AL-FARABI KAZAKH NATIONAL UNIVERSITY
Medicine and Health Care Faculty
Higher School of Medicine
Department of Fundamental Medicine

Program of the final exam in the discipline

NPBI 5302 Good practice - 5 ECTS

Expected results: Masters on the exam must demonstrate the following knowledge, skills and abilities:

know:

-The main provisions of the methodologies;
-conceptual approaches to design creation;
-The process of conducting preclinical biomedical research;
-The process of conducting clinical biomedical research
-The importance and value of the research results;
-Current guidance documents and their structure.

be able to:

-Identify the types of biomedical research;
-to organize a biomedical research;
-monitor the effectiveness of biomedical research;
-to use methodologies in the preparation of the justification for the reporting of research results.
-apply knowledge of regulatory and legal documents of the Republic of Kazakhstan;
-To use sources of up-to-date information, databases in the field of good practice of biomedical research for the continuous development and updating of knowledge and skills in the changing context of biomedical science and practice.
-Demonstrate professionalism and socially responsible citizenship, teamwork skills and leadership in order to improve the quality of professional practice and achieve the best results;
-to effectively exchange information in various contexts of professional and interpersonal communication, to organize effective information flows and management of biomedical research.

The approved form of the final exam is a written exam

Topics:

1. Relevance and typology of biomedical research. Ethical aspects of biomedical research.

2. Research design

3. Review of the regulatory international documents in the field of ethics of medical research. The history and principles of GLP.

4. Quality assurance system for laboratory research. The basic ethical principles of laboratory research.

5. Security Management

6. Data Management

7. Development of standard operating procedures (SOP).

8. Monitoring, auditing and inspection of laboratory tests.

9. Review of regulatory international documents in the field of ethics of medical research. The history and principles of GCP

10.Documents accompanying the clinical trial

11. The principle of informed consent

12. Product management. Training in the rules of handling the investigational drug

13. Monitoring, auditing and inspection of clinical trials.

14. General principles of clinical trial planning and analysis of their results.

Expected results after completing the study of the subject:
-To prepare a master for independent professional management activity, capable of successfully solving their professional tasks.
-To develop skills in mastering the latest organizational technologies and methods of good practice in biomedical research.
-To understand and apply the skills of using the acquired basic and fundamental knowledge of the good practice of biomedical research to successfully solve problems in professional organizational and managerial activities.

The approximate typology of exam tasks
Situational task: During the preclinical study, the testing laboratory must have written SOPs approved by the management of the testing laboratory, which are designed to ensure the quality and reliability of the data obtained by the testing laboratory during the research. Deviations from the SOP occurred during the study.
Tasks:
1.What types of SOP can be used in the study?
2. What needs to be done and to whom if deviations from the SOP occurred during the study?
3. What can be used as additions to the SOP?
Types of questions. 5 of them to choose from (2 from level I, 2 from level II, 1 from level 3):

1.Theories of good practice in biomedical research. Basic concepts and terms.Основные этические принципы проведения лабораторных исследований..

2. Describe the main components of the quality assurance system for laboratory research.
3. Describe the security management system.
4. Describe the data management system.
5. What are the main features of standard operating procedures?
6. Suggest a corrective action plan to supplement the SOP, and explain your thoughts? (Level III).
7. Suggest other possible methods of correcting this situation and explain your strategy (level III)
8. What parameters of the Quality Assurance System will require special control in this example? (Level III)
9. Discuss possible ethical and legal issues related to clinical research in general, subject to the involvement of underage patients (level II).
10. Assess whether the patient's safety has been compromised if information about the conducted clinical trial has been leaked and why....(Level II).
11. Assess the consequences of repeated violations of the SOP associated with an insufficient level of professionalism of the research participant... (Level II).

Instructions on the technology of the exam

1. The exam lasts 3 hours.
2. At the specified time, the student visits the website "app.oqylyq.kz ". 3. The student receives a username and password from the IS Univer. 4. Tickets for each student are issued automatically.
5. The exam begins with a mandatory observer (you can not turn off the camera and microphone): - You will need a laptop with a webcam or a home computer. Otherwise, you can use your smartphone's camera, for example, with the DroidCam client application.
6. The answer is printed in the OQYLYQ program itself. The acceptance of a handwritten response form on paper is NOT provided.
7. At the end of the exam, the student presses the "Done" button.

