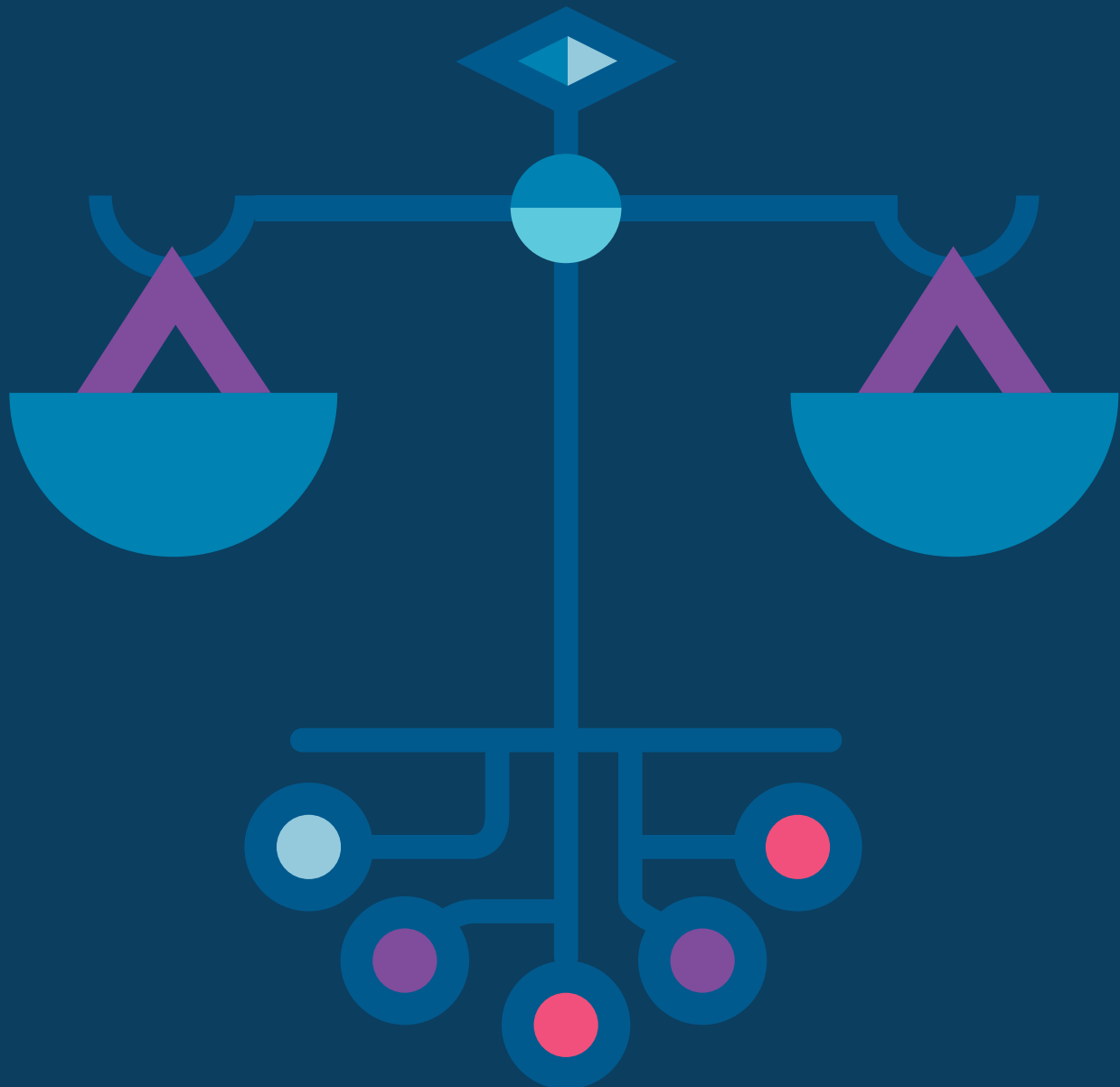


# Research Ethics

## Support and Review in Research Organisations



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# Research Ethics Support and Review in Research Organisations

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# Authors

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**David Carpenter**, Independent Consultant and Trainer in Research Ethics (equal co-author, writing – original draft, review and editing)

**Ron Iphofen**, Independent Research Consultant (equal co-author)

**John Oates**, The Open University (lead author, supervision, project administration, writing – original draft, review and editing)

**Andrew Rawnsley**, Teesside University  
(equal co-author, writing – original draft, review and editing)

**Birgit Whitman**, University of Birmingham  
(equal co-author, writing – original draft, review and editing)

---

# Reviewers

---

**David Anderson-Ford**, Association of Research Ethics Committees (AREC)  
Framework Author (reviewer)

**Kate Dunbar**, Secretary of University Research Ethics Committee (UREC) (reviewer)

**Bridget Egan**, AREC Framework author (reviewer)

**Peter Hedges**, UKRIO Advisory Board; University of Cambridge (lead reviewer of both documents)

**Simon Kolstoe**, University of Portsmouth; Ministry of Defence Research Ethics Committee (MODREC) (reviewer)

**Sam Lewis**, ARMA-Ethics Special Interest Group (SIG); University of Lincoln (reviewer)

**Alison Lloyd**, ARMA-Ethics SIG; Manchester Metropolitan University (reviewer)

**Marice Lunny**, King's College London (KCL) (reviewer)

**Ian Lyne**, ARMA-Board; University of Birmingham (reviewer)

**Hamish Macandrew**, ARMA (conceptualisation, project administration, reviewer)

**Stephanie Maloney**, ARMA-Board; University of Lincoln (reviewer)

**Rhys Morgan**, University of Cambridge (lead reviewer of both documents)

**Mitchell Parker**, Welsh Government (reviewer)

**James Parry**, UKRIO (conceptualisation, supervision, project administration, reviewer)

**Marie-Sophie Peyre**, European Research Council (reviewer)

**Margaret Rees**, UKRIO Advisory Board, AREC Framework reviewer,  
University of Oxford (reviewer)

**Julie Scott**, Anglia Ruskin University (reviewer)

**Gail Seymour**, University of Exeter (reviewer)

**Martin Stevens**, KCL (reviewer)

**Timothy Stibbs**, AREC Framework Author (reviewer)

**Anthea Tinker**, AREC Framework Author (reviewer)

**Josephine Woodhams** UKRIO (project administration, reviewer)

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This document provides guidance for UK research organisations on best practice for research ethics review processes and structures, taking as a starting point [A Framework of Policies and Procedures for University Research Ethics Committees](#) (2013) and the experience of its use across the sector. That framework was produced by the Association for Research Ethics Committees in 2013 and is now under the auspices of ARMA.

This document, produced jointly by ARMA and UKRIO, draws on the Framework but is not a second/revised edition; it is a new document, drawing on many other sources and key developments since 2013. We would like to acknowledge the editor and contributors of the 2013 framework for their original contributions to this important and ever more significant area of practice.

We would like to thank Emerald Publishing for copy editing and final production of this document.

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# Competing Interests

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**DC** is in receipt of an allowance for chairing an NHS Research Ethics Committee (REC) for the Health Research Authority (HRA); receives payment for delivering training and provision of expert ethics reviews of research from ARMA; continued work in developing this service and is Chair of the committee for Google DeepMind. **DC** has long established relationships with the co-authors and some of the reviewers. **DC** is also a member of the British Psychological Society (BPS) Ethics Committee, Portsmouth Hospitals NHS Trust clinical ethics committee and The Rowans Hospice Ethics and Governance Group.

**RI** and **JO** have worked together on the AcSS 'Consensus in Research Ethics' project and continue to work together on the EU-funded PRO-RES project. **JO** was Chair and is an active member of the Open University (OU) Human Research Ethics Committee (HREC). **RI** was a Senior Research Fellow for the OU and served on the OU HREC alongside him.

**JO** is a UKRIO adviser, ethics reviewer for the European Research Council and member of the European Commission Community of Experts. **JO** is lead for the British Psychological Society's Code of Human Research Ethics.

**AR** is a salaried employee of Teesside University, in research support capacity; author for Epigeum, Oxford University Press – in receipt of financial payments; contract research on behalf of Health Research Authority in past two years. **AR** has frequently worked in collaboration with **DC** on training delivery.

**AR** has worked previously with other co-authors, particularly **JO**, on paid contract research. **AR** delivered training on behalf of ARMA; current Chair of ARMA is Director of the department at Teesside University in which **AR** is employed. **AR** is author of Vitae Researcher Development Framework materials and was previously a Trustee for Association for Research Ethics and for UK Council for Graduate Education; **AR** is also a UKRIO advisor.

**BW** was employed by the University of Bristol and the University of Birmingham during the time of her contribution to this work. **BW** is a Governor for The Crypt School.

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# Contents

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<b>Introduction</b>	<b>10</b>
<b>Ethics and research organisations</b>	<b>12</b>
<b>Ethics in research</b>	<b>13</b>
<b>Guidance structure: how to use this document</b>	<b>14</b>
<b>Principles for the ethics and integrity of research</b>	<b>16</b>
<b>The Core Principles: Independence, Competence, Facilitation, Transparency and Accountability</b>	<b>18</b>
<b>Maintaining ethical standards within a research governance framework</b>	<b>20</b>
<b>Accountability and quality assurance</b>	<b>28</b>
<b>Providing supportive ethics reviews</b>	<b>29</b>
<b>RECs and governance</b>	<b>33</b>
<b>Ethics review and research data</b>	<b>38</b>
<b>REFERENCES</b>	<b>41</b>
<b>APPENDICES</b>	<b>42</b>
<b>Appendix 1: REC review panel checklist for applications</b>	<b>42</b>
<b>Appendix 2: Risk assessment matrix</b>	<b>46</b>
<b>Appendix 3: Audit tool aligned with core principles</b>	<b>55</b>

# Introduction

*Research Ethics Support and Review in Research Organisations* is the outcome of a development project under the auspices of the UK Research Integrity Office and the Association of Research Managers and Administrators. Concerns about the extent and quality of research ethics review in universities were stimulated by the publication in 2004 of a survey-based review (Tinker & Coomber, 2004) which revealed great variations across the sector, with a substantial number of universities at that time having no formal processes in place.

