UK University Research Ethics Committees Forum
Meeting held on Tuesday 21st October 2008, 11:00, at King’s College London

Attendees:

David Anderson-Ford, AREC-URECs Committee Chair
Roger Bone, Canterbury Christchurch University
Lorna Carter, OXTREC
Susan Cottam, University of Birmingham
Hazel Covill, Queen Mary, University of London
Lindy Dalen, Southampton University
Trudi Edington, University of Westminster
Carol Dawson, AREC
Nick Drey, City University
Helen Dougal, University College London
Rosanna Dowsett, Sussex University
Angus Duncan, University of Luton
David Hunter, Keele University

Sean Jennings, Institute of Education, University of London
Huzma Kelly, University of Westminster
Brendan Laverty, University of Birmingham
Maggie Newton, King’s College London (Forum Organiser)

Roger Bone, Canterbury Christchurch University
Lorna Carter, OXTREC
Susan Cottam, University of Birmingham
Hazel Covill, Queen Mary, University of London
Lindy Dalen, Southampton University
Trudi Edington, University of Westminster
Carol Dawson, AREC
Nick Drey, City University
Helen Dougal, University College London
Rosanna Dowsett, Sussex University
Angus Duncan, University of Luton
David Hunter, Keele University

1. Introductions

Those who had not previously attended were welcomed.

2. Notes of the meeting held on Tuesday 22nd July 2008

2.1. The notes were approved as a true record.

3. Matters Arising not covered elsewhere in the agenda

3.1. University REC Structures (previous item 7.2)

Maggie Newton agreed to add further posters supplied by members to the published PDF document (members to specify if they wish the contribution to be anonymous).

Action: Forum organiser/ forum members (email rec@kcl.ac.uk)

4. Association of Research Ethics Committees update

4.1. The Chairman of the AREC University Sector Committee briefly re-stated the aims of the Committee and how the relationship between the Forum and AREC had developed. He went on to report the following:

4.1.1. A draft AREC Strategic Plan went to AREC Council in October, key aims cover:

-o Regionalising some business
-o Networking
-o Training and education
-o Working together with the Department of Health

4.1.2. The UREC Sector Committee has been working on ways forward for the accreditation of URECs. A bid to HEFCE is being prepared which will seek funding for piloting an accreditation scheme. It was noted that any accreditation system would need to be flexible and that it was not the
intention to mirror the NHS system. It was further noted that the field of research ‘integrity’ is growing fast (e.g. developing UK RIO guidance, RCUK guidance and clinical trials regulations) – the importance of research ethics must not be forgotten within this.

4.1.3. The UREC Sector Committee has also been working on a continued programme of seminars and members were reminded that the next seminar will be on university structures.

4.1.4. It was noted that the Forum provides a valuable method of ensuring the work of the UREC Committee is informed by Forum members’ experiences so that policy and practice may be built from the ground up.

5. National Research Ethics Service publication of research summaries

5.1. Members were reminded that this item had been raised in response to the NRES open letter: http://www.nres.npsa.nhs.uk/news-and-publications/news/promoting-transparent-ethical-research/

5.2. The group felt that the publication of lay summaries agreed by the researcher seemed sensible but raised the following concerns:

5.2.1. Why is it necessary to publish the contact details of researchers?

5.2.2. The inclusion of details concerning research methodology could be detrimental to research (e.g. in the case of a PhD student whose methodology is then published prior to the actual study being conducted). In effect researchers are being forced to publish details about their planned research prior to conducting it as they cannot submit for ethical approval in any other way.

5.2.3. If the Principal Investigator is to authorize the published details this could place the responsibility for authorizing material for publication with research students (when it should properly rest with the supervisor).

5.2.4. Why is it necessary to publish details of projects which have not received approval? The duty to be accountable lies with the research ethics committee and issuing the details of projects which are not approved does not seem to fulfill this objective.

5.3. It was felt that it would be more beneficial to publish lists of approved projects in anonymous form e.g. with a lay title and a lay summary.

5.4. It was agreed that the matter should be referred to the AREC University Sector Committee with a request that the Committee write to NRES seeking clarification concerning why the intention seems to go beyond the original scope of the exercise and publish a number of details not included in the original plans.

Action: AREC University Sector Committee

6. Watching Briefs

6.1. Social Care Research

6.1.1. Members received a report (see Appendix A) from Maggie Newton concerning a round table meeting she and Anthea Tinker had attended to discuss the future arrangements for the ethical review of social care research.

