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| **Донецький національний медичний університет** | **MINISTRY OF HEALTH OF UKRAINE****Donetsk National Medical University****international medical faculty****Department of Psychiatry, Psychotherapy, Addiction and Medical Psychology** |
|  **FUNDAMENTALS OF BIOETHICS AND BIOSECURITY** **SYLLABUS** |
| Health care 22 | «Field of study» |
| Specialty 221 | «Dentisty» |
| Educational program | «Medicine» |
| Educational level | the second (master's) level of higher education |
| Discipline status | normative |
| Developers | Putyatin GG - Associate Professor, Ph.D., Head of the Department of Psychiatry, Psychotherapy, Narcology and Medical Psychology;Osokina OI - Professor, Dr. Med. Sciences, Professor of Psychiatry, Psychotherapy, Addiction and Medical Psychology;Yashchishina Yu.M. - Associate Professor, Ph.D., Associate Professor of Psychiatry, Psychotherapy, Addiction and Medical Psychology;Kabantseva AV - Associate Professor, Candidate of Psychology, Psychiatry, Psychotherapy, Addiction and Medical Psychology; |
| Approval | by the decision of the department, protocol № 3 from 12.10.2021methodical commission on disciplines, protocol № 3 from 05.11.2021Academic Council of the Faculty, protocol № from |
| Sighting | Head of the department \_\_\_\_\_\_\_\_\_\_\_\_\_ G.G. Putyatin Guarantor OP \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_V.G. TsentiloDean of the Faculty\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_S.I. Prisyazhna |

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**INTRODUCTION**

***The syllabus*** is a curriculum for the discipline, which is a "map" for the applicant, which presents the annotation, purpose (expected competencies), course content, recommendations for independent work and evaluation of results (current and final control), etc.

***A syllabus is*** a "contract" that contains a course policy that provides for the mutual responsibility of the student and the teacher, based on the principles of academic integrity, transparency and mutual respect in the student-teacher relationship.

Indicators of readiness for successful professional activity are the c***ompetencies*** acquired in the learning process, which consist of knowledge, skills and practical skills, ways of thinking, professional, ideological and civic qualities, moral and ethical values ​​of the future doctor.

**Information about teachers of the discipline " fundamentals of bioethics and biosecurity"**

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| **Teachers of the discipline Information** | **Information** |
| **Putyatin Gennady Gennadievich**  | Associate Professor, Candidate of Medical Sciences, Head of the Department of Psychiatry, Psychotherapy, Narcology and Medical Psychology.Email: [putyatin.g@gmail.com](putyatin.g%40gmail.com)Eye consultations: - Wednesday and Friday from 14:00 to 15:00Online consultation by prior arrangement with GoogleMeet on weekdays from 9.00 to 15.30 |
|  **Osokina Olga Ihorivna**  | Professor, Doctor of Medical Sciences, Professor of the Department of Psychiatry, Psychotherapy, Narcology and Medical Psychology.Email: [oosokina@ukr.net](oosokina%40ukr.net)Eye consultations:Online consultation by prior arrangement with GoogleMeet on weekdays from 9.00 to 15.30 |
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| **Kabantseva Anastasia Valeriyivna**  | Associate Professor, Candidate of Psychological Sciences, Associate Professor of the Department of Psychiatry, Psychotherapy, Narcology and Medical Psychology.Email: [a.v.kabantseva@dnmu.edu.ua](a.v.kabantseva%40dnmu.edu.ua)Oral consultations by prior arrangement - Wednesday andFriday from 13:00 until 15:00Online consultation by prior arrangement with GoogleMeet on weekdays from 9.00 to 15.30 |
| **Website of the Department** of Psychiatry, Psychotherapy, Narcology and Medical Psychology: <http://kafedrapsichiatrii.dsmu.edu.ua/>**Contact mobile phones**: +38 (050) 988-48-29; +38 (050) 817-58-70;**Information resources of the discipline "Medical Psychology"** is a learning platform Google Class, which hosts:1. Author's multimedia lectures.2. Methodical recommendations for conducting practical classes.3. Tests and situational tasks for current and final control of knowledge.4. E-textbooks, manuals, training videos, etc. |

**ANNOTATION TO THE DISCIPLINE**

**Fundamentals of bioethics and biosafety** - is a synthesis of scientific disciplines that regulate the moral, ethical and legal framework for regulating the acquisition and application of modern biological knowledge. Bioethics is a practical ethic that emerged as a set of moral norms with varying degrees of systematization, rationalization, composition, and institutional support.

**The course "Fundamentals of Bioethics and Biosafety" is an interdisciplinary discipline** that provides the foundations of legal knowledge to the applicant and is designed to form his scientific worldview within the framework of universal values.

**The subject** of the discipline is the consideration and resolution of controversial ethical issues that may arise in the process of medical practice, during biomedical research and experiments or in the case of a combination of these professional activities.

**The aim** of the discipline "Fundamentals of Bioethics and Biosafety" is to form the ability of future doctors to apply knowledge, skills and competencies to protect against the dangers of natural, man-made, social origin and create comfortable conditions for safe professional behavior, the need for strict ethical and moral norms, rules and principles in their practical activities.

