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University Research Ethics Committees as learning communities: identifying and utilising collaboratively produced knowledge in decision-making

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Introduction

Generally the establishment of University Research Ethics Committees (RECs) is not a novelty although many University RECs and devolved committees are still in their infancy. The *modus operandi* of these bodies is thus evolving and they may be seen as 'learning institutions', revising and rearranging practices over time (Schon, cited in Fry et al 2009). Tinker and Coomber reported in 2005 that nearly half of the RECs in their survey had been set up since 2000 and 'half of the University RECs and one-third of the devolved committees provided training for their members' (2005:7). They recommended *inter alia* that more guidance and support on research ethics training should be in place for researchers, students and REC members. In considering the framework within which the activities of a University REC are undertaken, we noted the questions about who is involved in the review and what type of research is examined. We explored the issue of decision making and diversity of membership and noted that that the structure of ethics review within a university does not *in itself* explain the success or otherwise of a university ethics review system. Rather, the efficacy or otherwise of a REC may be seen to relate to its effective decision making processes and how these are informed by the knowledge brought by members to the meetings of the REC.

Kimmell, concluding his work on ethics and values in applied social research, states that

Given that individuals differ in the ways they formulate their ethical appraisal of research, perfect consensus regarding the ethicality of a particular investigation cannot be expected. However, if the relative importance of the many factors that influence judgments pertinent to ethical decision making can be enumerated, clarified and weighed in subsequent research....social researchers may then be better able to deal effectively with their ethical dilemmas and obtain a fuller

¹ Our comments are the result of reflection on the decision making practices of a University Research Committee (the City University London Senate Research Ethics Committee) by three of its members. However, while the authors are all members of the City University SREC, the reflective account of our experiences are our personal views, not those of the SREC nor of City University London.

understanding of their differences through reasoned and informed discussion (1988: 136-137).

His conclusion constitutes the starting point for our consideration of one aspect of the decision making activities of RECs, specifically we reflect on how the learning arising from the review of research undertaken by a University Research Ethics Committee - a central part of its business - is captured and used by its members to support effective decision making, and, as a further concern how this process can be supported by a particular training methodology – that of case-based facilitated training.

The essential point is that the “whole is greater than the sum of the parts”, i.e. that the decision making process is enhanced by capturing the collaborative learning of the members of the University REC. The ways in which collaborative learning is captured and acted upon by members of University Research Ethics Committee is a neglected issue within the available literature, although Edwards in an earlier volume of *Research Ethics* discusses precedent and considers the ways in which a REC can capture and use this precedent in decision making (Edwards 2009). In directing attention to this process, we wanted to analytically engage with the issue of learning and decision making, ethics and politics, standpoints, and values and their relationship to training and education needs of members. One reason for doing this is to reflexively engage with our practice. The background to this note is the observation that, over the course of its year’s work, Committee members learn together. The knowledge produced by this collaborative learning is often explicitly referred to in the process of decision making, with members making reference to past decisions and related discussions. We consider that making explicit or rather *codifying* the often implicit or *tacit* knowledge of members is an important step in promoting effective decision making.

The knowledge produced by this collaborative learning also points to the need for diversity of members. This diversity of membership is founded on the idea that the committee needs and benefits from diverse and sometimes different points of view in the decision making process which seeks consensus. There is broad agreement in the literature and amongst practitioners that a university REC should seek to reflect a diversity of standpoints (c.f. Edwards 2009) and experiences, hence the role of lay representatives is important – a point that Economic and Social Research Council emphasises in its Framework for Research Ethics (FRE, ESRC 2010). However, the extra-academic knowledge that such lay members bring to the committee is rarely reviewed.

We draw on the literature associated with educational practice in identifying the SREC as a particular example of a ‘learning community’; such a community is defined as

a supportive group of people who come together to collaborate and learn together, they are usually facilitated or guided to achieve a specific outcome or agreed learning objective (Lewis and Allan, 2005:8)

In addition, such learning communities support ‘deep’ learning (Fry et al, 2009: 11), a mode of learning which is fundamentally reflective. Reflective practitioners are those who are

continually involved in the process of reflecting on experience and [are] capable of continually learning from experience to the benefit of future actions (Fry et al, 2009, p. 509).

