



UNIVERSITÀ  
DEGLI STUDI DI MILANO-BICOCCA

## SYLLABUS DEL CORSO

### Scientific ethics of research with living beings

2122-DOTT-MOD20

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#### Title

Scientific ethics of research with living beings

#### Teacher(s)

The course is organized through 2 modules:

1. Prof. Guido Cavaletti, Dr. Luca Crippa – Ethical and regulatory issues in animal studies
2. Dr.ssa Sara Casati - What ethical and regulatory framework for a Responsible Research involving human beings or using data/samples of human origin

#### Language

1<sup>st</sup>module - Since the course is aimed at the discussion of the Italian law/regulation and Ministry authorization form must be filled in Italian, the course will be held in Italian

2<sup>nd</sup>module - Italian (if foreign students will be enrolled English)

#### Short description

**Target audience:** PhD students with an interest in research ethics, with a specific focus both on animal studies and studies involving human beings or using data/samples of human origin

### **1<sup>st</sup> module: Ethical and regulatory issues in animal studies**

Guido Cavaletti, Luca Crippa – 4 hrs

The 2 topic of the course will be

- analysis of the contents of the “DECRETO LEGISLATIVO 4 marzo 2014, n. 26”
- description of the form to be filled in to request permission for animal studies

The first part of the course will be a lecture, the second part will be based on group practical activities (exercise) on a mock proposal.

At the end of the lecture the students will have the fundamentals of the current regulation according to EU and Italian laws and will be able to draft a full proposal for Ministry of Health approval.

At the end of the exercise the students will have the mock proposal evaluated by the teacher and by general discussion to identify strengths/weaknesses of the proposal according to EU and Italian laws.

### **2<sup>nd</sup> module: What ethical and regulatory framework for a Responsible Research involving human beings or using data/samples of human origin**

Sara Casati – 4 hrs

We will share the ethical-legal-social - ELSI horizon for research involving human beings or based on data and/or biological samples of human origin. Through the analysis of concrete projects by the PhD students, we will identify the fundamental steps where both the protection of the rights of participants and the compliance with ELSI requirements become the backbone of the same research protocol. Finally, we will discuss when and how to present a research protocol to an ethics committee, with particular reference to the Ethic Committee of the University of Milano-Bicocca.

Notes: The ELSI course will have a deliberative setting based on interaction and on proactive analysis of regulations as well as concrete projects. In particular, we work in small groups simulating the drafting of an informed consent rather than the articulation of a request for an opinion to the ethics committee from specific projects of the participants.

### **CFU / Hours**

CFU 1

Hours 8

### **Teaching period**

23/05/2022 9.00 am - 1.00 pm

24/05/2022 9.00 am - 1.00 pm

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