**Why study the discipline "Fundamentals of Bioethics and Biosafety"?**

*The study of the discipline will provide an opportunity to:*

* ***know and follow*** the laws, bioethical principles and rules governing the professional activities of doctors of various specialties, pharmacists and researchers, which contributes to the safety of new medical technologies in relation to the individual, humanity and the biosphere as a whole;
* ***provide a bioethical assessment*** of the application of the latest medical technologies in the field of genetic engineering and gene therapy, reproductive medicine, clinical trials of drugs;
* ***demonstrate*** knowledge of medical deontology and understanding of new ethical principles (principles of nooethics) and understand ways to prevent a global environmental crisis, essentially a noosphere crisis, which can be catastrophic and irreversible;
* ***be able to*** correctly use models of communication with patients, provide medical and ethical assessment of medical errors, iatrogenic, euthanasia and suicide, outline ways to prevent them;
* ***be able to*** identify and analyze conflict situations that arise at the intersection of medicine, biology, philosophy and law, and identify specific ways to resolve them; demonstrate an understanding of the legal regulation of the doctor-patient relationship.

**COURSE POLICY**

1. **Academic integrity**. Students are obliged to adhere to the principles of academic integrity, to be aware of the consequences of its violation.

*Academic integrity includes:*

* *independent performance of educational tasks, tasks of current and final control of learning outcomes;*
* *references to sources of information in the case of using borrowed ideas, statements, information;*
* *providing reliable information about the used research methods and sources of information.*

**2. Attendance is an important part of learning.** It is expected that all students will attend classroom practical classes of the course, as well as classes on the learning platform Google Class, to which each student has access.

Attendance is a mandatory component of assessment, according to

which points are accrued.

Works that are submitted in violation of deadlines without good reason are evaluated at a lower grade.

**3. Missed classes** must be completed no later than one week before the test session in contact hours at face-to-face consultations of the teacher and online. The schedule is posted on the department's website. Rearrangement occurs from

permission of the dean's office in the presence of valid reasons (for example, hospital).

**4. Behavior in class**. Inadmissibility of delays in classes, writing off and plagiarism, untimely performance of the task.

*When organizing the educational process at Donetsk National Medical University (DNMU), students, teachers and administration act in accordance with: Regulations on the organization of the educational process in DNMU, Regulations on the rights and responsibilities of students of DNMU, Regulations on organizing and conducting control measures, missed classes and rating increase, Regulations on distance learning at DNMU.*

**PRECISIONS AND POST-PRICES**

**Prerequisites.** The study of the discipline "Fundamentals of Bioethics and Biosafety" is based on knowledge of basic natural sciences: medical biology, biological physics with physical methods of analysis, higher mathematics and statistics, general and bioorganic chemistry, human anatomy, histology, cytology and embryology, Latin, history medicine, history of Ukraine and Ukrainian culture, philosophy, pharmacy and integrates with these disciplines

**Postrequisites.** Acquisition of competencies by applicants will allow to apply knowledge of the basics of bioethics and biosafety in the process of further study of disciplines of medical, pediatric, dental, pharmacological profiles. The discipline "Fundamentals of Bioethics and Biosafety" creates the basis for further study of clinical and hygienic disciplines. Lays the foundations for the formation of knowledge, skills and abilities, which are determined by the ultimate goals of the program, necessary for the next professional activity. Lays the foundations for the study of clinical disciplines by applicants.

**1.Description of the academic discipline**

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| --- | --- |
| parameter name | Characteristics of the discipline by form of study |
| Daytime | extramural |
| **FUNDAMENTALS OF BIOETHICS AND BIOSECURITY** |
| discipline status | required |
| the language of teaching, learning, and assessment | English |
| Total amount: credits / hours | 1,5/45 |
| Course | 1 |
| Semester | 1,2 |
| Number of content modules by distribution | 2 |
| Volume of loans | 1,5 |
| The amount of hours, including | 45 |
| Classroom | 20 |
| Final modular control | - |
| Individual work | 25 |
| Form of semester control | test |

**Program results: acquired abilities (competencies)**

*The discipline provides students with the following competencies:*

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| **INTEGRAL COMPETENCES** | *- ability to solve typical and complex specialized tasks and practical problems in professional activity in the field of health care, or in the process of training, which involves research and / or innovation and is characterized by complexity and uncertainty of conditions and requirements* |
| **GENERAL COMPETENCES** | *- ability to understand the subject area and understanding of professional activity;**- ability to search, process and analyze information from various sources;* *- ability to abstract thinking, analysis and synthesis; - ability to apply knowledge in practice;**- ability to adapt and act in a new situation;**- ability to work in a team;**- ability to act socially responsibly and consciously strive to preserve the environment;**- ability to exercise their rights and responsibilities as a member of society, awareness of the value of civil society, the rule of human rights and freedoms and the citizen of Ukraine;**- ability to preserve and increase moral, cultural and scientific values ​​and achievements of society, to use various forms of physical activity and lead a healthy lifestyle.* |
| **PROFESSIONAL COMPETENCES** | *- ability to use skills of concepts of bioethics and biosafety;**- ability to assess the impact of the environment on the health of the population (individual, family, population);**- ability to understand one's own professional self-actualization in the context of bioethics;**- ability to extrapolate the values ​​of bioethics and objective moral norms to practical life situations and professional activities.* |