In what follows, we attempt to illustrate our ideas about the need for education and training to meet the needs of members of a university REC, with the presumption that that our experience of a particular university REC is typical. We consider the following, firstly the committee's decision making practices and secondly, the types of knowledge that are brought to bear on these practices. This second section considers the needs of members of a REC in respect of formal, codified, knowledge, for example, the rules relating to data protection and informal, tacit, knowledge, that is, the learning which accrues to members of the REC in and through the routine decision making undertaken in REC meetings.

Section 1: Decision making

As the University Research Ethics Committee, members take ethical decisions that affect others. Following Kimmel (op. cit) there is need for clarity as to the basis those decisions are taken and as to whether the bases of decisions explicit or implicit.

The question arises as to whether it is desirable to be explicit about the factors informing decisions – which Kimmell affirms - and relatedly, the issue of whose rules/philosophical rules do we draw on and enunciate in our decision making? We consider, again following Kimmel, that this is a legitimate aim for a research ethics committee to pursue as the full explication of factors influencing decisions

....social researchers may then be better able to deal effectively with their ethical dilemmas and obtain a fuller understanding of their differences through reasoned and informed discussion (op. cit)

The issue raised by Kimmel's comment relates to the knowledge required of committee members and also *how* this knowledge is used in decision making. The implications for the education and training requirements of committee members are considered.

The decision making procedure of the City University Senate Research Ethics Committee does not operate according to a defined, codified, set of rules, nor does it explicitly espouse particular values relating to ethics and morality. Members participate in collective discussions without being bound to a formal institutional/institutionalised code/set of rules. Of course, the ethics forms which researchers are required to complete enunciate the University's requirements, including data protection arrangements. These forms are not randomly designed but are based on a wide and deep experience of many researchers, both members of ethics committees and applicants and as such come close to an explicit statement of the categories of potential problem that the committee wishes to review, although there is no guidance on how dilemmas should be resolved, except for an overwhelming presumption that the rights and well being of participants are paramount

The range of themes formally addressed in the Ethics Review form used in City University London is outlined the box below:

ETHICAL THEMES COVERED IN THE ETHICS REVIEW FORM

- **Self identification of potential ethical issues**
- including: potential harms and benefits to participants and society at large
- **Precautions in place to minimise harm to participants and researchers**
-including: precautions in respect of physically or psychologically intrusive interventions, avoiding coercion to participate, extra safeguards for children and vulnerable people, referral processes should any unmet needs of participants be identified or harm disclosed, avoidance of over-researching groups, safety of researchers, and psychological wellbeing of researchers.
- **Recruitment and consent**
-including: details of how participants are to be recruited and the procedures of obtaining fully informed consent.
- **Methodology**
- including: a justification of the chosen scientific method, details of the study inclusion and exclusion criteria and plans for dissemination.
- **Confidentiality**
- including: details of how participant confidentiality is to be protected, arrangements for data storage and management, and compliance with the data protection Act.
- **Other permissions**
- Have permissions been sought from appropriate external bodies (.e.g. NRES, NHS R&D Departments, the Criminal Justice System and other regulatory bodies)

The listing relates broadly to the wider issue of whether researchers ought operate according to well-defined research ethics checklists or according to a more general sensibility of 'do no harm' (Kellehear, 1989). Both approaches are based on philosophical foundations which are rarely explicated but inform both the construction of checklists (i.e. what is included as core ethics) and the general sensibility approach.

A third dimension however, irrespective of which approach is used, is the tacit knowledge produced and reproduced in and through the decision making practices of the REC.

The listing of key themes included in the Ethics Review in place in City University London, in line with ethics forms used in other universities, illustrates the range of knowledges required in the decision making of a university REC. We note that where extra-ethical issues are raised, these indicate the infusion of wider research governance matters in ethics decision making; in particular aspects relating to sponsorship, indemnity and the protection of institutional reputation. Ethics fall within the broader framework of research governance and the reputational protection of the institution. Hence, topics requiring the attention of university research ethics committees are often beyond the traditional understanding of ethics i.e. beyond considering the 'do no harm' dictum (Kellehear, 1989) and include decisions relating to data protection, to liability [of

the institution and individual researcher] and to wider legal issues. For example, the ESRC in its Framework for Research Excellence (ESRC, 2010) clearly identifies the need for ethics review to explicitly consider the position of funders in its deliberations. This latter issue is not explored being beyond the scope of this paper (although see Haggerty, 2004 for a discussion of regulatory control and ethics review systems).

