Chapter 4
Formulating National Standards for Research Ethics Support and Review: The UKRIO/ARMA Case

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Abstract   This chapter describes and analyses the background to and development of a national guidance framework for research ethics review that was commissioned by the United Kingdom Research Integrity Office and the Association of Research Managers and Administrators, and launched in 2020. Unlike the centrally-controlled UK Health Research Authority research ethics review system for health and social care research, ethics review of research outside these fields is not nationally controlled and is conducted within a wide variety of organisational structures. The development process had to adopt an approach that consulted widely and sought to ensure broad take-up of the guidance by offering a flexible approach to compliance with a set of superordinate principles, while meeting the expectations of the government funding body for the higher education sector as well as those of the UK research councils.

Keywords Research ethics review · Guidelines · Framework · Standards · UKRIO/ARMA

4.1   Introduction

Consistency, competence, and high standards are generally accepted as being the sine qua non for the review of research ethics protocols by research ethics committees (RECs). Until the early 2000s, the primary research ethics review activities in the United Kingdom (UK) were focused on a set of committees mostly concerned with medical research, under the auspices of the National Health Service (NHS), and a few newly formed within universities. But as such committees proliferated in the UK outside of the field of medical research, mainly in universities and in some charities and independent research organisations, there was little in the way of coordination and integration. Many different models of ethics review processes sprang up and concerns began to arise about the implications of such a totally decentralised and diverse system for the quality of reviews across the sector. The Association of

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Research Ethics Committees (AREC), initially established for chairs and secretaries of NHS RECs, welcomed members from these newly formed RECs and became a forum for exploring ways of building a set of common standards, paralleling the operating procedures already coordinating the NHS RECs. Work by a panel of AREC members, informed by discussions in a universities' forum also established by AREC, resulted in a guidance document launched in 2013 (Association of Research Ethics Committees (AREC) 2013). This document was well received by the sector. Increasing interest in being able to audit and document compliance with national expectations around research integrity led to the United Kingdom Research Integrity Office (UKRIO) and the Association of Research Administrators and Managers (ARMA) commissioning the development of national guidance based on the experience of institutions engaging with the AREC framework and the increasingly explicit expectations of research funding bodies for robust ethics review processes as part of a growing agenda around research integrity. The success of the AREC framework rested on its development in close liaison with the 'grassroots' of committee chairs, administrators and researchers as well as with the higher echelons of other stakeholders such as the major funding bodies. Led by a team including authors of the AREC document, the project to develop the UKRIO/ARMA guidance followed this approach to aim for the maximum buy-in by researchers and research institutions while also meeting the needs of funding and regulatory bodies in the UK.

4.2 Background

In 1991 the British Department of Health (DoH) formally established research ethics committees (RECs) in England to review proposed medical research projects, projects which were predominantly clinical trials of investigational medicinal products (CTIMPs) and trials of therapeutic approaches within the NHS. These committees were called Local Research Ethics Committees (LRECs). The establishment of LRECs in Wales and Scotland followed shortly afterwards.

With an increase in research involving more than one local area, multi-centre RECs (MRECs) were established in 1997 to review research proposals involving four or more local NHS areas. Responding to a need to continue to harmonise and standardise practice across all the RECs, the Central Office for Research Ethics Committees (COREC) was set up in 2000.

In consequence, there were many RECs across England, Scotland and Wales reviewing research proposals, with broadly similar structures and modes of operating. The Department of Health gave financial support to the independently formed AREC, which was incorporated as a limited company in 2002 initially as a forum primarily for chairs and secretaries of RECs to collaborate in considering issues in medical research ethics and the review practices of their committees. An important forum for developing this collaboration was established by the initiation of national conferences which tended on each occasion to focus on a specific research ethics topic, but also

served as a valuable means for members of the Association to network and to build and maintain its 'community of practice'.