**The result of the applicants' training is to KNOW and BE ABLE to:**

- *understand* the bioethical foundations of a doctor's professional activity;

- *understand* the basic laws, principles and rules governing the professional conduct of health professionals and researchers;

- *to identify and analyze* conflict situations that arise at the intersection of medicine, biology, philosophy and law, but also to identify specific ways to resolve them; - apply moral, ethical and professional norms in professional life;

- *interpret* the main historical and medical events;

*- use* new ethical principles (ie nooethics) to prevent a global environmental crisis, which can be catastrophic and irreversible;

- *identify* bioethical and legal issues of clinical trials of drugs and medical technologies;

- *use* professional normative vocabulary, demonstrate the culture of written and oral speech;

- *use* Greek-Latin medical terms in the practice of a specialist;

*- apply* moral, ethical and professional norms in professional life;

- *analyze* pre-conflict and conflict situations and facilitate their resolution;

- *demonstrate* an understanding of the legal regulation of the relationship "doctor - patient";

- demonstrate mastery of the principles of medical deontology;

- *to demonstrate* mastery of moral and ethical principles of attitude to a living person, his body as an object of anatomical and clinical research.

**CONTENT OF THE COURSE**

The course will be presented in the form of lectures (4 hours), practical classes (16 hours) and organization of independent work of applicants (25 hours).

**Lectures.**

The main types of lectures are informative lecture, lecture-discussion, lecture-presentation.

**Practical training.**

*The following teaching methods are used during practical classes:* verbal, visual, practical; explanatory-illustrative, reproductive, problem-based teaching, part-search, research; independent work of applicants on comprehension and mastering of new material of work on application of knowledge in practice and development of abilities and skills, methods of the organization and realization of educational and cognitive activity; stimulation and motivation of training, control, self-control.

*Mandatory types of work in the discipline "Fundamentals of Biotics and Biosafety":*

- to work out theoretical and practical tasks of practical employment;

- to work out the basic concepts of the topic (educational glossary);

- solve situational problems;

- solve test tasks.

Preparation of theoretical questions for practical classes involves the study of issues of the topic of practical classes. These issues could be considered both during the lecture and for self-study.

Students are encouraged to keep records of practical classes!

*The program of the discipline "Fundamentals of Bioethics and Biosafety" consists of one module, which contains the content module I. Fundamentals of Bioethics and Biosafety.*

