

**University Research Ethics Committees:
Their role, remit and conduct**

**Anthea Tinker, Professor of Social Gerontology and
Vera Coomber, Research Associate, King's College London**

Funded by the Nuffield Foundation

September 2004

ISBN 1 872342 22 1

Acknowledgements

The authors wish to thank the Nuffield Foundation which funded this research (grant OPD/00217/G/S2) and everyone who helped. In particular the staff from the Universities who replied both to the postal questionnaire and to the telephone interviews, the members of the Advisory Committee and Sharon Witherspoon of the Nuffield Foundation who was a source of unfailing support and advice.

We acknowledge with particular gratitude the contribution of the late Professor Sally Baldwin, who was a member of the Advisory Committee until her tragic death in October 2003.

The facts presented, and the views expressed in this report are, however, those of the authors.

Anthea Tinker
Vera Coomber

July 2004

For further information, contact: anthea.tinker@kcl.ac.uk

University Research Ethics Committees: Their role, remit and conduct
Anthea Tinker, Professor of Social Gerontology and Vera Coomber, Research
Associate, King's College London

CONTENTS

FOREWORD	5 - 7
SUMMARY	8 - 14
1. INTRODUCTION	15 - 21
a. Reasons for undertaking the research	
b. Background: Research Ethics Committees – where they exist	
c. Why there is concern about current practice for gaining ethical approval for research	
<i>i. The views expressed by the public about some research and ethical issues</i>	
<i>ii. The many related but uncoordinated changes that are taking place</i>	
<i>iii. The demands of funders</i>	
<i>iv. Specific issues to do with social science research</i>	
<i>v. The emphasis placed by policy makers and practitioners on the involvement of service users and how this can be achieved</i>	
<i>vi. The proliferation of small research projects</i>	
<i>vii. The increase in sales and marketing methods masked as research projects.</i>	
<i>viii. Falling response rates.</i>	
<i>ix. The implications of new legislation</i>	
<i>x. An increasingly litigious society and greater expectations of transparency and accountability</i>	
d. Interest is leading to research	
2. METHODS	21 - 23
a. The timetable	
b. The Advisory Committee	
c. The process of ethical approval	
d. The pre-pilot and pilot questionnaire	
e. The Universities approached	
f. The response rate to the questionnaire	
g. The telephone interviews	
h. The interest in the subject among respondents and willingness to share experiences	

i. Reasons for caution over the findings

3. FINDINGS 23 - 39

The key question is: To what extent do Universities undertake ethical scrutiny of research and if so how?

a. General ethical scrutiny of research

- i. *Did the University have any mechanism for ethical scrutiny?*
- ii. *Was there a formal policy?*
- iii. *Was there a specific individual responsible for ethical oversight of research?*
- iv. *Was there any evidence about the ethos of the University towards ethical issues?*
- v. *Other mechanisms including advice given to staff and students (including training)*

b. The presence of a Research Ethics Committee

- i. *Was there a Research Ethics Committee?*
- ii. *What did the Research Ethics Committee do?*
- iii. *How long had the Research Ethics Committee been in existence?*
- iv. *Did the Research Ethics Committee cover all disciplines?*
- v. *Did the Research Ethics Committee cover research by staff and students (undergraduate and postgraduate)?*
- vi. *What was the membership of the Research Ethics Committee?*
- vii. *Did members receive training?*
- viii. *What staff did the Research Ethics Committee have?*
- ix. *How many meetings did the Research Ethics Committee have?*
- x. *How many applications were considered?*
- xi. *How were applications dealt with?*
- xii. *What arrangements were there for delegated power?*
- xiii. *Did the Research Ethics Committee report to anyone?*
- xiv. *Was the process audited?*

c. The different forms of scrutiny

- i. *Distinguishing between LRECs and URECs*
- ii. *One UREC or a number of RECs?*
- iii. *Were there any special procedures to deal with research in the social sciences?*
- iv. *Were there specific procedures for ethical oversight of interdisciplinary research?*
- v. *Were there any specific procedures for ethical oversight of cross-institutional research?*

d. Measuring the level of scrutiny

- i. *How the level of scrutiny was assessed*
- ii. *The different levels of scrutiny*

4. CONCLUSIONS AND RECOMMENDATIONS 39 - 41

a. Conclusions

b. Recommendations

References	42 - 43
-------------------------	----------------

APPENDIX A	44
FOREWORD	

Over the last few years, there have been increasing calls for clearer and more transparent procedures to handle issues of ‘research governance’. All have given some prominence to the issue of ethical standards in the conduct of non-medical research involving human participants and what sort of independent ethical scrutiny might help to improve practice. Many funders, including the Nuffield Foundation, have called for increasing attention to this, and have promoted a wider discussion – through professional bodies, Universities UK and other forums – of why scrutiny might matter and what form of ethical scrutiny might be helpful.

But why this concern with ethical scrutiny? And what is ethical scrutiny *for*, what is it designed to do? The background is partly of course some dissatisfaction with the quality of the ethical discussion contained in some research proposals. Funders do receive applications in which the discussion of ethical issues is cursory or altogether absent; in which research even among the vulnerable population of ‘looked after’ children is deemed not ‘to raise any particular ethical issues’. Anecdotally, we might feel that such cases have been increasing, perhaps partly because of increasing incentives for less-experienced researchers to carry out research. But, on the other hand, there have been few cases, at least in non-medical social research, in which ethical practice has given rise to litigation, or claims of harm requiring compensation and so on. This may mean that ethical practice is generally good, and that in general its capacity to do harm is limited, at least in comparison with medical research. And it is also true that ethical research practice is not just a matter of the initial research design: it is, as many have argued, a matter of continued practice, of daily decisions negotiated in the conduct of research through-out a project. So what would initial ethical scrutiny and approval be designed to do? Is this simply a moral panic or a bureaucratic imperative?

I think it is more helpful to note that ethical practice, like other aspects of research, is subject to the changing expectations of all those who take part: participants, researchers, funders and employers. Some of these changing expectations relate to the increasingly explicit acknowledgement of the varying needs and interests of the different parties. So a properly functioning system of ethical scrutiny is, first, designed to ensure that there is an **explicit discussion** of fundamental matters of ethical concern before a project might go ahead. Researchers planning a particular project have their own interests in carrying out research. The point about early independent ethical scrutiny is that it submits such plans to some degree of outside scrutiny, raising issues that may require further thought, or

expressing concerns that some practices may simply be, on balance, unjustified. This model sees ethical practice as ineluctably part of a dialogue, in which prevailing social norms of what constitutes ethical practice are open to debate and are in principle justifiable.

On this reading, the existence of detailed ethical guidelines is not alone sufficient to encourage good ethical practice. There are many excellent ethical codes in Britain, and the best of these (such as the Social Research Association code) recognise that *judgement* is inevitably at the heart of the ethical conduct of research. They recognise that few ethical decisions are absolute, and many are based on substantive judgements that balance competing ethical principles, or that balance the proportionality of the benefit to the harm that a particular research project might yield. Ethical scrutiny, independent of the researcher, of individual research proposals is about creating the conditions for an explicit discussion about these judgements.

A second reason why funders are increasingly concerned about research governance and the role of ethical scrutiny within it is the issue of **accountability**. Again, we should be clear that one person's mechanism of accountability is another's bureaucratic gate-keeping mechanism. But the issues of accountability are real. From this point of view, the recent renewed attention paid to research governance is partly about ensuring that universities pay more attention to these issues, providing not only a climate for training, education and discussion of ethical practice but a clear framework of responsibility. It is about ensuring that institutions take the same sort of responsibility for ethical probity that funders have long insisted upon for financial obligations.

We should dispense with the red herring that any system of scrutiny can guarantee that the highest ethical standards are imposed, that any system will lead to correct (and only correct) decisions being taken. No procedure can guarantee substantively correct decisions. But if the principles of discussability and accountability are taken seriously, a system of ethical scrutiny that goes beyond the views of the individual researcher seems unarguable. The system of leaving all decisions to individual researchers or teams can also give no guarantee that correct decisions are reached each time.

Given the nature of most non-medical research involving human participants, it seems unlikely that the system used to evaluate medical research – which generally has a greater capacity to do harm, generally involves greater issues over conflicts of interest, and is better funded than non-medical research – would be appropriate. An important reason for being concerned that ethical scrutiny mechanisms be located in universities themselves is that this fosters both better dialogue and creates a clear climate of accountability, and one that, given the range of benefits and risks of non-medical research, researchers can interact with and influence appropriately. Such mechanisms would not be so independent of the researchers that they would risk becoming bureaucratic and unresponsive. On the other hand, institutional bodies have a larger perspective than the individual researcher and can bring multiple views to bear, from other disciplines and indeed through the

inclusion of lay members. Institutions have incentives to handle requests for scrutiny in a timely fashion and with a realistic notion of triage: focussing discussion on those cases where a real dialogue would be genuinely helpful, letting through the majority of unproblematic proposals, and refusing to sanction the small number of truly harmful proposals.

It is for this reason that the Foundation funded Professor Anthea Tinker and Ms Vera Coomber to carry out a comprehensive study of ethical scrutiny for non-medical research involving human participants, as it is actually carried out in universities. This follows a smaller and less extensive study carried out by Dr Andrew Webster and his colleagues, funded by the ESRC. Dr Webster, Dr Graham Lewis, Dr Nik Brown (at the University of York) and Professor Mary Boulton (at Oxford Brookes) have also produced a wide-ranging discussion document developing a Framework for Social Science Research Ethics. This is likely to form the basis of requirements by the ESRC and other funders for ethical scrutiny mechanisms. Professor Tinker's and Ms Coomber's research puts this into perspective by looking at what is happening on the ground.

This research published in this volume, which covers a remarkably representative sample of universities, shows that over the past two years there have been many constructive developments in UK universities, with the development of clearer frameworks for accountability and the development of more effective scrutiny mechanisms. But it may also suggest that while many universities have developed more effective guidelines, they have not always worked out a plan to ensure some form of appropriate scrutiny for all the relevant non-medical research. There may still be some lack of clarity about the circumstances in which scrutiny may be required, the circumstances when delegated authority may be appropriate and the criteria that might be used to 'triage' decisions. And it shows that scrutiny of student projects especially may require further thought.

All this is good empirical grist to the mill of discussions that are taking place about appropriate mechanisms. Professor Tinker and Ms Coomber have been scrupulous in documenting practice as it existed at the end of 2003 and early 2004. To many of the funders who have read this report, it suggests that while matters are much improved, there is still a way to go. We hope this will be a useful contribution to the debate about how ethical scrutiny might be improved, and about the range of institutional practices (for one size may not fit all) that would be useful. It may also focus attention on more practical matters, like the need for training and resourcing of ethical scrutiny bodies and others. All this will be to the good if the aim is to ensure that ethical standards remain high, and practice, because justifiable, is transparently good.

