

Università degli Studi di Padova



Intensive Course

“Ethics of Pediatric Research”

May 23-25, 2016
Padova, Italy

Scientific coordinator
Corrado Viafora

Course coordinators
Ioana Hiriscau, Jan Piasecki

FACULTY

- ♦ **MARA CANANZI** (Padova University Hospital, Italy)
- ♦ **CARLO GIAQUINTO** (University of Padova, Italy)
- ♦ **IOANA HIRISCAU** (University of Medicine and Pharmacy “Iuliu Hatieganu” Cluj-Napoca, Romania)
- ♦ **JAN PIASECKI** (Jagiellonian University, Kraków, Poland)
- ♦ **MAURIZIO SCARPA** (University of Padova, Italy)
- ♦ **ALESSIO VEDOVETTO** (Padova University Hospital, Italy)
- ♦ **KATHARINE WRIGHT** (Nuffield Council on Bioethics, UK)

BACKGROUND AND OBJECTIVES

Of all types of research involving human subjects, research on children is the one which has undergone the most profound evolution: from the initial banning to prevent any exploitation of vulnerable subjects, to the growing awareness that we should protect children and young people *through* research not *from* research.

As a consequence, the number of studies involving children is rapidly increasing all around the world. This phenomenon requires however the refinement of the traditional moral requirements of biomedical research (especially informed consent and risk assessment) in order to adapt them to the specific characteristics of children. Furthermore, these traditional moral requirements must be re-thought to deal with the ethical challenges posed by new research developments.

CONTENTS AND METHODS

Contents of the course include: (1) the evolution of the debate on the ethics of pediatric research; (2) scientific and methodological requirements of pediatric research; (3) normative requirements of research with children; (4) the concept of child's best interest; (5) consent and assent in pediatric research; (6) ethical and social issues in pediatric transplantation research, in pediatric rare diseases research and in in risky-behavior studies with adolescents; (7) the challenge of prioritizing research: hidden ethical challenges.

As to the *methods*, the course will combine lectures, group discussions and workshops. Course activities and materials are in English.

PARTICIPANTS

The course should be of interest for:

- health professionals working with children;
- children's health investigators;
- members of Research Ethics Committees (or IRBs);
- members of Research Institutions;
- government policy makers and legislators.

PROGRAMME DAY 1 - MONDAY, MAY 23, 2016

Morning

- 9.00-9.15 Welcome by the scientific coordinator
CORRADO VIAFORA
- 9.15-9.30 Introduction to the intensive course
JAN PIASECKI
- 9.30-10.30 A short history of research with children
IOANA HIRISCAU
- 10.30-11.00 *Break*
- 11.00-12.30 Research with children: scientific justification and methodological requirements
CARLO GIAQUINTO
- 12.30 *Lunch break*

Afternoon

- 14.00-15.00 Research with children and the concept of best interest
JAN PIASECKI
- 15.00-15.30 *Break*
- 15.30-17.00 Ethical issues in pediatric transplantation research
Lecture and workshop by **MARA CANANZI**
- 17.30 *Visit to the University of Padova Botanical Garden*

PROGRAMME DAY 2 - TUESDAY, MAY 24, 2016

Morning

9.00-10.30 Consent and assent in pediatric research
Lecture and group work by **JAN PIASECKI**

10.30-11.00 *Break*

11.00-12.30 Building a relationship of trust with the young patient:
experiences in oncology research
ALESSIO VEDOVETTO

12.30 *Lunch break*

Afternoon Nuffield Council on Bioethics report “Children and research:
ethical issues”
KATHARINE WRIGHT

14.00-15.00 Involving children and young people: a participatory
methodology

15.00-16.00 Prioritising research – hidden ethical challenges

16.00-16.30 *Break*

16.30-17.30 A critical review of ethical concerns – another look at ‘welfare’,
‘vulnerability’ and ‘assent’

20.00 *Dinner*

PROGRAMME DAY 3 - WEDNESDAY, MAY 25, 2016

Morning

9.00-10.30 Guidelines on pediatric research
Lecture and group work by IOANA HIRISCAU