**EDUCATIONAL - METHODICAL MAP OF THE DISCIPLINE**

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| --- | --- | --- | --- | --- |
| **Hours** | **Topics of lectures**  | **Literature,****inform. resource** | **Task** | **What is evaluated** |
| 1 | **Topic 1**. subject, tasks, principles and history of biomedical ethics (bioethics) as a field of medicine. subject and fundamentals of nooetics. the cost of human life and health. national and international documents on bioethics and human rights. | 1. Textbook "Fundamentals of Bioethics and Biosafety", Chapter 1, p. 7-22.2. Appendices 1-8, textbook "Fundamentals of Bioethics and Biosafety", p. 210-245.3. Multimediapresentation and films on this topicat schoolplatformGoogle Class.4. Educational glossary in sources and syllabus. | - to study and comprehend the theoretical material of section 1;- give answers to questions to consolidate topic 1;- learn the basic concepts of topic 1 | discussion of issues;- revealing the essence of the concepts of the topic;- oral report with substantiated conclusions. |
| 2 | **Topic 2**. bioethical, legal and social problems and biosafety of genetic engineering, gene therapy, genetic reproductive technologies and problems of human and animal cloning. medical-ethical and legal assessment of moral status of the fetus, artificial abortion, prenatal diagnostics. | 1. Textbook"Fundamentals of Bioethics and Biosafety", Chapter 6, p. 132-153.2. Multimedia presentation and films on this topic in the schoolGoogle Class platform.3. Educational glossary in sources and syllabus. | - to work independentlytheoretical material 6 of the manual;- give answers to questions to consolidate topic 3;- learn the basic concepts of topic 3. | - participation in the discussion of issues;- revealing the essence of the concepts of the topic;- oral answer to the question. |
| *The Google Class platform contains textbooks, methodical recommendations, multimedia presentations of topics that will help to clarify the main theoretical and practical issues of the course topics.* |
| **Hours** | **Topics of practical work** | **Literature,****inform. resource** | **Task** | **What is evaluated** |
| 1 | **Topic 1**. subject, tasks, principles and history of biomedical ethics (bioethics) as a field of medicine. subject and fundamentals of nooetics. the cost of human life and health. national and international documents on bioethics and human rights. | 1. Textbook "Fundamentals of Bioethics and Biosafety", Chapter 1, p. 7-22.2. Appendices 1-8, textbook "Fundamentals of Bioethics and Biosafety", p. 210-245.3. Multimediapresentation and films on this topicat schoolplatformGoogle Class.4. Educational glossary in sources and syllabus. | - to work independentlytheoretical material of section 1 and answer questions;- to get acquainted with the specified appendices;- according to appendices 2,3,5,7,8 to make on one question with options of answers, having specified correct. | -ability to define the concept of "biomedical ethics" as a branch of medicine, the subject and objectives of bioethics;- knowledge of the historical stages of development of medical ethics, bioethics and nooethics as a science;- demonstrate understanding of the rules and principles of bioethics;-demonstrate understanding of regulatory and international declarations on medical ethics, bioethics. |
| 2 | **Topic 2**. bioethical fundamentals of professional activity of doctor and pharmaceutical worker. relationship models in the "doctor-patient" system. medical deontology, medical errors, iatrogenia. | 1. Textbook "Fundamentals of Bioethics and Biosafety", Chapter 2, p. 23-42.2. Multimediapresentation and films on this topic, as well as a database of situational tasks and cases onGoogle Class learning platform.3. Educational glossary in sources and syllabus. | - independently study the theoretical material of section 2 and answer questions;- write written situational tasks according to the rules and principles of bioethics, using the knowledge gained in lectures, as well as a database of situational tasks and cases. | knowledge of the bioethical foundations of the professional activity of a doctor and a pharmaceutical worker;- demonstrate mastery of the principles of medical deontology;- knowledge of the principles of confidentiality (medical secrecy), their medical, ethical and legal aspects;- to determine the bioethical problems of interactions of medicine with pharmacists, the main tasks of pharmacovigilance;- to determine the moral aspects of medical errors and iatrogenic;- ability to analyze and solve situational problems on the rules and principles of bioethics. |
| 3 | **Topic 3**. bioethical and legal aspects of different medical specialties (obstetrics and gynecology, pediatrics, internal medicine, family medicine, psychiatry, surgery, oncology, transplantation and transfusion, dentistry). |  Textbook"Fundamentals of Bioethics and Biosafety", 3 -4 chapters, p. 43-99.2. Basic and auxiliary literature.3. Multimediapresentation and films on this topicat schoolGoogle Class platform.4. Educational glossary in sources and syllabus. | - independently study the theoretical material in 3-4 chapters and answer questions;- prepare reports on the following issues: bioethical aspects in obstetrics and gynecology, bioethical aspects in pediatrics, bioethical aspects in family medicine, bioethical aspects in oncology, bioethical aspects in dentistry, bioethical aspects in psychiatry and narcology, bioethical and legal aspects of HIV patients with AIDS, tuberculosis, sexually transmitted and infectious diseases;- prepare battles on key issues of bioethics: abortion and transplantology, transfusiology, xenotransplantation. | - ability to solve medical, ethical and legal problems in certain areas of clinical medicine;- ability to use communication skills with patients of different medical profiles;- demonstrate an understanding of the legal regulation of the relationship "doctor - patient";- provide medical, ethical and legal assessment of abortions;- provide medical, ethical and legal assessment of transplantology, transfusiology and xenotransplantation. |
| 2 | **Topic 4**. bioethical and legal aspects of hiv-infected patients, aids, tuberculosis, veneric and infectious diseases. ethical and legal aspects of life, dying, reanimation, death, eutanasia and suicide. | 1. Textbook"Fundamentals of Bioethics and Biosafety", Chapter 5, p. 100-131.2. Main and auxiliary literature.3. Multimediapresentation and films on the topic on the Google Class learning platform.4. Educational glossary in sources and syllabus. | - to work independentlytheoretical material 5 of the manual and answer the questions;- to prepare a battle on the key issue of bioethics - euthanasia. | - provide bioethical and legal assessment of dying and death;-determine the signs of death, the criteria for clinical and biological death;- provide medical, ethical and legal assessment of passive and active euthanasia;- provide medical, ethical and legal assessment of suicide. |
| 2 | **Topic 5**. bioethical, legal and social problems and biosafety of genetic engineering, gene therapy, genetic reproductive technologies and problems of human and animal cloning. medical-ethical and legal assessment of moral status of the fetus, artificial abortion, prenatal diagnostics.. | 1. Textbook "Fundamentals of Bioethics and Biosafety", Chapter 6, p. 132-153.2. Basic and auxiliary literature.3. Multimediapresentation and films on the given topicat schoolGoogle Class platform.4. Educational glossary in sources and syllabus. | - to work independentlytheoretical material 6 of the manual and answer the questions.- to prepare a battle on the key issue of bioethics - human and animal cloning. | - provide a bioethical assessment of the possibilities of genetic engineering;- identify bioethical and legal issues of human reproduction and new reproductive technologies;- to determine the bioethical aspects of surrogacy, abortion, prenatal diagnosis;-ability to justify the use of certain reproductive technologies;--determine bioethical aspects of genetic research, medical and genetic counseling;--provide medical, ethical and legal assessment of human and animal cloning. |
| 2 | **Topic 6**. bioethical aspects and biosecurity of research work, clinical tests of medical drugs and new medical technologists. bioethical committees. | 1. Textbook"Fundamentals of Bioethics and Biosafety", Chapter 7, p. 154-170.2. Main and auxiliary literature.3. Multimediapresentation and films on this topic in the schoolGoogle Class platform.4. Educational glossary in sources and syllabus. | - to work independentlytheoretical material 7 of the manual and answer the questions;- to prepare a battle on the key issue of bioethics - tests on animals and humans. | - the ability to assess the latest advances in biology and medicine in terms of determining the degree of their danger to man and society today and in the future;- to determine ethical norms in conducting biomedical research;- to determine the ethical principles of conducting experiments on humans and animals;- knowledge of alternatives to animal research;- to demonstrate mastery of moral and ethical principles of attitude to a living person, his body as an object of anatomical and clinical research. |
| 2 | **Topic 7**. the concept of biosafety. bioethical aspects and biosafety of the environmental impact on humans. double standard and bioterrorism technologies. | 1. Textbook"Fundamentals of Bioethics and Biosafety", Chapter 8, p. 171-192.2. Appendices 9-18, textbook"Fundamentals of bioethics and biosafety", p. 246-295.3. Multimediapresentation and films on this topicat schoolplatformGoogle Class.4. Educational glossary in sources and syllabus. | - to work independentlytheoretical material of section 8 of the manual and be ready to answer questions;- to get acquainted with the specified appendices, and also on appendices 9,11,12,13,14 to make on one question with options of answers, having specified correct. | -in to determine what belongs to the problem of biosafety;- distinguish risks by degree of danger;- distinguish between intentional and unintentional biological threats;- identify the risks associated with dual-use technologies;-determine the properties of biological weapons, factors and conditions that contribute to bioterrorism;- determine the legal regulation of the use of biotechnology;- to determine the legal aspects of prevention of biological pollution of the environment;-determine responsibility for violations of biosafety legislation. |
| 2 | **Topic 8**. modern biotechnologies with the use of genetically modified organisms and biosafety issues. | 1. Textbook"Fundamentals of Bioethics and Biosafety", Chapter 9, p. 154-170.2. Appendices 19-18, textbook"Fundamentals of bioethics and biosafety", p. 295-348.3. Multimediapresentation and films on this topic in the Google Class learning platform.4. Educational glossary in sources and syllabus. | - to work independentlytheoretical material of section 9 of the manual and be ready to answer questions;- to get acquainted with the specified appendices, and also on appendices 19-20,26,27,28 to make on one question with options of answers, having specified the correct;- watch one of the proposed films and make a short bioethical review. | -know the concept of GMOs and biosafety of GMO use;-determine the risks of GM plants and feeds, production of pharmaceuticals from GMOs, food;- know the legal framework in the field of biotechnology. |
| The Google Class platform contains textbooks, methodical recommendations, multimedia presentations of topics that will help to clarify the main theoretical and practical issues of the course topics. |

