


For more information about the Vienna School of Clinical research and our curriculum please visit our website:

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 Campus Vienna Biocenter
Helmut-Qualtinger-Gasse 2, 1030 Vienna, Austria

ETHICAL ASPECTS IN CLINICAL RESEARCH

Vienna, 17 - 18 October 2012



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ABOUT VSCR:

The Vienna School of Clinical Research (VSCR) is an international non-profit organization for continuing post-graduate education of physicians and other experts who are involved in clinical research. The VSCR has trained more than 6500 experts from over 90 countries in the last 10 years. Since 2001, approximately 20 different course modules have been developed, involving an international faculty of around 150 experts from more than 40 different countries. The courses cover all topics relevant to clinical trialists including GCP, trial design and methodology, evidence based medicine, biostatistics, clinical epidemiology, ethics, publication, project management and health outcomes research.

OUR PRIVATE/PUBLIC/ACADEMIC PARTNERSHIP:

Based on partnerships between public bodies (City of Vienna, Austrian Government, European Commission), academic centres (15 universities in Europe, US and Africa) and the private sector (pharma- and other industry), the VSCR has developed an educational programme that aims at optimizing clinical research by minimizing risk and cost and maximizing scientific value as well as ethical and quality standards. Public and private grants and income from course fees provide the funding for a scholarship programme that allows selected participants access to the VSCR educational programme. VSCR is partner of PharmaTrain, an educational initiative of IMI (Innovative Medicines Initiative) sponsored by the European Commission and EFPIA.

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Vienna School of Clinical Research

Ethical Aspects of Clinical Research

The role of the Ethics Committee in the light of relevant regulations

AGENDA

Vienna, 17 – 18 October 2012

Faculty Members:

Christiane DRUML	Austrian Bioethics Commission, Ethics Committee Medical University Vienna and General Hospital Vienna, Austria
Brigitte BLÖCHL-DAUM	Medical University of Vienna, Austria
Christian MADL	Medical University of Vienna and KH Rudolfstiftung, Austria
Maria PATRÃO NEVES	University of the Azores, Department of Philosophy, Portugal
Michael WOLZT	Medical University of Vienna, Austria

Training Coordination:

Neelam KAUL	Vienna School of Clinical Research, Austria
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DAY 1 – Wednesday, 17 October 2012

09:00 - 09:15	1. Welcome and Introduction	<i>Neelam KAUL Christiane DRUML</i>
09:15 – 10:00	2. Lecture What is Ethics in Research & Why is it Important? <i>The philosophy and historical background of ethics in clinical research</i>	<i>Maria PATRÃO NEVES</i>
10:00 – 10:15	Coffee Break	
10:15 – 11:15	3. Lecture Applicable Regulations, Declarations & Guidelines <i>Declaration of Helsinki, ICH GCP, EU Directive Differences between ethics committees</i>	<i>Christiane DRUML</i>
11:15 – 12:00	4. Lecture Why should research be ethically regulated?	<i>Christiane DRUML</i>
12:00 – 13:00	Lunch	
	<u>WORKING GLOBALLY</u>	
13:00 – 13:30	5. Lecture Cross-cultural Considerations in International Collaborative Research	<i>Maria PATRÃO NEVES</i>
13:30 – 14:15	6. Lecture Controversies in International Research	<i>Maria PATRÃO NEVES</i>
	<u>VULNERABILITIES</u>	
14:15 – 15:00	7. Lecture Vulnerable Patient Populations	<i>Christiane DRUML</i>
15:00 – 15:15	Coffee Break	
15:15 – 15:45	8. Lecture Ethics of Intensive Care Trials	<i>Christian MADL</i>
16:00 – 16:45	9. Discussion Ethics Behind Closed Doors	<i>Christiane DRUML</i>



DAY 2 – Thursday, 18 October 2012

09:00 – 10:00	10. Lecture Clinical Trials & Placebo Control	<i>Michael WOLZT</i>
10:00 – 11:00	11. Lecture Fraud and Misconduct	<i>Brigitte BLÖCHL-DAUM</i>
11:00 – 11:15	<i>Coffee Break</i>	
11:15 – 12:30	12. Workshop Informed Consent	<i>Brigitte BLÖCHL-DAUM</i>
12:30 – 13:30	Lunch	
13:30 – 15:30	13. Workshop For Ethics Committee Members <ul style="list-style-type: none">• <i>Define the role of an ethics committee</i>• <i>Protocol evaluation requirements from an ethics committee's point of view</i>• <i>Quality management</i>• <i>Scientific integrity – research misconduct</i>• <i>Administrative aspects</i>• <i>Clinical trial registry</i>• <i>Open access to results</i>	<i>Michael WOLZT</i>
15:30 – 15:45	Coffee Break	
15:45 – 16:45	Examination	
16:45 – 17:15	14. Workshop Mock IRB/IEC Meeting and Reviews-Discussion	<i>Michael WOLZT</i>
17:15 – 17:45	WRAP-UP & GRADUATION CEREMONY	

An application has been made to the EACCME® for CME accreditation of this event.

Ethical Aspects of Clinical Research

Vienna, 17 - 18 October 2012

COURSE DESCRIPTION

Designed for clinical researchers and ethics committee members, VSCR offers an ethics in clinical research course with information concerning legal, administrative and organizational aspects of ethics committees. Global ethical aspects will also be covered by this course. In a mock Ethics Committee-Meeting you will gain insight into the work of Ethics Committees.



LEARNING OUTCOMES

- Develop an understanding of the principles and basic considerations of ethics in clinical research
- Appreciate the roles and the responsibilities of ethics committees as defined by current regulations
- Learn about ethical clinical research in vulnerable patient populations
- Understand the legal, administrative and organisational aspects associated with ethics in clinical research
- Understand ethical aspects in global clinical research

FACULTY

Faculty members are contracted by the VSCR and committed to provide independent teaching of state-of-the-art principles. We proudly present our invited course faculty:

Christiane **DRUML**

(Austrian Bioethics Commission, Ethics Committee Medical University Vienna and General Hospital Vienna, Austria)

Brigitte **BLÖCHL-DAUM** (Medical University of Vienna, Austria)

Christian **MADL** (Medical University of Vienna & Hospital Rudolfstiftung, Austria)

Maria **PATRÃO NEVES** (University of the Azores, Department of Philosophy, Portugal)

Michael **WOLZT** (Medical University of Vienna, Austria)

APPLICATION CRITERIA

The following pre-requisites should be met by applicants:

- Should be a member of or regular consultant to an ethics committee, or be a clinical researcher involved in the conduct and/or ethical review of clinical trials
- Fluency in the English language

TUITION FEES

The course price of Euro 1.300,00 includes:

- Course fee
- Course material
- Lunch and refreshments during the course

Visit our website to register today

WWW.VSCR.AT

CERTIFICATES

Certificates will be provided to all participants attending at least 80% of the total course hours and completing the final course examination. This course has been submitted for accreditation to the following bodies:

- European Accreditation Council for Continuing Medical Education (EACCME)
- Österreichische Akademie der Ärzte“ (DFP)



THIS CERTIFICATE IS ACKNOWLEDGED FOR

- VSCR Basic Clinical Research Associates and Monitors Diploma
- Master of Science in Clinical Research



PROFIT OF OUR EARLY BOOKING DISCOUNTS

- book until 17 July 2012 and receive 10 % discount
- book until 17 Sept.2012 and receive 5 % discount

For information about **group- and early booking discounts**, please contact: vscr@vscr.at

