EFGCP 4th European Workshop on

Training for Research Ethics Committees

20 March 2013
Bezirksärztekammer Baden-Württemberg, Stuttgart, Germany

Organised by the

In partnership with the

www.efgcp.eu    info@efgcp.eu
Workshop Rationale & Aims

The European Forum for Good Clinical Practice (EFGCP) has organised three previous workshops on this topic. Each has been a collaboration with other bodies and all have been reported in the Journal of Medical Ethics:

1. A Workshop on *Research Ethics Committees in Europe - Current Arrangements and Resources for Training Members*  
   16 March 2007, Medical University of Vienna, Austria  

2. A Workshop on *How can Research Ethics Committees set and meet standards of good ethical practice - Standards, Accountability and Examples*  

3. A Workshop on *A Syllabus for Training of Research Ethics Committees*  
   7 April 2011, Landesarztekammer Baden-Württemberg, Stuttgart, Germany  
   J Med Ethics 2012;38:3 184-186 Published Online First: 20 September 2011 doi:10.1136/medethics-2011-100064

Full reports are available to EFGCP members on the website (http://www.efgcp.eu).

We are now holding the fourth workshop in this series, building on these meetings and the European Commission resources “European Textbook on Ethics in Research 2010” and “Syllabus on Ethics in Research 2010”. We will be collaborating with other partners.

**Our aim is to help develop training for new EC members in the EU.** The meeting will be “practical and tangible” focusing on the role of a new EC member and how we might provide effective training.

For delegates who attend, this workshop will provide:

- Information about current EU regulations on Clinical Trials of Medicinal Products and training in this area
- Access to experts experienced in EC training
- Access to training resources
- Access to practical examples of training
- An opportunity to contribute ideas to a training syllabus for ECs
- An opportunity for trainers to present and share their programmes
- An opportunity to look at a “Research Ethics CD”

All delegates will receive a full report on this meeting to help them develop their local training programme.
The programme has been divided into four sessions based on the syllabus; for each the following points must be developed:

i. Educational objectives
ii. Possible teaching methods
iii. Assessment

At our meeting in 2011 we developed a proposed syllabus founded on four areas:

**ETHICAL ANALYSIS**
- Have a balanced view of health care and research, recognising its benefits and harms
- Capacity to make a judgement upon the ethical standing of a research project

**SCIENTIFIC METHOD**
- Capacity to review the scientific standing of a project, according to national guidance
- Capacity to review the suitability of the applicant and the validity of the research

**WORK OF AN ETHICS COMMITTEE**
- Capacity to debate and reach consensus
- Commitment to ongoing training: to organise it (for the REC officers) and attend it (for REC members)
- Ability to work constructively with scientists and researchers, public and patients
- REC’s ability to explain its purpose and decisions openly to public and patients

**THE PURPOSE OF RECS AND THE REGULATORY FRAMEWORK**
- Understanding the role of RECs and other bodies involved in the regulation of research
- Understanding of national, European and international processes and guidance
- Understanding of the national law related to research
- Knowledge to assess insurance and compensation arrangements
Programme Committee

Hugh Davies  Health Research Authority, EFGCP, United Kingdom
Petra Knupfer  Landesärztekammer Baden-Württemberg, Germany

Workshop Language

The language of the Workshop will be English.

Workshop Venue

Bezirksärztekammer Baden-Württemberg
Jahnstr. 5
DE-70597 Stuttgart
Germany
Tel: +49 711 769 89 89 (Contact Person: Anita Reichmann) - Fax: +49 711 760 90 856

Registration & Information

The total number of seats being limited to 40, places will be allocated on a first come, first served basis striving to reach a balance in countries representation at European level. For any information please contact the EFGCP team at conferences@efgcp.eu / Tel: +32 2 732 87 83 or visit www.efgcp.eu
Agenda

09:00  Registration & Welcome Coffee

09:15  Welcome & Introduction to the Workshop

09:30  SESSION 1
Working on an Ethics Committee

Objectives:
• To explain practical arrangements of committee working
• To explain how the new member will learn as they attend meetings and how they can ask other committee members for advice and information
• To reflect on the knowledge skills and attitudes of ethical debate

10:30  Coffee Break

10:45  SESSION 2
The purpose of RECs, the role of a new member and providing training in the regulatory framework

Objectives: To provide new members with
• An understanding of the contribution of research to health and health care, recognising its benefits and harms
• An understanding of the role of ECs and other bodies involved in the regulation of research
• An understanding of national, European and international processes and guidance
• An understanding of the national law related to research
• Knowledge to assess insurance and compensation arrangements

12:15  Lunch and demonstrations of training

13:00  SESSION 3
Ethical (and legal) issues and analysis

Objectives:
• Have the capacity to make a judgement upon the ethical standing of a research project
• Work within the legal framework of the member state

14:30  Coffee Break

14:45  SESSION 4
Scientific method and critical appraisal

Objectives:
• Capacity to review the scientific standing of a project, according to national guidance
• Capacity to review the suitability of the applicant and the validity of the research

15:45  Panel discussion and conclusions
• Reinforcing leaning
• Developing a network of training resources

16:15  End of Workshop