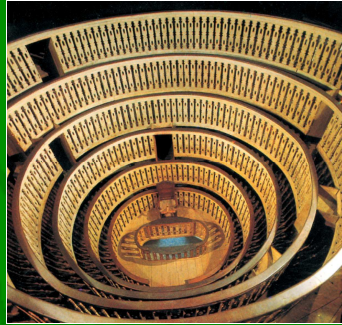


Università degli Studi di Padova



Intensive Course

“Ethics of Pediatric Research”

May 18-20, 2015
Padova, Italy

Scientific coordinator
Corrado Viafora

Course coordinators
Dena Davis, Mariassunta Piccinni

FACULTY

- ♦ **MAURIZIO BONATI** (Mario Negri Institute, Italy)
- ♦ **MARA CANANZI** (Padova University Hospital, Italy)
- ♦ **DENA DAVIS** (Lehigh University, USA)
- ♦ **CARLO GIAQUINTO** (University of Padova, Italy)
- ♦ **ENRICO FURLAN** (University of Padova, Italy)
- ♦ **MARIASSUNTA PICCINNI** (University of Padova, Italy)
- ♦ **TATJANA POPLAZAROVA** (GlaxoSmithKline Biologicals, Belgium)
- ♦ **ALESSIO VEDOVETTO** (Padova University Hospital, 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 re-thought to deal with the ethical challenges posed by new research developments such as, for example, pediatric genetic 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) scientific and methodological requirements of pediatric research; (3) normative requirements of research with children; (4) the issue of risk in pediatric research; (5) consent and assent in pediatric research; (6) ethical and social issues in vaccine research with children, in pediatric transplantation research and in pediatric genetic research.

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 18, 2015

Morning

- 9.00-9.15 Introduction to the intensive course
MARIASSUNTA PICCINNI
- 9.15-10.30 A short history of research with children
ENRICO FURLAN
- 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 Normative requirements of research with children
MARIASSUNTA PICCINNI
- 15.00-15.30 *Break*
- 15.30-17.00 Ethical and social issues in vaccine research with children
Lecture and workshop by **TATJANA POPLAZAROVA**
- 18.00** *Visit to Palazzo Bo and the Anatomical Theatre*

PROGRAMME DAY 2 - TUESDAY, MAY 19, 2015

Morning

9.00-10.30 The issue of risk in pediatric research
MAURIZIO BONATI

10.30-11.00 *Break*

11.00-12.30 Ethical issues in pediatric transplantation research
Lecture and workshop by **MARA CANANZI**

12.30 *Lunch break*

Afternoon

14.00-15.30 Consent and assent in pediatric research
DENA DAVIS

15.30-16.00 *Break*

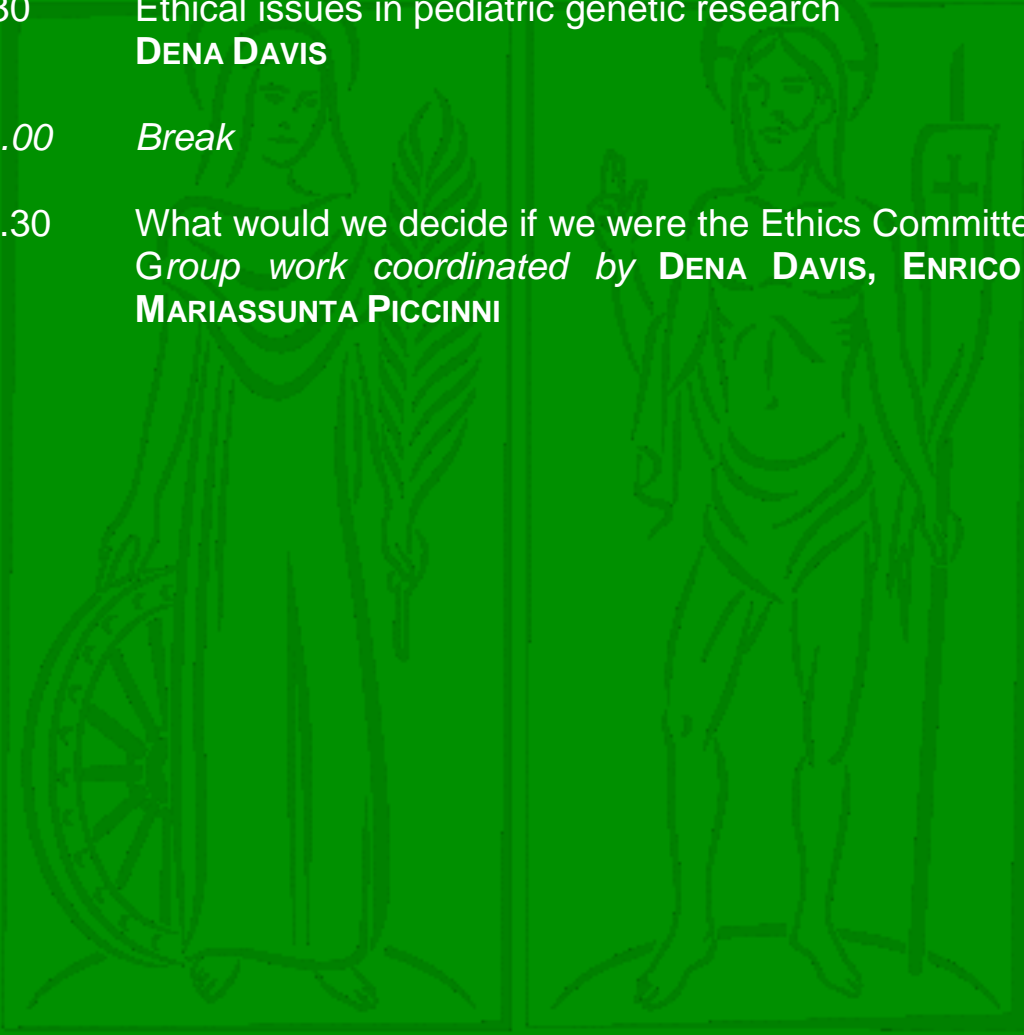
16.00-17.00 Building a relationship of trust with the young patient:
experiences in oncology research
Lecture and debate by **ALESSIO VEDOVETTO**

