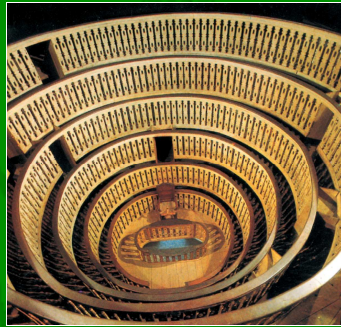


Università degli Studi di Padova



Intensive Course

# “Ethics of Pediatric Research”

May 12-14, 2014  
Padova, Italy

*Scientific coordinator*  
Corrado Viafora

*Course coordinators*  
Carlo Giaquinto, Mariassunta Piccinni

## FACULTY

- ♦ **ANNAGRAZIA ALTAVILLA** (“Espace Ethique Méditerranéen”, Aix-Marseille University, France)
- ♦ **MARA CANANZI** (Padova General Hospital, Italy)
- ♦ **MARINA CUTTINI** (“Bambino Gesù” Children’s Hospital, IRCCS, Roma, Italy)
- ♦ **CARLO GIAQUINTO** (University of Padova, Italy)
- ♦ **ESTHER MUNALULA NKANDU** (University of Zambia)
- ♦ **CRISTINA PARDINI** (University of Pisa, Italy)
- ♦ **MARIASSUNTA PICCINNI** (University of Padova, Italy)
- ♦ **TATJANA POPLAZAROVA** (GlaxoSmithKline Biologicals, Wavre, Belgium)
- ♦ **RODOLFO SARACCI** (National Research Council, Pisa, Italy)

## 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 widespread recognition of the need for this research in order to grant children treatments and drugs that have been specifically tested for that population.

As a consequence of the moral and epistemological justification of pediatric research, 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 rethought to deal with the ethical challenges posed by new research developments such as, for example, enhancement pediatric research.

This challenge must be taken up by all people involved in pediatric research (especially members of Research Ethics Committees) who wish to promote excellence in research while granting children the necessary protection, avoiding the risk that economical pressure compromises the moral and scientific soundness of the studies.

## CONTENTS AND METHODS

*Contents* of the course include: (1) the evolution of the debate on the ethics of pediatric research; (2) research with children in a globalized world; (3) scientific justification of pediatric research; (4) methodological requirements of pediatric research; (5) the standard of minimal risk in pediatric research; (6) ethical and legal considerations on consent and assent in pediatric research; (7) guidelines on pediatric research; (8) ethical and social issues in vaccine research; (9) ethical issues in pediatric enhancement research; (10) ethical issues in pediatric transplantation research.

As to the *methods*, the course will combine lectures, group discussions and workshops. All course activities and materials will be 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 12, 2014

### Morning

- 9.00-9.15: Welcome by the scientific coordinator  
**CORRADO VIAFORA**
- 9.15-9.30: Introduction to the intensive course  
**MARIASSUNTA PICCINNI**
- 9.30-11.00: A short history of research with children 50 years after the Helsinki Declaration  
**RODOLFO SARACCI**
- 11.00-11.30: *Break*
- 11.30-12.30: Research with children in a globalized world  
**ESTHER MUNALULA NKANDU**
- 12.30: *Lunch*

### Afternoon

- 14.00-15.00: Research with children: scientific justification and methodological requirements  
*Lecture by* **MARINA CUTTINI** and **CARLO GIAQUINTO**
- 15.00-15.30: *Break*
- 15.30-17.00: Research with children: scientific justification and methodological requirements  
*Workshop coordinated by* **MARINA CUTTINI** and **CARLO GIAQUINTO**

## PROGRAMME DAY 2 - TUESDAY, MAY 13, 2014

### VENUE: INSTITUTE OF PEDIATRIC RESEARCH

#### Morning

- 9.00-9.15: Welcome and presentation of the Institute of Pediatric Research
- 9.15-10.00: Normative requirements in research with children: an overview  
**MARIASSUNTA PICCINNI**
- 10.00-10.30: *Break*
- 10.30-12.15: The standard of minimal risk in pediatric research: a critical analysis of the current interpretations  
*Lecture and workshop by* **MARINA CUTTINI**
- 12.15-13.00: Visit to the laboratories of the Institute of Pediatric Research
- 13.00: *Lunch*

#### Afternoon

- 14.15-15.30: Consent and assent in pediatric research: ethical and legal considerations  
**ANNAGRAZIA ALTAVILLA**
- 15.30-16.00: *Break*
- 16.00-17.30: Ethical and social issues in vaccine research with children  
**TATJANA POPLAZAROVA**
- 20.00: *Dinner*

## PROGRAMME DAY 3 - WEDNESDAY, MAY 14, 2014

### Morning

- 9.00-10.30: Guidelines on pediatric research  
**ESTHER MUNALULA NKANDU**
- 10.30-11.00: *Break*
- 11.00-12.30: What would we decide if we were the Ethics Committee?  
*Group work coordinated by* **ESTHER MUNALULA NKANDU**
- 12.30: *Lunch*

### Afternoon

- 14.00-15.30: Ethical issues in pediatric enhancement research  
**CRISTINA PARDINI**
- 15.30-16.00: *Break*
- 16.00-17.30: Ethical issues in pediatric transplantation research  
**MARA CANANZI**
- 17.30: *Farewell cocktail*

## REGISTRATION

Registration to the intensive course will be open from December 1, 2013.

The course fee is:

- € 600 for early registration (until March 31, 2014);
- € 700 for registration after March 31, 2014 (from April 1 to May 5, 2014);
- € 350 for university students and PhD candidates.

The fee includes tuition and course materials, as well as refreshments, three lunches and a dinner.

Detailed information on registration and payment is available at <http://www.fisppa.unipd.it/master-bioethics>.

Participants are expected to make their own travel and accommodation arrangements. Please visit [www.masterbioethics.org](http://www.masterbioethics.org) under *Intensive Courses* for information.

## INFORMATION

Contact person:

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## VENUE

Sala delle Edicole

Department of Philosophy, Sociology, Education and Applied Psychology

P.zza Capitaniato, 3

35139 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.

## INSTITUTE OF PEDIATRIC RESEARCH

The venue of the second day of the Intensive Course is, meaningfully, the Institute of Pediatric Research. The tower hosting the Institute was officially opened in June 2012 and is the biggest European research centre devoted to pediatric diseases.

The Institute was built thanks to the joint efforts of Padova City Council, Padova Province, Veneto Region, Padova Chamber of Commerce, Padova Industrial Zone Consortium, but mainly thanks to the Fondazione Città della Speranza (City of Hope Foundation), which contributed to the construction of the tower with 32 million Euros.

The City of Hope Foundation is a non profit organization, created in 1994 with the mission of financing clinical and research projects for improving children's health. Over the last 20 years the foundation has financed more than 60 research projects and the building of six major clinical and research pediatric facilities within the Veneto Region.

The new research tower was designed by the Italian architect Paolo Portoghesi: it has the shape of an angel, but it also hints at the DNA double helix, to symbolize both the idea of trust in science and the importance of care for the suffering other.

The Institute hosts about 350 researchers coming from various departments of Padova University Hospital and from two private foundations (Penta foundation and La Nostra Famiglia IRCCS Medea).