Sharon Witherspoon
Deputy Director

The Nuffield Foundation

University Research Ethics Committees: Their role, remit and conduct
Anthea Tinker, Professor of Social Gerontology and Vera Coomber, Research Associate, King's College London

SUMMARY

Background

Ethical issues in research are becoming of major importance as society becomes more aware of the rights of individuals. Many funders, including the research councils, are increasingly emphasising research governance, and ethical review is one aspect of this. However, little is known about what Universities do in the way of ethical scrutiny. Not only are Universities where a large proportion of research takes place, but also guidance on research governance is aimed at them. The focus of this research is on **human subjects** outside the remit of National Health Service (NHS) Local Research Ethics Committees (LRECs). The key question is: ***To what extent do Universities undertake ethical scrutiny of research and if so how?*** Although the focus is on Research Ethics Committees the wider perspective is also considered.

There are a number of reasons why there is concern about current practice for gaining ethical approval for research. These include the views expressed by the public about some research and ethical issues, the many related but uncoordinated changes that are taking place, the demands of funders, specific issues to do with social science research, the emphasis placed by policy makers and practitioners on the involvement of service users and how this can be achieved, the proliferation of small research projects, the increase in sales and marketing methods masked as research projects, falling response rates, the implications of new legislation such as the Freedom of Information Act 2000, Data Protection Act 1998 and Human Rights legislation, and an increasingly litigious society and greater expectations of transparency and accountability.

How the research was done

The research took place between April 2003 and June 2004, with most of the Questionnaires being completed in Autumn 2003. Following scrutiny by

King's College Research Ethics Committee a pilot for a national postal questionnaire was undertaken. 115 Universities in the UK were then invited to complete a postal questionnaire and 87 did (a response rate of 76%) with 78 (68%) completing the questionnaire. The nine who responded, but did not complete the Questionnaire, did so for justifiable reasons. A small number of respondents did not complete the Questionnaire in full as they were in an evolving situation. Telephone interviews were held with a sample of 30 respondents, selected from the 57 Universities where the respondent had indicated that they were willing to take part in a brief interview. The selection sought to ensure a mix of old and new Universities, single Research Ethics Committees (RECs) and devolved models of ethical scrutiny and to represent institutions across different regions.

From both surveys there was great interest in the subject among respondents and willingness to share experiences.

Despite the high response rate there is need for *caution over the findings*. These include the fact that there is less information than we would have wished about RECs other than the main University one, what is written and recorded e.g. advice on the Web or written guidance may not always represent the true situation, there are some inconsistencies in the answers, in some cases not all the respondents answered all the questions, we did not take account of the user perspective, and it is likely that there were Research Institutes or Centres in the Universities which would not be subject to procedures for University staff and so not included in our survey. In addition, most of the Questionnaires were completed in the Autumn of 2003 and many of those Universities where the scrutiny system was being developed at that time may now have systems in place.

The findings

The key question is: To what extent do Universities undertake ethical scrutiny of research and if so how?

Although the focus is on Research Ethics Committees an attempt was made to get behind this by asking about wider aspects of ethical scrutiny in the institution.

We answer this question in four ways by drawing on the empirical data to examine:

a. General ethical scrutiny of research

- *Most Universities did have some form of ethical scrutiny or were developing some mechanism.*
- *Three quarters had a formal policy.*
- *Slightly more than a half had a specific individual responsible.*
- *Universities are showing an awareness of the need for training and guidance on ethical issues and there were some good examples of advice (often on the Web).*

b. The presence of a Research Ethics Committee

- ***Four in five had a Research Ethics Committee***
Additionally of the 28 Universities that did not respond formally, at least 18 have evidence on their websites of central or devolved Research Ethics Committees. It must not be assumed that the non-responders do not have mechanisms for ethical scrutiny.
- ***Most University Research Ethics Committees (URECs) had a wide range of duties, not solely related to scrutiny of research applications, including responsibility for ethical issues and the provision of advice.***
- ***While a quarter were set up before 1990 nearly half had been set up since 2000.***
- ***Of those interviewed half felt that there were some instances in the past where specific areas or projects had not been scrutinised but that their systems were much tighter now.***
- ***Most of the Research Ethics Committees covered research by staff and students but not all covered that by undergraduate students.*** The latter is currently the subject of discussions in the social and health care fields.
- ***Who is on a REC is crucial.*** It could be argued that peer review ensures that the reviewer is familiar with the field. However, fellow researchers do not necessarily know best and a small circle of people can be open to criticism of cronyism. In the questionnaire we did not define *lay* and have had to take the answer as the respondents interpreted it. We are fairly certain that this means people other than researchers and/or outside the University. ***Four in five Universities had some lay members*** with one third having one and one third having two. This was mainly where there was a single REC and there is little evidence of widespread use of lay members at a devolved level. ***Just under half of URECs had student members.***
- ***Half of URECs and one third of the devolved committees gave training*** to their members.
- ***Slightly more than four in five had an administrator*** (but only one fifth of these were full time) but one in five did not.
- ***How often should a REC meet*** to be able to meet the needs of researchers who need ethical approval? It would be thought that they need to meet very frequently, whether at University or at a devolved level to avoid delays. RECs do not seem to meet very frequently. Where there was one REC about half met between one and three times a year and where there were devolved systems the proportions were very similar. However in both cases additional meetings or working via correspondence where needed was possible. This is an example where it would have been useful to consult a sample of applicants to see if this pattern met their needs.
- A possible measure of the scrutiny system is to see how many applications they deal with although this will, of course, have to include the existence of a devolved REC .
Without undertaking more detailed research on the number of potential applicants it is not possible to estimate what would be a reasonable number of applications for a REC (either a central or devolved one) to ensure ethical scrutiny. However, half of

the valid answers showed that there were only between one and fifty applications per year. On this evidence, where there is a UREC, in a significant number of cases they do not appear to be scrutinising all the research that is being done.

- It could be argued that a test of flexibility is how far decisions can be delegated. However, this can mean that it gives too much power to one person and that consistency is lost unless there are firm guidelines.
- Nearly all the Universities allowed delegated power to the Chair and/or sub committee of the REC for minor amendments and most for urgent research applications and one in five for student projects.*
- *Three quarters of the URECs had to make a formal report to someone or some body*
- *There appeared to be no external audit of the ethical process in any of the Universities which had a telephone interview.*

c. The different forms of scrutiny

- *Although the survey did not throw up major problems about the division between Local Research Ethics Committees (LRECs) and URECs subsequent developments may have made this more complex.*
- *One third (22/63) of the Universities had one central REC only. Just under two thirds (59%) had more than one – in some cases this consisted of a combination of School/Faculty/Department. There was no evidence over whether the levels of scrutiny were the same for a central REC and others.*
- *Of the 59 responses, two thirds of the Universities had no special arrangements for the social sciences.*
- *One in three made special arrangements for cross-institutional research.*

d. Measuring the level of scrutiny

How the level of scrutiny was assessed

In order to get a better picture of the level of ethical scrutiny of research in the 78 universities that fully or partially completed the Questionnaire **10 criteria were selected:**

- is there a REC, whether single or devolved?
- does the scrutiny cover staff research?
- does the scrutiny cover student research?
- do the REC Committee members have a spread of disciplines?
- is there training for members?
- does it have lay members?
- does it have student members?
- does it have an Administrator?
- clarity and volume of documentation in hard copy or on Website: terms of reference, details of committee membership etc.

- clarity and volume of documentation in hard copy or on Website: guidance for researchers, code of practice, consent forms, application forms, example of consent form etc.

It was felt that 57 of the universities could be fairly assessed and taking all the above answers into account the documentation of each University was examined and they were divided into the following:

- complete criteria (score of 10) 5/57
- many of the criteria (score of 8-9) 25/57
- some of the criteria (score of 5-7) 21/57
- a few of the criteria (score of 1-4) 4/57
- none 2/57

Whilst it is appreciated that this is a crude method of assessing the effectiveness of ethical scrutiny, nevertheless, it does indicate that a high number of Universities do fulfil sound basic criteria. ***Based on the 10 criteria it is pleasing that nearly one in ten of the 57 Universities met all of them and six in ten met eight. It is disappointing that one in ten of the 57 only met four or fewer. This includes two that did not meet any. This cannot be a reason for complacency.***

Conclusions and recommendations

a. Conclusions

Our broad conclusion is that when our survey was carried out in Autumn 2003, the majority of Universities were aware of the need for ethical scrutiny for research on human subjects and many of those Universities where the scrutiny system was being developed at the time of the completion of the Questionnaire may now have systems in place. However, in some cases practice seemed to lag behind awareness and there were both very good examples and some poor ones.

Nearly all the Universities surveyed had a mechanism for ethical scrutiny or were developing one. For three quarters this was a formal Research Ethics Committee. Had we undertaken this survey in 2000 the picture would have been very different. This is because nearly half of our respondents had set up their REC since 2000. Other encouraging signs are the willingness to share experiences and to learn from others, the fact that most had lay members and four in five an administrator.

Universities are becoming increasingly aware of the need for ethical scrutiny in the Social Sciences. There is also growing awareness that research ethics should have a wide application, encompassing disciplines such as the Humanities, Business Studies, Art and Design.

Looking more broadly at the ways in which ethical scrutiny can be judged, however, while seven in ten met eight or more of the ten criteria it may be a cause for concern that one in ten met only four or fewer. In other words they might have had a REC but it lacked some crucial ingredients such as the lack of lay membership or an administrator. Also the apparent small number of applications, in the case of some RECs may be an indication that not all research involving human subjects receives ethical scrutiny and further clarity on the issue of scrutiny of student research be sought.

On organisation there is a very complex picture with probably no two systems exactly the same. It is an evolving situation with many Universities currently in the process of developing their systems. The benefits of a central or devolved system of scrutiny are being debated.

Two general models emerge:

- a single, central UREC, with responsibility for scrutiny of all applications, policy and guidance;
- a multiple model, whereby Faculties/Schools/Departments have their own RECs or groups where applications are scrutinised and a UREC which has responsibility for policy and guidance and perhaps scrutiny of a small number of applications.

The advantage of a single model is a University-wide standard of scrutiny with common standards. A disadvantage is that some research could slip through the net if certain disciplines feel that the model is not suitable for them and refuse to use the REC.

