fourth, in case of disagreement with the assessment results, another teacher who has the appropriate professional competence and is appointed by the department for the current academic year may be involved in checking the written works of applicants. In the absence of a coordinated opinion of the teachers on the assessment of the applicant's work, the issue is brought to a meeting of the department, and the issue is resolved in accordance with the "Regulations on Appeals at Igor Sikorsky Kyiv Polytechnic Institute" http://osvita.kpi.ua/node/182 .

Procedure for appealing the results of assessment control measures

On the day of the announcement of the results of the control measure, the applicant has the right to individually ask all the questions that interest him regarding the results of the control measure. If the applicant does not agree with the assessment, he has the right to appeal to the dean's office of the faculty, which is regulated by the "Regulations on Appeals at Igor Sikorsky Kyiv Polytechnic Institute" https://osvita.kpi.ua/node/182. In order to ensure the objectivity of the assessment of written works, they are checked by two teachers of the department (lecturer; teacher conducting practical classes, or another teacher who is competent in this discipline and determined by the department).

Academic integrity

When using copyrighted content, analytical research results, and/or other information, applicants must cite the source.

The policy and principles of academic integrity are defined in Section 3 of the Code of Honor of the National Technical University of Ukraine "Igor Sikorsky Kyiv Polytechnic Institute" (https://kpi.ua/code). In the event of a need to check academic texts prepared for applicants for the presence of text borrowings, the applicant may contact the teacher or the responsible person of the department for checking academic texts.

Norms of ethical behavior

The norms of ethical behavior of applicants and employees are defined in Section 2 of the Code of Honor of the National Technical University of Ukraine "Igor Sikorsky Kyiv Polytechnic Institute" (https://kpi.ua/code).

Distance learning

Online courses are provided in case of force majeure circumstances (in particular, quarantine measures) and for inclusive education of applicants with special needs.

Inclusive learning

The academic discipline is designed for students with special educational needs, but it should be taken into account that it places a heavy load on the visual apparatus. Depending on the special needs of students, distance learning may be used.

8. Types of control and rating system for assessing learning outcomes (RSO)

Current control . Current control includes work in lectures, practical and laboratory classes, completion of an individual assignment (abstract), as well as writing a modular test. The detailed distribution of points between types of classes is given in the table below.

No.	Control measure	%	Weighted score	Number	Total
1	Performing practical work	40	5	8	40
2	Abstract	40	40	1	40
3	Modular test work (MKR)	20	20	1	20
Total					**100**

- *1. Work in practical classes.*

The maximum amount for work in practical classes is 40 points. There are 8 practical tasks to complete. Each task is rated at a maximum of 5 points: a complete and exhaustive answer – 5 points, a minor error – 4 points, a minor error and an incomplete answer – 3 points, a major error – 2 points, and no answer – 0 points.

- *2. Abstract.*

The maximum amount for an essay is 40 points (20 points for the essay and 20 points for the defense of the essay, +10 points (additionally) for publishing an article on the topic of the essay): full and exhaustive disclosure of the topic – 20 points, minor errors in the disclosure of the topic – 15 points, minor errors and incomplete disclosure of the topic – 10 points, major errors and an undisclosed topic – 5 points, lack of an essay – 0 points.

- *3. Modular test work.*

The maximum amount for completing the MCR is 20 points. The MCR consists of 40 test tasks. Each answer is evaluated at a maximum of 0.5 points : a complete and exhaustive answer - 0.5 points, a minor error - 0.375 points , a minor error and incomplete answer - 0.25 points , a major error - 0.125 points , no answer - 0 points.

The evaluation criteria for each test must be announced to students.
before publishing and completing tasks.

Calendar control .
Calendar control is carried out twice a semester (weeks 7-8 and 14-15) as a monitoring of the current status of implementation of the requirements of the syllabus and the rating assessment system.

		First calendar control	**Second calendar control**
Calendar control period		**7-8 weeks**	**14-15 weeks**
Conditions for obtaining a calendar check	Current control	≥ 50% of maximum current rating	
	Lecture work	2	3
	Performing practical work	15	30
	Abstract	-	7
	MKR	-	-
Maximum current rating		**22**	**40**

Semester control: credit. The conditions for admission to semester control are given in the table.

Mandatory condition for admission to the test		
1	Current rating	RD ≥ 40
2	Current control measure	Modular test work
3	Practical classes	Performing practical tasks
4	Abstract	Execution and defense of the abstract

At the last scheduled class, students are informed of their current rating, indicating whether they are allowed/not allowed to take the test. If the semester rating is 60 points or higher, the applicant can receive the test automatically. In case of disagreement or a rating of less than 60 points, the test is taken in the form of a test.

Table of correspondence of rating points to grades on the university scale :

Number of points	*Rating*
100-95	Perfectly
94-85	Very good
84-75	Good
74-65	Satisfactorily
64-60	Enough
<60	Unsatisfactorily
Admission conditions not met	Not allowed

9. Additional information on the discipline (educational component)

The questions submitted for semester control correspond to the topics of lectures and practical classes.

Recognition of learning outcomes acquired in non-formal/ informal education is carried out in accordance with the “Temporary Regulation on the Procedure for Recognition of Learning Outcomes Acquired by Students of Igor Sikorsky Kyiv Polytechnic Institute in Non-formal/ Informal Education” (https://osvita.kpi.ua/node/119).

The working program of the academic discipline (syllabus):

Compiled by: Ph.D. , Assoc. Lutsenko T.M.

Approved by the TMBI Department (Minutes No. 1 dated 08/28/2023)

Approved by the methodological committee of the faculty/NII (minutes No. 1 dated 09/1/2023)