A report on the EFGCP Workshop “A Syllabus for Training of Research Ethics Committees”

7 April 2011
Bezirksärztekammer Baden-Württemberg
Stuttgart, Germany
# CONTENTS

Abbreviations Used

Summary

1. Introduction
   - Process and provenance
   - Purpose of the report
   - How this paper might be used

2. The Attributes for a REC and Its Members: A Syllabus for Training

3. Training Resources

4. Task, Training Needs and Resources for a REC and Its Members

Appendices

I. References

II. Writing Group

III. Faculty

IV. Delegates

V. Programme of the workshop
ABBREVIATIONS USED

EFGCP  European Forum for Good Clinical Practice  
REC  Research Ethics Committee  
SOPs  Standard Operating Procedures

SUMMARY

This paper reports a European Forum for Good Clinical Practice (EFGCP) workshop held in 2011 to consider a REC training syllabus, subsequent training needs and resources. The syllabus that was developed was divided into 4 competencies: committee working, scientific method, ethical analysis and the regulatory framework. Appropriate training needs for each, with possible resources were discussed. Lack of funding for training was reported as a major problem but affordable alternatives were debated. Strengths and weaknesses of this approach were discussed and the resultant proposal will be disseminated through the EFGCP and member states’ RECs.
1. **INTRODUCTION**

**Process and provenance**

Delegates at the workshop recognised there must be wide, inclusive, consultation when writing a report. Proposed steps are:

<table>
<thead>
<tr>
<th>STEPS</th>
<th>DATE</th>
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<tbody>
<tr>
<td>Workshop</td>
<td>7 April 2011</td>
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<tr>
<td>Draft report written by writing group</td>
<td>April 2011</td>
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<tr>
<td>Review by faculty and delegates</td>
<td>May 2011</td>
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<tr>
<td>Presentation to EFGCP Ethics Working Party</td>
<td>May 2011</td>
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<tr>
<td>Rewrite by writing group</td>
<td>June 2011</td>
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<tr>
<td>Re-edit by writing group</td>
<td>June 2011</td>
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<tr>
<td>Posted on EFGCP website</td>
<td>June 2011</td>
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<tr>
<td>Discussed at EFGCP annual meeting</td>
<td>January 2012</td>
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<tr>
<td>Progress review</td>
<td>Autumn 2012</td>
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**Purpose of the report**

The meeting recognised the enormous contribution made by the honorary members of research ethics committees and all at the workshop agreed any proposal must kindle members’ interest rather than dampen their enthusiasm. This syllabus is therefore presented cautiously to help committees but not burden them with a long list of “required competencies”. It follows the example of Larcher et al (2010), when they drew up possible core competencies for clinical ethics committees. They were anxious to avoid:

“fettering it (the ethics committee and its members) with undue bureaucracy or unrealistic expectations of essentially voluntary groups”

while recognising that, in their field,

“the increased profile of clinical ethics support will mean that those who provide it will ultimately need to demonstrate that they do so competently and that they achieve appropriate ethical and legal governance standards”.

One of the strengths of RECs is that as such it provides complementary and cumulative experience. Committee officers (chairs, vice chairs and coordinators/secretaries) have an expanded role and no individual member can be
expected to meet all the expectations within a syllabus. This is precisely the reason for having committees at all - to share our knowledge and help others consider research studies.

**How this paper might be used**

i. As a guide or orientation for new members.
ii. As a guide to committees considering their competency and training needs.
iii. As a guide for trainers.
iv. As a route to material for REC members and trainers.
v. As a prompt and template to develop consistency and competency in RECs across the EU.

**2. THE ATTRIBUTES FOR A REC AND ITS MEMBERS: A SYLLABUS FOR TRAINING**

Workshop participants identified a number of attributes that a REC and its members should have. These can be grouped in four categories, as schematised below. Click on each item for more details.