Outside of the medical and health research field, ethics review for other research with humans was not widely available around this time. By far the greater part of such research was carried out by researchers in universities. While some universities had well-founded RECs that had been operating successfully for some time, others had only embryonic systems or none at all. The lack of a coordinated national approach was highlighted in a King's College London survey carried out in 2003–4 (Tinker and Coomber 2004). This found that of the 87 universities that responded (out of 115 contacted) only two in five had any form of ethics review that had been in place for more than four years, and one in five had no processes for ethics scrutiny at all. While this survey documented a rapidly increasing awareness in universities of the need for universal scrutiny of research with humans, it also showed great variation in practice, with some universities having opted for a centralised model yet with others having devolved responsibility for ethics review to departmental levels.

The National Research Ethics Service (NRES) was founded by the DoH in 2007, bringing together COREC, MRECs and LRECs under a common umbrella body, with the aim of further standardising review practices under a common governance framework.

As the membership of AREC grew, by 2007 the Association had developed working collaborations both within and beyond the UK. In the UK, productive links were established with Universities UK, the United Kingdom Research Integrity Office (UKRIO) and with NRES, and links were strengthened with the DoH, inputting into new developments in ethics review including the Integrated Research Application System. Beyond the UK, connections were made with EUREC, the European network of RECs, and the European Forum of Good Clinical Practice. Drawing on the 'grass-roots' experience of reviewing a wide range of research proposals across nations, AREC was able to influence the development of policies and practices from a sound evidence base, as well as working within the Association to iron out differences between RECs in the interest of fostering common best practice standards.

The King's College survey of research ethics review of human research projects outside of the medical and health field highlighted a stark contrast between the two sectors and AREC welcomed a large influx of members from the university sector as awareness grew of the increasing concern with research ethics by funders and other stakeholders (Tinker and Coomber 2004). Work began towards the encouragement and development of high-quality REC practice in this sector. An important development at this time was the setting-up by AREC members of a Universities Ethics Forum, an informal space where people involved with university RECs could share experiences much as the prior membership of AREC had been encouraging. Views expressed in this forum, and discussions at an AREC conference, led to a working group of AREC members coming together to draw on universities' practices to develop an initial guidance document to set some common standards and principles, and to contribute further towards building better coherence and uniformity of research ethics review in the UK higher education sector. The working group

brought together a wide range of experience in different universities and in different roles within governance and ethics review structures.

4.3 The Case Study

4.3.1 First Steps: The AREC Framework

The challenge faced in this project was presented by the great diversity of approach and practice in the sector at the time. In part, this diversity had arisen because the development of REC systems had been taken forward at the level of individual institutions which differed greatly in the volume and types of research with humans carried out within them, and the location of the research within their structures. As well as this diversity, governance structures varied and the governance locations and management lines within which RECs could sit also affected how reviewing was carried out and overseen. For example, a university with a very active research area in psychology was likely to have a departmental level committee dealing with both staff and students' research, while a university with less human-based research spread across several faculties was more likely to have a higher-level REC handling applications for review. Some universities had a high-level ethics committee that rarely reviewed applications but rather set policy and oversaw the reviewing of several departmental level RECs, while others had a single REC handling all reviewing. It was clear to the working group that a 'one-size-fits-all', such as was largely the case with NHS RECs, was not going to be feasible or practical in meeting the varied needs of this range of institutional structures and disciplinary specialisms.

The solution adopted by the working group was to concentrate on developing a framework that had sufficient flexibility to be able to accommodate this range of variation within universities but at the same time to provide common standards and an audit tool to allow for evidencing compliance with these common standards (Association of Research Ethics Committees (AREC) 2013). At an early stage, a set of four guiding principles was proposed and elaborated, a novel development given that there had been no such explicit principles for ethics review in existence previously, even though principles for ethical research conduct have a clear and very long history.

The first principle, *independence*, was established as a basic requirement for a REC to be able to deliberate in its evaluations of research ethics protocols without conflicts of interest. This stresses the need for reviewers to have sufficient distance from the researchers applying for review to enable them to undertake a balanced, objective analysis of the risks and potential harms in a research proposal and the adequacy of the researchers' plans to eliminate or at least minimise and mitigate the risks. Clearly, ethics review by academic members of a department where the same members are also colleagues of researchers applying for review would not meet this

criterion, yet at the time of elaborating this principle there were indeed ethics reviews being conducted with just this flaw.