**SAMPLES OF TESTS AND SITUATIONAL TASKS**

Current, intermediate and final test control is carried out using tests of format A "Choose the correct answer" and format B "Provide an answer to the proposed situational task (case)".

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| **Scale** | **Characteristics of answers** |
| А | over 90% correct answers |
| В | 85-90% of correct answers |
| С | 75 -84% correct answers |
| D | 68-74% of correct answers |
| Е | 60-67% of correct answers |
| FX | 31-59% correct answers |

*Examples of test tasks*

1. The qualities of biological weapons include:

A. Easy accessibility.

B. Ease of manufacture.

C. Production of a significant number of pathogenic microorganisms.

D. Easy to store and transport.

E. All answers are correct.

2. A man was admitted to the burn unit with a significant surface of the skin of the face and upper extremities. The patient consciously asks the doctor to "help him die" because he understands that he will not be able to continue his professional activity. What are the doctor's actions?

A. Introduce a sedative to the patient and invite a psychotherapist.

B. Carry out resuscitation measures.

C. Fulfill the patient's wishes.

D. Consult the chief physician.

E. Consult with the patient's relatives.

3. A young woman was admitted to the department for voluntary termination of pregnancy. She is asked to introduce test substances 48 hours before the abortion to study their teratogenic effects on the 12-week-old fetus. Under what conditions is it possible to conduct this study?

A. Informing relatives of the pregnant woman.

B. Consent of relatives of the pregnant woman.

C. Permission of the Ethics Committee.

D. Execution of informed consent.

E. Permission of the chief physician.

*Example of situational tasks (case)*

The patient went to a mammologist with complaints of chest pain. Appropriate diagnostic measures were performed and a diagnosis was made that required treatment with hormonal drugs. The cost of the drug (2 tablets) is UAH 500. There is an analogue, the cost of which is UAH 90, but the doctor did not say so. What is the ethical problem of this situation?

**INDEPENDENT AND INDIVIDUAL WORK**

*Performing independent and individual work is an integral part of successful completion of the course and is assessed separately.*

Tasks for independent work include:

- keeping a workbook;

- writing an abstract, essay, thesis, messages;

- creating a presentation on the topic of the course;

- passing the test on the subject of the discipline;

-preparation of messages, presentations using various information sources;

- performance of individual work.

**CONTROL QUESTIONS FROM THE DISCIPLINE**

**"FUNDAMENTALS OF BIOETHICS AND BIOSAFETY"**

*The list of questions that the applicant must master when studying the discipline (form of control - credit).*

1. Definition, subject, tasks, principles and history of biomedical ethics, nooethics.

2. Bioethics and the formation of the national health care system in Ukraine.

3. Fundamentals of biosafety in Ukraine.

4. The cost of living and human health. Biological and anthropological status of the human embryo. Dignity and inviolability of human life from the moment of its fertilization to natural death.

5. Bioethical problems of life, death, resuscitation and death. Definitions, types of euthanasia and their bioethical evaluation.

6. Bioethical aspects of research work: experiment and clinical research. Principles of evidence-based medicine and their bioethical evaluation.