Responding to the challenge, and following work over a number of years with research ethics committee (REC) chairs and members, and with research administrators and managers, in 2013 the Association of Research Ethics Committees released *A Framework of Policies and Procedures for University Research Ethics Committees*. This publication recognised the value of seeking to achieve a degree of consistency across universities in the processes for ethics review of research.

Building on the work done to produce the 2013 framework, and with contributions from many of the original authors, the present guidance is intended primarily for an audience of persons in research organisations who are responsible for ensuring that research is carried out to high ethical standards. This will include persons in policy and management roles, along with chairs and members of research ethics committees. While not directly intended for researchers, this guidance may also be informative for them and aid a better understanding the role their institution plays in supporting their ethical practice.

This document has the following broad aims:

- to synthesise developments in academic work on ethics and integrity, the expectations of research funders and government and existing examples of good practice.
- to support research organisations in achieving high standards of research ethics review and contributing to the development of a positive culture of integrity and ethics in research.
- to provide a means for the valid audit of processes in order to demonstrate maintenance and enhancement of standards in the specific practices of individual research organisations.

It also offers benchmark policies and processes which organisations can use to create or revise institutional practices in order to support the functions of research ethics committees. In addition, it is intended to support continued reflection, evaluation and development towards a set of common best practice standards, while reflecting the autonomy of organisations to determine how to apply them in their particular research environments.

This guidance reflects – and is in accord with – other relevant initiatives, guidance from UKRIO and other bodies, and the expectations of funding bodies. It has been produced to harmonise with research ethics expectations and practices in Europe and more widely.

Ethics review in medical, health and social care research has a distinctive nature and context, and is supported by the unified national governance system

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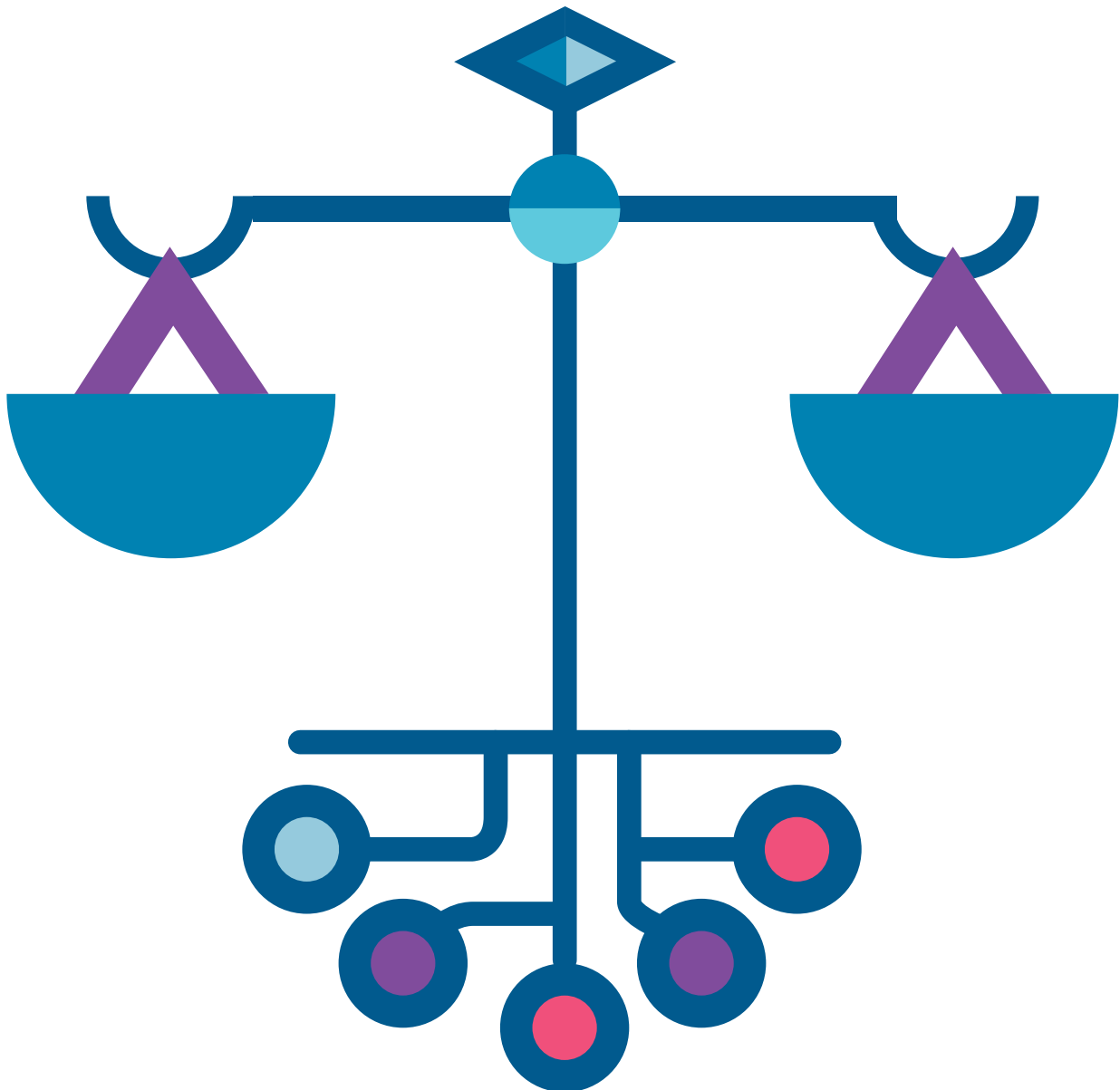
## Introduction

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of the Health Research Authority; the UK Policy Framework for Health and Social Care Research (2018). Research with non-human animals similarly has a distinctive regulatory framework under the authority of the Home Office.

Recognising the need for a common approach to supporting ethical practice for all other disciplines of research, the present guidance draws on a body of

work and experiences from across the disciplinary spectrum, while being dominated by no single perspective. Although the focus of research ethics review and support tends to be on research with humans, research organisations should recognise that ethics issues can also arise in all research domains and, therefore, organisational processes should not exclude such cases by default.



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# Ethics and research organisations

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As public institutions and centres for the generation and transmission of knowledge for the public good, research organisations should aim to meet high ethical standards in all aspects of their work.

Across all fields of research, and through every phase of research from conception to impact, developing and maintaining a well-informed and coherent approach to ethics – which supports researchers in their endeavours – will help to meet the need for consistent best practice across the sector. This is especially significant for international research where ethics have increasingly come to the fore, which presents challenges that need to be met by robust institutional support.

While formal ethics review and the issuing of ethics opinions by properly constituted research ethics committees is a core function, this should be part of, and integrated with, a broader institutional set of related functions. These might include research training, integrity policies and governance processes that provide guidance and support throughout the research cycle, from conception to dissemination and application.



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# Ethics in research

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The field of ethics has a long history of intellectual endeavour; critically examining, determining and explicating basic concepts for what can constitute morally good ways of living. Central to this endeavour has been the notion of beneficence – ‘doing and promoting good’ – with the accompanying notion of non-maleficence; ‘doing no harm’. ‘Doing no harm’ has been a canon of medical practice since Hippocrates and focuses on the potential for direct physical harm to a patient.

When applied to the general field of research, this establishes a basic orientation, but offers little guidance as to what may constitute ‘goods’ and ‘harms’ in other fields of research. Across the whole range of research types, of which medical research is only one, there is an increasing understanding of the benefits which might arise from research and the many potential harms that can equally arise, and that a focus on direct harm to individuals is far too narrow a view. With increasing focus on research outputs and their impacts, and greater interest in translational research, attention is also being drawn to the breadth of potential ‘goods’.

Derived from the concerns focused on gathering data from individual persons, as well as the basic principles of beneficence and non-maleficence, there is a broad consensus that research should explicitly consider basic human rights and seek to implement a principle of respect. This implies an acceptance of diversity within lifestyles, values and attitudes, and that persons should be allowed to make autonomous choices without coercion. Respect should also be given to a person’s wishes for privacy and the protection of personal information. In some circumstances public interest may require a careful analysis and balancing of personal and social benefits and harms.

The evolving nature of most forms of research opens new opportunities for benefits and at the same time for potential harms (e.g. internet-mediated research). In this context, the capacity to apply ethical reasoning becomes crucial. Cultivating and maintaining high standards of research ethics as an active concern for all researchers is a key responsibility for research organisations’ research ethics processes. Complying with research ethics requirements, mandates of research funding bodies and needs for adequate indemnity provide further drivers.

Responsibility for ethical research conduct rests not only with the researcher, or researchers, but also with funders, hosts and sponsoring institutions. The establishment and maintenance of well-founded ethics support processes to aid researchers is a key role for research organisations to fulfil.

The wide differences in organisational and management structures in research organisations mean that there is no single template or ‘one size fits all’ solution to developing processes which ensure high ethical standards in research. The variations in scale and types of research that characterise research organisations demand customised solutions to best meet specific local needs.

For these reasons, a principles-based approach to defining what counts as best research ethics practice offers the flexibility and adaptability that is required. For principles to be effective in guiding and supporting high standards, however, they need to be practical, easily interpreted and implementable.

# Guidance structure: how to use this document

This guidance document comprises a series of topic-based sections. Each section contains – in a ‘tiered’ form – firstly, a summary of the key points, secondly, the rationale lying behind these points and, finally, a more complete description of the background context with references. The guidance covers the following areas:

- a description and justification of the principle-based approach
- the set of four Core Principles to guide the design and implementation of best practice in ethics review and support processes
- guidance on how high standards of ethics review and support processes can be established and maintained in a governance framework
- detailed guidance on the structure and operation of research ethics committees
- assuring accountability and quality
- data in the context of research ethics



## Principles for the ethics and integrity of research

### Key points

- **The use of ‘principles’ in research ethics is well-established, but there is a variety of different principle sets in current use and it is important to be aware of this**
- **Research ethics as a field has widened considerably to include a number of different areas, each with their own parameters and principles: this includes ‘research integrity’ and ‘responsible research and innovation’ (RRI)**
- **The most widely used principles for research ethics review are the ‘Belmont Principles’**

## Rationale for key points

The proliferation of ‘principles’ of various kinds has been a feature of the rapidity with which various bodies and institutions have pushed forward the agenda of research ethics, thereby expanding the remit of the field. There are various sets of ‘principles’ in current use that include a number of different forms:

- Principles that were established in the ‘developmental phase’ of research ethics review and research ethics committees in the 20<sup>th</sup> century, such as the World Medical Association (WMA) [Declaration of Helsinki](#) - Ethical Principles for Medical Research Involving Human Subjects, first agreed in 1964 and periodically revised subsequently.
- Principles in research funders’ ethics codes, such as that of the Economic and Social Research Council’s (ESRC) [Framework for Research Ethics](#) (2020).
- Principles used to standardise international practice, such as the [Singapore Statement on Research Integrity](#) (2010).
- Principles established by intergovernmental and governmental bodies, such as United Nations Educational, Scientific and Cultural Organization (UNESCO), UK Policy Framework for Health and Social Care Research from the Health Research Authority (HRA), or the US Office of Research Integrity (ORI).
- Numerous professional bodies’ codes of practice, such as those of the Association of Social Anthropologists (ASA) of the UK and the Commonwealth; British Psychological Society (BPS); British Sociological Association (BSA); Social Research Association (SRA) and Political Studies Association (PSA).
- Institutional principles defined in internal documents for staff, students and research ethics committee members in universities and research organisations.