But independence alone does not guarantee a good, thorough, and well-informed ethics review. It needs to be complemented by the application of the second principle, *competence*. As well as ensuring that those reviewing cases have adequate experience and knowledge, a well-founded REC needs clear operating procedures and terms of reference, for which the working group developed a set of recommendations, based on what consultations with REC chairs and administrators identified as best practice at that time.

The working group also intended the review principles to help RECs overcome and indeed change what was a dominant view, that ethics review was a hurdle to be overcome and then put behind as the research progressed. Instead, the group wished to promote *facilitation* as the third core principle; that seeking an ethics review should come to be seen by researchers as a positive component of their research process, one that could enhance the quality of their work rather than merely 'police' it and avoid the common charge of being 'obstructive'.

Finally, to counter another common view, that the workings of RECs were obscure and hidden, with the reasons for decisions not being clear, the fourth principle, *openness*, was intended to promote practices of transparency, such as keeping clear records of decision-making and making explicit the reasons for decisions when these are communicated to applicants.

Following discussion of these principles in a workshop associated with the 2009 AREC national conference, the group then engaged in a period of consultations with a range of stakeholders, with funding bodies such as the Economic and Social Research Council (ESRC), with the Health Research Authority (the body responsible for the ethics review of medical research), with Universities UK and through a number of joint actions with learned societies in the social sciences through the Academy of Social Sciences.

To help to ensure alignment across the social sciences, members of the working group engaged with parallel developments in guidance, codes and practices for ethical research conduct underway in bodies including the ESRC, the British Psychological Society and the Social Research Association. The AREC universities research ethics forum proved to be a further crucial consultation mechanism, especially in relation to the feasibility of the structural and process guidance being developed. A Universities Development Group, which emerged naturally as the AREC forum became a source for sharing ideas for best practice, played an additional collaborative role in ensuring alignment with governance developments in universities.

A further parallel development, by Universities UK (UUK), was the consultation on the first Concordat on Research Integrity, which had similar high-level aims to the AREC project in seeking to support common standards of best practice in research integrity. Integrity and ethics share common ground, and the Concordat recognised the role of the university sector's REC review processes as an element of research integrity. Members of the AREC group contributed to the consultation on the Concordat, which was published in 2012 (UUK 2012). The self-assessment tool,

an audit framework, which the AREC group had developed, nicely helped to serve the new reporting requirements of the Concordat.

The extensive co-production process finally led to the publication in 2013 of the AREC Framework of Policies and Procedures for University Research Ethics Committees (Association of Research Ethics Committees (AREC) 2013), promoted by AREC as a set of guidelines to help higher education institutions develop their research ethics review policies, structures, and procedures.

4.3.2 Second Steps: UKRIO/ARMA Guidance

Recognising the increased interest that the university sector was showing in seeking guidance on research ethics, senior officers in UKRIO and ARMA decided that a further useful step would be to build on the experience of the AREC framework, taking account of developments in the field, to produce an authoritative publication giving clear guidance on how best to manage research ethics review, not only for universities, but also for other research organisations. And, in addition, for this guidance to be aligned with the key principles of research integrity that were being promoted by the Concordat on Research Integrity, to support an open culture of auditing and reporting on institutional actions. A project team was formed, incorporating key members of the previous AREC working party as well as further representation across the research community. The team had useful links with other research ethics initiatives such as the revision of ethics codes of learned societies, ethics review within the Health Research Authority ambit, research councils' requirements for ethics review in the UK and ethics review practices in the European Research Council.

While the liaison and consultations that informed the AREC framework had been informal and largely opportunistic, the greater ambition for the UKRIO/ARMA guidance meant that formal processes of involvement with stakeholders were necessary not only for the adequate consideration of the relevant issues but also for the guidance to be perceived as being firmly grounded in the practicalities of research organisations' governance structures and processes, the criteria by which research integrity is scrutinised and the values and principles inherent in scientific research. To these ends, senior officials in UKRIO and ARMA established broad memberships of a steering and an advisory group, representing the necessary breadth of interests. Regular reporting and sharing of drafts with these two groups, and responding to their critical evaluations, while time-consuming, nevertheless led to a sense of shared ownership and hence willingness to adopt and endorse the final outputs.