Section 2 Training and education: Responding to different knowledge needs

Two approaches to training and education are identified, the first concerns what might be determined as a ‘superficial approach’ as REC members we need to know about rules and regulations and how the wider research ethics community deliberate; this is broadly a didactic training model, allowing the transmission of the basic concepts of ethical theory and principles amongst other things. The second approach, which we term a ‘reflective approach’, aims to capitalize on the knowledge and experience of individual members as well as the collective knowledge and experience of the committee as a body in its own right. This model is much more concerned with deep learning and might be better described as education rather than training. Such an approach could use case studies to facilitate group explication of the application and practice of our reasoning, attempting to identify the values informing our practice. This process is a key feature of reflective practice (Fry et al 2009)

These two models learning have been identified as highly desirable aspect of the knowledge base of clinical ethics committees (Gillon, 2010) but we suggest are also of relevance to general REC. These two models are connected: the reflective approach to training helps to make explicit our own decision making processes and bring an external lens to our own learning and the superficial approach provides the basic information upon which the decisions taken are based:

It is important to clarify that the principalist approach to ethics , which, broadly speaking provides a general guide to ethics using the principles of respect for autonomy, nonmaleficence, beneficence and justice to guide decisions and the causist approach which argues that ethics decisions should be based on concrete examples, are not aligned to the models of education and training presented here (the reflective approach and the superficial approach). While the former uses case-based training – concrete examples – and the latter, requiring transmission of facts, **may** involve didactic approaches, a simple equation of reflective/case-based training and superficial/didactic approach is not presumed. We acknowledge however that both approaches are not necessarily incompatible with each other.

<p>Model 1: Reflective Approach (Capturing existing knowledge to optimise decision-making amongst members)</p> <p>EDUCATION → CODIFYING KNOWLEDGE VIA CASE STUDY FACILITATED REFLECTION → MORE EFFECTIVE</p>	<p>↔</p>	<p>Model 2 : Superficial Approach (Up-skilling the members)</p> <p>TRAINING → IMPACTS ON KNOWLEDGE ABOUT THE SPECIFIC DIMENSIONS OF ETHICS → THIS KNOWLEDGE</p>
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COLLABORATIVE DECISION MAKING		UNDERPINS DECISIONS OF INDIVIDUAL
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Model 1: Reflective approach (Capturing existing knowledge to optimise decision-making amongst members)

The model supposes the following sequence: education involves codifying knowledge via case –study facilitated reflection and this will lead to more effective collaborative decision making.

The late Lord Bingham, formerly the Senior Law Lord, said in 2000 ‘it’s a judge’s professional duty to do what he reasonably can to equip himself to discharge his judicial duties with a high degree of competence’ (2000:71). The activities of the members of Research Ethics Committees may be considered ‘judgmental and applying, by analogy the words of Lord Bingham to the members of the REC it is clear that such members have a professional duty to ‘do what they reasonably can to equip themselves to discharge’ their REC judging duties. We acknowledge that a REC is not a legal decision making body, however, we are struck by the number of REC ethical issues that arise that have legal implications; data protection, safeguarding of vulnerable adults, child safeguarding and researcher health and safety to name the most obvious. It is almost certainly true that most REC members are not lawyers by background or training but we have looked to law to see what lessons there might be on business of judging since the REC is tasked with judging fairly all applications before it and for many applications the affect of law and its regulations is of significance.

Drawing on the example of law training for the REC, it is suggested that it should be case study based and give REC members a chance to apply the law to the case study facts and together make a judgement.