20.00 *Dinner*

PROGRAMME DAY 3 - WEDNESDAY, MAY 20, 2015

Morning

- 9.00-10.30 Ethical issues in pediatric genetic research
DENA DAVIS
- 10.30-11.00 *Break*
- 11.00-12.30 What would we decide if we were the Ethics Committee?
Group work coordinated by **DENA DAVIS, ENRICO FURLAN,**
MARIASSUNTA PICCINNI



REGISTRATION

The course fee is 400 € (250 € for university students and PhD candidates). The fee includes tuition and course materials, as well as one dinner and the visit to Palazzo Bo and the Anatomical Theatre (see next page).

The deadline to register is May 10, 2015.

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 under *Intensive Courses* for information.

INFORMATION

Contact person:

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Department of Philosophy, Sociology, Education and Applied Psychology

E-mail: emmbpadova@gmail.com

VENUE

Sala delle Edicole

Department of Philosophy, Sociology, Education and Applied Psychology

P.zza Capitaniano, 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.

organised by

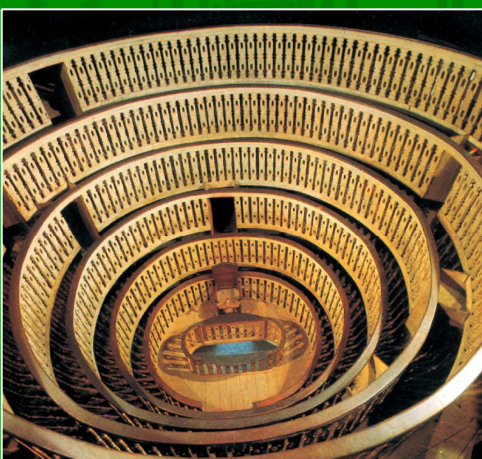
Department of Philosophy, Sociology, Education and Applied Psychology
and Department of Woman and Child Health, University of Padova, Italy

PALAZZO BO AND THE ANATOMICAL THEATRE

PALAZZO BO is the main seat of the University of Padova. The name (Bo, i.e. ox) may derive from its proximity to the quarter traditionally occupied by the *Bechariarum* (butchers) or by the fact that cattle were traded there in former times. An inn with an ox as a sign had already been mentioned in a document of 1364 under the name of *Hospitium Bovis*. But the original core of the Bo is much older, as there were buildings on the site as early as the 13th century. In 1539, the University acquired full ownership and, architecturally, the 16th century was the key period for the Palazzo Bo.



The best-known room in the Palazzo Bo is the **AULA MAGNA**, the Great Hall. One of the most evocative symbols in the history of the University and of its staff and alumni is undoubtedly the podium which, according to tradition, was used by Galileo himself. It was located in the Aula Magna until mid-way through the 19th century, when it was moved due to renovation work on the hall.



Also dating from the 16th century is the world's first permanent **ANATOMICAL THEATRE**. 1446 is the date of the earliest documents mentioning the use of anatomical theatres made of wood, which were erected and dismantled as needed for public dissections. It was the anatomist Girolamo Fabrici D'Acquapendente who took the initiative of having a permanent anatomical theatre built. It was inaugurated in 1595 and remained in use until 1872.