6.1.2. It was clarified that the intention is to produce guidance for all social care research and noted that the issue of how independent university research ethics committees are may be key.

6.1.3. It was noted that some universities already have reciprocal arrangements in place with local authorities and clarified that the intention is not to replace arrangements which are already working well.

6.2. ESRC Research Ethics Framework
6.2.1. The Chairman of the AREC University Sector Committee reported that a response had been received from Professor Ian Diamond following a letter from the AREC-UREC Committee. Professor Diamond has indicated that the ESRC intend to review the Research Ethics Framework in 2009 and will be seeking views at this point. He confirmed that the Committee has now been added to the list of respondents. The Chairman asked members to send in any comments they feel should be taken into account when the review occurs.

Action: Members to send feedback (caroldawson@arec.org.uk)

6.3. Human Tissue Act

6.3.1. It was noted that there is emerging guidance concerning exemptions relating to short term storage of human tissue.

6.3.2. It was noted that AREC is responding to the Human Tissue Authority guidelines out for comment at the moment.


6.5. UK Data Archive – nothing to report

7. Any Other Business

7.1. One item was deferred for future discussion and a second was referred to the AREC University Sector Committee.

7.2. Future sessions

It was agreed that future topics for discussion will be ‘Insurance, indemnity and sponsorship’ and ‘Supervision’. Members agreed to contact Maggie Newton volunteering to lead on these items.

Action: Members to email forum organiser (rec@kcl.ac.uk)

7.3. PART II – Controversial and dangerous research: political, legal and cultural contexts presenting particular risks to the researched and the researcher

7.3.1. Maggie Newton opened the discussion by circulating a list of examples where researchers from universities have run into difficulties while conducting research over the last two years. She went on to identify the following issues as being relevant to a discussion of controversial and dangerous research:

- Risk assessment
- Insurance
- Local law
- Overseas research (particular legal, social and cultural contexts)
- Records Management
- The management of student research
- Issues of academic freedom
- The role of ethics committees
- To this was added: the potential for attracting coverage by tabloid newspapers
7.3.2. It was generally agreed that the safety of the researcher is of equal interest to an ethics committee as that of the participants.

7.3.3. It was felt that a number of the examples cited may not have been through ethics review (and felt that, had it been, the difficulties might have been avoided).

7.3.4. It was noted that:
   
   o Research such as this has always been conducted, we are simply more aware of the issues it raises than was previously the case.
   
   o The Terrorist Act 2006 heightens these issues.
   
   o If an ethics committee wishes to consider the safety of researchers as well as participants within its remit, then its remit goes beyond that of research with human participants.
   
   o A study published by the ESRC's Qualiti National Centre for Research Methods [http://www.cardiff.ac.uk/soci/quliti/CIReport.pdf](http://www.cardiff.ac.uk/soci/quliti/CIReport.pdf) concerning risks to the well-being of qualitative researchers may be of interest.
   
   o It is important for ethics committees to remain aware of what is happening on the ground so they can fully engage applications and understand where the researcher is coming from.
   
   o There are more sensitivities in overseas research than used to be the case.
   
   o Some institutions had developed standardized risk assessment forms to be used by all researchers traveling abroad.
   
   o Research conducted by overseas students within their own home country remains an issue.
   
   o Many universities are not providing the resource necessary to support overseas students (whether conducting research or not).
   
   o Risk to researchers working overseas may be mitigated where the organization has already established a research centre (particularly in the case of student researchers where support is then available and the research can be conducted in a safe environment).
   
   o Training for researchers in how they intend to publish their research may be something universities should look into if they wish to avoid adverse publicity.
   
   o Some members had found that, with student research, considerable anxiety might have been avoided if student researchers had exercised a little more common sense in how they conducted their research. One institution had developed specific guidelines for risk assessment following a student going missing.
   
   o Another institution's UREC had started asking for the submitting School's 'One researcher' policy and had found that this encouraged Schools to produce policies for their researchers going out into the field alone.
   
   o When studying illegal activities researchers should engage with local authorities before commencing the research.
   