The advantage of a devolved model is that the scrutiny can be tuned to the particular discipline and any professional Codes of Practice. A disadvantage is that some areas might not exercise rigorous scrutiny.

b. Recommendations

The objective of this research was to produce empirical findings. It was not to produce a set of guidelines. Ethical scrutiny is not just making sure that any specific 'code' is lived up to, but that there is some real engagement with the ethical dilemmas or issues raised in research. Nevertheless there are certain recommendations, which come out of the research. These are:

- a need to heighten awareness in Universities of the importance of ethical issues in research;
- more opportunity for inter-University discussion of the subject;
- all Universities should consider subjecting themselves to an audit using agreed criteria by which they may be judged (either the one we used or another) and estimate how they could improve;
- more guidance and support on research ethics training for researchers, students and REC members and this could include more inter-University collaboration;
- all funders should insist on evidence of ethical approval;

- funders and other bodies such as HEFCE will need to consider additional funding for Universities to cover the costs of ethical scrutiny procedures;
- all RECs should consider having lay members. This includes any devolved RECs (there was little evidence of widespread use of lay members at devolved level);
- we have noted the advantages and disadvantages of both single and devolved models, good practice and devolved models but also appreciate that we do not have sufficient evidence to answer the question of whether a Faculty/ School/ Department committee is independent enough;
- Universities should consider seriously whether there is need for a full time administrator, how frequently RECs should meet, how they can consider and process applications that satisfies independent ethical scrutiny but is not too bureaucratic, and how independence is to be achieved;
- there is a lack of clarity about the scrutiny of student research and this needs further discussion. If the draft recommendations in the Doyal Report are accepted, they will have major implications in terms of finance and time and these need to be examined;
- consideration should be given to revising the timetable for student research projects to give longer time;
- a need for clear central guidance from HEFCE on the underpinning principles, the legal arguments and acceptable procedures and processes, to enable Universities to work out best practice, for example over check lists, consent and application forms and advice. However, good practice guidelines will only work if put into practice.
- attention should also be drawn to the burgeoning research taking place outside LRECs and Universities. Market research companies, some specialist institutes and other research bodies have no recognised way of gaining ethical scrutiny.

1. INTRODUCTION

a. Reasons for undertaking the research

Ethical issues in research are becoming of major importance as society becomes more aware of the rights of individuals. Many funders, including the research councils, are increasingly emphasising research governance, and ethical review is one aspect of this. However, little is known about what Universities do in the way of ethical scrutiny. Not only are Universities where a large proportion of research takes place, but also guidance on research governance is aimed at them. The focus of this research is on human subjects outside the remit of National Health Service (NHS) Local Research Ethics Committees (LRECs). This includes research **on human subjects** undertaken by disciplines such as pharmacy, nutrition, physiotherapy and sports science which involves, for example, taking blood, testing food products on people and measuring muscle strength, as well as the wide body of social science research. The key question is: ***To what extent do Universities undertake ethical scrutiny of research and if so how?*** Although the focus is on Research Ethics Committees the wider perspective is also considered.

b. Background: Research Ethics Committees – where they exist

In the NHS there is a well-established mechanism for scrutinising research. This is through a Local Research Ethics Committee (LREC). The Department of Health (DH) defines this as ‘the committee convened to provide independent advice to participants, researchers, funders, sponsors, employers, care organisations and professionals on the extent to which proposals for the study comply with recognised ethical standards’ (DH, March 2001, p.19). Their primary responsibility is: ‘to ensure that the research respects the dignity, rights, safety and well-being of individual research participants’ (DH March 2001, p. 33). It is not their role to give legal advice although they may draw attention to possible legal implications.

LRECs were set up by the NHS in 1991 and exist in every region. It appears that the main investigation envisaged uses the classical medical method of a randomised control trial. As well as covering NHS property and staff etc they cover patients. However, NHS users (as well as relatives and carers of such patients) are within their remit.

The establishment in 2000 of the Central Office for Research Ethics Committees (COREC), with the consequent standardisation of procedures and forms, means that there has been uniformity across England from October 2002 over terms of reference, membership and procedures for LRECs. Another way of helping to establish some uniformity is through the well-established Association of Research Ethics Committees (AREC), which meets regularly to discuss matters of mutual interest. The focus of the Association has been primarily medical with an emphasis on trials involving drugs or other interventions but it is now becoming increasingly involved in non-medical research.

In contrast there are no agreed procedures for University research. The Higher Education Funding Council for England (HEFCE) issues no advice. There appeared to be no research which gave an overall picture of what Universities do or do not do to ensure that ethical issues are addressed. However a small modest (unfunded) research project by one of the authors (Tinker, 2001) on the 24 research projects funded by the Economic and Social Research Council (ESRC) under the Extending Quality of Life (EQUAL) Growing Older initiative produced some findings from many different social science disciplines. The researchers were asked about the procedures they normally had to go through to get ethical approval, any special arrangements for social science research and any problems encountered. The results showed that these procedures varied from institutions with three committees for applicants to go through and, in two cases, no committee at all. It also showed that a few research institutions were starting to set up special arrangements for the social sciences. These varied from a special committee in a School to one nominated person in a Department.

A Research Ethics Committee (REC) in a University may be a central University one (UREC) and/or devolved committees. The advantages of a University Research Ethics Committee are that it is a mechanism using a structured, transparent process with university-wide standards, giving parity of treatment for all applicants; it allows for a

range of disciplines to be represented and ideally includes lay members. Its disadvantages can be a bureaucratic process, high workload and slow response time if it does not meet frequently. A devolved system of Research Ethics Committees at faculty/school/department level may allow greater focus on specific disciplines, a quicker response to applicants and less bureaucracy. Disadvantages of a devolved system can include inconsistencies in approach across disciplines and a lack of transparency outside the Faculty/School/Department. In neither case is the REC like an LREC, as it is still part of the University, retaining accountability and responsiveness to the University.

In addition the split between what an LREC covers and what a University Committee might cover is by no means as straightforward as would appear, although there are the guidelines issued by the Central Office for Research Ethics Committees (COREC). Paragraph 3.1 of Governance Arrangements for NHS Research Ethics Committees (GAFREC) states that ethical advice from the appropriate NHS REC is required for any research proposal involving:

- a. patients and users of the NHS. This includes all potential research participants recruited by virtue of the patient or user's past or present treatment by, or use of, the NHS. It includes NHS patients treated under contracts with private sector institutions;
- b. individuals identified as potential research participants because of their status as relatives or carers of patients and users of the NHS, as defined above;
- c. access to data, organs or other bodily material of past and present NHS patients;
- d. fetal material and IVF involving NHS patients;
- e. the recently deceased in NHS premises;
- f. the use of, or potential access to, NHS premises or facilities;
- g. NHS staff recruited as research participants by virtue of their professional role.

(see also p.33)

c. Why there is concern about current practice for gaining ethical approval for research

i. The views expressed by the public about some research and ethical issues

There is growing research on both healthy participants and vulnerable groups such as 'looked after' children, people with mental health incapacity and older people at the end of life (see, for example, research funded by the ESRC and the Joseph Rowntree Foundation). Reports do not always mention the ethical issues involved. Indeed the Nuffield Foundation has funded research on such groups and has expressed concern about its ethical review (Nuffield Foundation 2002). Concerns were summarised by the Minister of Health (Hunt, 2001 in his introduction to *Research Governance Framework for Health and Social Care* when he said 'This country is fortunate to be able to draw on a wide range of research within the health and social care systems. Most of this is

conducted to high scientific and ethical standards. However, recent events have made us all painfully aware that research can cause real distress when things go wrong'. Of course, no form of ethical scrutiny can guarantee that things will not still go wrong.

ii. The many related but uncoordinated changes that are taking place

These include initiatives being taken by DH in the context of Research Governance and also the Data Protection Act, 1998. Governance of research is defined as setting standards, defining mechanisms to deliver standards, monitoring and assessing arrangements and improving research quality and safeguarding the public (by enhancing ethical and scientific quality, promoting good practice, reducing adverse incidents and ensuring that lessons are learned and preventing poor performance and misconduct). (DH, March 2001, p. 2). It applies to 'all research, which relates to the responsibilities of the Secretary of State for Health' (DH, March 2001 p. 3).

Advice was given by DH in *Governance Arrangements for NHS Research Ethics Committees* (DH, July 2001) and specifically in the context of the *Research Governance Framework for Health and Social Care* (DH, March 2001 and 2003). This Framework indicates that LRECs need to be reviewed.

iii. The demands of funders

Many funders of research, including the Nuffield Foundation (2002 and 2004) and the Wellcome Trust, will not give grants if ethical approval has not been obtained.

iv. Specific issues to do with social science research

Much University research concerns disciplines such as nutrition, pharmacy and physiology where ethical approval is essential for research on healthy volunteers. Ethical issues are also important for social scientists who have had little guidance apart from those produced for medical trials and by their own professional bodies. The limited evidence from the research quoted above (Tinker, 2001) showed that researchers seeking ethical approval where there are procedures for their research find that they often have to follow the medical model i.e. complete a long form focusing mainly on possible clinical interventions. But more serious appears to be the lack of attention paid by some social science researchers about the need to consider ethical issues and to undergo a process of scrutiny (Gilhooly, 2002). Whilst there have been few cases in non-medical social research in which ethical practice has given rise to litigation, compensation claims and so on, scrutiny in this area is a major concern in a culture which requires greater accountability, particularly in research involving vulnerable populations.

The ethical dimension of research in the social sciences is longstanding. Increasing attention is also being paid to lessons that can be learned from health; for example about how to bring staff into the development of a culture in which ethical issues are of prime importance (Carlisle, 1997). The role of users and ethical issues are the focus of growing research and comment (e.g. Tozer and Thornton, 1995, Tinker, 1997, 1998). The same is the case for particular subjects of research such as older people (Butler, 1990, Peace,

1999) and children (Roberts and Wellard, 1997). Criticisms of research, including ethical issues, involving disabled people are very strong (e.g. Barton 1996, Beresford, 1996, Turner *et al*, 2003).