10.30-11.00 *Break*

11.00-12.30 Ethical issues in pediatric rare diseases research
Lecture and group work by MAURIZIO SCARPA

12.30 *Lunch break*

Afternoon

14.00-15.00 Ethical issues in risky-behaviour studies with adolescents – focus on confidentiality
IOANA HIRISCAU

15.00-15.30 *Break*

15.30-17.00 What would we decide if we were the Ethics Committee?
Group work coordinated by JAN PIASECKI, IOANA HIRISCAU

17.00-17.30 Final test for ECM purposes
(only for Italian participants who wish to get ECM credits)

REGISTRATION

The course fee is 600 € (300 € for university students and PhD candidates). The fee includes tuition and course materials, as well as one dinner and the visit to the University of Padova Botanical Garden (see next page).

For Italian participants: attending the course will give ECM credits (ECM stands for “Educazione Continua in Medicina”, i.e. Continuing education in medicine). The following professional figures can get the credits: medico chirurgo, infermiere, infermiere pediatrico, biologo, psicologo, farmacista, terapeuta occupazionale, educatore professionale, terapeuta della neuro e psicomotricità dell’età evolutiva.

The deadline to register is May 15, 2016.

Detailed information on registration and payment is available at <http://www.medicinamolecolare.unipd.it/ethics-pediatric-research>.

Participants are expected to make their own travel and accommodation arrangements. Please visit www.masterbioethics.org under *Intensive Courses* for information.

INFORMATION

Contact person:
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VENUE

Centro Universitario Padovano
Via degli Zabarella, 82
35121 Padova (Italy)

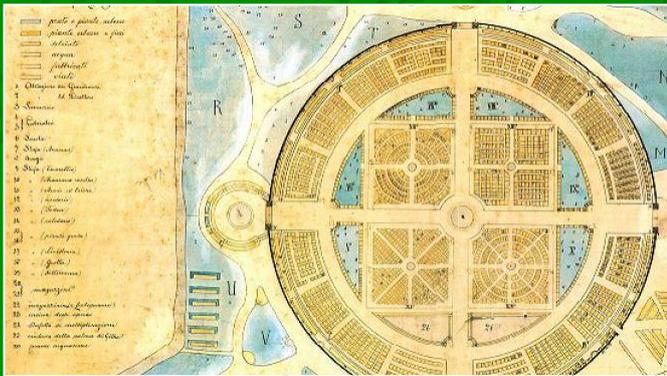
ERASMUS MUNDUS MASTER OF BIOETHICS

The intensive course is part of the Erasmus Mundus Master of Bioethics (EMMB), a master programme organised by a consortium of three European universities: KU Leuven (Belgium), Radboud Universiteit Nijmegen (The Netherlands) and Università degli Studi di Padova (Italy). Participants to the intensive course will therefore join EMMB students from all over the world.



THE BOTANICAL GARDEN

The University of Padova **BOTANICAL GARDEN** was founded in 1545 upon deliberation of the Senate of the Venetian Republic. It is the world's oldest academic botanical garden that is still in its original location. It was devoted to the growth of medicinal plants, the so-called "simple plants" (*Orto dei semplici*) which produced natural remedies, and also to help students distinguish genuine medicinal plants from false ones.



The Botanical Garden was steadily enriched with plants from all over the world, particularly from the countries that participated in trade with Venice. Consequently, Padua had a leading role in the introduction and study of many exotic plants, and a herbarium, a library and many laboratories were gradually added to its Botanical Garden.

In 1997, it was listed by UNESCO as a World Heritage Site.

In 2014 the Biodiversity Garden was added to the historical garden. The species in the Biodiversity Garden exhibition are about 1,300. They live in environments sharing the same humidity and temperature characteristics, simulating the climatic conditions of the planet's biomes, from tropical to sub-humid, temperate and arid zones. The position of the plants in each environment and of the aquatic plant lake reflects a phytogeographic division – the exhibition is a voyage through the Earth's vegetation (in America, Africa and Madagascar, Asia, temperate Europe and Oceania).