   o If a researcher intends to ask participants about their involvement in illegal activities, he/she must make it clear beforehand what the obligations concerning disclosure are. Researchers also have a responsibility to consider their professional as well as their legal obligations to disclose information to a third party. (The group agreed that the issue of disclosure in specific contexts would make an interesting discussion topic in its own right).
o An ethics committee cannot ‘approve’ an illegal action. The difficulty is negotiating the ‘grey’ areas and engagement with local authorities is key here.

o There is no clear legislation in place to protect researchers. The development of codes of conduct and best practice is therefore essential.

o Consideration should also be given to what support mechanisms are in place to help researchers deal with traumatic events.

o It must be recognized that these issues go beyond research with human participants and encompass a wide variety of disciplines.

o It was felt that the responsibility for student research rests with the supervisor who must provide assurances to the ethics committee concerning arrangements to be made. Part of this responsibility includes being realistic with students concerning what they will be able to achieve.

o Training for REC members is vital in ensuring they understand the limits of the RECs responsibilities as well as their duty to take reasonable steps. There is a danger of REC approval being seen as a ‘guarantee’ of safety, which it is not.

o The ability of the REC to consult experts is key, (it was noted that the Social Research Association have a mechanism for requesting guidance).

7.3.5. It was agreed that members who were able to share their policies with colleagues would do so. Ideally these will go on the AREC website in the members only section.

Action: Members to send useful documents (caroldawson@arec.org.uk)

8. Date and Time of next meetings

The next Forum meeting will be at 11:00 on 10th February 2008 at King’s College London

Maggie Newton
27th October 2008

To find out more information about:
- UK URECs Forum please email Maggie Newton (rec@kcl.ac.uk).
- Association of Research Ethics Committees (AREC)/University Sector Committee please email Carol Dawson (caroldawson@arec.org.uk).
- Enquiries about AREC membership to taragraham@arec.org.uk

It would be helpful if any changes in University REC contact information throughout 2008 and 2009 could be sent to all.

Update: The next four meeting dates are:
- 11:00 on Tuesday 10th February 2009 at King’s College London
- 11:00 on Tuesday 7th July 2009 at King’s College London
- 11:00 on Tuesday 27th October 2009 at King’s College London
Arrangements for a Social Care Research Ethics review system
Briefing note following Round Table meeting 30th September 2008

A meeting was held with key stakeholder groups (see end for list of attendees) to discuss the planned implementation of a Social Care Research Ethics Committee. The meeting included briefings concerning the proposed Social Care Research Ethics Committee, current arrangements made by University Research Ethics Committees, and processes operated by the National Research Ethics Service (NRES) for NHS research.

Stephen Goulder reported that the Social Care Research Ethics Committee will:
- Review ‘orphan research’ that does not already have access to research ethics review (e.g. research conducted by independent units)
- Conduct review of multi-site, cross-national projects
- Review research referred by local councils who deem projects to be ‘high risk’
- Review adult social care research (arrangements for research with children will be considered at a later date)
- Review research falling under the Mental Capacity Act 2005
- Review social care research funded by the Department of Health.
- Encourage the participation of service users (e.g. through membership of the SREC)
- Be appointing a Chair by the end of 2008 and members in early 2009
- Launch by the end of this financial year.

It was noted that it is difficult to ascertain the number of projects that will come through the new SREC system.

Anthea Tinker and Maggie Newton circulated a briefing note (attached) concerning current arrangements for research ethics within the university sector.

Janet Wisely reported that the National Research Ethics Service:
- Deals with 450 queries per month
- Has 118 RECs in operation. This will be reduced to 100 by April 2009 as there is currently overcapacity.
- Reviews 7,000 applications per year. Of these 1,000 are clinical trials.
- Takes 40 days to deliver an opinion for each application.
- Has a fast track system in place for low risk (particularly student) research, however, poorly presented applications mean there is a high rate of returned submissions. (It was noted that for undergraduate projects the Supervisor has to be the PI).
- Is developing a toolkit for research falling under the Mental Capacity Act 2005. 234 Mental Capacity Act applications have been received of which 7 were outside of the NHS’s normal remit (i.e. would previously not have been submitted to NRES). The greatest problem for NRES is confusion arising concerning when the Mental Capacity Act 2005 applies and when Clinical Trials Regulations (which supersede MCA) apply.
- Now uses the Integrated Research Application System. This system is recognised by organisations such as the MHRA and Ministry of Justice who accept the form and therefore don’t require researchers to fill in further documentation.