The most widely used set of basic principles for research ethics (review), has been those first formulated as the ‘Belmont Principles’, and widely disseminated by Beauchamp and Childress (2001).

**These principles are normally given as:**

- **Respect for persons (and their autonomy)**
- **Beneficence**
- **Non-maleficence**
- **Distributive justice (ensuring benefits and burdens are shared equitably)**

Research integrity principles are wider in scope since they apply to good research conduct more broadly and not just to research with human participants, or to the way in which research is designed. The Singapore Statement (2010) is a major document widely disseminated as an attempt to find harmony between different international standards. As such, it forms the basis of a number of other codifications of research integrity principles, such as that of the European Code of Conduct for Research Integrity (2015) and the University UK’s Concordat to Support Research Integrity (2019).

**The Singapore Statement’s four principles are:**

- **Honesty**
- **Accountability**
- **Professional courtesy and fairness**
- **Good stewardship**

# Principles for the ethics and integrity of research

## Background context for the rationale

In the first ten years of this century, there was a move away from thinking of research ethics as principally the domain of human participant research in the clinical or biomedical sciences, to embracing a much broader set of disciplines, such as the social sciences and humanities, conducting research that also involves human participants. This also included a broadening of the traditional locus of research ethics as research with human participants to include research in fields and topics in which human subject participation was either minimal or not fundamental, or indirect.

In many cases, this broadening of the scope of research ethics meant that principles originally established to define the scope of research ethics with human subjects in the biomedical sciences were, at least initially, inappropriately extended into other disciplines or areas of research without due consideration for the differences in disciplines.

Many disciplines were required to reflect and establish principles more suited to the concerns and contexts in which those disciplines performed research. This includes the diverse kinds of persons' involvement and participation in research as data sources, taking account of methodologies diverging widely from hypothesis-and-testing research designs established a-priori in research protocols setting out every detail of the research process, through to exploratory approaches that evolve as the research progresses.

To this end, a whole range of methods has had to be considered: immersive and adaptive fieldwork; deceptive techniques and covert research; process-based iterative research design; co-production and action research; internet-mediated techniques; and research taking place in a visible or public context or in non-controlled or uncontrollable environments.

At the same time as this broadening of the scope of research ethics, the issue of how research is conducted and published was brought under more scrutiny, linking the wider idea of 'research integrity' to the traditional idea of 'research ethics'. The relationship of 'research integrity' to 'research ethics' is a matter of contention, but many established codes of practice now make a distinction which treats the traditional conception of 'research ethics' as 'research ethics review'. This being the process of setting out criteria upon which proposed research projects will be reviewed and the process of reviewing proposed research according to those criteria – as an element of the wider concept of 'research integrity', which includes principles about the conduct of researchers, the practices of authorship, publication practices, peer review practices and – above all – the ways in which data are handled, analysed and interpreted, and 'outcomes' established on the basis of data.

The 'Belmont Principles' have been influential, informing the development of a variety of different codes of conduct for research. The principles themselves have been much debated. Sometimes the principles of beneficence and non-maleficence are linked to show how the two principles work together. The first principle also has variants which prioritise 'respect for persons' with autonomy as one possible way in which this respect can be shown, where autonomy is a core societal value, recognising that this is not universally true.

This latter interpretation is of most importance to research taking place in (often non-Western) cultural contexts in which a different conception of 'personhood' has wide currency and in which autonomy is not a feature. 'Personhood' in this sense is not limited to an 'individual', but situates persons in communities having different moral standards from



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those in which personal autonomy is considered the critical criterion for being a person.

Most current sets of principles used in the various codes discussed earlier are based around the 'Belmont Principles' and research ethics review in practice has commonly used ideas, such as the appropriate balance between benefits and risks or the importance of obtaining consent from participants, as a way of ensuring choice to participate in research as the basis for most decision making about the ethical design of projects at the review stage. It should be noted that these principles have also been applied in research contexts in which human participants are not directly part of the work. In such cases, the principles of beneficence and non-maleficence tend to become prioritised as these principles do not solely apply to working with human participants, but also to a range of other possible harms, including, for example, to researchers themselves and to ecosystems.

Even this broader conception of the range and scope of research integrity has been expanded further through the agenda of 'Responsible Research and Innovation' (RRI), in which research integrity, including the traditional conception of research ethics, is considered as one element in the all-encompassing aim of ensuring that research is always 'with and for society'.

In practice, principles are an important way in which decision making by research ethics committees can be done with reference to agreed standards of judgement that are reasonably consistent, and for which a wide degree of consensus has been reached. As such, these principles are the fundamental 'starting-points' for ethical reasoning about research. Attempting to achieve a balance between the principles can be difficult, but the form in which they are given permits interpretation in specific

cases while ensuring that research ethics committees across different institutions and organisations are working to a similar set of standards. The difficulties of establishing criteria for review, or, so to speak, 'where the lines are drawn' in applying the principles when reviewing research, are much more substantial and attention to these issues will be paid to this tricky area later in this document.

It is also worth noting that it has not been typical to apply the broader principles of research integrity, such as those of the Singapore Statement or associated principles of codes, directly at the level of research ethics committees. It ought to be more widely recognised that these principles provide the broad framework and ethos defining the context in which research ethics committees work, with specific principles such as 'courtesy and fairness' or 'accountability' having an important role for the conduct of ethics review itself, as well as in the conduct of research.

Future policy development in this area and the way in which institutions put their research ethics processes in place may need to think more consistently about the way in which the broader set of research integrity principles frames the subsets of principles operable in research ethics review and other areas of their operation. The current situation is that research integrity principles, more typically, form the basis of a code of practice or are maintained separately from principles and procedures for research ethics review. It is the intention of this document to move towards a more inclusive and consistent approach.

The following principles relate specifically to the conduct of research ethics committees rather than the ethics of the research which they are designed to review.

# The Core Principles: Independence, Competence, Facilitation, Transparency and Accountability.

## 1. INDEPENDENCE

**All institutional processes supporting best practice in research ethics, including formal and informal reviews, training and support, must operate free from conflicts of interest so that the application of ethics principles and reasoning is neither impeded nor compromised.**

This principle must be upheld by:

- a) Ensuring that the research ethics committee (REC) includes members from a range of disciplines and also includes members from outside the academic unit or units covered by the committee and external members e.g. members of local communities.
- b) Establishing a constitution and terms of reference which guarantee each REC the freedom to make ethics judgements and issue opinions on applications for review that are consistent with legal, policy and human rights standards.
- c) Including representation from groups external to the institution in RECs and other processes. For example, this may involve service users, members of faith groups, experts by experience and delegates from industry. In an hierarchical structure of RECs, for example where there is a top-level REC and sub-RECs at departmental levels, external representation may not be essential at sub-REC level if resources are limited. Maintaining objectivity and avoiding bias and conflicts of interest, however, must remain a core principle at all REC levels.
- d) Linking RECs to an overarching policy body which has oversight for the maintenance of consistent research ethics standards, monitors performance and provides a means to manage appeals against REC decisions.

## 2. COMPETENCE

**Ethics review and other processes supporting institutional best practice and sector standards must be consistent, coherent and well-informed.**

This principle must be upheld by:

- a) Ensuring that REC membership includes ethics expertise covering the range of research that it reviews and that access to legal advice is available.
- b) Recognising, through workload allocation or other compensations, that contributing to ethics review and other support processes is accepted and recognised institutional work, as is the preparation by researchers of ethics protocols and applications for review.
- c) Establishing standard operating procedures that are regularly reviewed.
- d) Ensuring regular review of REC processes.
- e) Providing regular training for REC members and others providing research ethics support to ensure adequate expertise for supporting new and emerging research areas.
- f) Drawing on current national and international developments in research ethics to inform support and training for REC members and researchers.

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### 3. FACILITATION

**Ethics review and other supporting processes must make the facilitation of ethically sound research a priority. This will be evidenced by researchers viewing engagement with institutional research ethics processes as positive and valuable for all phases of their research.**

This principle must be upheld by:

- a) Ensuring that procedures balance duties of care with enabling and supporting ethical research and innovation.
- b) Providing training for researchers in ethics issues and in the policies and mechanics of ethics review, seeking to develop researchers' autonomy and skills in making reasoned ethics judgments.
- c) Progressing formal ethics review efficiently and rapidly within defined timeframes, with appropriate analysis of risk and the associated proportionality of review, with mechanisms for 'fast-track' review in exceptional and well-justified situations.
- d) Ensuring that application forms for review are clear, easy to complete, request only necessary detail, and that guidance and template examples of information sheets, consent forms, invitation letters, recruitment materials and other routinely used documents are available to aid researchers.
- e) Making opportunities available for researchers to seek informal advice on ethics issues at any stage in their research activity.
- f) Encouraging researchers to include the cost of preparation for ethics review when seeking funding.

### 4. TRANSPARENCY AND ACCOUNTABILITY

**Decisions and advice by RECs must be open to public scrutiny and responsibilities must be recognised and discharged consistently.**

This principle must be upheld by:

- a) Making a clear and easily accessible (e.g. web-based) public statement of the policies and processes for maintaining high standards of research ethics.
- b) Ensuring that there is a publicly accessible primary point of contact for research ethics in the institution.
- c) Maintaining consistent summary records of research ethics review and support processes that are made publicly available in a timely manner, while protecting confidentiality and sensitive data.
- d) Making regular reports to the overarching policy body, at least once a year, evidencing REC performance in responding to applications for formal ethics review, including data such as the number and types of opinions given and the average time taken to complete reviews.