7. Bioethical bases of professional activity of the doctor.

8. Models of the relationship between doctor and patient.

9. Principles of truthfulness, informed consent, confidentiality (medical secrecy).

10. The patient's relationship with the staff of medical institutions and the family.

11. The role of the family in medical decisions.

12. Medical-ethical and legal assessment of medical error and iatrogenic in clinical practice.

13. National and international documents governing the moral and ethical, professional and legal activities of medical personnel and ensuring human rights.

14. Bioethical, legal, social problems and biosafety of medical genetics, genetic engineering and gene therapy, genetic reproductive technologies of modifications of human and animal nature.

15. Medical and ethical problems of human and animal cloning.

16. Medical-ethical, social and legal problems and biosafety of human reproduction and new reproductive technologies, bioethical problems of family planning (contraception and natural methods of family planning).

17. Medical-ethical and legal assessment of artificial abortion.

18. Ethical, legal and social aspects and biosafety of prenatal diagnosis and population screening studies.

19. Bioethical problems of neonatology and pediatric practice.

20. Bioethical aspects and biosafety in surgery, transplantology, transfusiology.

21. Organ donation, collection and donation.

22. Biotic problems of life, dying, resuscitation and death.

23. Definitions and criteria of death.

24. Bioethical and legal problems of euthanasia and suicide with the assistance of a doctor.

25. Medical, ethical and legal issues and biosafety of prevention, diagnosis and treatment of HIV-infected people with tuberculosis, sexually transmitted diseases and infectious diseases.

26. Bioethical aspects and biosafety of research: experiment and clinical research.

27. Types and role of alternative technologies (mathematical modeling, computer technology). Ethical view on the use of animals in scientific research and educational process.

28. Principles of evidence-based medicine and their bioethical evaluation. Archie Cochran is the founder of evidence-based medicine.

29. Biomedical ethics and deontology in the prevention and treatment of psychosomatic pathology.

30. Bioethical aspects of suicide and murder. The role of emergency psychological care.

31. Bioethical problems of alcoholism, drug use and tobacco smoking, palliative medicine. Prevention, rehabilitation and resocialization.

32. Bioethical aspects and biosafety of agricultural technologies

33. Bioethical problems of interaction of medicine with formation.

34. Biomedical ethics and biosafety of clinical trials of drugs, new medical technologies.

35. Monitoring and prevention of side effects of drugs.

36. The system of pharmacological supervision in Ukraine.

37. Bioethical and legal problems of advertising in medicine and pharmacy.

 **Control of educational achievements**

*The system of assessment of students' academic achievements*

Criteria for students' knowledge assessement from both theoretical and practical training parts:

* grade *"excellent"*: the student has mastered the theoretical material, deeply and comprehensively knows the content of the discipline, basic principles of scientific sources and recommended literature, thinks and builds the answer logically, freely uses the acquired theoretical knowledge in analyzing practical material, expresses his attitude to certain problems, demonstrates a high level of practical skills;
* grade *"good"*: the student has mastered the theoretical material, has the basic aspects of primary sources and recommended literature, teaches it; has sufficient practical skills, expresses his views on certain issues, but assumes certain inaccuracies and errors in the presentation of theoretical content or in the analysis of demonstrated practical skills;
	+ grade *"satisfactory"*: the student has mainly mastered the theoretical knowledge of the discipline, is guided by primary sources and recommended literature, but answers unconvincingly, confuses concepts, additional questions cause the student feel uncertainty or lack of stable knowledge; answering questions of a practical nature, reveals inaccuracies in knowledge, insufficiently evaluates the facts and phenomena related to his future activities;
	+ grade *"unsatisfactory"*: the student has not mastered the material of the discipline, does not know the scientific facts, definitions, almost does not navigate in the original sources and recommended literature, has no scientific thinking and practical skills are not formed.

*Tasks for self work, criteria and assessment.*

Students' self work, which is provided by the topic of the lesson along with the classroom work, is assessed during the current control of the topic in the relevant lesson. Assimilation of topics that are submitted only for self work is checked during the final module control.

 *Forms of modular control and assessment criteria.*

Module grade is determined on the basis of the sum of grades of current educational activities (in points) and grades of final module control (FMC) (in points), which is set when assessing theoretical knowledge and practical skills according to the list defined by the discipline program.

The maximum number of points that a student can score during the study of each module is 200, including for current learning activities - 120 points, according to the results of the final module control - 80 points.

Thus, the parts of the results of the assessment of current educational activities and the final module control are 60% and 40%, respectively.

During the assessment of mastering each topic of the module the student is given grades on a 4-point (traditional) scale and on a multi-point scale using the University's accepted and approved assessment criteria for the discipline. This takes into account all types of work provided by the methodological development for the study of the topic.

Students' knowledge should be assessed in each lesson (on each topic). In one lesson, a student can get several grades for different activities (oral answer, practical skills and abilities, written or computer control, etc.).

Scores on the traditional scale are converted into points.

Recalculation in points is carried out before the final modular control (or at the last lesson for disciplines, the form of control of which is a test).

