COURSE SYLLABUS AND COURSE REQUIREMENTS
2023-2024 II

Course title	*Ethical issues in medical research*
Course Code	***MSM608ANEG***
Hours/Week: le/pr/lab	*3/0/0*
Credits	*3*
Degree Programme	*MSc*
Study Mode	*Full time*
Requirements	*Short presentation, written research proposal, test exam*
Teaching Period	*Spring*
Prerequisites	*-*
Department(s)	***Institute of Behavioral Sciences (Medical Faculty); Institute of Translational Medicine (Medical Faculty).***
Course Director	
Teaching Staff	*Dr. Szolcsányi Tibor, Dr. Tóth Luca; Dr. Birkás Béla*

COURSE DESCRIPTION

A short description of the course (max. 10 sentences).
Neptun: Instruction/Subjects/Subject Details/Basic data/Subject description

The aim of the course is to provide students with an overview of the most relevant ethical aspects of biomedical research. The course also discusses in detail the principles of the Declaration of Helsinki, the Declaration of Taipei, and other relevant international guidelines on the ethical conduct of human studies. In addition, during the course students acquire knowledge about the most significant psychosocial factors influencing the expectations and observed behavior or symptom perception of study participants. Finally, the course also gives students detailed practical information on how to write and submit research plans for ethical approval.

SYLLABUS

Neptun: Instruction/Subjects/Subject Details/Syllabus

1. GOALS AND OBJECTIVES

Goals, student learning outcome.
Neptun: Instruction/Subjects/Subject Details/Syllabus/Goal of Instruction

- To help students develop sensitivity to the ethical aspects of biomedical research.
- To help students develop skills for using ethical considerations and reasoning.
- To give students an overview of the most basic international ethical standards of medical research.
- Highlighting the relevance and significance of human-related factors in scientific experiments such as the effect of being observed, the role of subjective biases in symptom perception, and placebo /nocebo effect.
- To assist students in acquiring practical knowledge about how to write and submit a research plan for ethical approval.
- To enable students to choose the best type of study for clinical or preclinical trials

2. COURSE CONTENT

Neptun: Instruction/Subjects/Subject Details/Syllabus/Subject content

	TOPICS
LECTURE	1. Introduction. What is ethics, and what is the role of ethics in healthcare, and in medical research? 2. The most basic international ethical standards of modern healthcare, and their relevance in research ethics. 3. How to respect the autonomy and dignity of research participants? Confidentiality, privacy, and informed consent. The WMA Declaration of Taipei. 4. The most basic ethical issues raised by clinical trials. Scientific reliability, the integrity of science and the ethical standards of scientific publication. 5. Balancing harms and benefits and balancing between the interest of research participants and the interest of future patients. The WMA Declaration of Helsinki. 6. Pitfalls of the communication with participants (suggestive communication, placebo) and the effects of the patient-investigator relationship (interpersonal factors, effects of being observed). 7. Different types of ethical approvals used on the field of BME. 8. Different types of ethical approvals used on the field of BME 9. Mini conference: short presentations and discussions. 10. Mini conference: short presentations and discussions 2. 11. Consultation on the assignment task for preparing an ethical approval. 12. Concluding remarks, final discussions, multiple-choice test exam.

DETAILED SYLLABUS AND COURSE SCHEDULE

ACADEMIC HOLIDAYS INCLUDED

LECTURE

week	**Topic**	**Compulsory reading; page number (from … to …)**	**Required tasks (assignments, tests, etc.)**	**Completion date, due date**
1.	Introduction. What is ethics, and what is the role of ethics in healthcare, and in medical research?	-	-	-
2.	The most basic international ethical standards of modern healthcare and their relevance in research ethics.	*European Textbook on Ethics in Research*, pages 7-32.	Participation in the case-study discussions	-
3.	How to respect the autonomy and dignity of research participants? Confidentiality, privacy, and informed consent. The WMA Declaration of Taipei.	*European Textbook on Ethics in Research,* pages 33-94.	Participation in the case-study discussions	-
4.	The most basic ethical issues raised by clinical trials. Scientific reliability, the integrity of science and the ethical standards of scientific publication.	*European Textbook on Ethics in Research,* pages 95-118; 143-166.	Participation in the case-study discussions	-
5.	Balancing harms and benefits and balancing between the interest of the research participants and the interest of future patients. The WMA Declaration of Helsinki.	*European Textbook on Ethics in Research*, pages 167-197..	Participation in the case-study discussions	-
6.	Pitfalls of the communication with participants (suggestive communication, placebo) and the effects of the patient-	*Advanced social psychology: The state*	-	-