**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

**Committee work**
- 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

**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

In paragraph 4 we provide a more detailed report of the tasks and training needs identified by participants to the workshop.
3. **TRAINING RESOURCES**

Participants named a number of training methods and resources that might suit the present syllabus. Needs will vary from member state to member state and guidance must accommodate this.

**International, national or supra regional training days**

These are an opportunity to provide efficient access to expertise and can be used to promote a consistent approach. It's also an opportunity to network or meet other REC members so they don’t become entrenched in one way of working or seeing research. They are expensive and time consuming to organise and run and honorary members / volunteers may have restrictions on their time away from work. The benefits may be confined to delegates, as the whole committee doesn't attend. It’s necessary to consider how to spread this learning. Ideally, the implementation of supra regional training days might be accompanied by a well structured program for disseminating the knowledge among individual REC members.

**REC break-out session / away days**

These allow the REC to talk without the pressure of applications to review, helping members to get to know each other and therefore work together more effectively. Groups who know each other will find it easier to discuss issues openly, agree, disagree and strive for consensus. It may also ease recruitment. Ideally they should be held once a year. Many REC members, struggling to complete their reviews and having pressures of work, might think that annual meetings mean even more time-consumption. However, in the long run such meetings ease REC’s communication and team work and so save time.

**Visiting a research site**

This would provide the opportunity for REC members to gain an understanding or research procedures. REC members’ participation in research and their experience would be another possible resource!

**REC “in – committee” training and learning**

Committees may be considered to “set their own style and example” and opportunities to reflect on these can help the REC identify good and poor practice, both individually and as a group. It is in this way the “soft skills” of committee working and debate” may be best learnt and developed. A good chairman can facilitate this within the regular meetings but it may also need separate, “non-business” meetings with an external facilitator. This is the best way to assess the members’ and committee’s working but does require help or training in self evaluation and reflection. It wouldn’t work without these skills.
Tutoring/coaching or mentoring in committee

- **A REC officer** with responsibility for overseeing members’ training and the competence of the committee might be able to provide directions and access to resources for members. These would have a particular role for new members.

- **Training by members for other members** Committees will contain a wide range of professional expertise so meetings are an obvious opportunity to share knowledge and expertise. Presentations could be arranged during breaks between application reviews or after the agenda items. This will also help the committee members appreciate and value each others’ talents and work together. All this makes it an affordable and effective resource that all RECs could benefit from.

- **“Lunch& learn”** Some committees assemble for lunch before the agenda or stay on afterwards. These are an opportunity to arrange educational sessions.

**E-Learning**

This medium can be wide reaching, and is useful for single, straightforward topics. Once developed, it can be economic but the financial resources and expertise needed to establish a course (and update it) are often underestimated. For any particular purpose websites need to be identified and validated. Its role in developing critical analysis and ethical debate are less certain, but it can certainly contribute to a programme “blended learning”.

**Access to material**

RECs need easy (electronic) access to:

- International and national guidance.
- Regulations.
- Governance documents.
- Medline.
- The scientific and ethical literature.
## 4. Task, Training Needs and Resources for a REC and its Members

