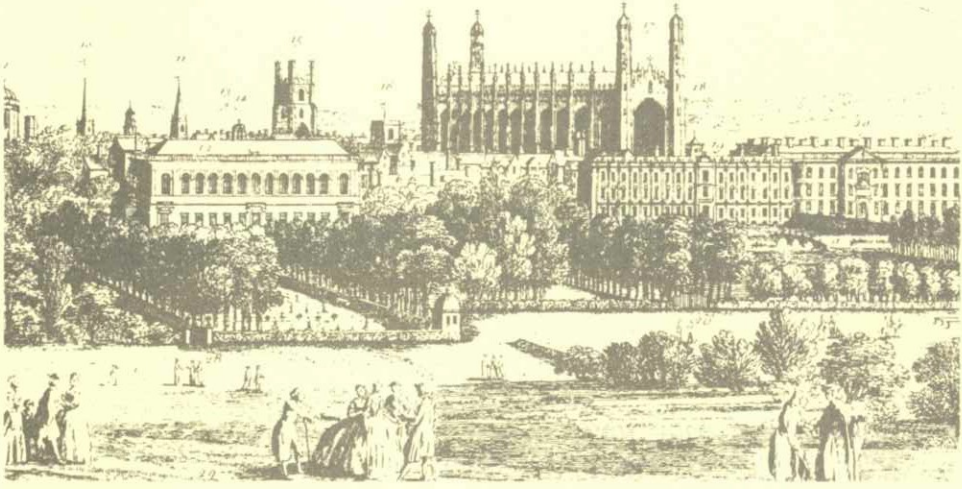
ETHICAL REVIEW OF CLINICAL RESEARCH

15th ANNUAL TRAINING CONFERENCE

ROBINSON COLLEGE, CAMBRIDGE

11th - 14th DECEMBER 2005



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CONVENED BY

CCRA

THE CLINICAL CONTRACT RESEARCH ASSOCIATION
AND
INSTITUTE OF GENERAL PRACTICE & PRIMARY CARE
UNIVERSITY OF SHEFFIELD

INTRODUCTION

Now in its 15th year, the series of "Ethical Review of Clinical Research" conferences has become valued as an important training resource for ethics committees in the UK. They serve a wide constituency (see Who Should Attend) across the medical research community. This breadth is reflected in the diversity of backgrounds/specialities represented and is one of the strengths of the conferences that are designed to be highly participative, learning experiences.

The conferences employ a variety of teaching styles including plenary lectures, question/answer and discussion sessions, small group discussions and a series of parallel workshops. The CCRA has deployed the foremost experts in their fields and the high standards of the college accommodation provide an ideal venue.

Delegates from previous conferences have consistently reported the value of the conference being residential allowing time for informal discussion of the day's sessions. The pace is fast and time for reflection is important to learning.

This year the conference will focus, through the protocol review sessions, on working towards reaching consensus.

Detailed training folders will be provided. These contain many relevant guidelines and reports.

The conference has proved to be very popular and early booking is recommended.

OBJECTIVES

The objectives of the conference are:

- To provide practical training for ethics committee members;
- To develop a consensus for the ethical review of clinical research;
- To provide an opportunity to discuss the function of a successful ethics committee;
- To identify current best practice in ethical review

WHO SHOULD ATTEND

The conference will be of value to members, chairs and administrators of RECs and Trust R & D leads. In fact, to all those involved in clinical research and its ethical review.

The conferences have always received CPD approval.

PROGRAMME

Sunday 11th December 2005

1400 - 1445	Registration	
		Session Chair: Dr Gary Butler
1500	Introduction And Overview	Dr Bev Holt
1515	An Introduction to the Group Work	Professor Nigel Mathers
1550	The Role of Lay Members on RECs	Canon Ian Ainsworth-Smith
1620	*Tea*	
1650	Group Review of Protocols - I	
1805	Discussion of Results of Protocol Review Session I	Dr Gary Butler
1835	*Close*	
1915	*Buffet Dinner*	

Monday 12th December 2005

		Session Chair: Dr Gary Butler
0930	Understanding The Ethics Of Research Design I - **Quantitative**	Professor John Saunders
1000	Understanding The Ethics Of Research Design II - **Qualitative**	Professor Nigel Mathers
1030	Questions & Answers	
1100	*Coffee*	
1130	Group Review of Protocols - II	
1245	Discussion of Results Of Protocol Session II	Dr Gary Butler
1315	*Lunch*	
		Session Chair: Ms Anna Ernsting
1430	An Introduction to Genetic Research	Professor Norman Nevin
1515	Research Governance and Ethics – What is the Difference?	Ms Amanda Hunn
1550	*Tea*	
1620	Specialised Topic Based Workshops I	
1735	*Close*	
1915	*Sparkling Wine Reception and Conference Dinner*	