Some professional organisations of social scientists, such as the Social Policy Association and the Academy of Learned Societies for the Social Sciences, are becoming increasingly concerned about ethical issues but without necessarily agreeing on the way forward. Some professional bodies (e.g. British Sociological Association, 2002) are also producing ethical guidelines. Of particular importance are those provided by the Social Research Association (SRA), originally produced in the 1980s and continually updated (SRA, 2003). The SRA Guidelines are interesting in that guidelines or codes are not just to be imposed but there is a recognition that there needs to be a dialogue and discussion about competing aims. The guidelines 'are framed in the recognition that, on occasions, the operation of one principle will impede the operation of another.....the guidelines do not attempt to resolve these choices or to allocate greater priority to one of the principles than to another' (SRA, 2003, p. 10). A frequently quoted set of guidelines in our survey was that of the British Psychological Society (BPS) (BPS, 2000). The Social Policy Association is another organisation that is paying increasing attention to ethical issues. It ran a Workshop on this issue which showed the complexity of the issues (Dean (ed), 1996) and has subsequently addressed the problems on other occasions. The Academy of Learned Societies for the Social Sciences has held a number of seminars on the topic.

Some professions, such as nursing, also produce guidelines (Royal College of Nursing, 2004), as do those involved in educational research (British Educational Research Association (2000). A more recent development has been advice given by a Government Department. The Department of Work and Pensions (DWP) published *Doing the Right Thing* in 2003 (DWP, 2003). The Government Chief Social Researchers' Office is currently developing, in consultation with other government departments, an ethical framework to underpin the scrutiny of government research. The Framework will support government social researchers in upholding their ethical and legal obligations while commissioning and conducting social research, by communicating principles, proposing a process for scrutinising proposed projects and signposting sources of advice and guidance. It is anticipated that individual departments and devolved administrations would use this framework to support the development of departmental specific protocols designed to address their specific concerns and underpin written documentation that enables ongoing monitoring. The Framework will be in place by the Autumn. Further work is taking place on different models of scrutiny under different circumstances. On the international front a European Consortium (RESPECT) has produced a consultative document *Code of Practice for Socio-Economic Research* which aims to form the basis for a voluntary code of practice across Europe (RESPECT, 2003).

The Department of Health has expressed specific concern about social care. Although the Association of Directors of Social Services (ADSS) Research Group advises the

ADSS and individual social services departments about the ethics, quality and relevance of studies for research covering more than one social services department, there is no other formal route for social care research. DH appointed Professor Jan Pahl to lead a consultation about research in social care. She said 'At present the NHS has a well-established system of local Research Ethics Committees, but there is no comparable system for social care research. This means that the ethical aspects of research proposals may be scrutinised by one of a number of different bodies, or may not be the concern of anyone outside the research team' (personal communication, 14.6.2001). A small seminar was hosted by DH on this topic (DH September 2001). Much of the debate focused on the problems, similar to those in policy, of creating a distinction between research on social and health care. There appears to be no decision yet but one outcome may be the setting up of some new body equivalent to the LREC system. There is still some concern as this may mirror the more bureaucratic medical model of scrutiny without the resources that fund that model. This is one reason why some funders such as the Nuffield Foundation take the view that it is better to locate the mechanism within the researcher's institution.

Concern about ethical approval for social science research is already being expressed. For example the Nuffield Council on Bioethics have looked at the ethical issues raised by research into behavioural genetics. The Wellcome Trust, a major funder of biomedical research, also funds some social science research and say that 'The forms of ethical scrutiny which some of these proposals require do not fit squarely into the research ethics committee model which covers health and biomedical research' (personal communication 22.10.2001). The ESRC initiated (August 2002 and 2003) reviews of Ethics and the Social Sciences, which will yield valuable information especially over international comparisons but they are not empirical national surveys and are restricted to the social sciences. This 2003 – 04 study by the Universities of York and Oxford Brookes has reviewed the issues with regard to ethical concerns and ethical review and has set out a framework for considering ethical issues and a mechanism for implementing it (www.york.ac.uk/res/ref). Our study gives complementary information.

v. The emphasis placed by policy makers and practitioners on the involvement of service users and how this can be achieved e.g. ethical issues about who should be involved and under what conditions and how conflicting user views should be weighed.

vi. The proliferation of small research projects

This is a result of trends such as the growth in Masters courses involving dissertation projects (where it is important to learn about ethical issues) and the pressures on professionals outside the academic world to include research as part of their job. There are issues over whether ethical approval for these projects should be the same as for other researchers or more or less stringent. Some supervisors have argued at conferences attended by the authors that students have to learn by their mistakes and cannot be

expected to be as stringent. Others feel that since student research is research carried out by inexperienced people new to research, it also requires some form of scrutiny (see p.28).

vii. *The increase in sales and marketing methods masked as research projects.*

viii. *Falling response rates.* This is understandable given fears about the whole area of surveillance in modern society and lack of confidentiality about data. There are, of course, other reasons such as fear of crime and the growing use of entry phones.

ix. *The implications of new legislation such as the Freedom of Information Act 2000, Data Protection Act 1998 and Human Rights legislation.* The implications of the legislation are that much greater care has to be exercised over the rights of individuals including that of information collection, storage, use and access, and re-use of longitudinal data.

x. *An increasingly litigious society and greater expectations of transparency and accountability*

d. Interest is leading to research

Encouragingly the concern about ethical standards, particularly related to the social sciences, has led to a number of research projects. The ESRC has already been mentioned and the researchers at the Universities of York and Oxford Brookes have (at June 2004) produced four Working Papers and a Project Update which are on their website. The objective of their research is to develop a framework for Social Science Research Ethics. This research stems partly from discussions held by the Strategic Forum for the Social Sciences in the UK, which is composed of all the major funders of social science research, the Academy of Social Sciences, the British Academy, the Government's Chief Social Research Officer and key research directors in Whitehall. This Forum were aware of developments within the Department of Health in relation to research governance, and the distinct possibility that a research ethics review model derived from the medical sciences would be imposed across all research areas. The Forum agreed that this would be highly inappropriate for the social sciences, on the grounds that it would severely constrain research activities that met the existing ethical criteria relevant for the social sciences, and so restrict the capacity of the social sciences to generate socially useful knowledge. Accordingly, the York and Oxford Brookes teams were commissioned by the ESRC to research this area and will be reporting to the ESRC shortly. In more detail the researchers aim to produce 'a set of basic guidelines for ethics scrutiny and practice and provide a series of case-based illustrations that indicate how they might be interpreted in different research contexts' (Webster, 2004, p. 8).

Another piece of ESRC funded research is at Southampton University and is on Consent.

2. METHODS

a. The timetable

The research took place between April 2003 and June 2004, with most of the Questionnaires being completed in Autumn 2003.

b. The Advisory Committee

An Advisory Committee, chaired by Lord Sutherland, met twice and also commented on drafts (see **Appendix A**).

c. The process of ethical approval

An application to carry out the research was made to King's College Research Ethics Committee and was agreed subject to some minor modifications.

d. The pre-pilot and pilot questionnaire

The draft Questionnaire was discussed at length with the Research Ethics Committee Administrator at another University, who made useful suggestions as to how the Questionnaire could be made more user-friendly. The revised Questionnaire (available from the researchers) was then piloted to six Universities. No revisions being indicated, the Questionnaire was then posted to the remaining 109 Universities.

The accompanying letter was addressed to the Vice Chancellor (or equivalent). Included with the covering letter and Questionnaire was an acknowledgement of receipt form, incorporating a request to let the researchers know to whom the questionnaire had been passed to within the University.

e. The Universities approached

115 Universities in the UK were invited to complete the questionnaire. This included two from Northern Ireland, 9 from Wales, 13 from Scotland and 91 from England. Included in the English Universities were the 18 University of London Colleges that have University status.

It was decided to restrict the research to Universities in the UK, rather than to all higher education (HE) establishments because the majority of HEFCE research funding goes to Universities and University status institutions. In addition, to contact a larger number of institutions would not only impact on the timetable and budget but also would cause problems in the collation and analysis of the data.

f. The response rate to the questionnaire

Of the 115 Universities invited to complete a postal questionnaire, 87 (76%) responded formally to the request, with 78 (68%) completing the Questionnaire in whole or in part. The small number of respondents who did not complete the Questionnaire in full were in an evolving situation. Of the nine Universities who responded but did not complete the Questionnaire, five felt they did not conduct research that was relevant to the survey,

three were in the process of developing a scrutiny system and one could not complete the questionnaire due to time constraints.

The very high response rate (see Edwards et al, 2002 and Smeeth and Fletcher, 2002) was probably due to a number of factors:

- the high level of interest in the subject and eagerness to learn from others;
- a thoughtfully worded accompanying letter which ‘invited’ respondents to take part;
- the promise of anonymity;
- a relatively short questionnaire;
- the inclusion of two stamped addressed envelopes, one for the return of the acknowledgement and the other for the return of the completed questionnaire.

There was no evidence of bias in the 28 non-responding Universities. They were not disproportionately drawn from ‘old’ and ‘new’ Universities (i.e. established before or in/after 1992), research activity or region.

g. The telephone interviews

30 Universities were selected for interview from the 57 where the respondent had indicated that they were willing to take part in a brief interview. The selection sought to ensure a mix of old and new Universities, single RECs and devolved models of ethical scrutiny and to represent institutions across different regions.

h. The interest in the subject among respondents and willingness to share experiences

This was shown by:

- the high response rate to the postal questionnaire;
- the willingness to take part in a follow up telephone interview;
- the openness with which the respondents to both the questionnaire and interview gave their answers – often appearing to be disarmingly honest;
- the seniority of those who replied – where it was not the Chair or Secretary of the CREC nearly all were at levels just below the Vice Chancellor/Principal;
- letters and notes on the questionnaire saying that they welcomed the research and asking to be kept in touch. As well as the great interest there appeared to be a willingness to be open and to share experiences. Many appeared to be feeling their way, especially those which had just been established, and were keen to hear about the experiences of others.

i. Reasons for caution over the findings

Although this research report is based on a very high response rate to a postal questionnaire there are a number of caveats that must be taken into account:

- the conclusions are based on the responses to the questionnaires and, as with all questionnaires, are dependent on the knowledge of the respondent. However, respondents seemed very willing to be open about their procedures;

- we are dependent on who filled in the questionnaire and the extent of their knowledge (although in over half – 52% - of cases it was someone with direct involvement or responsibility in the REC);
- there is less information than we would have wished about RECs other than the main University one. It was the intention that extra questionnaires would be completed where there was more than one REC. In the event only seven Universities did this. These related to School or Faculty Committees;
- what is written and recorded e.g. advice on the Web or written guidance may not always represent the true situation e.g. there is anecdotal evidence (not in this research) that many researchers in one University with a highly developed Web resource on research ethics did not use the ethical scrutiny mechanism. We have no evidence whether this happened on any widespread scale;
- there may be some inconsistencies in the answers;
- in some cases not all the respondents answered all the questions;
- we did not take account of the user perspective (part of the original application which was not funded) although many of those who responded were also applicants;
- it is likely that there were Research Institutes or Centres in the Universities which would not be subject to procedures for University staff (we know that this is the case for some);
- most of the Questionnaires were completed in the Autumn of 2003 and many of those Universities where the scrutiny system was being developed at that time may now have systems in place.