<table>
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<tr>
<th>Tasks</th>
<th>Training Needs</th>
<th>Training resources</th>
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| The REC and its members should have a balanced view of health care and research, recognising its benefits and harms. | - An introduction to medical and health care history.  
- An introduction to research history, the benefits research has brought and its attendant risks.  
- The relationship between health care and research: how they fit.  
- An introduction to the modern development of drugs and medical devices. | ![Testing treatments](image) by Imogen Evans, Hazel Thornton, Iain Chalmers |
| The REC and its members should have an understanding of:            | ![Governance Arrangements for NHS REC](image)  
| (a) Its role.                                                       | ![Standard Operating Procedures](image)                                         |
| (b) That of other bodies involved in the regulation of research.    | ![Declaration of Helsinki](image)  
|                                                                  | ![European Clinical Trials Directive](image)  
|                                                                  | ![GCP Guidelines](image)                                                       |
| The REC and its members should have access and understanding of International, European and national guidance and processes. | - An introduction and discussion of the REC’s role protecting research subjects and facilitating research.  
- Access to the committees’ governance and SOPs.  
- An introduction and opportunity to work with material currently sent to the RECs.  
- An understanding of the role of other regulators, how this links to the REC’s role and how differences can be resolved.  
- An opportunity to assess and reflect on our own expertise and where we need to study.  
- An opportunity to assess and reflect on others’ expertise. |
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<th><strong>Tasks</strong></th>
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<tr>
<td>The REC and its members should have an understanding of the law related to research, relevant to its role.</td>
<td>• Access to relevant National law.</td>
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<td>Annual online assessment for members of the Wien University REC</td>
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| The REC and its members should have the attributes to conduct its debate and reach consensus. | • Commitment to reading documents.  
• Time and teaching to develop skills to read and analyse documents (critical appraisal).  
• The “soft skills of working together”:  
  • Time to consider the required attributes.  
  • Skills of debate and ethical analysis.  
  • A willingness to tolerate and accommodate other views.  
  • Empathy.  
  • Humility.  
  • Courage. | “12 Angry Men” vignettes from the NRES Research Ethics CD |
| The REC and its members should have the knowledge and skills to review the scientific standing of a project, according to national guidance. | • An explanation of the REC’s role in this (given the national variation).  
• Training in analysis of research questions and appropriate methods.  
• Training in different research designs - quantitative and qualitative.  
• A structure explaining the current regulatory framework for drug development.  
• Training in statistics relevant for RECs.  
• Training to understand the fair use of placebo.  
• Training to understand equipoise. | |

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<th><strong>Tasks</strong></th>
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| The REC and its members should have the knowledge, skills and attributes to review the suitability of the applicant and the validity of the research. | • Time to consider the researchers' role, constraints and motives.  
• Time to consider how we assess the research team: CV, GCP training, resources, experience, skills, empathy with subjects.  
• Opportunity to consider and understand how “conflicts of interest” may arise and how they should be handled.  
• Contracts and payment to researchers. |

**Training resources**  
(For illustration only we have put some examples. We envisage contributions from other member states to be included here to construct a “European resource”)
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<tr>
<th>Tasks</th>
<th>Training Needs</th>
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| The REC and its members should have the knowledge skills and attributes to review the ethical standing of a project. | - Time to consider the ethical aspects of a research project and how we might how we might break it down into its “ethical domains”.  
- A consideration of the common ethical models – duty based, rights based and consequentialism.  
- Time to reflect on our judgements and how we make them.  
- Consideration of the ethical aspects of:  
  - Recruitment.  
  - Inclusion and exclusion criteria.  
  - Consent:  
    - Patient autonomy.  
    - Principles of informed consent.  
    - Information provided for the participant.  
  - Evaluating the benefits and risks (safety and risk management).  
  - Judging the burden of the study.  
  - Assessing payments to subjects both volunteers and patients.  
  - Confidentiality and data management:  
    - Data storage.  
    - Sample storage.  
  - End of trial policy:  
    - Publication policy.  
    - Information to past participants.  
    - Trial registration publication or open access arrangements.  
  - Post-trial care for patients and possible access to therapy.  
  - Research involving particular groups:  
    - Children.  
    - Elderly.  
    - Mental health. | (For illustration only we have put some examples. We envisage contributions from other member states to be included here to construct a "European resource")