A lecture with no attendee participation aimed purely at imparting knowledge about for instance, the complex, hotch potch of legislation and common law around confidentiality and data protection, would not only be deeply dull but also unmemorable for members of the REC. If it is true (and it probably is otherwise lawyers would be out of jobs) ‘most of us are only vaguely aware of what is legal and what is not’ and ‘researchers, and others, are left confused about what the law really says’ REC members should be trained in the relevant law. Law training for a REC, indeed any training for a REC, ought to include case – based examples of the sort of issues that RECs face, then provide an opportunity to debate and decide followed by reflection and feedback. Bespoke, case study based training for a university REC committee would provided an opportunity for the members of that particular REC to improve their knowledge of a particular relevant subject area, law or otherwise, and also learn how to apply it and together reach a judgement on a particular application.

Model 2: Superficial Approach: Up-skilling the members

This model assumes that didactic training will impart formal knowledge about dimensions of ethics; legal requirements e.g. the Mental Capacity Act (2005) and this formal knowledge will underpin decisions of individual members.

Legal issues relating to data protection, confidentiality, consent and health and safety (to name a few) frequently arise when an application for ethical approval is being

considered. But the law rarely provides the answer to a REC concern about an aspect of the research project. Rather the law provides the REC with a framework which must be applied to the particular facts of that application and then the REC must use its collective judgement.

Take for instance principle seven of the Data Protection Act, 1998 ('the Act') which mandates 'Appropriate technical and organisational measures shall be taken against unauthorised or unlawful processing of personal data and against accidental loss or destruction of, or damage to, personal data.' The Act does not specifically tell the REC if it would be lawful for a researcher to store on an unencrypted laptop research data about individual children's reading ages as compared to their chronological ages. The Information Commissioner's website advises us that 'There is no "one size fits all" solution to information security. The security measures that are appropriate for an organisation will depend on its circumstances, so you should adopt a risk-based approach to deciding what level of security you need.' And so the REC looks to the circumstances and adopts a 'risk-based' approach, whatever the REC thinks that might be. Presumably it means that the security steps the REC requires should be proportionate to the risks involved and reasonable in all the circumstances.

When confronting an issue such as what is appropriate in the circumstances, individual REC members each bring their own perspectives and approach. As individuals they can, and often do, judge applications differently. The primary role of the REC chair is to ensure that these views are aired and the committee reaches a collective judgment on the application. It helps if the committee members have opportunities to attend training together in order to better appreciate each other's perspective and develop a shared approach to judging an application. REC training can help, but there is training and then there is training as our two-part model of training (model 1 and model 2) illustrates.

Conclusion

In this reflective note we have attempted to explore the different sets of knowledge and the related training and education requirements of the diverse membership of Research Ethics Committees. On the one hand, what we have termed formal knowledge (i.e. the knowledge of legal requirements and procedures, such as those relating to the Data Protection Act, 1998 or the Mental Incapacity Act, 2005) can be transmitted to participants via formal training, using traditional didactic modes of instruction. However, an oft-neglected category of knowledge refers to the knowledge generated by the Committee in the course of its deliberations – what might be called 'learning knowledge'/'internal learning; this knowledge is tacit, it is rarely codified. It draws on and consolidates the pre-existing knowledge and experience of the diversity of experience and knowledge of the different members. Exploring and attempting to codify this tacit knowledge requires specific methodologies, we suggest that case –based facilitated training approaches already in use to train legal personnel, might offer a viable approach.

Research Ethics Committees are learning communities and can collaboratively identify and capitalise on the collective knowledge of membership for the purpose of more effective decision making with clear values. Transparency of the REC decisions is an important element: Kimmell's argument which emphasises the rationale for seeking such transparency is apt:

if the relative importance of the many factors that influence judgments pertinent to ethical decision making can be enumerated, clarified and weighed in subsequent research....social researchers may then be better able to deal effectively with their ethical dilemmas and obtain a fuller understanding of their differences through reasoned and informed discussion (1988: 136-137)

Exploring the values that inform the decisions of individual members via a collaborative process can, we suggest, be useful in supporting the effectiveness of an individual REC. Clarity about the bases of ethics review decisions will further clarify the role and function of ethics review committees, reinforcing the legitimacy of decisions taken and prompting ethical reflection amongst the research community of the REC's institution.

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