3. FINDINGS

The key question is: To what extent do Universities undertake ethical scrutiny of research and if so how?

The main aim of the research was find out how Universities consider ethical issues in research, what procedures they have in place and what problems (if any) arise. The study covers all types of research on human subjects (i.e. not animals) undertaken in Universities in the United Kingdom not covered by LRECs. We were looking for any evidence of ethical scrutiny mechanisms whether University wide or Faculty/ School/ Department based and therefore devised a number of different questions to capture the type of scrutiny.

Although the focus is on Research Ethics Committees an attempt was made to get behind this by asking about wider aspects of ethical scrutiny in the institution.

We answer this question in four ways by drawing on the empirical data to examine:

a. **general ethical scrutiny of research**

- b. **the presence of Research Ethics Committees**
- c. **different forms of scrutiny**
- and then:**
- d. **attempting to measure the levels of scrutiny in each of the responding Universities by various criteria.**

(nb all the answers below refer to the University REC unless otherwise stated and the numbers and percentages are of those who replied to the relevant question).

a. General ethical scrutiny of research

i. Did the University have any mechanism for ethical scrutiny?

(q Does your University have any mechanism for ethical scrutiny of non-medical research on human subjects?)

73 (94%) of the 78 respondents who completed the questionnaire said they had some kind of ethical scrutiny and four (5%), did not. However, the answers show that the latter did appear to have some scrutiny albeit somewhat vague e.g. 'peer review', 'emphasis on corporate social responsibility'. In addition it was clear that some of the 73 who replied 'yes' included vague statements such as 'self policing' 'via local trained gatekeepers'. One that said that procedures were being developed.

Most Universities did have some form of ethical scrutiny or were developing some mechanism.

ii. Was there a formal policy?

(q Does your University have a formal policy that provides guidance on the ethical dimension of research conducted within or on behalf of the organisation?)

75% said that they did have a formal policy, 21% said no and 4% said it was in progress. For one in three this was through guidelines or codes of practice. There were a variety of other answers.

Three quarters had a formal policy.

iii. Was there a specific individual responsible for ethical oversight of research?

(q Is there a specific individual responsible for ethical oversight of research activities?)

Slightly more than half (56%) did have someone who was responsible while slightly fewer than half (44%) did not.

Slightly more than a half had a specific individual responsible.

iv. Was there any evidence about the ethos of the University towards ethical issues?

Although this was not a specific question in the questionnaire, in the telephone interviews most felt that most people in the University did know about the need for ethical scrutiny although two of the 30 felt that there were probably some who did not know. The most common way of promulgation was via the Website which was mentioned by one third of those interviewed.

We do not have sufficient information to answer this question.

v. Other mechanisms including advice given to staff and students (including training)

There were a number of other mechanisms which Universities adopted to increase awareness of ethical issues. These included written advice to staff, written advice to students and general advice and guidance.

Written advice to staff

Some respondents gave categorical advice to staff e.g. one said 'If you judge a referral to the ethics committee to be unnecessary, you are responsible for that decision and its consequences'. One innovative University sent out their research ethics brochure with the pay packets of all academic staff. They also send emails to all new staff and researchers and include the topic in staff induction and supervisor's courses. But they said 'there are still areas that are difficult to reach though'. Half of the Universities provided formal training for researchers in ethical issues. In three of these cases it was for students only and in one it was said to vary with the School.

Nine of the sixteen Faculties/Schools/Departments that answered said that they did give advice although in one case it was only for PhD students and in two it varied from School to School. In very few cases was this available on the Web. Where it was not available on the web five of the 27 sent documentation.

Written advice to students

See above. One was very stern and told undergraduates 'No dissertation containing data that was gathered without ethics approval, or gathered not exactly according to what was approved, will be accepted for assessment purposes. In other words, it will be given a mark of zero'.

General advice and guidance

Nearly all the Universities (88%) provided formal advice to researchers while six did not and one did it through policy and professional journals. In less than half the cases was this available on the web. Where it was not one third provided documentation.

Thirteen of the fifteen Faculties/Schools/Departments also provided advice with one third being available on the web. Four in five of the 47 who answered the question gave guidance about applications. One in five gave no guidance.

There were some very good examples of advice and guidance. For example one University has a general code for supervisors and others extensive guidance and guidelines. Others had codes of good practice; ethical guidelines for teaching and research, model consent forms and advice, such as on payment to research subjects. Others had detailed advice about research on particular groups such as children. Another targeted Heads of Schools so that they knew that they were responsible for ensuring that all research gets ethical scrutiny because this is an absolute condition of the insurance and if any problems arose over research that did not have ethical clearance, they would not be covered by the insurance. Another recommended check lists so that it was clear whether or not ethical approval was needed. In cases of doubt there was a designated officer in each School to give advice.

Universities are showing an awareness of the need for training and guidance on ethical issues and there were some good examples of advice which was often on the Web.

b. The presence of a Research Ethics Committee

The Case for Research Ethics Committees is the title of the 4th Discussion Paper by the Universities of York and Oxford Brookes team (Boulton et al, 2004). They discuss the strengths and limitations of some current mechanisms of ethical regulation and governance in Social Science research. These are self-regulation on the basis of Professional Codes of Practice, review by peers in the funding process, opportunistic review by University research committee, higher degree committees or Research Director, accountability to a Project Advisory Group and scrutiny by a Research Ethics Committee. On the latter they say ‘Of all of these mechanisms, scrutiny by a properly constituted research ethics committee seems the most appropriate.’ (Boulton et al, June 2004, p.2).

i. Was there a Research Ethics Committee?

(q Does your University have a Research Ethics Committee?)
64 of the respondents (83%) did have a Research Ethics Committee while 12 (16%) did not (see page 34 for the breakdown of single or devolved models). One stated that they were just setting one up. However, of the twelve that did not it appeared that in only seven cases was there no ethical scrutiny at all. One of the latter stated ‘no, but our emphasis is on corporate social responsibility’. Some realised that this would become essential such as one which did not have a formal REC and said ‘This is something that the University realises it will have to address shortly’. In some cases even longstanding committees were widening their scope to include all human participants.

The more widespread use of RECs, whether at a University or devolved level, has cost implications.

Four in five had a Research Ethics Committee.

In addition, of the 28 Universities that did not respond formally, at least 18 have evidence on their Websites of central or devolved Research Ethics Committees. It must not be assumed that the non-responders do not have mechanisms for ethical scrutiny.

ii. What did the Research Ethics Committees do?

41 Universities enclosed documentation and/or gave a website reference (including one under review), detailing their REC's Terms of Reference. Typically, they were between a half and two pages long, embedded in a document which also included the constitution of the ethics committee, its operational procedures, reporting arrangements, composition, membership, induction and training for members, and how declaration of interests operated.

Although the wording and extent of the Terms of Reference showed wide variation, there were four basic elements common to all Research Ethics Committees:

- responsibility for ethical issues relating to research involving human participants, including maintaining standards and provision of advice to researchers;
- responsibility for ensuring production and maintenance of Codes of Practice and guidance;
- ethical scrutiny of research applications from staff and, in most cases, students;
- reporting and monitoring.

Most RECs had a wide range of duties, not solely related to scrutiny of research applications, including responsibility for ethical issues and the provision of advice.

iii. How long had the Research Ethics Committee been in existence?

Some Universities have shown a longstanding concern for ethical issues in research, while others have more recently set up mechanisms, as the climate of discussion has changed. The length of time that a REC has been in place could be the result of a number of factors for which no information is supplied. In just under a quarter (23%) of cases they were set up before 1990. One third (33%) were set up in the 1990s and the remainder (44%) since 2000. Indeed 16% were set up in 2003/4. One in five were set up between 1996-99.

While a quarter of RECs were set up before 1990 nearly half had been set up since 2000.

iv. Did the Research Ethics Committee cover all disciplines?

[q Are there any examples where people/departments don't submit?]

Although this question was not specifically asked in the questionnaire, half of those interviewed felt that there were some instances in the past where specific areas or projects had not been scrutinised; two of these specifically citing social science. However, most

felt that their systems were much tighter now and that these and similar omissions would not happen nowadays. Five felt that there were still some areas where ethical scrutiny was not carried out but in two of these they felt that the system was still new and greater awareness would prevail; another said that there were problems in trying to get an ethics policy to fit all. Only one said that there were such examples ‘all the time’. Interestingly, several of those interviewed saw the areas where there should be greater awareness of the need for ethical scrutiny as now being in subjects such as Business Studies or the Humanities, including Art and Design, for instance for videoing or covert observation. Many respondents were especially aware of the ethical issues involved in research on particular groups such as children. Oral history was also mentioned as a field where ethical scrutiny was needed.

This question was only asked in the interviews where half felt that there were some instances in the past where specific areas or projects had not been scrutinised. A small number felt that omissions might still be occurring in some disciplines.

v. Did the Research Ethics Committee cover research by staff and students (undergraduate and postgraduate)?

While Universities stated that research by staff [52/62] and postgraduates [56/62] was scrutinised a smaller number undertook this role for undergraduates [43/62]

In the interviews the 30 (of whom 22 had multiple RECs) respondents were asked: ‘Are there differences between how staff and student research projects are handled?’ In most cases, there was no difference between how staff and student research projects are handled, since supervisors usually sign the student’s application and it becomes, in effect, ‘staff’.

There were also a number of different formal scrutiny mechanisms for student research. In two cases, scrutiny by the Research Director or Dean of Faculty; in another, scrutiny by supervisors and only sent to the School REC if involving vulnerable subjects; in one School, undergraduate research was looked at by two people in the department and in another, undergraduate and postgraduate research applications were looked at in the School and PhD applications went to the UREC. Two universities had different application forms for students and one had block ethical approval if the research did not involve humans. One noted that ‘In the social sciences, a lot of thought is being given to managing the students’ research where it involves working with young people’. One School had problems around ‘sensitive topics and the inability of young, inexperienced students to appreciate the implications for participants’.

Research by others shows that student research presents particular problems (see, for example, Ashcroft and Parker, 2003 and Foot and Sanford, 2004). Not only are the students, by their very nature, inexperienced but also the time scale is usually very tight for them. There are two views over whether student projects should be subject to the

same ethical scrutiny as that done by staff. On the one hand it could be argued that students have to start somewhere and should be allowed to make mistakes but others (Ashcroft and Parker, 2003) argue that the same standards should prevail. The latter also argue that it may be preferable for students to concentrate on literature-based research or work with a person or team of experienced researchers either on their project or linked to it.

