ETHICS IN HEALTH RESEARCH

CU characterization:

CU name:
Ethics in Health Research

Scientific area acronym:
MIS

Duration:
Semiannual

Working hours:
56

Contact hours:
16

ECTS:
2

Observations:
N/A

Teacher in charge and respective teaching load in the CU:
Inês Fronteira – 14 hours

Other teachers and respective teaching load in the CU:
Cláudia Conceição – 2 hours

Intended learning outcomes (knowledge, skills and competences to be developed by the students):
After this unit, students should be able to:

1. Define the basic principles of moral foundations of bioethics.
2. Analyze ethical questions underlying a research involving human beings.
3. Understand the elements that comprise the informed consent.
4. Write an informed consent adequate to the research design.
5. Write an ethically adequate research protocol, suitable for submission to an Ethics Committee.

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Syllabus:

I. Historical evolution of Bioethics: Code of Nuremberg, Helsinki Declaration, Belmont report, Common Rule, International Conference on Harmonization

II. Moral Theory: utilitarism and Kantianism and their application to biomedical research

III. Ethical Concepts:

-Moral Status (problem and theories, practical guidelines, vulnerable populations)

-Respect for autonomy: nature of autonomy, capacity of autonomous choice, meaning and justification of informed consent, disclosure, understanding and voluntariness)

-Non maleficence (concept, distinctions and rules governing nontreatment, optional treatments and obligatory treatments, protecting incompetent patients)

-Beneficence (concept, obligatory beneficence and ideal beneficence, balance between benefits, costs and risks)

-Justice (concept, fair opportunity and unfair discrimination, vulnerability and exploitation, national and global policy and the right to health care)

IV. Informed consent: concepts, principles, modalities and basic elements, utilization of data and record keeping, the process of submitting a research protocol to the ethics committee

V. Conflict of interest: concept and implications for research using humans

Teaching methodologies (including assessment):

We will present moral theories and ethical concepts in lectures and debate in plenary sessions their application to specific cases.

The assessment will consist in an individual written assignment. The assignment will consist in writing the ethical and legal implications chapter of a research protocol. Students can write this chapter for a study they want to conduct otherwise, a study will be provided by the teacher.

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References for consultation / mandatory existence:

- Beauchamp T, Childress J (2009) Principles of Biomedical Ethics. 6th Edition. New York: Oxford University Press.
- Jennings B, Steinbock B, Gostin L Bayer R (eds.) (2006) Public Health Ethics: Theory, Policy, and Practice. New York: Oxford University Press.
- Marshall, Patricia A. Ethical challenges in study design and informed consent for health research in resource-poor settings. Special Topics in Social, Economic and Behavioural (SEB) Research report series; No. 5). WHO. 2007.
- Ethical and Policy Issues in Research Involving Human Participants. National Bioethics Advisory Commission. Bethesda, USA. 2001. (http://bioethics.georgetown.edu/nbac/human/oversumm.html)