



INSTITUTO DE HIGIENE E  
**MEDICINA TROPICAL**  
DESDE 1902

## ETHICS AND HEALTH RESEARCH

### *CU characterization:*

#### *CU name:*

Ethics and health research

#### *Scientific area acronym:*

XXXX

#### *Duration:*

Semiannual

#### *Working hours:*

N

#### *Contact hours:*

22h

#### *ECTS:*

N

#### *Observations:*

NA

### *Teacher in charge and respective teaching load in the CU:*

Jorge Beirão de Almeida Seixas - 20 hours (T -10; S -6; OT-4)

### *Other teachers and respective teaching load in the CU:*

Dinora Lopes- 4 hours (T- 2; OT-2)

### *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, including aspects related to animal experimentation.

### *Syllabus:*

- Historical aspects of the development of ethics applied to biomedical sciences.



- Basic ethical concepts in biomedical research involving human subjects (respect, beneficence and justice).
- Principles of clinical studies and clinical trials.
- Contents of a Study Protocol.
- Essential elements of the Informed Consent form.
- Submitting a Study Protocol to the Ethical Committee.
- Ethical challenges in clinical studies in low and middle income countries.
- Ethics and animal experimentation

***Evidence of the syllabus coherence with the CU intended learning outcomes:***

The main components of the syllabus (basic concepts, presentation of main sources of principles of ethics in biomedical research on humans and animals, examples of good practices, namely information to participants, informed consent, and dissemination of results) are coherent with the objective of developing the capacity to prepare a research protocol which respects the norms and standards applied by ethics committees.

***Teaching/learning methodologies articulated with pedagogical model:***

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:***

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.

***Evidence of the teaching methodologies coherence with the CU intended learning outcomes:***

During lectures basic knowledge and skills will be acquired. During group case studies students will develop the capacity to identify and describe the generic challenges of a biomedical research study protocol. While individually preparing a Study Protocol or while analyzing a real life case, they will be capacitated to submit a biomedical research project to an Ethical Committee

***References for consultation / mandatory existence:***

Beauchamp T, Childress J (2009) Principles of Biomedical Ethics. 6th Edition. New York: Oxford University Press.

Rivera, R., Borasky, D. (2009). Research Ethics Training Curriculum, 2<sup>nd</sup> 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..



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(<http://bioethics.georgetown.edu/nbac/human/oversumm.html>)

Ethical Challenges of Research. e-Source Book, in e-Source Behavioral and Social Science Research.

[http://www.esourceresearch.org/portals/0/uploads/documents/public/kelty\\_fullchapter.pdf](http://www.esourceresearch.org/portals/0/uploads/documents/public/kelty_fullchapter.pdf)

Current Issues in Research Ethics : Privacy and Confidentiality

<http://ccnmtl.columbia.edu/projects/cire/pac/foundation/>