	investigator relationship (interpersonal factors, effects of being observed).	*of the science*, pages 63-101		
7.	Different types of ethical approvals used on the field of BME.	*Coursea – „Design and Interpretation of Clinical Trials" https://www.coursera.org/learn/clinical-trials* *Coursea – „Introduction to Systematic Review and Meta-Analysis" https://www.coursera.org/learn/systematic-review*	-	-
8.	Different types of ethical approvals used on the field of BME.	*„Design and Interpretation of Clinical Trials" https://www.coursera.org/learn/clinical-trials* *Coursea – „Introduction to Systematic Review and Meta-Analysis" https://www.coursera.org/learn/systematic-review*	-	-
9.	Mini conference: short presentations and discussions.	-	Participation in the discussions	-
10.	Mini conference: short presentations and discussions.	-	Participation in the discussions	-
11.	Consultation on the assignment task for preparing an ethical approval	-	-	
12	Concluding remarks, final discussions. Multiple-choice test exam	-	-	-

3. ASSESSMENT AND EVALUATION

(Neptun: Instruction/Subjects/Subject Details/Syllabus/Examination and Evaluation System)

ATTENDANCE

In accordance with the Code of Studies and Examinations of the University of Pécs, Article 45 (2) and Annex 9. (Article 3) a student may be refused a grade or qualification in the given full-time course if the number of class absences exceeds 30% of the contact hours stipulated in the course description.

Method for monitoring attendance *(e.g.: attendance sheet / online test/ register, etc.)*

Attendance sheet

ASSESSMENT

Cells of the appropriate type of requirement is to be filled out (course-units resulting in mid-term grade or examination). Cells of the other type can be deleted.

Course resulting in mid-term grade *(PTE TVSz 40§(3))*

Mid-term assessments, performance evaluation and their ratio in the final grade *(The samples in the table to be deleted.)*

Type	Assessment	Ratio in the final grade
Short presentation	*Max 5 points*	*10%*
Preparing assignment for research approval	*Max 5 points*	*10%*
Test exam	*Max 27 points*	*80%*

Opportunity and procedure for re-takes (PTE TVSz 47§(4))

The specific regulations for improving grades and resitting tests must be read and applied according to the general Code of Studies and Examinations. E.g.: all tests and assessment tasks can be repeated/improved at least once every semester, and the tests and home assignments can be repeated/improved at least once in the first two weeks of the examination period.

The test-exam can be retaken during the 15th week of semester, and during the first two weeks of the exam period. The short presentation can be repeated during 13th week, and during the first two weeks of the exam period.

Grade calculation as a percentage

based on the aggregate performance according to the following table

Course grade	Performance in %
excellent (5)	85 % …
good (4)	70 % ... 85 %
satisfactory (3)	55 % ... 70 %
pass (2)	40 % ... 55 %
fail (1)	below 40 %

The lower limit given at each grade belongs to that grade.

4. SPECIFIED LITERATURE

In order of relevance. (In Neptun ES: Instruction/Subject/Subject details/Syllabus/Literature)

COMPULSORY READING AND AVAILABILITY

Primary readings

- Hughes, J., Hunter, D., Sheehan, M., Wilkinson, S., & Wrigley, A. (2010). *European textbook on ethics in research*. Publications Office of the European Union.(PDF)
- Baumeister, R. F., & Finkel, E. J. (Eds.). (2010). *Advanced social psychology: The state of the science.* Oxford University Press. Chapters: Ch. 3. pages 63-101; Ch. 11. pp. 385-419; Ch. 20. pp. 733-757. (PDF)
- Coursea – „Design and Interpretation of Clinical Trials" https://www.coursera.org/learn/clinical-trials
- Coursea – „Introduction to Systematic Review and Meta-Analysis" https://www.coursera.org/learn/systematic-review

Further compulsory readings

- *The WMA Declaration of Helsinki* (available online)
- *The WHA Declaration of Taipei* (available online)
- *The Codex of Bioethics* (published by the Medical Research Council, Hungary). (available online)
- Beins, B. C. (2017). *Research method: A tool for life*. Cambridge University Press. Chapter 14. pages 361-391.(PDF)

RECOMMENDED LITERATURE AND AVAILABILITY

- Brown, W. A., & Brown, W. A. (2013). *The placebo effect in clinical practice*. Oxford University Press. Chapters 2-5., pages 23-82.(PDF).
- Resnik, D. B. *The ethics of research with human subjects: Protecting people, advancing science, promoting trust* (Vol. 74). Springer, 2018. (available at the Institute of Behavioral Sciences, Library).