The following additional points were noted:
- Problems still arise concerning the difference between research, service evaluation and audit but it was agreed that this would require a separate meeting.
The main reason why research councils turn down social science projects is because of poor (or missing) research methodology. It was noted that, while ethics committees don't judge research methodology, they need to know what it is in order to give approval.

Many universities put their student applications through their own systems prior to allowing submission to NRES in order to filter out poor applications.

The ideal would be for each application to go through just one ethics committee (e.g. universities recognising the approval of another HEI rather than requiring separate ethics approval). Such reciprocity would require a set of minimum standards and consistency in the 'frameworks' being followed.

There remains a significant body of research which is undertaken by independent bodies that do not have ethics approval processes (and as such can often conduct research at less cost and in less time). It was felt that research funders had a significant part to play in requiring research ethics approval regardless of who was conducting the research.

Stephen Goulder, Maggie Newton and John Woolham agreed to draft a brief guidance paper (or roadmap) for a range of audiences (researchers, HEI ethics committees, funders and local Councils) on appropriate ‘review pathways’ for different kinds of social care research. This could also usefully contain recommendations for working arrangements between the different systems. The full group will meet again in December to discuss the draft guidance.

**Maggie Newton**  
**October 2008**

(Please note that this note is not an official minute of the meeting)

**Attendees**  
Caroline Bryson  Nuffield Foundation  
Stephen Goulder  Social Care Institute for Excellent (Chair of SREC Advisory Group)  
Anne Harrop  Joseph Rowntree Foundation  
Maggie Newton  AREC University Sector Subcommittee/ King’s College London  
Jan Pahl  University of Kent  
Elaine Sharland  ESRC Strategic Advisor for Social Work & Social Care  
Phil Sooben  ESRC  
David Stanley  University of Northumbrian  
Martin Stevens  Social Services Research Group/ King’s College London  
Anthea Tinker  Association of Research Ethics Committees/ King’s College London  
Andrew Webster  University of York  
Teresa Williams  Government Social Research Unit  
Janet Wisely  National Research Ethics Service  
John Woolham  Association of Directors of Adult Social Services
Key features and issues within University sector research ethics committees

Some University Research Ethics Committees (URECs) have been running for ten years or more, many are relatively new. A variety of systems are used including a single central UREC, a hierarchy of review committees with one co-ordinating UREC, or a number of unconnected RECs. Review procedures include face-to-face meetings, electronic systems and review by correspondence.

Key features of most university systems include: a large number of (often low risk) student projects (and conflicting views concerning the desirability of undergraduates conducting research with human participants); a wide variety of disciplines and research methodologies represented (with increasing numbers of interdisciplinary, mixed method projects); ensuring independence of review through the appointment of lay members and those external to departments submitting applications.

External influences

No standard operating procedures or benchmark standards at present.

Law defining what URECs can do
- EU Clinical Trials Directive 2001/20/EC
- Human Tissue Act 2004
- Mental Capacity Act 2005

Research conducted overseas
- Requirements of, and for, local review
- Different local expectations and standards

Legal requirements affecting applicants
- Data Protection Act 1998
- Children Act 1989, 2004
- Human Tissue Act 2004
- Mental Capacity Act 2005

Professional codes of conduct
- Set (sometimes conflicting) standards for researchers to follow

Data archiving requirements
- ESRC, British Academy and others require research data to be archived for further use

ESRC Research Ethics Framework
- Compliance to ensure funding

Universities, their role, remit and conduct
- ‘Gold-standards’ for URECs identified

Association of Research Ethics Committees
- Formal voice for URECs.
- Developing role in setting standards/accreditation

US Federal Wide Assurance
- Compliance to ensure funding

National Research Ethics Service
- Ascertaining when NHS review required and what obligations the university has when NHS review is undertaken (e.g. sponsorship, additional review or report to UREC)

Internal drivers and features
- Resourcing issues (supporting review, training, monitoring)
- Tailoring review to reflect the level of risk presented within a proposal
- Interface with research governance requirements (legal, professional, institutional)
- Training provision for reviewers and applicants
- What role does the student supervisor play in review?
- Sponsorship (particularly insurance)

Challenges
- Identifying which guidance, legislation and procedures apply
- Ensuring researchers are not over-burdened with information (leading to lack of engagement)
- Negotiating complex systems for time critical projects (particularly student projects)
- Training new intakes of students and staff each year