Before the final module control on the basis of grades on the traditional scale, set during the study of the module (for each lesson and for an individual task), the arithmetic mean (AM) of grades on the traditional scale calculates, rounded to 2 (two) decimal places. The resulting value is converted into a score on a multi-point scale as follows:

|  |  |
| --- | --- |
| Scale | 200 points |
| Disciplines culminating in FMC | СА : 5 х120 |
| Disciplines that end with a test | СА : 5 х 200 |

Points for individual tasks are awarded to the students only if they are successfully completed and defended.

The number of points awarded for different types of individual tasks depends on their scope and significance, but not more than 10-12 points. They are added to the amount of points earned by the student in the classroom during the current academic activity. In no case may the total amount of points for current educational activities exceed 120 points.

 *Forms of semester control and assessmentn criteria.*

The final module control is carried out after the completion of the study of all topics of the module at the last control lesson from the module.

Students who have attended all the classes provided by the curriculum in the discipline and have scored at least the minimum number of points during the study of the module are admitted to the final module control. A student who, for good or bad reasons, has missed classes, is allowed to work off academic debt until a certain date.

Forms of final control should be standardized and include testing of theoretical and practical training.

The maximum number of points that a student can score during the final module control is 80.

The final module control is considered credited if the student scored at least 60% of the maximum amount of points for FMC (not less than 48 points).

The number of points that a student scored in the discipline is defined as the arithmetic mean of the number of points from all modules of the discipline (the sum of points for all modules is divided by the number of modules of the discipline).

Incentive points (not more than 12 points) for winning points at international and national subject competitions may be added to the number of points scored by the student in the discipline, but in no case may the total number of points for the discipline exceed 200 points.

|  |  |  |
| --- | --- | --- |
| Score in the 200-point system | Score in the traditional four-point scale | ECTS system score |
| 180-200 | 5 | A |
| 164-179 | 4 | B |
| 150-163 | C |
| 135-149 | 3 | D |
| 120-134 | E |
| <120 | 2 | FX |

 **Recommended sources**

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 **Additional resources**

* + <http://www.bioethics.net>
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**EDUCATIONAL GLOSSARY**

**Abortion i**s an involuntary or artificial (medical) termination of pregnancy until the fetus cannot be considered viable. There are early A. (up to 12 weeks) and late (from 13 to 27 weeks of pregnancy).

**Genetically engineered safety (biosafety)** is a system of measures aimed at preventing or reducing to a safe level the adverse effects of genetically engineered organisms on human health and the environment during the implementation of genetic engineering.

**Biological ethics** is a modern direction of ethical thought, where productive attempts are made to combine the latest advances in biology and medicine with spirituality and ethical principles.

**Biological weapons** are weapons that deliberately affect the object against which they are used by infection with pathogenic microorganisms and other biological agents, including viruses, infectious nucleic acids and prions.

**Vaccination or vaccination** - the introduction of antigenic material in order to generate immunity to an infectious disease that prevents infection or reduces its negative effects.

**Vivisection** - an operation performed for experimental purposes on a living organism, usually an animal with a central nervous system, to review the internal structure of life.

**HIV infection is a socially** dangerous infectious disease that develops as a result of infection with human immunodeficiency virus.

**The Declaration of Helsinki** is a document developed by the World Medical Association, which is a set of ethical principles for the medical community concerning research ethics and experiments on humans.

**Genetics -** a branch of biology, the science of heredity and variability of traits of organisms, methods of managing them and the organization of hereditary material ;.

**Genetically modified organism (GMO**) is an organism whose genotype has been altered by genetic engineering.

**Genetic engineering** - a set of techniques, methods and technologies for obtaining recombinant RNA and DNA, isolation of genes from the body, manipulation of genes, their introduction into other organisms and the cultivation of artificial organisms after removal of selected genes from DNA.

**Gene therapy (gene therapy**) is a set of genetically engineered (biotechnological) and medical methods aimed at making changes in the genetic apparatus of human somatic cells (DNA fragment).

**Medical deontology** is a set of ethical norms and principles of behavior of a medical worker in the performance of his professional duties.

**Prenatal diagnosis** - a comprehensive prenatal diagnosis to detect pathology at the stage of fetal development.

**Donor (in medicine)** - people who voluntarily donate a portion of their own blood or their organ (tissue) for transplantation to the recipient.

**Clinical research** - a scientific study with human participation, which is conducted to assess the effectiveness and safety of a new drug or to expand the indications for the use of an already known drug.

**Fertilization is the fusion** of male and female gametes, as a result of which the diploid set of chromosomes characteristic of this species is restored, and a qualitatively new cell is formed - a zygote (fertilized egg, or unicellular embryo).

**In vitro fertilization** is a medical technology that allows you to obtain human reproductive cells (eggs and sperm), to carry out in vitro fertilization and to obtain embryos.

**Infectious diseases** - health disorders of humans, animals, plants in the form of diseases caused by viruses, various bacteria, protozoa, parasitic fungi, helminths, products of their activities (exotoxins, endotoxins), pathogenic proteins (prions), capable of being transmitted from infected organisms are healthy and prone to widespread.

**Patient informed consent is a procedure** by which a subject voluntarily confirms his or her consent to participate in a particular clinical trial after reviewing all the features of the study that may influence his or her decision.

**Euthanasia is** the practice of terminating (or shortening) the life of a person or animal suffering from incurable diseases, experiencing unbearable suffering, granting a request without medical indications in a painless or minimally painful form to deprive the patient of life.