Reflecting the greater engagement of universities with improving their processes around research ethics following the launch of the 2012 Concordat on Research Integrity, the UKRIO/ARMA project aimed to highlight the importance of building support for researchers throughout all stages of the research cycle. It sought to extend beyond the inevitably pre-emptive formal review carried out by RECs of protocols developed before the associated research data collection starts. With the proliferation

of research methods in the social sciences, exploratory and co-produced research does not easily sit with reviews of ethics protocols before the ethics issues involved have been fully revealed, which is what a single engagement with a REC traditionally required. Nor does a lack of consultation with the expert knowledge held by REC members help with the preparatory phases of research when design and methods are being planned.

An early stage in the development of the new guidance was to validate the four basic principles for ethics review that had initially been proposed as the core of the AREC framework, by testing them with the advisory and steering groups, to see if they still held up in the new research environment. No challenges to them were expressed and it was recognised that working from such 'top-level' principles was an important feature, allowing them to be implemented flexibly across a range of different research organisations' structures.

Another key element, providing research organisations with a common, structured approach to auditing and reporting externally on ethics review, was the provision of a self-assessment tool. This had been a successful part of the AREC framework, and it was important to ensure that such a tool would be compliant with the expectations of the Concordat on Research Integrity for annual reporting to the Higher Education Funding Council for England. Again, input from the advisory and steering groups was vital here. The development of the second version of the Concordat went forward in parallel with the development of the new UKRIO/ARMA guidance and engaging with the professional network around this topic was instrumental in keeping alignment.

The authoring team made a joint decision that it was important to draw out and make explicit the underlying rationale for the guidance to be offered. This resulted in a very extensive first full draft of 45 pages (more than 13,000 words). While this led to a rich dialogue as the consultation on this draft proceeded, comments were beginning to be made that it was looking like a somewhat 'unwieldy' document for its intended use. As well as comments from the steering and advisory groups, reactions were sought from a wide range of academics and administrators involved with research ethics. Members of the authoring team had been instrumental in taking forward the Academy of Social Sciences 'Generic Ethics Principles in Social Sciences' project (2013) which ran from 2010 to 2016. This project, while focused on principles for ethical research conduct, also included critical discussions of the processes of ethics review and evidenced acceptance of the four core principles for review first set out in the AREC framework. This project also generated a social network that proved to be of great value in garnering comment and support for the UKRIO/ARMA work.

On the completion of the second draft, building on comments from the initial consultations, its size had grown even more and discussions within the team could have easily become polarised due to conflicting comments coming through from the consultation; some praising the thoroughness of treatment and welcoming the full justification of the approach, while others were reacting in a totally opposite way, saying how a much briefer, concise document was needed, simply setting in clear terms 'how to do' ethics review. Some of the key stakeholders commented that this was a 'deal-breaker'. Quite negative comments were being made that the guidance

would not be well received and would not be recommended across the sector unless there was a radical rethink of the length. Although the team was wedded to the fuller treatment, in part because of the work that had gone into it, it was also realised that some potential users, pressed for time as many are, would not be prepared to 'wade through' the full document to get to the prescriptions it offered. Achieving a consensus and thus facilitating take-up was a crucial aim, so the team managed to find an eclectic solution by drawing an analogy with the 'quick-start guide' often supplied alongside a full operating manual for equipment. As the third and final draft was being prepared, taking in further comments, a parallel, heavily edited version was created, omitting much of the rationale and background material in the full version, halving its size. With the agreement of the steering and advisory groups, the two versions then went into production for web delivery and were launched simultaneously by UKRIO and ARMA on April 8th, 2020 (UKRIO/ARMA 2020).