Tuesday 13th December 2005

Session Chair: Professor Nigel Mathers

0930	Ethical Issues Arising in Paediatric Research	Professor Terence Stephenson
1015	The New Human Tissue Act and Research Ethics Committees	Dr Richard Huxtable
1100	*Coffee*	
1130	Specialised Topic Based Workshop II	
1245	*Lunch*	
1400	The Ethical Issues Raised by Advances in Genetics	Professor Norman Nevin
1445	Legal Issues of Consent	Dr Richard Huxtable
1530	*Tea*	
1600	Specialised Topic Based Workshop III	
1715	Implementation of the Ad Hoc Review Findings	Speaker from COREC
1800	*Close*	
1915	*Buffet Dinner*	

Wednesday 14th December 2005

Session Chair: Ms Anna Ernsting

0915	Group Review of Protocols - III	
1030	Discussion of Results of Protocol Review Session III	Dr Gary Butler
1100	Progress Towards Consensus – Overview, Summary and Closing Remarks	Professor Nigel Mathers
1130	*Coffee*	
1145	Completion/Handing in of Conference Evaluation Forms & Collection of Conference Attendance Certificates	
1200	*Close*	

DEPARTURE

PARALLEL WORKSHOP SESSIONS

Three seventy-five minute workshop sessions will be run during the conference. To ensure that delegates can attend their chosen workshops from the nine workshops offered (described in the insert) please indicate your preferences on the application form, giving an **extra choice** alternative (marked*) should any workshop be over subscribed.

WORKSHOP A:	Healthy Volunteer Studies
WORKSHOP B:	Pharmaceutical Research
WORKSHOP C:	Qualitative Research
WORKSHOP D:	The Interface Between R&D Hosts and RECs
WORKSHOP E:	Issues of Consent with Particular Reference to Special Patient Groups
WORKSHOP F:	Ethical Issues Arising From Advances in Genetic Research
WORKSHOP G:	Statistical Problems Solved
WORKSHOP H:	A Survival Guide for New REC Members
WORKSHOP I:	Legal Issues in Clinical Research

FACULTY

Canon Ian Ainsworth-Smith	Vice Chair, South East MREC
Dr Elizabeth Allen:	Director of Scientific Affairs, GDRU, Quintiles Ltd
Dr Gary Butler:	Lead Teaching Fellow In General Practice, University Of Sheffield
Ms Anna Ernsting:	Senior Clinical Research Scientist, GlaxoSmithKline Plc
Dr Bev Holt:	Consultant Anaesthetist
Ms Amanda Hunn:	OREC Manager, Yorkshire & The Humber
Dr Richard Huxtable	Lecturer in Medical Law & Ethics, University of Bristol
Professor Nigel Mathers:	Director, Institute Of General Practice, University Of Sheffield
Professor Norman Nevin:	Chairman, Gene Therapy Advisory Committee
Professor John Saunders:	Consultant Physician, Nevill Hall Hospital, Abergavenny
Professor Terence Stephenson	Dean, Faculty of Medicine & Health Sciences, University of Nottingham
Statistician	
Speaker from COREC	

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PARALLEL WORKSHOPS & WORKSHOP LEADERS

WORKSHOP A: **HEALTHY VOLUNTEER STUDIES**

Leader: **Dr Bev Holt**, Consultant Anaesthetist
Dr Elizabeth Allen, Director of Scientific Affairs, GDRU, Quintiles Ltd

This workshop describes the types of studies conducted in healthy volunteers that may be submitted to LRECs. It will outline the differences in reviewing therapeutic and non-therapeutic research applications. It will emphasise the questions to be asked when viewing applications involving the initial studies of new drugs in healthy volunteers.

WORKSHOP B: **PHARMACEUTICAL RESEARCH**

Leader: **Ms Anna Ernsting**, Senior Clinical Research Scientist/Study Manager GlaxoSmithKline plc

The drug development process is complex, expensive, high risk and can take up to 12 years to complete, encompassing 4 phases of clinical trials. Industry and Ethics Committees need to conform to ICH, the EU Directive and Research Governance. This workshop will address any issues that delegates wish to raise from these processes.