**Elimination of infectious diseases -** the destruction of infectious diseases in one region of the world, or reducing the prevalence of infectious diseases among the population of a particular region to zero, or reducing the global prevalence of infectious diseases to insignificant.

**The embryo** is the primary stage of the body's development, it is a fertilized egg up to 8 weeks of pregnancy.

**An epidemiological investigation** is the identification of the source of infection in each case of infection, if possible, the restoration of the entire "chain" of transmission of infection and at the same time measures are taken to prevent the spread of infection.

**Epidemiological triad** - a model that allows you to assess the causality and interaction of agents that spread infectious disease. The triad is a methodology that characterizes infectious diseases because it determines the interaction between the environmental agent, the virus, and the host.

**Ethics** - a science that studies morality; philosophical discipline that studies morality, social norms of behavior, customs.

**Social ethics is** a branch of applied ethics that studies ethical relations - values, goals, responsibilities of a person in society.

**The Code of Ethics of Pharmaceutical** Workers of Ukraine is a document that defines the ethical norms of professional conduct and responsibility of pharmaceutical workers in the conditions of formation of market relations. K.'s goal is to declare principles based on universal values.

**Disabled** - a person with a persistent dysfunction of the body due to disease, injury or birth defects, which leads to disability, the need for social assistance and protection.

**Intrauterine insemination** is an assisted reproductive technology that involves injecting a man's specially prepared sperm directly into a woman's uterus.

**Human cloning** is a predictable methodology that consists in creating an embryo and subsequently growing from the embryo people who have the genotype of an individual, existing or existing.

**The Hippocratic oath** is a medical oath that expresses the fundamental moral and ethical principles of physician behavior.

**A dentist is a professional** who has special knowledge and skills for the practical implementation of diagnosis, treatment and prevention of diseases of the teeth, mouth and maxillofacial area in general.

**Medical secrecy** is a medical, legal, socio-ethical concept, which is a prohibition of a medical worker to disclose to third parties information about the patient's health, diagnosis, examination results.

**Elimination of infection** - reducing the prevalence of infectious diseases in the global population to zero

**The noosphere** is the realm of the mind; the sphere of interaction between society and nature, within which intelligent human activity becomes a determining factor of development.

**Nooethics** - the ethics of the noosphere stage of civilization.

**The Nuremberg Code** is an international document that regulates the principles of medical research on humans.

Palliative **care** is a comprehensive approach aimed at ensuring the highest possible quality of life for palliative patients and their families, by preventing and alleviating suffering through early detection and accurate diagnosis of symptoms of pain and disorders.

**Filling is a way** to restore the shape and function of a tooth destroyed by caries. Most of the ethical issues are related to this function of dentistry.

**The rule of truth** is a rule that assumes the mutual obligation of the healthcare professional and the patient to tell the truth.

**Presumption of consent (disagreement)** - a person during his life must give his consent to the use of their own organs, tissues and cells after his death. If there is no will for life, then the written consent of close relatives of the deceased is possible.

**The principle** of "do no harm" is a Latin saying, which is one of the main precepts of medical ethics and a fundamental principle of emergency medical care around the world.

**Psychiatric care** is a type of specialized medical care that includes examination of mental health, prevention, diagnosis of mental disorders, treatment, supervision, care and medical and social rehabilitation of persons suffering from mental disorders.

**Psychogeny** - a mental illness, or rather a type of mental illness caused by mental trauma (severe experience).

**Resuscitation** - a set of measures aimed at restoring severely impaired or lost vital functions of the body (cardiopulmonary and cerebral functions).

**Assisted reproductive technologies (ART)** - a set of techniques aimed at achieving pregnancy, during which some or all stages of conception are carried out outside the body of the expectant mother.

**Recipient (genetics)** - a cell into which the genetic material of the donor cell is transferred.

**Biological death** is an irreversible cessation of vital functions of the organism, which occurs after clinical death.

**Clinical death** is a condition in which the body is within a few minutes after cessation of blood circulation and respiration, when all external manifestations of life (respiratory arrest and palpitations) completely disappear, but the tissues have not yet undergone irreversible changes.

**Brain death is** a complete and irreversible loss of all human functions by the human brain, which is registered against the background of a working heart and forced lung ventilation.

**Stem cells** are non-specialized cells capable of unrestricted division, which give rise to new cells during tissue formation and in the process of their regeneration.

**Suicide is** the intentional infliction of one's own death, often out of desperation, often caused by mental disorders such as depression, bipolar disorder, schizophrenia, alcoholism, or drug addiction.

**Surrogacy is** an assisted reproductive technology in which a woman voluntarily agrees to become pregnant in order to bear and give birth to a child who is biologically alien to her, who will then be raised by other genetic parents.

**Transplantation** is a method of transplanting an organ or tissue (graft) taken from a donor, as well as cloned tissues, artificial implants (electronic, metal and others), most often by surgery.

**Hospice** - a medical institution in which there are seriously ill patients with a predicted fatal outcome. The institution employs mainly middle and junior medical staff, access to patients is open to relatives and friends.

**Iatrogenic** - erroneous or inadequate actions of the medical worker, both unconscious and conscious, which led to the disease, complication or death of the patient.

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The glossary is formed according to the following sources:

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