The audit tool in Appendix 3 has been added to enable institutions to audit themselves against these standards. The following sections provide guidance on operational approaches to achieving compliance with the Core Principles.

# Maintaining ethical standards within a research governance framework

## Key points

- A fundamental aim of good practice in ethics review is to ensure consistency and comparability of ethical standards for research.
- Higher Education Institutions' (HEIs) and other research organisations' (ROs) ethics review has often been highly variable and inconsistent, lacking a national co-ordination system.
- There are four main areas of research ethics committee operations that require some degree of formalisation in order for consistency to be achieved:
  1. Institutional research ethics and integrity policy.
  2. Constitution and terms of reference for ethics committees.
  3. Training and development of ethics committee members.
  4. Standard operating procedures for ethics committees.

## Rationale for key points

The combination of operating independently and variability in ethics review implementation in HEIs presents a challenge when ensuring high standards of ethics review, ensuring consistency in the way in which review decisions are reached across the sector, and enabling comparability with other systems of review. Ethical standards need a degree of comparability between institutions in order to allay concerns that the ethics of research may be held to a higher standard in one system than another, and to facilitate transfer of favourable REC opinions across institutions and avoid duplication of effort.

Research ethics committees should operate with a clear policy statement that covers the rationale for their existence and some sort of institutional commitment to upholding ethical research standards. A policy on research ethics and integrity is a statement approved by one of the institution's authoritative bodies.

Ethics committees should operate with a formally agreed and approved constitution and terms of reference which clarify the functioning of the committee.

Effective RECs require agreed minimum standards of training and competence on the part of their members, which may be achieved through programmes at institutional, faculty, departmental or research centre/unit level. The aim of the training should be to provide individuals with confidence in their abilities to conduct thorough and consistent ethics scrutiny of all types of research.

A Standard Operating Procedures (SOPs) document will be required unless the constitution and terms of reference spells out in detail matters of committee practice that ensure consistency and competency. If they stipulate only the composition and remit of the committee, and not the form that the process of ethical decision making will take, then some form of SOPs, however minimal, will be necessary.

### Background context for rationale

Historically, research ethics review in universities and other higher education organisations in the UK became more commonly employed during the early years of this century and followed implementation of systems of review deployed within the NHS for health research.

It is possible to see the widespread deployment of ethics review in universities as a response to those external developments. The nature of higher education institutions, however, has meant that implementation within institutions in response has always lacked the central co-ordination of a national system: progress in implementation has, on the whole, been incremental, highly variable and inconsistent. Although research ethics committees in universities have developed in parallel to external ethics review systems, they have operated independently from, and shared only limited practice with, those systems. Internationally, the variance of approaches is even greater.

If a perception exists that standards of ethics review are variable or inconsistent, then this raises doubt about the whole edifice of ethics review. Without comparability, decisions reached can be perceived as arbitrary, based on differing assumptions or, worse, open to undue influence. Research participants, funders and the public need to be assured that ethics review standards are consistent. Variability is not helpful in achieving this.

What is the reason for this variability and inconsistency? It was recognised in the 2013 *AREC Framework of Policies and Procedures for URECs* (University Research Ethics Committees) that “different universities will want to retain autonomy and flexibility in how the review process is managed.” This is still true: different institutions have different structures, staff and student numbers, different scale and volume of

research. The point of research ethics review based on the principles of research ethics and integrity, however, is to ensure ethical research and to abide by commonly agreed standards in achieving this. If this is to be done, then structural or operational differences in institutions cannot affect the ethical force of those principles and standards.

The same standards apply for a large complex organisation and to a small single discipline college, to work done by undergraduate students and to multi-partner international collaborations by staff. There may be better or less effective ways of meeting standards and putting principles into practice, but there is no gradation of success. Standards are either met or they are not met.

This is not to underestimate or make light of the sometimes difficult problems in meeting standards, nor is it to disregard the need for different institutions to go about the task in their own way that suits their structure. Research ethics committees must, however, operate within established standards for review to ensure that research is conducted ethically and that review determining whether research is ethical or not is based on decision making that is reached consistently and with accountability and transparently.

It is important not to confuse matters of ethical substance with matters of the implementation of administration systems for ethics review. While the operations of a research ethics committee are shaped partly by administrative functions, some of those operations are fundamental to enabling a decision making process, which puts into practice matters of ethical substance and in the performance of which ethical standards are employed. Consistency is critical to this process.

### Institutional research ethics and research integrity policies

Policy in this area should cover research integrity more broadly as well as research ethics review. A policy statement that specifies the rationale and ethos of the institution's commitment to ethical standards for research and to ensuring research integrity should be closely connected. **The key elements of such a policy statement should be:**

- clear, including expectations of those conducting or supervising research and what, in turn, can be expected from the HEI/RO and/or REC.
- consistent with institutional practice and the formal support that is provided to ensure the policy is upheld.
- policy on research integrity should define clearly what constitutes misconduct in research practice and the sanctions that may be applied.
- easily and publicly available in various forms, including documents and on institutional web pages.
- regularly reviewed and updated as needed.
- maintained under a clear reporting and/or responsibility line within the institution, such as a central research office, the University Secretary's or governance office, or to a senior manager with portfolio responsibilities for research and/or governance.

In order for ethics review to have any purchase as a process ensuring ethical standards of research, this must operate within an institutional context in which those standards – and the need to uphold them – are clearly stated for both internal and external parties. Where such policy statements are supplemented or included alongside procedural or guidance

documentation related to the process of ethics review, the statements related to process should be simple, on the lines of requiring staff and students to submit relevant research projects for appropriate ethics review and to follow the decision of the REC and the consequences of not doing so.

### Constitution and terms of reference for a research ethics committee

**These should include:**

- The objectives and remit of the committee.
- The specific functions and duties of the committee.
- The reporting lines and responsibilities of the committee.

**Such a clarification of the remit and function should include statements about:**

- maintaining ethical standards of practice in research.
- protecting human participants in research.
- protecting researchers from harm.
- preservation of participants' rights.
- taking account of legitimate interests of other individuals, bodies and communities, associated with the research and providing reassurance to the public and to outside bodies that their legitimate interests have been protected.

**It may also be helpful to refer to the four principles earlier in this document and confirm that:**

- the aim of the committee is to facilitate, not hinder, valuable research and to protect researchers.



## Maintaining ethical standards within a research governance framework

The terms of reference should provide clear statements about the duties of the committee. This provides clarification not only for members of the committee, but for applicants and other stakeholders such as human participants and external bodies.

### Such duties include:

- receiving details of research proposed to be carried out, whether by staff or students, where the research might reasonably be considered to raise ethical questions.
- The consideration of such research on behalf of the senior academic body of the institution, and to provide an ethics opinion on the research. Whether: a) favourable as proposed; b) conditionally favourable, under certain defined conditions or specific requirements; c) or unfavourable; and to advise on the basis of such ethics opinions.
- following a favourable opinion, to exercise powers to require the halting of research if substantive ethical problems are identified as the project progresses until such time as any such concerns have been remedied to the satisfaction of the REC.
- withdrawing a favourable opinion when concerns such as those identified above are not remedied to the satisfaction of the REC.

As part of the constitution and terms of reference of a committee, it can also be helpful to provide brief role descriptors for members, including the officers of Chair, Vice-Chair and Secretary. Establishing the duties of each role provides an extra layer of clarity for the performance of these roles but also helps to maintain the principle of competence.

## Training and development of committee members

The effectiveness of ethics committees relies largely on the degree to which research organisations are able to build appropriate structures and create a culture that recognises the central place that ethics review occupies in good research practice. Ethics training plays a central role in this process; such training should be on-going and become an integral part of research practice.

REC members should be sufficiently trained in: the substantive ethical issues on which they may be required to make decisions; the basis upon which ethical decisions can be made, using commonly agreed and shared ethics principles; and the administrative process of conducting REC business. Such training should be reviewed regularly and updated to ensure current ethical issues concerning new research methodologies presenting ethical issues are properly considered. New members of RECs should be appropriately briefed and trained as well as existing REC members. Training should be delivered by persons sufficiently competent in both substantive ethical matters and governance processes. If necessary, different persons may need to deliver relevant training in the two areas.



### Standard Operating Procedures

#### The operation of ethics review

**The Standard Operating Procedures (SOPs) should expand on the terms of reference of a REC by stipulating:**

- a requirement for ethics review of all research involving human participants conducted by individuals employed by or claiming an affiliation with or registered as students within that institution.
- criteria for ethics review of other forms of research not involving human participants and exemptions where appropriate.
- the ways of ensuring that ethics review is independent, competent and timely.
- how the dignity, rights and welfare of research participants are protected.
- how the legitimate interests of other individuals, bodies or communities associated with the research are considered.
- how the safety of the researcher or researchers will be considered.
- how informed judgements of the scientific merit of proposals will be made, or how to ensure that such judgements have already been made.
- how informed recommendations to the researcher if the proposal is found to be wanting in some respect will be made.

### The constitution of a Research Ethics Committee

**The SOPs should set out the principles concerning membership of a REC, which should normally:**

- be multidisciplinary.
- represent diversity.
- require the chair to be a senior member of academic staff with experience in research and/or research ethics.
- include at least one appropriately trained external member (typically referred to as a 'lay' member – normally reimbursed for out of pocket expenses) with no affiliation to the department, university or research institution.
- have members with a broad experience of and expertise in the areas of research regularly reviewed by the REC, and who have the confidence and esteem of the research community.
- include at least one member who is knowledgeable in ethics as a field of study.
- include individuals who reflect the demographic diversity of the local community.
- have members who represent a broad range of methodological expertise.
- be constituted so that conflicts of interest are avoided.

This would normally mean that a REC has at least 10 members, and preferably 12, to ensure diversity of views and range of expertise. While a REC of such size may not be possible in smaller organisations, the core principle of competence must still be upheld by ensuring that members have the necessary breadth of experience and skills.