The DH Working Group on Ethical Review of Student Research in the NHS has argued that student research in both the health and social care fields should be subject to a new form of scrutiny (Doyal, 2004). This would be under a new committee – Student Project Ethics Committees (SPECs) which would be established in Universities and other Higher Educational Institutions (UHEIs) in partnership with, and responsible to, the appropriate Strategic Health Authority. This is a controversial finding as it would mean a great deal more work for UHEIs and would mean that they would also have to deal with NHS matters i.e. student projects on patients, on NHS property etc.

While nearly all Research Ethics Committees covered staff and postgraduate research, not all covered students. The lack of clarity in this area is currently the subject of discussions in the social and health care fields.

vi. What was the membership of the Research Ethics Committee?

Who is on a REC is crucial. It could be argued that peer review ensures that the reviewer is familiar with the field. However, fellow researchers do not necessarily know best and a small circle of people can be open to criticism of cronyism. About thirty years ago the medical profession was arguing that only medically qualified people should consider their applications while now there is general acceptance that a broader range of disciplines gives a more balanced view. Similarly it is accepted, and is compulsory for LRECs, that some members should be lay. One definition of a lay member could be a person who is independent of the University, either as an employee or in a non-executive role, and whose primary personal or professional interest is not in a research area. A key function of a lay member is to bring the perspective of the participant to the committee.

Three of the issues about membership concern the involvement of disciplines other than that of the applicant, lay members and student members.

The involvement of disciplines outside the one being considered

This was considered in the 30 interviews. 21 Interviewees cited the key consideration in recruiting members of URECs and Faculty/School/Departmental RECs as being that a spread and balance of disciplines is maintained. Some members were recruited by the Heads of Schools/Departments, by Senate, on the recommendation of Faculty Deans, by the Vice-Chancellor or the Academic Board. Some members were the Chairs of School Committees and some were volunteers with the representation of each School ensured. Other interviewees did not mention this spread of disciplines but said recruitment was by ballot, appointment from the Council and Senate and the inclusion of active

researchers at the recommendation of School Committees. One interviewee said that you 'have to grow members'.

We were not able to gain sufficient information to answer this question with certainty.

Lay membership

In the questionnaire we did not define lay (with hindsight we should have asked for this) and have had to take the answer as the respondents interpreted it. We are fairly certain that this means people other than researchers and/or outside the University. Four in five of the 64 Universities that answered this question had lay members. For those that had lay members just over one third had two members and just under one third had one. Nine had three members, four had four, one had five and two had six.

For the 17 Faculties/Schools/Departments the figure was lower (only two had lay members). The two Faculties/Schools/Departments that answered this had one each.

Four in five Universities had some lay members with one third having one and one third having two. This was mainly where there was a single REC and there is little evidence of widespread use of lay members at a devolved level.

Student members

27 Universities (44%) did have student members on their UREC and 35 (56%) did not. Most had one (23 of the 26 who replied) while three had two. These were recruited via the student council or union, or nominated by postgraduate students. A further two Universities were considering having student members.

For the five Faculties/Schools/Departments where there is information each had one member.

Just under half URECs had student members and just over half did not.

vii. Did members receive training?

Nearly half of the URECs said that they gave training to their members and nearly half did not. The remainder said that it was available if required or was under consideration.

For those who gave training a wide variety of methods were used with the most popular being in-house courses, briefing and external courses. Using documentary guidance or codes of practice is another useful way of giving training and more than four in five did this.

For the 17 Faculties/Schools/Departments one third gave training but two thirds did not.

The training included Workshops, briefings, an induction pack and an interactive session with the Chair of the REC. Most of the 17 (15) Faculties/Schools/Departments used documentary guidance or codes of practices.

In about half the cases of both the UREC and the Faculties/Schools/Departments the advice was available on the Web.

Half of URECs and one third of the devolved committees gave training to their members.

viii. What staff did the Research Ethics Committee have?

The administration of a REC necessitates dedicated staff. Of the 64 Universities that responded to this question four in five (54) had an administrator and less than one in five (10) did not. The proportions were the same for the 17 Faculties/Schools/ Departments that answered. However only one in five held this post full time and four in five were part time (sometimes working in another sphere for the rest of the time). For the Faculties/Schools/Departments only two of the 14 were full time.

Four in five had an administrator (but only one fifth of these were full time) but one in five did not.

ix. How many meetings did the Research Ethics Committee have?

How often should a REC meet to be able to meet the needs of researchers who need ethical approval? It would be thought that they need to meet very frequently if research is not to be held up. The responses show that RECs do not meet very frequently. Where there was one REC about half met between one and three times a year while one in ten met between nine and ten. In Universities with a devolved system the proportions at this level were similar. In one University meetings were held weekly and followed the BPS guidelines (but it had no lay members).

In the telephone interviews respondents were asked ‘Is the frequency of meeting thought to give the right balance between the need for a speedy response to applicants and the need to take advice or seek further information? Is some of the scrutiny done by correspondence?’ None of the interviewees felt that there were any problems with the frequency of meeting of the RECs, although one felt that the system was too new to judge yet. Four RECs worked by correspondence, four RECs could or do operate on an ad hoc basis to obviate any delays. Two Universities which had devolved ethical scrutiny saw this as an advantage in avoiding delays. Most of the interviewees said that urgent applications could be dealt with by Chair’s action, email or correspondence.

RECs do not meet very frequently. Both where there was a central REC and where there was a devolved system only one in ten met between nine and ten times a year while about half met between once and twice. However, in both cases additional meetings or working via correspondence was possible. This is an example where it

would have been useful to have consulted a sample of applicants to see if this pattern met their needs.

x. How many applications were considered?

A possible measure of the effectiveness of RECs is to see how many applications they deal with. Without a more detailed analysis (e.g by assessing the numbers of staff and students and the kinds of research they are involved in) it is not possible to make an assessment about what number is appropriate. However, one would question the effectiveness of ethical scrutiny if virtually no applications are received by a UREC unless there is a devolved system.

Of those Universities with one REC only which specified the number of applications it had dealt with in the last year two had one, seven had between twelve and fifty and the remaining five had more. For those with a devolved system over a third of URECs had considered no applications, about half dealt with between one and fifty applications and the rest had between 92-115 or were unable to state an exact number.

Looking at the 16 Faculties/Schools again there is not a pattern of large numbers being considered. Leaving out the three which had just started one had 210 applications, one had 70, three had 40-50 while the rest (8) had between three and 20.

Without undertaking more detailed research on the number of potential applicants it is not possible to estimate what would be a reasonable number of applications for a REC (either a central or devolved one) to ensure ethical scrutiny. However, half of the valid answers showed that there were only between one and fifty applications per year. On this evidence, where there is a UREC, in a significant number of cases they do not appear to be scrutinising all the research that is being done.

xi. How were applications dealt with?

The telephone interviews revealed that a variety of methods were used for applications to the UREC. Half had standard forms (three of those had different ones for students, two had different ones at departmental level and one was moving to forms tailor made for different departments). A further three used checklists and four had set headings or suggested layouts for summary applications. Six said that Departments/Schools had a variety of procedures. Three were still considering procedures.

The telephone interviews showed that there appeared to be no filtering system of applications before the UREC considered them. Generally where there were Faculty/School/Department RECs, problem cases could be seen by the UREC or if a decision could not be reached. In answer to the question 'who looks at the applications and ensures that research gets ethical scrutiny' the telephone interviews showed a variety of answers from Deans to tutors.

It is not possible to generalise about procedures from the replies as there was such variety but it would be worth Universities endeavouring to work out common practice, for example over check lists, consent forms and other forms.

xii. What arrangements were there for delegated power?

It could be argued that a test of flexibility is how far decisions can be delegated. However, this can mean that consistency is lost unless there are firm guidelines and that it may give too much power to one person.

The answers to the question 'Does the Chair and/or sub-committee have any delegated power of decision making in any of the following areas: size of funding, student projects, urgent applications or minor amendments' did not give a full and representative account of the amount of delegation but the question must be asked how independent can any such delegation be?

Nearly all the Universities who answered the question allowed delegated power for minor amendments and most for urgent research applications. Caution must be exercised because of a low response rate to the next group but for student projects one in five allowed delegation.

xiii. Did the Research Ethics Committees report to anyone?

Of the 65 Universities that responded three quarters (47) said that they did while twelve (18%) said 'no' while six (9%) said that they will do in the future. One quarter of those that said they did sent a copy of their latest report with their completed questionnaire. Virtually all the Universities interviewed had a reporting system whereby the UREC made an annual report to the University Senate/Board/Council and Faculty/School/Dept committees and groups made an annual report to the UREC or sent it minutes and lists.

For the Faculties/Schools/Departments ten of the seventeen said that they did report while four said no, two will do so in the future and one was unsure. Five of the ten sent reports.

Three quarters of the URECs did have to report while the remainder did not.

xiv. Was the process audited?

There appeared to be no external audit of the ethical process in any of the Universities that had a telephone interview. However, this may not be the true picture. Virtually all the Universities interviewed had a reporting system whereby the UREC made an annual report to the University Senate, Board or Council and devolved RECs made an annual report to the central REC or sent it minutes.

There appeared to be no formal external audit of the ethical process in any of the Universities which had a telephone interview.

c. The different forms of scrutiny

i. Distinguishing between LRECs and URECs

(q How is it decided whether any piece of research is scrutinised by the University's REC or by an NHS LREC?)

Although nearly three quarters of the respondents (72%) said that they followed the guidelines of the Central Office for Research Ethics Committees (COREC) (see p.16) in a few cases the University insisted on seeing either all or some of the applications as well. In one University all applications had gone to the LREC until very recently but it was now setting up its own REC.

In the telephone interviews seven described the relationship with their LREC as close, quite close, and/or growing; several interviewees said that there was a dialogue with LRECs, two described the relationship as 'formal'. Six said the relationship was not close at UREC level but was at departmental level depending on the type of research undertaken.

Although the questionnaire and interviews did not throw up many problems about the division between what the REC and LRECs do subsequent discussions at conferences and personal communications have found that the division is not as clear cut as might be expected and the situation is a constantly evolving one.

Although the survey did not throw up major problems about the division between LRECs and URECs subsequent developments may have made this more complex.

ii. One UREC or a number of RECs?

