ETHICAL PRINCIPLES OF BIOMEDICAL RESEARCH

CU characterization:

CU name:
Ethical Principles of Biomedical Research

Scientific area acronym:
SI

Duration:
Semiannual

Working hours:
28

Contact hours:
8

ECTS:
1

Observations:
Mandatory CU

Teacher in charge and respective teaching load in the CU:
Jorge Seixas – 7 hours

Other teachers and respective teaching load in the CU:
Dinora Lopes – 1 hour

Intended learning outcomes (knowledge, skills and competences to be developed by the students):
Students will acquire knowledge on the basic principles of bioethics applied to biomedical research. They will be able to identify and describe the generic challenges of a biomedical research study protocol and the difficulties of designing and implementing ethically sound study protocols, namely in special settings and vulnerable populations. They will develop skills to cope with these difficulties, in order to be able to produce a study protocol suitable for submission to an Ethics Committee.

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Syllabus:

I. Historical aspects of the development of ethics applied to biomedical sciences
II. Basic ethical concepts in biomedical research involving human subjects (respect, beneficence and justice)
III. Principles of clinical studies and clinical trials
IV. Ethics in animal experimentation
V. Contents of a Study Protocol
VI. Essential elements of the Informed Consent form
VII. Submitting a Study Protocol to the Ethical Committee
VIII. Ethical challenges in clinical studies in low and middle income countries

Teaching methodologies (including assessment):

The Unit is organized in lectures introducing the themes, followed by group discussion. Case studies will be presented and discussed in support of the learning objectives. Assessment will be continuous during the contact time. Students with a research project already defined will be asked to produce a Study Protocol to be submitted to an Ethics committee. For others, the analysis and discussion of a real-life case will be requested.

References for consultation / mandatory existence:

- Childress, J. F. (2001) Principles of Biomedical Ethics, 5th Ed. Oxford University Press.
- Rivera, R., Borasky, D. (2009). Research Ethics Training Curriculum, 2nd Ed. Family Health International. E6 Guideline for Good Clinical Practice. (1996) European Agency for the Evaluation of Medicinal Products.
- Marshall, P, A. (2007). 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.
- Ethical and Policy Issues in Research Involving Human Participants. (2001) National Bioethics Advisory Commission. Bethesda, USA.