### Processes

#### SOPs should set out:

- a requirement to use a prescribed form of application, and who should complete, sign and validate the application prior to submission.
- the time within which a fully completed application is normally considered by the REC and provisions for exceptions.
- arrangements for requesting amendments and arrangements for dealing with appeals.

#### Tiered review systems, devolved and/or proportional review; expedited review

This is a critical area for most higher education institutions because of the differences of institutional structure and volume outlined earlier in this section. The employment of 'tiered review' systems is one way to maintain clear and consistent standards and permit for differences in administrative implementation suited to different institutional needs without affecting the task of meeting review standards.

If a tiered review system is employed, however, the operations must be set out clearly, and using some form of standard operating procedures for such approaches is essential. Tiered review is effectively a system of ethics review in which alternatives are provided, in addition to full ethics committee review, with movement of applications through those routes determined by clearly defined criteria.

How these tiers of review are set up can be very flexible as long as the criteria are clear and safeguards put in place for when applications do not meet these criteria. In the UK HRA system a route known as 'proportionate review' is used to deal more quickly with the review of applications that are considered to have

no or minimal material ethical issues, as defined by clear criteria. Some universities have a tier referred to as 'light touch' review. A similar route in the USA review system calls this approach 'expedited review'.

These types of approaches usually involve referring applications, through a form of devolved review, to review panels or bodies that have a different composition from a full research ethics committee and therefore are able to meet more regularly or be convened with more flexibility. This approach can also be used to deal with high volumes of applications, such as student projects for a specific point in a university term or semester.

#### The important issues to specify in such forms of devolved review are:

- what criteria are used to permit applications to use alternative routes.
- what the review arrangements are for those alternative routes.
- a mechanism for 'upward' referral if it is considered necessary to undertake full review.
- clear standards of ethical review in a devolved review process that are the same as those used as for full committee review.

The first two points above are especially important. In determining that applications use alternative routes for review, this is *not* implying that review will be less rigorous or that standards will be lower, only that certain applications may be reviewed more quickly or more flexibly than other applications that require full committee scrutiny. Criteria such as 'low risk' do not imply lower standards of review, only that the applications so determined can often be reviewed by fewer people than a full committee and therefore be reviewed more quickly. 'Low risk' in such cases implies

that the ethical issues are more straightforward and more easily considered. Therefore, what counts as 'low' risk needs to be clearly stipulated.

It is also important to make clear that 'fast-track' review does not mean that applications made without sufficient time to receive full review, even though it is required before research can commence, can be treated differently. Institutions may want to have a system in place for genuine urgencies but this should be kept separate from the tiered review approaches and used in exceptional cases only.

A 'tier' in such systems will usually be linked to a hierarchy of risk, complexity, or applicant type, but other forms of tiered review are possible. Such tiers could be used to ensure that student project ethics review is done separately from other projects permitting for flexibility in how such work is reviewed, or to enable the process of applying for ethics review and receiving an ethics opinion to become part of the learning outcomes for student work.

There should, however, be no assumption that student projects are less risky; enthusiasm and some naivety can lead to students proposing high risk research. Different disciplines within an institution could have tiers applied to their needs, where project design is iterative and not easily specified in protocols for review; or tiers could be set up enabling process-based reviews, with applications returning for review at different stages of a project. The options available are very flexible, as long as the principles of research ethics and the principles of research committee operation are upheld.

A tiered approach can ensure that ethics review is done rigorously *and* efficiently, and adaptable and sensitive to differing institutional circumstances.

## Monitoring

Although RECs themselves will probably not be resourced to undertake proactive monitoring, all research organisations should establish appropriate procedures to monitor the conduct of research which has received favourable ethics review until it is completed. Continuing review is important where the research design or the context in which it takes place (e.g. in times of political volatility), is likely to bring up new ethical issues. Monitoring should be proportionate to the nature and degree of risk associated with the research. It should include consideration of best-practice procedures for the secure holding and preservation (or destruction where appropriate) of the data.

Where a REC considers that a monitoring report raises significant concerns about the ethical conduct of a study, it should request a full and detailed account of the research for full ethics review. Where it is judged that a study is being conducted in a way that is unethical, it should consider the withdrawal of its favourable opinion and recommend that the research be suspended or discontinued.

RECs should normally expect reports from researchers detailing any unanticipated adverse events arising during the research and providing a brief summary on completion of the research.

The SOPs should set out the detail of the monitoring arrangements.

### Other informal procedures and guidelines

Procedures and guidelines that are of a more informal nature might be included in SOPs. Such procedures could include areas such as the conduct of meetings, the treatment of applicants meeting the committee (where this facility is available), or where different RECs within one institution come to different opinions, as well as dealing with complaints.

### Making information on ethical review available

A publicly available ethics policy should be clearly available in document form and as a webpage on an institutional website. In addition to this statement, an overall governance document setting out the constitution and terms of reference, the standard operating procedures and all the relevant guidance needed to meet and maintain ethical standards should be in place, either as webpage text, a downloadable document, or both.

If the publicly available statement is clearly signposted on an institutional webpage, then it may be possible to refer to a complete document held on an internal intranet site, available on request. Best practice in achieving openness and transparency, however, would be for such documents to be available to the public. Whatever approach is taken, these documents should be easily reviewed, managed, and revised when necessary. Single documents are easier to manage than multiple documents.



# Accountability and quality assurance

## Accountability and quality assurance

The decisions of a REC must be transparent and accountable through its governance structure. Summary details of all research projects reviewed by a REC together with evidence of the ethics review and outcomes should be recorded and made available for institutional reporting and audit. Subject to any necessary requirements of security and confidentiality the records should also be available for public scrutiny if requested.

Institutions might have a degree of flexibility on the operational ethics review level, but it is considered good practice for a high-level oversight committee to be in place to which each ethics review committee in the institution is accountable. The oversight committee provides the strategic steer on policies and procedures including the monitoring of RECs. Research ethics and integrity arrangements for an institution should be publicly available. A Responsible, Accountable, Consulted and Informed (RACI) analysis is one way of helping to clarify the governance structure:

**Responsible:** Those who do the work to achieve the task

**Accountable:** The one ultimately answerable for the correct completion of the deliverable or task and who delegates the work

**Consulted:** Those whose opinions are sought, with two-way communication

**Informed:** Those who are kept up to date on progress, often only on completion of the task; usually one-way communication

The oversight committee might receive an annual report from each REC. Fostering a supportive two-way communication between the operational ethics review committees and the oversight committee is essential and as part of the annual report process RECs might be encouraged to make a presentation to the strategic committee. A visit from members of the oversight committee to the research ethics committees to observe a meeting and ensure best practice and coordinated working to policy across all RECs within the institution should be considered.

The oversight committee should be set up to hear appeals. The remit of RECs is normally limited to ethics review, but integrated working with the research governance function in the organisation is important to ensure the integrity of the research and allowing REC members to focus on ethics issues.



# Providing supportive ethics reviews

## Providing supportive ethics reviews

In providing an ethics review service, RECs should be supportive and transparent. Support should be available at all stages throughout the life course of a project including early advice, and user-friendly application forms and template documents. The

process of review should be clear, consistent and defensible; this is typically demonstrated by the application of a reviewing framework underpinned by accepted moral theory or theories.

### Key points

- RECs must be easily accessible providing support as necessary.
- Application forms should be constructed in such a way as to encourage researchers to reflect on key ethical issues.
- RECs should focus their reviews on matters of ethics.
- RECs should adopt structured approaches to review drawing on appropriate moral theory.
- RECs must always justify opinions, providing clear rationales.

## Rationale for key points

RECs are often seen as overly bureaucratic and obstructive. This poor image can be readily addressed by being supportive throughout the life course of a research project. Researchers are often surprised to find that RECs are motivated by an endeavour to give favourable opinions to ethical research – this motivation should be made clear within ROs. It is further evidenced by the provision of advice aiming to ensure that a favourable opinion is secured. Sadly, many researchers see RECs as inaccessible until the final stages of research design.

It is self-evident that the opinions of RECs should be well-reasoned, drawing on moral theory. Reviews should therefore be structured, consistent and balanced. This last point is particularly important; opinions must include appropriate positive feedback

as well as any necessary constructive criticisms. This approach allows regular researchers to build their skills in designing and delivering ethical research.

## Background context for rationale

Ethical design and management of research is the responsibility of the researcher and the task of the REC is to ensure that the researcher has met his/her responsibilities. The researcher must be supported in designing ethical research; support mechanisms include:

- Readily accessible advice from peers/supervisors and also the REC.
- Well-designed application forms which assist in the identification of ethical issues.
- Guidance regarding the structure and content of the research proposal or protocol.

## Providing supportive ethics reviews

- Clear guidance regarding the structure and content of participant facing documents and other media – including materials aimed at the provision of information and recording of consent.
- Appropriate and accessible training in ethics.
- Easy access to guidance documents at institutional level and beyond – these should include codes of conduct both general and discipline specific.

A well-designed application form will include sections requiring details of ethics protocols that invite the researcher to reflect on the ethical issues associated with their proposed research, identify key issues and describe necessary mitigation strategies (see Appendix 1). The key purpose of the application form is to facilitate the researcher's analysis of ethical issues associated with their research. The tendency to focus on ethical problems and challenges should be avoided. Many examples of research seek to contribute to some public good and researchers should be encouraged to highlight these, thus producing a positive ethical case for conducting their research.

If all the above support mechanisms are in place the REC should expect applications which are ethically sound. It should be immediately noted that the focus of REC review should be on the research as provided in protocols and proposals rather than the content of an application form. Applications in the absence of core documents suggest a lack of detailed planning which is unlikely to result in ethical research. Protocols and proposals should provide the REC with evidence of the overall design of the research, including the involvement of human participants, where relevant. The protocol should normally be accompanied by evidence of peer review or, in the case of students, satisfactory assessment and feedback. This last point is particularly important – it is not the task of the REC to review

methodology and design in detail, other than to take a view on the overall soundness of the research, aided by expert review where necessary. Of course it is possible that proposed research could be so obviously methodologically flawed that it will not yield worthwhile outcomes, could expose participants to unnecessary risk and, at the very least, will be a waste of their time. Proposals of this nature are obviously unethical and the review is likely to be unfavourable. The REC should focus on matters of ethics. Before considering the criteria a REC might deploy in ethics review it is worth noting a few areas which fall outside of ethics review:

- RECs should not focus on matters of methodology and design unless they raise ethical issues such as exposing participants to avoidable risks and burdens.
- RECs are not constituted to provide legal or policy review. For example, matters such as lawful processing and storage of data lie within the purview of research governance.
- RECs should not provide a proof reading service. Unless participant documents are so badly constructed that they don't serve the ethical purpose for which they are designed, the REC should avoid review outcomes referring to matters of spelling, grammar and syntax.
- RECs provide ethics review rather than checking compliance with internal or external policy – again this is a matter for governance.