One third (22/63) of the Universities had one central REC (a UREC) only. Just under two thirds (59%) had more than one – a UREC and different combinations of School/Faculty/Department committees. One example of a UREC was set up in 1980, has fourteen members, including one lay member, and a part-time Administrator, meets monthly and dealt with approximately 200 applications in the last year. One University with a devolved system has a UREC which was set up in 1998, has seventeen members including one lay and one student, a part-time Administrator and meets three times a year; the UREC has an advisory and policy-setting role and the University has a further three RECs at School level. In another University with a devolved system, one of its seven Departmental RECs has fourteen members, including a student member and a part-time Administrator; it deals with about 80 applications a year and every project has an independent reader (i.e. from within the department but not involved with the project) and the REC meets three times a semester but has a sub-board that meets on an ad-hoc basis if an urgent decision is required; it will shortly start reporting formally to the UREC, which has an advisory and policy-setting role.

There was limited evidence from the telephone interviews over why a particular model was chosen. This question was answered in a number of ways by nine interviewees. Most said it was based on the medical model and/or they had looked at other models in

Universities, the NHS and other organisations; one model was still being developed and was being reviewed annually; one had developed from two departmental committees set up several years ago; two were tailored to the University's requirements following discussion. There was a view that ethical scrutiny should not be a bureaucratic burden and must be seen to be facilitating research. However, one of the main roles of a REC is to ensure that the participants are protected.

University follows the Faculty/School/Department and sets up a UREC

In some cases it was the School/Faculty/Department that had started a REC and then the University followed on. In one University, where they are just setting up a UREC the Psychology Unit already had one. Another University is about to set up a UREC following the lead from some Departments. Another is moving to a University policy with scrutiny at a Department level.

UREC sets up devolved system

In some cases there appeared to be very extensive guidance to Schools but what happened in practice seemed very variable. One said 'Really the biggest debate is over research in different Schools. There are difficulties in trying to write one ethics process to fit all, trying to impose discipline and policy on all the Schools. The annual review is very important and it should pick up problems'. They had had one area where the ethical scrutiny process was not being carried out.

Who should do what?

A central issue is how to ensure that there is appropriate ethical scrutiny throughout the University and that systems are seen to be 'fair' and sufficiently flexible to deal with different kinds of research. For example how much does a central REC need to know to ensure ethical scrutiny? Is it enough for devolved RECs to report annually? In some cases the UREC did not know what their devolved committees were doing. For example at one the UREC is supposed to receive the minutes of the School RECs but the administrator confessed that they did not really know what was going on.

However the positive side to devolution is that giving some responsibility to Schools/Faculties/Schools may heighten awareness of procedures and responsibilities. One said 'Several years ago, before there was much awareness of ethical issues it was a different story'.

Where there were multiple RECs the nine telephone interviewees indicated that the UREC had responsibility for policy and procedures, provided guidance, received reports and provided advice/scrutiny in problematical cases. In four cases the UREC saw respectively postgraduate and staff applications, staff applications, applications involving vulnerable groups.

Would it be helpful to have some agreement about the levels of scrutiny? For example a list could be drawn up of research, such as that based solely on literature, that was

excluded and examples given of other types of research where there may be uncertainty. Some Universities use a checklist to guide researchers through this process. A triage system might also be possible, whereby certain types of research could be dealt with by a sub-committee.

An interesting example is one University where they started with a central REC and then devolved to Schools. They have found this unsatisfactory because there was no central control of policy; no systematic recording of how effective local monitoring is and no provision for staff development. They have decided that there will no longer be total devolution to Schools and may develop a hybrid option.

The issue of Research Centres may be different if they are separate from the main Faculty/School/Department system. It would be worrying if they were outside the University system.

One third (22/63) of the Universities had one central REC only. Just under two thirds (59%) had more than one – in some cases this consisted of a combination of School/Faculty/Department. There was no evidence over whether the levels of scrutiny were the same for a central REC and others.

iii. Were there any special procedures to deal with research in the social sciences?

Of the 59 responses to this question 35 (59%) said that there were not and applications were considered with the rest, one said that they were planning to do so while 23 (39%) said that there were special arrangements. These consisted of a variety of methods. In eight cases this was a School/Faculty/Departmental committee. In the remainder of the cases it was much vaguer including 'working group', 'Schools have their own (unspecified) procedures', 'by post and chair's action', reference to 'external codes of practice and guidelines'.

In the telephone interviews 24 of the 30 (of which it must be remembered 22 had more than one REC) said that social science research was subject to ethical scrutiny, one said that it would be and one said that they were about to set up a social science REC. Two of the 24 said that all research in the institution was social science and another two said that all research in that Faculty/School was social science. One said that there was also a great awareness of the need for ethical scrutiny in the Humanities, for instance in the compiling of oral history. In answer to the follow up question about whether social science was handled differently most said that it was not but one said that in their School every project had an independent reader at the pre-submission state and another said that, under their new system, scrutiny will be tailored to the type of research.

There is no doubt that the social sciences have not had the long experience of seeking ethical approval that their medical colleagues have (Foster, 2001) and there are examples of leading social scientists resisting any form of external review (e.g. Furedi, 2003). In our survey one University said 'The social sciences have needed a lot of convincing that

social science research should have ethical scrutiny'. On the other hand Psychology has sometimes led the way and had a REC before the University set one up. There were other examples where this subject seemed to have led the way e.g. by having well thought out procedures.

The use of professional guidelines was mentioned by a number of respondents and those by the British Psychological Society appeared to be widely used and appreciated. However, guidelines are helpful but are not the same as a scrutiny mechanism and even professional bodies that produce them recognise that they are not sufficient by themselves. For example the Social Research Association specifically advises that RECs should be seriously considered (SRA, 2003). This raises the issue of the competence of such a committee, which must include members who understand social science research methods and also be prepared to take advice.

A complicating factor is that, as one University put it, 'social science is a broad term nowadays and has crossed over into other areas of the University, where the applications were considered by the central REC'. For example some nutrition and pharmacy research involves social science research methods such as questionnaires.

Of the 59 responses, two thirds had no special arrangements for the social sciences.

iv. Were there specific procedures for ethical oversight of interdisciplinary research?

More than four in five said that they did not have special arrangements and the rest (17%) did not. Of those that did there was no pattern to the answers. They included stating that it was up to the Principal Investigator (PI), a special panel could be set up, by ensuring representation of 'other' departments.

A complicating factor is that of similar standards of ethical scrutiny. For example, one said 'The UREC is aware that there are overlaps in the types of project done by each faculty and it is important to ensure a common approach so that no-one could say that a particular application would have got through one of the other committees'.

v. Were there any specific procedures for ethical oversight of cross-institutional research?

An issue that can slow up research is where ethical approval has to be obtained from more than one institution. When asked if there were special arrangements for this of the 60 Universities that answered one in three said yes and two in three said no. Of the 21 that said yes one quarter (5) said that research had to be approved by all institutions. There was only one example of all the other answers which included 'partner organisations need to agree to use our procedures', 'special panel if needed', 'arrangement to accept each others decisions', 'PI takes responsibility'.

One in three made special arrangements for cross-institutional research.

d. Measuring the level of scrutiny

i. How the level of scrutiny was assessed

In order to get a better picture of the level of ethical scrutiny of research in the 78 universities that fully or partially completed the Questionnaire, the following ten criteria were selected:

- is there a REC, whether single or devolved?
- does the scrutiny cover staff research?
- does the scrutiny cover student research?
- do the REC Committee members have a spread of disciplines?
- is there training for members?
- does it have lay members?
- does it have student members?
- does it have an Administrator?
- clarity and volume of documentation in hard copy or on Website: terms of reference, details of committee membership etc.;
- clarity and volume of documentation in hard copy or on Website: guidance for researchers, code of practice, consent forms, application forms, example of consent form etc.

Looking at the evidence from the data, these criteria seemed to be associated with clearer models of what scrutiny is for and demonstrated a seriousness of purpose.

Other criteria that might be relevant but was felt that they could not be fully and/or fairly assessed from this model of research, included:

- independence of pressures from within the University;
- efficiency of Committee;
- number of applications considered;
- arrangements for delegated powers;
- auditing of the process audited (telephone interviews only);
- the ethos of the university.

While we have information on all of the above it was not possible to make a judgement and/or a fair assessment from the answers.

Ten criteria were identified where evidence was available to assess the level of scrutiny.

ii. The different levels of scrutiny

Of the 78 Universities that had completed Questionnaires in whole or in part, 21 (27%) had recently been or were in the process of setting up RECs, were reviewing or changing their system or had not given sufficient information to be fairly scored as scrutiny was devolved to Faculties/Schools/Departments; all research at one University which had a predominantly medical focus went to an LREC and one Questionnaire was incomplete.

Since many of these Universities were not in a position to fulfil the criteria, either because their scrutiny system was under development or there was insufficient information on their questionnaire, it was not felt equitable to include them in this assessment. The remaining 57 fully completed Questionnaires (73%) were focused on URECs, with the exception that two were from Faculty/School RECs. The 57 Universities were scored from the Questionnaires and documentation, using the first eight criteria above, and then with the two documentation criteria included, (this was not sent in all cases, and it is appreciated that this does not necessarily mean that there is no documented terms of reference, guidance etc.), with the following results:

<u>Score out of 8 criteria</u>	<u>No. of Universities</u>	<u>Single or devolved model</u>
0	2	Both have no REC
1	1	Devolved
2	0	
3	2	Both single
4	3	1 single; 2 devolved
5	5	1 single; 4 devolved
6	22	(includes a Faculty REC) 4 single; 18 devolved
7	15	(includes a School REC) 7 single; 8 devolved
8	<u>7</u>	4 single; 3 devolved
Total	<u>57</u>	

<u>Score out of 10 criteria</u>	<u>No. of Universities</u>	<u>Single or devolved model</u>
0	2	Both have no REC
1	1	Devolved
2	0	
3	1	Single
4	2	1 single; 1 devolved
5	4	Includes one with Documentation unseen – on Intranet 1 single; 3 devolved
6	9	Includes one with Documentation unseen - on Intranet 3 single; 6 devolved
7	8	(includes a Faculty REC) 2 single; 6 devolved
8	13	(includes a School REC) 3 single; 10 devolved
9	12	6 single; 6 devolved
10	<u>5</u>	2 single; 3 devolved

Total 57

Taking all the above answers into account the documentation of each University was examined and they were divided into the following:

- complete criteria (score of 10) 5/57
- many of the criteria (score of 8-9) 25/57
- some of the criteria (score of 5-7) 21/57
- a few of the criteria (score of 1-4) 4/57
- none 2/57

Whilst it is appreciated that this is a crude method of assessing the effectiveness of ethical scrutiny, nevertheless, it does indicate that a high number of Universities do fulfil sound basic criteria. Based on the ten criteria it is pleasing that nearly one in ten of the 57 Universities met all of them and six in ten met eight. It is disappointing that one in ten of the 57 only met four or fewer. This includes two that did not meet any. This cannot be a reason for complacency.