Scale of answers assessment

Rating	**Criteria**	**Scale, points**
Excellent	1. all key aspects are included and presented logically; 2. high accuracy (relevance, no redundancy) and constant attention to the issue; 3. excellent integration of theoretical issues; 4. providing relevant examples; 5. in-depth analysis and theoretical substantiation of this problem (if applicable), all key aspects are identified and interpreted; 6. fluency in professional terminology	90 - 100
Good	1. all key aspects are included and presented logically;	75 - 89

	2. constant focus on the issue with satisfactory accuracy, relevance and / or some redundancy; 3. satisfactory integration of theoretical issues; 4. lack of examples; 5. satisfactory analysis and theoretical substantiation of this problem (if applicable), most of the key aspects are identified and interpreted; 6. correct use of professional terminology	
Satisfactory	1. most key aspects included; 2. satisfactory focus on the issue - some errors and / or noticeable redundancy; 3. theoretical problems presented without noticeable integration; 4. Providing bad examples or no examples; 5. some analysis and theoretical substantiation of this problem (if applicable), most of the key aspects are identified and interpreted; 6. correct use of professional terminology	50 - 69
Failure (FX)	1. most of the key aspects are missing; 2. lack of attention to the issue - not relevant and significant redundancy; 3. some theoretical problems presented in some way; 4. no or no relevant examples; 5. some analysis and theoretical substantiation of this problem (if applicable), most of the key aspects are missing; 6. omissions in the use of professional terminology	25 - 49
Failure (F)	1. missing all the key aspects; 2. lack of attention to the issue - not relevant and significant redundancy; 3. some theoretical problems presented in some way; 4. no or no relevant examples; 5. lack of analysis and theoretical substantiation of this problem (if applicable), all key aspects are omitted; 6. omissions in the use of professional terminology	0-24

Grading system

Letter Grade	Grade Point Value	Percentage	Conventional Grade
A	4,0	95-100	Excellent
A-	3,67	90-94	
B+	3,33	85-89	Good
B	3,0	80-84	
B-	2,67	75-79	
C+	2,33	70-74	
C	2,0	65-69	Satisfactory
C-	1,67	60-64	
D+	1,33	55-59	
D	1,0	50-54	
FX	0,5	25-49	Failure
F	0	0-24	
I (Incomplete)	-	-	"Incomplete" (shall not be taken into account when calculating GPA)

Exam Guide

1. The exam is conducted as scheduled.

2.Students and the teacher must know the date and time of the exam.

3.The exam lasts 3 hours.

4. At the time indicated in the table, the student enters the classroom. Students who do not show up are given a “0” grade.

5. The student shows ID. Receives an exam card.

6. 2 hours the student writes the answer to the question on the exam paper, handwritten answer

the sheet is submitted on paper.

7. At the end of the exam, the student is evaluated.

8. It is prohibited to use a telephone, gadget or other device during the exam. When viewing Procter, the student is given a grade of "0".

9. The order of the Ministry of Finance of the Republic of Kazakhstan and the Ministry of Health of the Republic of Kazakhstan is approved for use.

10. In the event of a student's failure to appear for obvious reasons (family situation, if he is ill)

According to university rules, the exam is due another day.

Basic literature :

1. Guidelines for the experimental (preclinical) study of new pharmacological substances. Mironov A.N. and the collection.authors. M.: Vulture and K, 2012. - 944 p.
2. Quality management system in laboratories. 2013, WHO. The manual, 271 p.
3. Competence model for leaders/laboratory managers. VAZ, 2019, 59 p.
4. Laboratory Management, Principles and Processes, Fourth Edition by Dr. Denise M. Harmening, June 30, 2020

Additional literature:

1. http://kharkiv-lab.com/wp-content/uploads/2017/03/QMS02-A6_ru_EB.pdf . Quality management system: preparation and management of laboratory documentation; approved manual – sixth edition. Document CLSI QMS02-A6. Wayne, Pennsylvania: Institute of Clinical and Laboratory Standards; 2013.
2. Decision of the Council of the Eurasian Economic Commission No. 81 dated November 3, 2016
"On approval of the Rules of good laboratory practice of the Eurasian Economic Union in the field of circulation of medicines";
3. GOST 33044-2014 "Principles of good laboratory practice"
4. Directive 2010/63/EC of the European Parliament and of the Council of the European Union of 22 September 2010 on the protection of animals used for scientific purposes (Complies with the requirements of the European Economic Area);
5. Guidelines for the maintenance and use of laboratory animals. Eighth edition / translated from English. Edited by I.V. Belozertseva, D.V. Blinova, M.S. Krasilshchikova. – M.: IRBIS, 2017. – 304 p.;
6. Methodological guidelines for the maintenance and use of laboratory animals (Guidelines for the care and use of laboratory animals. Publishing House of the National Academy. – Washington, D.C., 2011);

WWW resourses:

2. Clinical and Laboratory Standards Institute (CLSI) https://clsi.org/
3. https://www.nice.org.uk/
4. Independent Certification and Expertise Center https://www.nice-consulting.ru/services/obuchenie-speczialistov-laboratorij/
5. «Adilet» https://adilet.zan.kz/rus/docs/V1500012207

-