4.4   Analysis

Because the ethics review of UK research in health and social care is subject to 'top-down' governance by the NHS Health Research Authority, compliance with well-defined standard procedures for all reviews is controlled. With no such overarching control mechanism for ethics review in other fields, procedural standards have by necessity been 'home-grown' by the research organisations, primarily universities. While, as described above, several initiatives within the sector have sought to bring about a degree of consistency, the autonomy of governance by the research organisations is widely respected and indeed guarded, meaning that compliance with common standards can only be by voluntary rather than enforced adherence. As far as the actual procedures for ethics review are concerned, change is relatively easy even if it takes time to go through the institutional processes necessary to approve or amend standard operating procedures. Structural changes, for example in how a REC fits within a governance framework, are typically more resistant to change, and dependent on the review cycles and changes in top-level management. But there are external pressures for compliance, notably from national funding bodies such as the Higher Education Funding Council for England and the UK research councils, which have expectations that need to be met for the maintenance of research integrity. International funding bodies such as the European Research Council also set requirements for ethics review of projects and programmes that they fund. These external pressures mean that the availability of national guidance is attractive to research organisations but at the same time it needs to be flexible and practicable for the variety of structures and processes across the sector.

For these reasons, it was crucial in developing the UKRIO/ARMA (2020) guidance that it be seen to be wanting to support shared values and expectations, working democratically with key stakeholders and gatekeepers. This meant that it was necessary to recognize expertise and to identify where it was located, so establishing the

memberships of the steering and advisory groups, and ensuring that communications were clear and timely, and that deadlines for comments allowed sufficient time. These were key to success.

It was also important to develop the guidance as driven by a set of clearly specified principles, rather than by rigid prescriptions of processes and structures, to allow for their implementation in a variety of ways, adapted to the local circumstances of research organisations.

4.5 Lessons Learned

A key lesson learned from the extended development period for the UKRIO/ARMA documents was that to produce guidance that will be accepted and acted on must indeed take a long time. This is because consultation, indeed very wide consultation, is crucial to success. And there needs to be consultation throughout, not at solely a single point in the process. Comments must be seen to be acted on, and involvement of stakeholders in at least two draft stages helps to ensure that this is achieved and helps to keep them on board to spend the time critically evaluating drafts, knowing that their comments will be taken seriously.

Involving a wide range of commentators, across the potential users of the guidance and including those influential persons who would facilitate or impede adoption, is crucial to success. A lot of time was spent during the development period of this guidance making personal contact with commentators and encouraging them to stay involved. This was particularly important where disagreements arose, for example over the length of the guidance, and sharing the solution personally with the people who felt most strongly about this was key to gaining their support.

Finding the eclectic solution, to produce the summary and full version, was, on reflection, a vitally important final step. If the team had tried to compromise by 'watering down' the full version, trying to reach a compromise position, it is likely that no-one would have been fully satisfied. So the lesson here is to keep an open, creative mind, even when a project is well under way.

4.6 Implications and Recommendations for Policymakers

For policies to be effectively implemented in 'tight' governance structures, those who are responsible for the implementation need to be convinced of the value of the policies in addition to being subject to contractual imperatives and sanctions for non-implementation. A key aspect of a policy's value lies in the extent to which it is based on trustworthy research-based evidence. Arguably the same top-level criteria apply to the assessment of the ethical soundness of research as to its scientific rigour, and these criteria map well onto three of the core principles of ethics review that frame the UKRIO/ARMA guidance: independence, competence and transparency.

Facilitation is not applicable in the same way. If it is accepted that the integrity value of scientific research includes ethics as well as soundness of method, interpretation and claims, then policymakers evaluating research should be looking for evidence that the conduct and ethics review of a research project comply with these principles.

Thus, where significant ethics issues are evident in a piece of research being scrutinised, evaluators should be looking at least for a clear statement that a 'favourable opinion' was given on the research by a named REC (or Institutional Review Board (IRB) in the case of research ethics influenced by US terminology). While IRBs and UK Health Research Authority RECs are governed by national standard operating procedures, this is not necessarily the case for institutional RECs outside of these. Due diligence in such cases could usefully include checks on the research ethics pages of the relevant institution's website, looking for evidence of compliance with an ethics framework such as that of UKRIO/ARMA. Further guidance and support on evaluating the 'ethicality' of research can be found in the PRO-RES (https://pro res-project.eu/) website assets.

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