[European Textbook on Ethics in Research](#)
<table>
<thead>
<tr>
<th>Tasks</th>
<th>Training Needs</th>
<th>Training resources</th>
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<tr>
<td>The REC and its members should have the knowledge to assess the liability, insurance and compensation, appropriate for its national role.</td>
<td>• The national arrangements liability, insurance and cover for this, and how the REC works with other parties.</td>
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<td>Back to table</td>
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<td>(For illustration only we have put some examples. We envisage contributions from other member states to be included here to construct a “European resource”)</td>
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<tr>
<td>The REC should have a training programme to maintain its competence (responsibility of its officers) while the REC members should commit to continuing development and work to keep up to date.</td>
<td>• To determine what the REC needs to know • To match training needs with possible (local) resources</td>
<td>One or two coaches in each REC supporting “on-the-job training”. Coaches meet nationally once or twice a year to draw up learning aids, checklists, etc.</td>
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<tr>
<td>The REC and its members should be able to work constructively with scientists and researchers.</td>
<td>• An understanding of the place of research in health care, and how researchers plan, seek funding and conduct research. • An understanding of medical / health care progress and how science and knowledge advance.</td>
<td>Question-specific guidance of the IRAS application for RECs</td>
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<td>The REC and its members should be open and able to explain its purpose, deliberations and decisions to public and patients.</td>
<td>• An opportunity to reflect on processes and how they might be open and transparent • An opportunity to consider the public understanding of science, research and health care • An opportunity to define the RECs role and how it can best be presented</td>
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APPENDICES

I. References


Davies H 2010 How should we teach research ethics? Research Ethics Review 6(2):43–47


Davies H, Wells F, Druml C 2008 How can we provide effective training for research ethics committee members? A European assessment J Med Ethics;34:301

Larcher V, Slowther A Watson A 2010 Core competencies for clinical ethics committees Clinical Medicine 10 (1):30-33

Gillon, R What attributes should clinical ethics committees have? BMJ 2010; 340:c2496


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Frank Wells EFGCP, United Kingdom
IV. Delegates

<table>
<thead>
<tr>
<th>Name</th>
<th>Position and Organization</th>
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<tbody>
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<td>Dag Bruusgaard</td>
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<td>Ester Cairoli</td>
<td>Intern National Research Ethics Service</td>
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<td>Hugh Davies</td>
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<td>Bioethics Research Programme, Malta</td>
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<td>Gerd Mikus</td>
<td>Deputy Head of Department, University of Heidelberg, Clinical</td>
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<td>Mark Turtle</td>
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<td>Gillian Vale</td>
<td>Administrator, Beaumont Hospital Ethics (Medical Research) Committee, Dublin</td>
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<td>Anne G. Vinsnes</td>
<td>Professor, Faculty of Nursing, Trondheim</td>
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<tr>
<td>Frank Wells</td>
<td>National Research Ethics Advisor, Immediate Past Chairman, Ethics Working Party EFGCP</td>
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V. Programme of the workshop

08:30 Registration & Welcome Coffee
09:00 Welcome to the Workshop: Dr Georg Hook, Chairman of the Stuttgart Ethics Committee, Germany
09:10 Top. 1 Introduction and Aims: Why training? Why fear quality assurance?
Lessons from UK and Germany
Frank Wells, EFGCP, United Kingdom
Jürgen Helm, University of Halle, Germany
09:40 Break-out into work groups:
Define tasks, training needs and resources to support RECs
Moderation: François Hirsch, Institute for Health Technologies, Inserm/Aviesan, France
11:00 Coffee Break
11:15 Report & Discussion
Moderation: Hugh Davies, National Research Ethics Service (NRES), EFGCP, United Kingdom
Petra Knupfer, Landesärztekammer Baden-Württemberg, EFGCP, Germany
12:30 Lunch
13:15 Top. 2 Attributes and training methods for effective RECs?
Lessons from 12 angry men
Hugh Davies, National Research Ethics Service (NRES), EFGCP, United Kingdom
Ester Cairoli, National Research Ethics Service (NRES), United Kingdom
An assessment of learning in the Vienna Medical University Research Ethics Committee,
Ernst Singer, Medical University, Vienna
13:45 Break-out into work groups:
Define attributes & find methods to achieve these attributes
Moderation: Jürgen Helm, University of Halle, Germany
14:45 Coffee Break
15:00 Report & Discussion: Tangible result development
Moderation: Hugh Davies
Petra Knupfer, Landesärztekammer Baden-Württemberg, EFGCP, Germany
16:00 Feedback and Consensus of the Day
16:30 End of Workshop