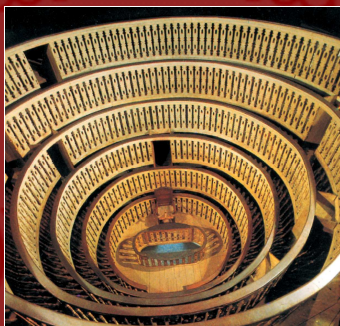


Università degli Studi di Padova



Intensive Course

# “Ethics of Pediatric Research”

May 13-15, 2013  
Padova, Italy

*Scientific coordinator*  
Corrado Viafora

*Course coordinators*  
Marina Cuttini, Carlo Giaquinto, Mariassunta Piccinni

organised by  
Department of Philosophy, Sociology, Education and Applied Psychology  
and Department of Woman and Child Health, University of Padova, Italy

## FACULTY

- ◆ **ANNAGRAZIA ALTAVILLA** (“Espace Ethique Méditerranéen”, Aix-Marseille University, France)
- ◆ **MARINA CUTTINI** (“Bambino Gesù” Children’s Hospital, IRCCS, Roma, Italy)
- ◆ **PAOLO DE COPPI** (Department of Woman and Child Health, University of Padova and Great Ormond Street Hospital for Children, London, UK)
- ◆ **PAOLA FACCHIN** (Department of Woman and Child Health, University of Padova, Italy)
- ◆ **CARLO GIAQUINTO** (Department of Woman and Child Health, University of Padova, Italy)
- ◆ **SUSANNA LIVADIOTTI** (“Bambino Gesù” Children’s Hospital, IRCCS, Roma, Italy)
- ◆ **ESTHER MUNALULA NKANDU** (University of Zambia)
- ◆ **MARIASSUNTA PICCINNI** (University of Padova, Italy)
- ◆ **MARTINA PIGAZZI** (Institute of Pediatric Research, Padova, Italy)
- ◆ **TATJANA POPLAZAROVA** (GlaxoSmithKline Biologicals, Wavre, Belgium)
- ◆ **MICHELA POZZOBON** (Institute of Pediatric Research, Padova, Italy)
- ◆ **FRANCESCA ROCCHI** (Pharmacologist expert in pediatric clinical trials, Roma, Italy)
- ◆ **RODOLFO SARACCI** (National Research Council, Pisa, Italy)
- ◆ **ROSELLA TOMANIN** (Department of Woman and Child Health, University of Padova, 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.

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 in particular the risk that economical pressure compromise the moral and scientific soundness of the studies.

## CONTENTS AND METHODS

*Contents* of the course include: (1) economical and social pressure on international biomedical research involving children; (2) the evolution of the debate on pediatric research; (3) the scientific justification of pediatric research; (4) methodological and ethical 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 using databases and population registers.

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.

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## PROGRAMME DAY 1 - MONDAY, MAY 13, 2013

### Morning

- 9.00-9.15: Welcome by the scientific coordinator  
**CORRADO VIAFORA**
- 9.15-9.30: Introduction to the intensive course  
**MARINA CUTTINI**
- 9.30-10.30: A short history of research with children  
**RODOLFO SARACCI**
- 10.30-11.00: *Break*
- 11.00-12.30: Research with children: scientific justification  
*Lecture and workshop by* **CARLO GIAQUINTO, SUSANNA LIVADIOTTI and FRANCESCA ROCCHI**
- 12.30: *Lunch*

### Afternoon

- 14.00-15.30: Methodological requirements and ethical issues  
*Lecture and workshop by* **MARINA CUTTINI**
- 15.30-16.00: *Break*
- 16.00-17.00: Research with children: using databases and population registers  
**PAOLA FACCHIN**

## PROGRAMME DAY 2 - TUESDAY, MAY 14, 2013

### VENUE: INSTITUTE OF PEDIATRIC RESEARCH

#### Morning

- 9.00-9.15: Welcome and presentation of the Institute of Pediatric Research
- 9.15-10.00: Legal requirements in research with children: an overview  
**MARIASSUNTA PICCINNI**
- 10.00-11.30: The standard of minimal risk in pediatric research: a critical analysis of the current interpretations  
*Lecture and workshop by* **MARINA CUTTINI**
- 11.30-12.00: *Break*
- 12.00-13.00: Consent and assent in pediatric research: ethical and legal considerations  
**ANNAGRAZIA ALTAVILLA**
- 13.00: *Lunch*

#### Afternoon

- 14.00-15.00: Visit to the laboratories of the Institute of Pediatric Research
- 15.00-15.30: *Break*
- 15.30-17.00: Research projects within the Institute of Pediatric Research: the ethical issues  
*A panel discussion with* **PAOLO DE COPPI, MARTINA PIGAZZI, MICHELA POZZOBON, ROSELLA TOMANIN**
- 20.00: *Dinner*

## PROGRAMME DAY 3 - WEDNESDAY, MAY 15, 2013

### Morning

- 9.00-10.00: Guidelines on pediatric research  
**RODOLFO SARACCI**
- 10.00-10.30: *Break*
- 10.30-12.00: What would we decide if we were the Ethics Committee?  
*Group work coordinated by* **RODOLFO SARACCI**
- 12.00-12.30: New European regulation on clinical trials and medicinal products for human use  
**ANNAGRAZIA ALTAVILLA**
- 12.30: *Lunch*

### Afternoon

- 14.00-15.30: Ethical and social issues in vaccine research  
**TATJANA POPLAZAROVA**
- 15.30-16.00: *Break*
- 16.00-17.30: Pediatric research in developing countries  
**ESTHER MUNALULA NKANDU**
- 17.30: *Farewell cocktail*

## REGISTRATION

Registration to the intensive course will be open from December 1, 2012.

The course fee is:

- € 600 for early registration (until March 31, 2013);
- € 700 for registration after March 31, 2013 (from April 1 to May 6, 2013).

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

Detailed information on registration and payment will be available at [www.filosofia.unipd.it/post-lauream/master/intensive-courses](http://www.filosofia.unipd.it/post-lauream/master/intensive-courses).

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

Department of Philosophy, Sociology, Education and Applied Psychology

Palazzo del Capitano

P.zza Capitaniato, 3

35139 Padova

## ERASMUS MUNDUS MASTER OF BIOETHICS

This course is part of the Erasmus Mundus Master of Bioethics programme, organised by a consortium of three European universities: the KU Leuven (Belgium), the Radboud Universiteit Nijmegen (The Netherlands) and the Università degli Studi di Padova (Italy).

Participants of the intensive course will therefore join EMMB students from all over the world.

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## 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, Chamber of Commerce of Padova, Consorzio Zona Industriale of Padova, 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 18 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, La Nostra Famiglia IRCCS Medea).