4. CONCLUSIONS AND RECOMMENDATIONS

a. Conclusions

Our broad conclusion is that when our survey was carried out in Autumn 2003, the majority of Universities were aware of the need for ethical scrutiny for research on human subjects and many of those Universities where the scrutiny system was being developed at the time of the completion of the Questionnaire may now have systems in place. However, in some cases practice seemed to lag behind awareness and there were both very good examples and some poor ones.

There is increasing awareness by Universities of the importance of ethical scrutiny for research on human participants. This includes developments in the field of research governance and ethics and we found a keenness to respond to them. Nearly all the Universities surveyed had a mechanism for ethical scrutiny or were developing one. For three quarters this was a formal Research Ethics Committee. Had we undertaken this survey in 2000 the picture would have been very different. This is because nearly half of our respondents had set up their REC since 2000. Other encouraging signs are the willingness to share experiences and to learn from others (demonstrated very clearly in the responses to the survey), the fact that most had lay members and four in five an administrator.

Looking specifically at different disciplines Universities are becoming increasingly aware of the relevance of ethical scrutiny in the Social Sciences. There is also growing

awareness that research ethics should have a wide application, encompassing disciplines such as the Humanities, Business Studies, Art and Design.

Looking more broadly at the ways in which ethical scrutiny can be judged, however, while seven in ten met eight or more of the ten criteria it may be a cause for concern that one in ten met only four or fewer. In other words they might have had a REC but it lacked some crucial ingredients such as lay membership or an administrator. Also the apparent small number of applications, in the case of some RECs, may be an indication that not all disciplines were covered. There is some indication that not all research involving humans subjects receives ethical scrutiny and further clarity on the issue of scrutiny of student research should be sought.

On organisation there is a very complex picture with probably no two systems exactly the same. It is an evolving situation with many Universities currently in the process of developing their systems. The benefits of a central or devolved system of scrutiny are being debated.

Two general models emerge:

- a single, central UREC, with responsibility for scrutiny of all applications, policy and guidance;
- a multiple model, whereby Faculties/Schools/Departments have their own RECs or groups where applications are scrutinised and a UREC which has responsibility for policy and guidance and perhaps scrutiny of a small number of applications.

The advantage of a single model is a University-wide standard of scrutiny with common standards. A disadvantage is that some research could slip through the net if certain disciplines feel that the model is not suitable for them and refuse to use the REC.

The advantage of a devolved model is that the scrutiny can be tuned to the particular discipline and any professional Codes of Practice. A disadvantage is that some areas might not exercise rigorous scrutiny.

b. Recommendations

The authors have been at pains in this research to present the empirical findings in an impartial way. The objective was not to produce a set of guidelines. Ethical scrutiny is not just making sure that any specific 'code' is lived up to, but that there is some real engagement with the ethical dilemmas or issues raised in research. Nevertheless, we feel able to make some recommendations. These are:

- a need to heighten awareness in Universities of the importance of ethical issues in research;
- more opportunity for inter-University discussion of the subject;

- all Universities should consider subjecting themselves to an audit using agreed criteria by which they may be judged (either the one we used or another) and estimate how they could improve;
- more guidance and support on research ethics training for researchers, students and REC members and this could include more inter-University collaboration;
- all funders should insist on evidence of ethical approval;
- funders and other bodies such as HEFCE will need to consider additional funding for Universities to cover the costs of ethical scrutiny procedures;
- all RECs should consider having lay members. This includes any devolved RECs (there was little evidence of widespread use of lay members at devolved level);
- we have noted the advantages and disadvantages of both single and devolved models, good practice and devolved models but also appreciate that we do not have sufficient evidence to answer the question of whether a Faculty/ School/ Department committee is independent enough;
- Universities should consider seriously whether there is need for a full time administrator, how frequently RECs should meet, how they can consider and process applications that satisfies independent ethical scrutiny but is not too bureaucratic, and how independence is to be achieved;
- there is a lack of clarity about the scrutiny of student research and this needs further discussion. If the draft recommendations in the Doyal Report are accepted, they will have major implications in terms of finance and time and these need to be examined;
- consideration should be given to revising the timetable for student research projects to give longer time;
- a need for clear central guidance from HEFCE on the underpinning principles, the legal arguments and acceptable procedures and processes, to enable Universities to work out best practice, for example over check lists, consent and application forms and advice. However, good practice guidelines will only work if put into practice;
- attention should also be drawn to the burgeoning research taking place outside LRECs and Universities. Market research companies, some specialist institutes and other research bodies have no recognised way of gaining ethical scrutiny.

References

- Ashcroft, R and Parker, M (2003) 'The ethical review of student research in the context of the governance arrangements for research ethics committees' in Eckstein, pp. 53-56
- Association of Research Ethics Committees Newsletter (August 2001)
- Barton, L (1996) 'Sociology and disability: some emerging issues' in Barton, L (ed.) *Disability and Society: Emerging issues and insights*, Longman, pp. 3-17
- Beresford, P (1996) in Dean, M (ed.) pp. 41-47

- Boulton, M, Brown, N, Lewis, G and Webster, A (June 2004) *Implementing the ESRC Research Ethics Framework: The Case for Research Ethics Committees*. Discussion Paper 4 (www.york.ac.uk/res/ref)
- British Educational Research Association (2000) *Ethical Guidelines*
- British Sociological Association, (2002) *Statement of Ethical Practice*, <http://www.britisoc.org.uk/ethgu2.htm>
- British Psychological Society (2000) *Codes of Conduct, Ethical Principles and Guidelines*. BPS
- Butler, A (1990) 'Research ethics and older people' in Peace (ed.) pp. 162-170
- Carlisle, D (1997) 'Moral maze' *Health Service Journal*, 3.4.97 pp. 26-27
- Dean, M (ed.) (1996) *Ethics and Social Policy Research* University of Luton Press/SPA
- DH (March 2001) *Research Governance Framework for Health and Social Care*. DH.
- DH (July 2001) *Governance Arrangements for NHS Research Ethics Committees*. DH
- DH (September 2001) *Consultation Meeting on Governance Arrangements for Ethical Review of Social Care Research*
- DH (2003) *Research Governance Arrangements for NHS Research Ethics Committees*. Draft. DH
- Department of Work and Pensions (2003) *Doing the Right Thing*. DWP
- Doyal report (2004) *The Ethical Governance and Regulation of Student Projects: A Draft Proposal*. DH
- Eckstein, S (2003) *Manual for Research Ethics Committees*, Centre for Medical Law and Ethics, King's College London
- Edwards, P *et al*, (2002) 'Increasing response rates to postal questionnaires: systematic review' *British Medical Journal* Vol. 324, 18.5.2002, pp. 1183-1185
- Foot, H and Sanford, A (2004) 'The use and abuse of student participants', *The Psychologist*, 17, 5, 246-259
- Foster, F (2001) *The Ethics of Medical Research on Humans*, Cambridge University Press
- Furedi, F (2003) Presentation to the Association of Research Ethics Committees, London, 14.11.03
- Gilhooly, M (2002) 'Ethical issues in researching later life' in Jamieson, A and Victor, C (eds.) *Researching Ageing and Later Life*, Open University Press
- Hunt, Lord (2001) in DH March 2001
- Nuffield Foundation (2002) *How to apply for a research grant*
- Nuffield Foundation (2004) *How to apply for a project grant*
- Nuffield Foundation Working Party on issues raised by research into behavioural genetics. www.nuffieldfoundation.org/bioethics
- Peace, S (ed.) (1990) *Researching Social Gerontology*. Sage
- Peace, S (ed.) (1999) *Involving Older People in Research: 'An amateur doing the work of a professional?'* Centre for Policy on Ageing
- RESPECT (2004) *Code of Practice for Socio-Economic Research*. RESPECT www.respectproject.org/code
- Roberts, H and Wellard, S (1997) 'Hearing voices' in *Community Care*, 16-22.1.97, pp. 24-25

- Royal College of Nursing (2004) *Research Ethics: RCN Guidance for Nurses*, RCN
- Smeeth, L and Fletcher, A (2002) 'Improving response rates to questionnaires' *British Medical Journal*, 18.5.2002, Vol. 324, 18.5.2002, pp. 1168-1169
- Social Research Association (2003) *Ethical Guidelines*, Social Research Association.
- Tinker, A (1997) 'The other side of the fence' *BMJ* Vol.315, 22.11.97 pp. 1385-6
- Tinker, A (1998) 'How it feels to be 'on the other side of the fence' in a longitudinal study' *Generations Review*, Vol 8, No. 3, pp. 5-6
- Tinker, A (2001) 'Ethics Committees – Help or Hindrance?' *Generations Review*. 11, No. 3, pp. 11-12, 18
- Tozer, R and Thornton, P (1995) *A Meeting of Minds: Older People as Research Advisors*. York University
- Turner, M, Brough, P and Williams-Findlay, R.B. (2003) *Our Voice in our Future: service users debate the future of the welfare state*, Joseph Rowntree Foundation
- Webster, A (2004) 'New ESRC National Guidelines for Research Ethics' in *Social Research Association Newsletter*, February 2004
- Wellcome Trust *Biomedical Ethics Research Summaries*
<http://www.wellcome.ac.uk/en1/mismisethres.htm>

Appendix A

University Research Ethics Committees: Their role, remit and conduct

Advisory Committee Members

Chairman:
Lord Sutherland

Professor Sally Baldwin
Director, Institute for Research in the Social Sciences, University of York

Mr Peter Brown
Secretary, The British Academy

Dr Carolyn Davies
Department of Health
Research and Development Division

Ms Sue Duncan
Government Chief Social Research Officer

Professor Ian Forbes
Chair of the Council of the Academy of Learned Societies for the Social Sciences (AcSS)

Mr Michael Powell
Consultant, Universities UK

Ms Ros Rouse
Associate Director of Research, ESRC

Mr Rama Thirunamachandran
Director, Research and Knowledge Transfer
Higher Education Funding Council for England

Sharon Witherspoon
Deputy Director,
The Nuffield Foundation

The researchers from King's College London:

Professor Anthea Tinker
Principal Investigator and Grantholder

Vera Coomber,
Research Associate