RECs should only be receiving 'review-ready' protocols and documents; this can be assured by adding an administrative step (undertaken by the REC secretary/clerk) where applications are validated and quality checked before being presented to the REC. Having established what RECs should not be doing it is now easier to highlight their roles regarding ethics review.



## Providing supportive ethics reviews

The process of ethics review necessarily includes reference to the criteria underpinning the review – to be discussed below. The starting position of the REC should ideally be an intention to provide a favourable opinion giving the reasons why this should be the case – obviously resulting in a complimentary review identifying the ethical merits of the study. In some cases a clear favourable opinion will not be possible and specific conditions will need to be added to it. In other cases more serious, necessary conditions will result in a provisional opinion.

Ethical concerns will rarely be of sufficient magnitude to result in an unfavourable opinion. RECs should never adopt a starting position of searching for potentially limiting conditions. A positive stance results in a search for what is good about a proposal rather than what is wrong with it. In continuously striving for consistency and transparency RECs must adopt a structured approach to review. This structure can be achieved by identifying ethical domains – the ‘headings’ under which review can be focused. The Health Research Authority has identified the following:

- Social or scientific value; scientific design and conduct of the study – including public involvement.
- Recruitment arrangements and access to health information, and fair research participant selection.
- Favourable risk benefit ratio; anticipated benefits/risks for research participants (present and future).
- Care and protection of research participants; respect for potential and enrolled research participants’ welfare & dignity.
- Informed consent process and the adequacy and completeness of research participant information.
- Suitability (in terms of experience and skills) of the applicant and supporting staff.

This list is provided as an example – research organisations might have different domains, but all should have them and communicate them clearly. How can the domains be used to provide a positive ethics review? The addition of a theoretical perspective is necessary. Using virtue ethics as an example; MacFarlane (2009; 2010) has identified the following virtues which might characterise ethical research and ethical researchers:

- **Courage**
- **Respectfulness**
- **Resoluteness**
- **Sincerity**
- **Humility**
- **Reflexivity**

A search for these under each of the domains could result in a review which might compliment the researcher on a courageous design with identified risks which have been suitably mitigated. Furthermore, evidence of respect for participants might be found in the involvement of the public and potential participants in the design and conduct of the research or in the tone of participant facing media. Resoluteness might be reflected methodologically, for example robust approaches to research questions and hypotheses including triangulation.

The appropriately humble and reflexive researcher will identify limitations of the proposed research. While the starting point should always be a search for ‘the good’ it is equally clear how the combination of domains and theory can be used to identify ethical concerns. A design might be viewed as reckless in not taking sufficient account of risks to participants. It might also be viewed as disrespectful perhaps by the tone of participant information or a failure to seek consent in circumstances where it is clearly necessary.

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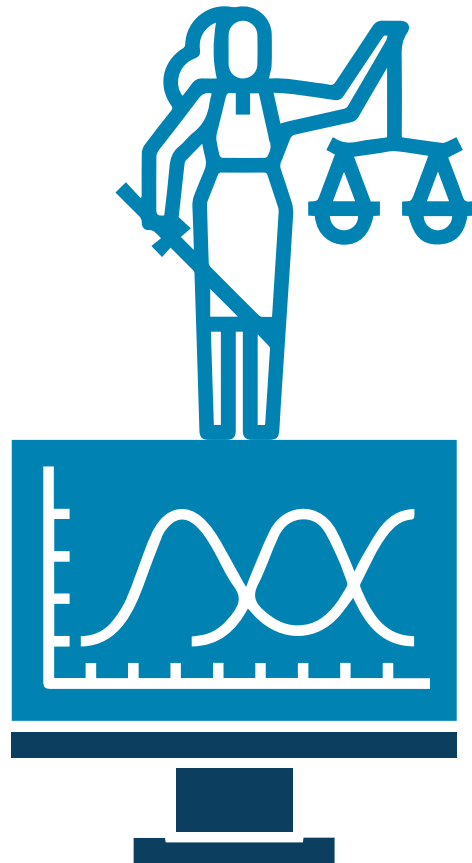
## Providing supportive ethics reviews

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Virtue ethics is only one example of theory which might be deployed within each of the agreed domains. Other examples include the principles outlined earlier in this framework, or principles identified by other general and discipline specific organisations. Some RECs prefer to adopt more familiar normative ethics theory such as utilitarianism or deontology. The latter might focus on a 'do as you would be done by' or 'the golden rule' approach where REC members endeavour to place themselves in the role of participant. The former is often adopted by RECs when considering matters such as the balance of burden and benefit or the overall worthwhileness of a project. It is entirely possible that the adoption of differing theories will lead to differing conclusions, however, those conclusions must always be defensible.

RECs should also be mindful of the guidance provided to researchers by the learned societies associated with their academic disciplines as well as wider international declarations and treaties. Researchers should use these documents to frame reflexive accounts of the ethics of their research; they should feature prominently in the ethics section of the research protocol. The REC should evaluate the ways in which guidance has informed ethical design. Researchers should be reminded that it is not acceptable to make blanket claims such as 'this study complies with The Declaration of Helsinki'; appropriate elements of the proposal should be cross referenced to the relevant sections of a declaration, code, set of guidelines or treaty.

Finally, in the course of ethics review, RECs must be constantly aware of their role in balancing duties to protect participants and the wider public, their institution and, of course, researchers and duties to facilitate ethical research and empower responsible researchers.





# RECs and governance

## RECs and governance

### Key points

- Research ethics review should be distinct from research governance and decisions over whether research can go ahead.
- Ethics and governance are both linked to different aspects of research integrity – ethics is primarily linked to good professional research practice, governance to responsible research sponsorship.
- The independence of a REC depends upon it being risk aware without being risk averse.
- Consistency in REC practice and procedure needs to be balanced by variability in the individual missions of research organisations.
- Good research design is vital to ethical research practice.
- RECs should aim to be facilitative in their support of high quality, safe research practice.
- Some ground-breaking, highly innovative research may necessarily contain risks and/or be considered intrusive. Both the culture and constituency of RECs must acknowledge this and suggest how it can be best accomplished.
- To maintain their independence RECs should only be in a position to offer a ‘favourable opinion’ concerning the ethics of a research proposal; the ‘approval’ must remain in the hands of the governance process.
- Corporate image or other institutional protections must be kept separate from REC practice.
- Both governance and research ethics review must be adequately resourced for good practice to be sustained.

### Rationale for key points

The failure to keep the functions of research governance separate from the review of the ethics of a research proposal is one of the reasons researchers have tended to see ethics review as ‘obstructive’. Governance is primarily an accountability issue concerned with the overall management of research. While ethics review gives primacy to professional integrity, governance remains an institutional concern, as research sponsors and/or managers, institutions are responsible for ensuring that research is designed and delivered according to an agreed protocol. Those responsibilities include

ensuring that research is conducted ethically and, if necessary, via full ethics review.

This is not to deny the role of the institution in helping to ensure the integrity of research. It has a duty of care to monitor legal liabilities and ensure that adequate indemnity is in place. Necessarily this makes institutions ‘risk averse’. RECs examining the ethics of a research proposal should not have to be concerned with corporate reputation which may be in conflict with core ethics principles. A truly independent ethics committee requires heightened ‘risk awareness’ which they can pass on to the researcher, not an aversion to risk.

The pressure to achieve uniformity, arising from the demands of research councils to follow their preferred research ethics frameworks, may ensure some consistency, but individual institutions should still be free to express their particular research missions. At the same time research must be ethically designed from the outset, 'defensible' in design and practice together with an ethical and positive case made for conducting it. Researchers can benefit from experts on a REC in terms of extra insights, the anticipation of other harms or the possibility of additional benefits, expert advice, guidance, ongoing support and mentoring. Facilitative guidance from a REC could raise awareness of risk, without obstructing the pursuit of knowledge and social justice.

Ethical research can challenge existing norms and legislation. Risks must sometimes be taken for the advancement of knowledge and/or in the public interest. Both governance and ethics review must recognise that research may require taking risks so RECs need to include members who are knowledgeable and/or experienced with both ethics and emerging methodological issues and practices.

If the institutional risk in conducting a project is too great, it will not be allowed, but the ethics of a project can be assisted by a committee owing no allegiance to any corporate body, or any vested interests. It is best carried out by volunteers acting in the 'public interest', able to offer an 'opinion' favourable or otherwise, but not expected to 'approve' a research proposal. That should be a concern of governance.

To be effective the practice of research governance and research ethics review must be adequately resourced. Resourcing must be linked to REC membership, support for research managers, the processes and procedures applicable to both, together with their education and training and updating in the form of continuing professional development.

## Background context for rationale

The important distinction that NHS review has maintained between review and governance (<https://www.hra.nhs.uk/about-us/committees-and-services/>) has not been mirrored in all REC arrangements. Some institutions have repeated the errors of the US IRB system – that is, the failure to keep the functions of research governance, separate from the review of the ethics of a research proposal. The extensive body of literature covering North America (the US and Canada) illustrates the nature of this obstruction. There is too much to reference here, but a major useful source can be found in a series of articles in van den Hoonaard & Hamilton (2014).

Governance is primarily an accountability and control issue – it essentially concerns the overall management of research. (Simple guides to research governance can be found at the Reason Network: [http://adcs.org.uk/assets/documentation/reason\\_Research\\_Governance\\_Guide\\_FINAL.pdf](http://adcs.org.uk/assets/documentation/reason_Research_Governance_Guide_FINAL.pdf)).

