Academic year 2021./2022.

Course title: Ethics in Biomedical Research

Department

Adress

Total ECTS points

Course leader: Prof. Tonči Matulić, PhD

Course associates

Teaching plan

	No. classes
Lecture	10
Seminar	6
Practical	0
Total	16

1 class = 45 minutes

Course description

Introduction to ethics in biomedical research on human beings. A review of the ethical dimensions of biomedical research on experimental animals. Historical examples of abuses of biomedical research and the maturing of ethical awareness of the importance of ethics in biomedical research. Fundamental and clinical research. The superiority of the human being in biomedical research. Types and status of subjects involved in biomedical research. The relationship between society and science. Relationship between ethics and biomedical research. Basic ethical principles of biomedical research with special reference to their development and presentation in relevant international and national documents. The doctrine of *informed consent* and its application in biomedical research. The nature and composition of ethical bodies for evaluating the ethics of biomedical research.

Learning outcomes

1. Identify the importance of ethics in biomedical research
2. Interpret fundamental ethical principles in biomedical research
3. Reproduce the application of ethical principles in biomedical research
4. Recognize and analyze the ethical aspects of biomedical research
5. Compile an ethical evaluation of your own biomedical research

Course content

Lecture

	Lecture topics	Number of classes/hours
1.	Introduction to ethics in biomedical research	2
2.	Ethical principles in biomedical research	3
3.	Informed consent in biomedical research	2

4.	International and national documents of biomedical research	2
5.	Ethical bodies of biomedical research	1
6.	-	-
7.	-	-
8.	-	-
9.	-	-
10.	-	-

1 sat = 45 minuta

Seminars

	Seminar topics	**Number of classes/hours**
1.	Historical examples of abuses of biomedical research	2
2.	Preclinical and clinical biomedical research	2
3.	Types and status of subjects in biomedical research	2
4.	-	-
5.	-	-
6.	-	-
7.	-	-
8.	-	-
9.	-	-
10.	-	-

1 sat = 45 minuta

Practice

	Practice topics	**Number of classes/hours**
1.	-	-
2.	-	-
3.	-	-
4.	-	-
5.	-	-
6.	-	-
7.	-	-
8.	-	-
9.	-	-
10.	-	-

1 class = 45 minutes

Literature

1. *The Nuremberg Code* (1947), Nuremberg: International Military Tribunal.
2. World Medical Association (1964), *Helsinki Declaration: Ethical Principles for Medical Research Involving Human Subjects*. Fortaleza (2013): 64th General Assembly of WMA.
3. National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (1979.), *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research*. Washington, D.C.: Department of Health, Education, and Welfare.
4. Council of Europe (1997), *The Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine*. Oviedo: Council of Europe.
5. World Health Organization (2005), *Handbook for Good Clinical Research Practice (GCP): Guidance for Implementation*. Geneva: World Health Organization.
6. Upravni odbor za bioetiku (2010), *Smjernice za članove istraživačkih etičkih povjerenstava*. Strasbourg: Vijeće Europe.
7. Directive 2010/63/EU 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* (2010). Official Journal of the European Union (L 276/33).
8. Ministarstvo poljoprivrede (2013), *Pravilnik o zaštiti životinja koje se koriste u znanstvene svrhe* (NN 55/2013).
9. CIOMS – Council for International Organizations of Medical Sciences (2016), *International Ethical Guidelines for Health-Related Research Involving Humans*. Geneva: CIOMS.
10. Hrvatska liječnička komora (2016), *Kodeks medicinske etike i deontologije*. Zagreb: Hrvatska liječnička komora (NN 55/2008 i 139/2015).
11. Hrvatska komora dentalne medicine (2019), *Kodeks dentalne etike i deontologije*. Zagreb: Hrvatska komora dentalne medicine (NN 67/2019).
12. Pellegrino, Edmund – Thomasma, David (1981), *A Philosophical Basis of Medical Practice: Toward a Philosophy and Ethic of the Healing Professions*. Oxford – New York: Oxford University Press.
13. Borovečki, Ana (ed.) (2003), *Etika u medicinskim istraživanjima i kliničkoj praksi*. Zagreb: Nacionalno bioetičko povjerenstvo za medicinu Vlade Republike Hrvatske – Doktorski studij Biomedicina i zdravstvo Medicinskog fakulteta Sveučilišta u Zagrebu.
14. Matulić, Tonči (3 2011), *Bioetika.* Zagreb: Glas Koncila.
15. Matulić, Tonči (2 2011), *Medicinsko prevrednovanje etičkih granica*. Zagreb: Glas Koncila.
16. Beauchamp, Tom – Childress, James (8 2019), *Principles of Biomedical Ethics*, Oxford – New York: Oxford University Press.

es

CV (*curriculum vitae*) and bibliography of course leader

Tonči Matulić was born on October 26, 1966 in Supetar on the island Brač in Croatia and finished primary school in 1981 in his native Postira on the island of Brač. He passed high school in 1985 from the Archbishop's Gymnasium in Split. He graduated in philosophy and theology in 1991 at the Catholic Theological Faculty (CTF), University of Zagreb. He was ordained a priest of the Diocese of Hvar in 1992. He began his postgraduate studies in moral theology in 1991 at the CTF of the University of Zagreb and continued in 1993 at the Higher Institute of Moral Theology "Academia Alphonsiana" of the Pontifical Lateran University in Rome, where he received his master's degree in 1995 and his doctorate in 1998. He studied bioethics in 1995 at the Sacro Cuore Catholic University School of Medicine in Rome, and in 1996 at the Joseph and Rose Kennedy Institute of Ethics at

Georgetown University in Washington, D.C. He started lecturing at the Department of Moral Theology of the CTF of the University of Zagreb in 1999. From 2005 to 2010 he was Vice Dean for Science, and from 2012 to 2017 he was Dean. From 2009 until today, he is the head of the Department of Moral Theology. He has been a full professor since November 2016. He has been a member of the editorial board of the Theological Review since 2001 and was the editor-in-chief from 2011 to 2016. He was the president of the Croatian section of the European Society for Catholic Theology from 2014 to 2021. He has been the President of the Association of Former Students of the KBF of the University of Zagreb since its founding in 2016 until today. He is a member of several domestic and international professional organizations. Since 2001 he has been a member of the Ethics Committee of the University Hospital Center Zagreb, and since 2008 he has been a member of the Ethics Committee of the Medical Faculty of the University of Zagreb, especially since 2014 he is a member of its special Institutional Review Board for biomedical research. From 2002 to 2005 and from 2008 to 2010 he was a member of the National Bioethical Commission for Medicine. He has published twelve (12) books, more than one hundred scientific and professional papers in domestic and international journals and proceedings and has prepared three (3) proceedings. He has participated in more than eighty domestic and international symposia as an invited lecturer. The focus of his scientific research is moral theology, bioethics, medical ethics, social ethics, ethics in science and higher education, and the dialogue between theology and natural sciences.
https://www.bib.irb.hr/pregled/profil/17277