WORKSHOP C: **QUALITATIVE RESEARCH**

Leader: **Professor Nigel Mathers**, Director, Institute of General Practice, University of Sheffield
Dr Gary Butler, Lead Teaching Fellow, General Practice, Institute of General Practice, University of Sheffield

The Qualitative Research workshops will be an interactive forum for delegates to bring their own questions and issues around qualitative research so that, after the session, they will have a greater understanding of the nature of qualitative research and, therefore, the proposals coming before their ethics committees

WORKSHOP D: **THE INTERFACE BETWEEN R&D HOSTS AND RECS**

Leader: **Ms Amanda Hunn**, OREC Manager, Yorkshire and The Humber

The Ad Hoc Advisory Group, on the operations of NHS Research Ethics Committees, has highlighted that the site specific assessment process provided by LRECs is "cumbersome, appearing to add little value to local approval by the host organisation". One of its conclusions is that site specific assessments should be delegated to the host organisation. This work shop will discuss site specific assessments, other interface issues, flow of applications and the sharing of information that may be beneficial to delegates from R&D.

WORKSHOP E: **ISSUES OF CONSENT WITH PARTICULAR REFERENCE TO SPECIAL PATIENT GROUPS**

Leaders: **Professor John Saunders**, Consultant Physician, Nevill Hall Hospital, Abergavenny

Many protocols involve the use of patients who may not be able to give fully competent consent. These include the unconscious, the ICU patient, the demented, the psychiatric patient, the young child and several others. This workshop will explore the problems of obtaining consent for these patients and similar groups. Withholding research in these groups could be to deny them possible benefits.

WORKSHOP F: **ETHICAL ISSUES ARISING FROM ADVANCES IN GENETIC RESEARCH**

Leader: **Professor Norman C Nevin**, Emeritus Professor in Medical Genetics Queen's University, Belfast & Chairman, GTAC

Advances in human genetics have major implications for the conduct of clinical research. This workshop will consider some of the issues raised by these developments, such as, genetic information and how it differs from other clinical information, confidentiality, informed consent particularly in relation to the storage and use of tissues and bodily fluids for genetic research, genetic databases, and the implications of genotyping participants in pharmaceutical research.

WORKSHOP G: **STATISTICAL PROBLEMS SOLVED**

Leader: **To Be Announced**

Many REC members have limited statistical experience and often no statistical support on the committee. If the statistical design is flawed then is it ethical to conduct the trial? This workshop will cover some of the fundamental statistical concepts that relate to study design issues. We will concentrate on your specific problems, however in previous workshops statistical significance, Power and sample size estimations have been popular.

WORKSHOP H: **A SURVIVAL GUIDE FOR NEW REC MEMBERS**

Leader: **Canon Ian Ainsworth-Smith**, Vice Chair South East MREC

This workshop is designed for new members of RECs. Its object is to ensure that members have the confidence to take on their new role and are adequately equipped to do so. Participants in the workshop are invited to bring examples of any difficulties that they anticipate or are currently experiencing.

WORKSHOP I: **LEGAL ISSUES IN CLINICAL RESEARCH**

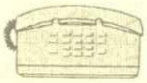
Leader: **Dr Richard Huxtable**, Lecturer in Medical Law & Ethics, University of Bristol

There are many legal issues involved in research in humans, including the application of informed consent, the use of children, the unconscious, and others unable to give consent for themselves. These and other legal aspects will be addressed in this workshop.

ROBINSON COLLEGE, CAMBRIDGE

Robinson College, the newest of the Cambridge colleges, offers high standards of conference facilities and catering at a reasonable cost, and has been chosen as the regular venue for this series of training conferences. The college is a few minutes walk from the historic centre of the city, and has non-restricted parking available nearby. Delegates are accommodated in single study bedrooms with private facilities. The college is situated in several acres of attractive wooded gardens, providing a relaxed setting for the conference.

HOW TO REGISTER



Provisional bookings: Please Telephone (0116 271 9727) or Fax (0116 271 3155) your provisional booking to us and confirm by returning the completed form(s) and cheque to us **within six weeks**. If payment has not been received by this time your booking will be cancelled.

FEES: The conference fee is **£820.00** plus VAT for **payments received** before 28th October 2005, and **£900.00** plus VAT for payments received thereafter.

The fee includes accommodation, all meals, and comprehensive training materials.

Payment should be by cheque made payable to 'CCRA Conferences'. Payments must be received within six weeks of a provisional booking, or by Friday 26th November (whichever is the sooner) to secure the booking. Reduced fees are available for delegates who do not require accommodation; please enquire.

Cancellations:

If cancellation of a confirmed booking is received in writing before **Friday, 25th November**, the registration fee will be refunded less a £100 + VAT administration fee. We regret that no refund can be made for cancellations made after this time. However, a substitute delegate will be welcome at no extra cost, provided that we are notified in writing at least seven working days before the start of the conference.

FURTHER DETAILS

For further details contact the conference secretariat:
Tel. 0116 271 9727, fax. 0116 271 3155