



UNIVERSITÀ  
DEGLI STUDI DI MILANO-BICOCCA

## SYLLABUS DEL CORSO

### Ethics of research with living being

2223-DOTT-MOD06

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#### Title

Ethics of research with living being

#### Teacher(s)

Prof. Guido Cavaletti, Dr. Annalisa Canta, School of Medicine and Surgery  
Dr. Sara Casati - What ethical and regulatory framework for a Responsible Research involving human beings or using data/samples of human origin

#### Language

Italian / English

#### Short description

##### 1st module: Ethical and regulatory issues in animal studies

Guido Cavaletti and Annalisa Canta - 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

### **Target audience**

PhD students with an interest in research ethics, with a specific focus on animal studies

### **2nd module: Ethics of Research with Living Beings**

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 and the participants' engagement and the compliance with ELSI requirements become the backbone of the same research protocol, with a particular attention to

- Participatory & Informational processes/tools (raising awareness – scientific citizenship; dynamic consent; Material/Data Transfer Agreement ...)
- Risk assessment and risk mitigation
- Framing & processing within a RRI horizon  
Finally, we will discuss when and how
- to present a research protocol to an ethics committee, with reference to the Ethic Committee of the University of Milano-Bicocca,
- query and ask for samples/data to an access committee.

### **Target audience**

PhD students/Researchers responsible of projects involving human beings or using data/samples of human origin or impacting on humans

### **CFU / Hours**

1 CFU / 8 hrs

### **Teaching period**

1st module: 09/05/2023 9.00 a.m - 1.00 p.m.

2nd module: tbd

**course registration on "Segreteria online": from 18/04/2023 to 02/05/2023**

### **Sustainable Development Goals**

QUALITY EDUCATION

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