Ethics and governance are both concerned with integrity – good science and proper behaviour by researchers – but while ethics give primacy to professional integrity, governance remains an institutional concern. Institutions typically take on the role of sponsor (not to be confused with funder). A research sponsor is responsible for ensuring that research is appropriately designed and delivered according to an agreed protocol. Its responsibilities include that of ensuring that research is conducted ethically; in pursuit of this responsibility the institution must ensure that ethics review, ideally concluding with a favourable opinion, is undertaken either internally, or where necessary, elsewhere.

For a REC examining the ethics of a research proposal it is no help if it is caught up in ensuring regulations are followed, or seeking to protect the reputations

of funders and corporate bodies; this is a matter of governance and may indeed conflict with core ethics principles. A truly independent ethics committee requires heightened 'risk awareness', not an aversion to risk, by distancing itself from corporate concerns and thinking about how researchers can get their jobs done successfully, safely and with the highest concern for the interests of their subjects/participants and others potentially affected by the research.

The development of RECs in the UK was strongly influenced by the ESRC Framework for Research Ethics, which required institutions that had researchers with ESRC grants to have established RECs, which had a certain format. While it is true that there is a lot of variability, this does provide a framework to which many university RECs have to operate. Such pressure to uniformity may ensure some consistency, although individual institutions may wish to express their particular interests and concerns related to their institutional missions.

Good researchers will always think about the ethical issues of their project from the outset; research must be ethically designed, thus anticipating and mitigating any concerns which might arise in its conduct. Furthermore an ethical design will not just ensure that the research is 'defensible' in design and practice; in the best examples it will ensure that there will be an ethical imperative for conducting it – a positive case.

The benefit that researchers can expect from other experts is any extra insights that can anticipate problems they might not have thought about, or additional benefits, thus assisting in ethical design. Researchers can benefit from additional advice, guidance and ongoing support and mentoring. Facilitative (particularly early) guidance from a REC could raise their awareness of risk, without obstructing their pursuit of knowledge and social justice.

At times research can challenge existing norms and legislation. If one is held back by unfounded fear of the law, policy or misperceived boundaries, then some of the risks that are a necessary element in the advancement of knowledge will not be taken. Therefore, it follows that governance should be facilitative; if governance gets in the way of research, social justice can be undermined. Ethics review recognises that research may require taking risks and chances – since it necessarily intervenes in others' lives – again 'alert' but not 'averse' to risk. Some research is necessarily intrusive in the lives of those being researched and can also be invasive; the latter implying more risk than the former. Research activities – especially innovative ones – and outcomes may even require the movement of boundaries of cultural norms and values, so, as indicated earlier, the membership of RECs needs to include members who are knowledgeable/experienced with both ethics and emerging methodological issues and practices. This argument can be found more fully articulated in Iphofen (2011, 2017).

There is little doubt that a way must be found to 'manage' research in an efficient and effective manner, so governance is an essential element of the process. What must be guarded against, however, is the pretence that a committee or other body concerned with governance can also offer a truly independent ethics opinion. Governance must be done by an effective management process – if the institutional risk in conducting a project is too great, it will not be allowed. But the ethics of a project can be assisted by a committee owing no allegiance to any corporate body, or any vested interests.

It is best carried out by volunteers acting in the 'public interest' – which means the interests of research subjects/participants, researchers and, of course, the

community or society at large. In doing so they can truly 'advise and guide' and perhaps 'warn' against dangers not perceived by the researcher. Academic freedom, the ability to pursue safe research in the interest of the advancement of knowledge can be severely compromised when RECs get this 'balance' wrong (Hedgecoe, 2015). They should, therefore, not be in a position where they hold a trump card used to prevent the research from taking place – that in itself would undermine their ability to reflect upon the risks dispassionately.

It is acknowledged that some institutional RECs may have a 'reject' option. The argument here – for the reasons advanced – would be to suggest such an option to be inappropriate. The idea of 'approving' a proposal implies that the REC takes some degree of responsibility for the governance of the research. It is in the nature of research that things can 'go wrong' in ways the REC could not have foreseen. In a worst case scenario, the 'approval' of a project that did cross ethical lines would require an accountability route that returns to the REC. Since its institutional independence would then be compromised and the voluntary status of members brought into question, it is important that RECs see their role as providing ethics 'opinions', they should not 'approve' research. Approval also implies an ability to monitor research engagements in the field – rarely is that possible.

The outcome of an ethics review should be an opinion relating to the research protocol; for example, the REC could conclude that it is content to give a favourable opinion subject to the research being conducted in accordance with the protocol it has reviewed. Permission to proceed is a matter of governance – the accountable source of approval. This distinction is important – it dissolves the myth of ethics review being the last 'obstacle' to overcome before research can proceed. It is also, however, the

case that research managers, or corporate concerns will often not permit research to proceed without such a favourable opinion. While some degree of 'overlap' between governance and ethics review is inevitable (See Appendix 2) 'merging' the processes of governance and ethics would give rise to the conflicts discussed here.

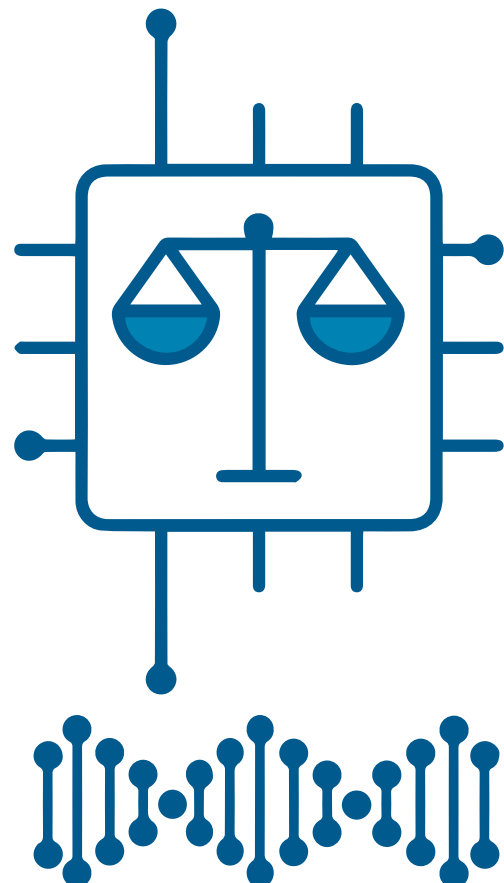
There are lessons for the integrity of research in all of this. The avoidance of fraud, corruption, plagiarism and misuse of data cannot be secured by legislation alone. Someone with ill-intent will always find a way around the law if there is both incentive and opportunity to do so. Research integrity relies upon the maintenance of a practice culture, which proscribes such bad behaviour – researchers knowing when there are risks of stepping beyond moral and legal guidelines and seeking the advice of all those involved to resolve their problems. Of course, there will be times when the organisational infrastructure condones risks that it should not have done when the balance between corporate benefits and the risks to participants is skewed in the wrong direction (Hedgecoe 2013).

The implication of this perspective is that while a research governance/management committee, department or other body, may be in a position to 'approve' a project going forward, or not – this should not be a requirement or in the gift of a REC. Instead, the culture, constitution and constituency of a REC should be to give an 'opinion' – favourable or unfavourable, to a research proposal. It should not be seen as preventing or permitting the research to proceed – opinions simply do not have that role – however, as a matter of good governance one would normally expect a favourable ethics opinion as an important consideration in deciding whether research should proceed.

## RECs and governance

In both cases the grounds for an opinion should be clearly stated and the practice incorporated in any SOPs (see above). Therefore it may be the case that RECs will issue a 'statement of opinion' with regard to a research proposal – in practice the research institution may choose to employ such a statement in its decision about whether or not to 'approve' the research to proceed.

To be effective the practice of research governance and research ethics review must be adequately resourced. Since both are vital to a favourable corporate image, professional and institutional indemnity and the respect, dignity and welfare of researchers and their subjects and/or participants, such resourcing must be seen as part of good management practice. Resourcing must be linked to REC membership, support for research managers, the processes and procedures applicable to both – together with their education and training – and updating in the form of continuing professional development. Adequately resourcing REC operations is a measure of institutional commitment to ethical research practice.



# Ethics review and research data

## Ethics review and research data

### Key points

- How 'data' is defined is an important consideration in dealing with research data effectively in ethics review.
- 'Personal data' as defined by various data protection regulations is only one part of what might constitute data in research and much research 'data' are not regulated in the same way.
- Some disciplines that undergo ethics review might not use the term 'data' in the same way, or at all, and applying the same approach to such research is unhelpful and potentially hinders effective ethics review in those disciplines.
- There are ethics and integrity issues associated with the move to open data.

### Rationale for key points

Growing attention is now paid to all aspects of the gathering, processing, handling, analysis, storing and sharing of data in research ethics and integrity. Research ethics review has tended to focus on how data are obtained, while there is increasing realisation that ethics issues arise in how data are handled and analysed in the production of research outcomes that reach the research record and are disseminated in publication or other outputs. There is a clear overlap here with research integrity and governance processes. Thus, ensuring that institutional policies on ethics review and research governance are coherent is an important concern.

The use of 'data' as a term is not without its problems. For natural and social sciences, engineering, computer science and other disciplines, in which the work depends on the gathering, generation or obtaining of data – which are then subjected to testing, modelling, analysis or other such analyses – the use of the term 'data', when applied in research ethics and research integrity,

is reasonably self-evident. Research is conducted in many disciplines, however, in which the principal activity is not the use of 'data' in these senses. This is particularly the case when applied to disciplines that are not usually classified as 'sciences'. Even within traditionally 'scientific' disciplines, there are different forms of understanding about what constitutes 'data'. In arts-based domains, research activities and outputs may take forms such as performances, exhibitions, artefacts or media productions.

Within the context of research ethics and integrity, it is important to be aware of the differences between disciplines. Where researchers are proposing research and designing protocols in which the understanding of data fits an established model, the ethical issues raised are likely to be very different from those using more iterative designs or working in non-traditional ways. Efforts should be made to understand how ethics review, and research integrity more broadly, can take account of research materials and practices in disciplines not fitting a standard 'data-driven' model.



### Open Data

The open research agenda is driving increased requirements for demonstrating the integrity of research and making research data publicly available in a data repository. This is often a requirement of editors and publishers, increasing the complexity of research data management with appropriate consent.

### Background context to the rationale

Research policy language can often obscure the important difference in terminology applied to 'data' and, as such, can inadvertently push 'non-data-driven' research to the margins or force those disciplines to adapt their self-understanding to that which has currency in the 'sciences'. Similarly to the way in which early attempts to harmonise research ethics review in the biomedical sciences with other disciplines meant that the same framework was used inappropriately for disciplines with very different and diverging aims and methods, the use of the term 'data' insensitively can suggest to researchers working in 'non-data-driven' research, that the tenets of research ethics and integrity somehow do not apply to their work.

This is obviously a misunderstanding, since all research can be judged from an ethics perspective, but where this misunderstanding exists it has been nurtured by a failure in policy making and governance to pay attention to the differences between disciplines and to the modus operandi of research in a sizeable and important group of disciplines in the contemporary academy.

For instance, while it does not take a big leap of imagination to see that historians use 'data' of some kind, such data are very different in kind from those typically worked with by social scientists. Data may be gathered or obtained, not usually from

living human subjects, but from textual, archival or journalistic and media sources. Where there is overlap between some kinds of historical research and social sciences is in the area of oral history, where living human subjects are involved, even if the methods of analysis are different.

Some forms of historical research may use elements of social science-like analysis. The variety and forms of historical research 'data' are complex, however. Indeed, the humanities in general do not typically conceive of research in terms of 'data', but in terms of 'sources' and 'material'. Creative disciplines conceive of research in terms of 'material' and 'practice'. Such sources, material and practices are subject to theoretical development and interpretation, the permutations of which are often as complex as that taking place in 'data-driven' disciplines.

Where has the 'data' gone in all of these ways of doing research? It is the use and common understanding of the term 'data' that is not easily circumscribed in these disciplines. It is important not to view such work as less rigorous: to treat these disciplines without this consideration is to do a disservice to important and insightful new knowledge reached using novel methods.

What are 'data' for the geologist: the rock or the measurements, or both? If both, are these different *kinds* of data or to be treated in the same way, even though the first is a physical object and the second an abstraction from that object? What are data for the botanist: the plant or that which is obtained from the plant such as molecular or morphological information? How does the practice of naming plants in botanical taxonomy use data? How do data inform such work, the terminology or the classifications? How can ethical practice in the variety of forms of research in arts-based disciplines or in engineering and technology be encompassed?

Availability of data also facilitates more opportunities for collaboration on an international scale and encourages cross disciplinary research. Easier access to data will allow researchers at all stages of their career to make best use of available data, avoiding duplication of data collection and ineffective use of resources/funding available for research.

The enquiry by the UK Science and Technology Committee (2018) highlighted the need for transparency in clinical research in line with the open access to research data agenda.

There is an increasing requirement for demonstrating the integrity of research and availability of research data in a data repository and this is becoming a requirement of funders, editors and publishers, increasing the complexity of research data management.

### Anonymisation and confidentiality

There are considerable ethical and legal risks especially in light of data protection changes such as the European Union General Data Protection Regulation (2018). These legal and ethical requirements need to be managed when moving to an 'open access to data' approach as appropriate information on participants in research and subsequent anonymization/de-identification are often essential for legal compliance and assurance of the public.

Considerable resource is required for the anonymisation process and little guidance is available to researchers or REC members about how to anonymise data while maintaining meaning for its future use (particularly complicated for research in ethnography and anthropology – where context and personal details make the substance of the research) and further work is required in this field.

Without the appropriate assurances some disciplines may find it harder to recruit participants to research, and this may lead to results that are less meaningful in a number of ways. Institutional policies and technical systems to support the ethical sharing of data are important and the work involved in designing and maintaining these systems is considerable.

Little work has been done to understand participants' expectations of anonymisation and de-identification processes or their views on the long-term storage and future uses of data. Evidence-based guidance needs to be developed ensuring that voices of participants and researchers from a range of disciplines are included in those discussions to inform the management of big data and data using social media. Recommendations developed in line with this approach will increase participants' confidence that their data will be stored and shared appropriately. The rapid developments in the fields of digital health and genomics are highlighting ethics issues around consent and trust, as has the increasing use of data gathered from social media and 'big data' in general.



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# Appendices

## Appendix 1: REC review panel checklist for applications

Title	<ul style="list-style-type: none"> <li>• Short, clear and descriptive.</li> </ul>
Abstract	<ul style="list-style-type: none"> <li>• A summary of the main points of the research, written in terms easily understandable by a non-specialist and containing no complex technical terms.</li> </ul>
Investigators	<ul style="list-style-type: none"> <li>• Names and institutional attachments of all persons involved in the collection and handling of individual data and one person named as Principal Investigator (PI).</li> <li>• Research students should include a supervisor's electronic signature and comments as evidence of supervisor support.</li> </ul>
Schedule	<ul style="list-style-type: none"> <li>• Has the research been adequately planned so it will be carried out in a timely manner?</li> </ul>
Methodology	<ul style="list-style-type: none"> <li>• Outline the method or methods that will be employed to collect and analyse data. Any relevant documents, such as interview or survey questions, should be sent with the completed proforma.</li> <li>• Are all documents for applicants worded appropriately?</li> </ul>
Participants	<ul style="list-style-type: none"> <li>• Give details of the population targeted or from sample will be obtained and how this sampling will be done.</li> <li>• Information on participants should include:             <ul style="list-style-type: none"> <li>• Age</li> <li>• Specific vulnerabilities</li> <li>• Cultural sensitivities</li> <li>• <a href="#">PREVENT safeguarding programme</a></li> </ul> </li> </ul>
Recruitment procedures	<ul style="list-style-type: none"> <li>• Are there details of how potential participants will be identified/chosen and how they will be approached?</li> <li>• Is there any possibility for coercion and if so how has this been addressed? For example, are there any 'power' relationships where the participants are known to the researcher either personally or professionally? Have these relationships been recognised and steps taken to avoid or taken into account?</li> <li>• Have participants been informed of the time commitment expected of them and their right to decline to offer any particular information?</li> <li>• Have participants been given sufficient time to permit making an informed decision?</li> <li>• Are eligibility criteria clearly set out?</li> </ul>

## Appendix 1: REC review panel checklist for applications

<p>Consent</p>	<ul style="list-style-type: none"> <li>• Consent forms and information sheets must be included in the application and where there are separate participant groups, separate consent and information forms for each group must be supplied. These need to include the following or a rationale for any variance:</li> <li>• PI contact details and an alternative contact.</li> <li>• Institutional email addresses should be used by default.</li> <li>• Is there clear information on how and when a participant may withdraw from the research, without affecting their rights and the success of the research project? For example, a date after which it may not be possible for participants to withdraw consent and request destruction of data.</li> <li>• Is there information about how and to whom a complaint might be addressed?</li> <li>• Is there clear information about the processing and storage of data including evidence of compliance with the EU's General Data Protection Regulation (GDPR)?</li> </ul>
<p>Where and when will the research be carried out and the data collected?</p>	<ul style="list-style-type: none"> <li>• Researchers should give details of where and when data will be collected with an explanation of why the research needs to be conducted in the chosen setting or location. For example, if it will take place on private, corporate or institutional premises, information must be given on any approvals that have been gained/are required.</li> </ul>
<p>Literature review</p>	<ul style="list-style-type: none"> <li>• Researchers should give a brief review of the existing literature or previous research. They should clarify whether the proposed study replicates prior work and/or duplicates work done elsewhere and/or has an element of originality.</li> <li>• Is there sufficient evidence that an exhaustive literature search has been carried out to confirm that the research project is of sufficient quality, and not overly duplicating any previous work?</li> </ul>
<p>Which guidelines will be followed?</p>	<ul style="list-style-type: none"> <li>• Researchers should provide information on which guidelines will be followed. For example: BERA, BPS, BSA, SRA, MRS, SPA.</li> </ul>

## Appendix 1: REC review panel checklist for applications

<p>Data protection and information security</p>	<ul style="list-style-type: none"> <li>• Has data protection and security been addressed adequately?</li> <li>• Where research involves the collection of personal information about individuals, researchers should have registered their project with the appropriate institutional data protection officer, or follow other procedures prescribed by their institution and they should confirm that this has been done. If collection of personal sensitive data is proposed appropriate safeguards should be in place.</li> <li>• Details of procedures and a schedule (including dates) for the storage and disposal of data to comply with the Data Protection Act and GDPR should be included, with the earliest and latest date for the destruction of original data, where it is required. Also, any archiving arrangements that have been agreed/permitted should be included in the project schedule. Researchers should also be aware of institutional information security policy and guidance.</li> </ul>
<p>Research data management</p>	<ul style="list-style-type: none"> <li>• Have participants been given accurate information and given appropriate consent for the research data to be reused and/or published?</li> <li>• If not covered elsewhere in their application or in a data management plan, researchers should give details of how their research data will be managed and published. Necessary compliance with any funding body requirements should also be described.</li> </ul>
<p>Deception</p>	<ul style="list-style-type: none"> <li>• Researchers should provide details of the withholding of any information from participants, or misrepresentation or other deception that is an integral part of the research.</li> <li>• Where used, any such deception should be fully justified.</li> <li>• Is there any indication that applicants might feel coerced, constrained, or otherwise induced to participate against their will?</li> </ul>
<p>Risk of harm</p>	<ul style="list-style-type: none"> <li>• Researchers should detail any foreseen risks to participants or researchers (e.g. home visits) and based on a risk assessment, the steps that will be taken to minimise/counter these (ref. Project risk assessment matrix). Where any risks to participants or researchers exist, have they been addressed adequately?</li> <li>• If the proposed study involves contact with children or other vulnerable groups, researchers should confirm that, where necessary, the requirements of the Disclosure and Barring Service have been met and provide the relevant reference number and period covered for each person involved in the research. Researcher should also be aware of institutional safeguarding policies and guidance.</li> <li>• Have participants been given information or contacts for emotional support if needed?</li> </ul>

## Appendix 1: REC review panel checklist for applications

<p>Incidental disclosures and findings</p>	<ul style="list-style-type: none"> <li>• If there is a risk that disclosures raising concerns for the safety of participants or others, have relevant measures been explained?</li> <li>• If there is a risk that research procedures could reveal information about the health of participants or their relatives have any responses which might be taken by the researcher been explained? This is particularly important with any research involving the collection of human tissue, DNA analysis and imaging techniques.</li> <li>• If there is a risk of disclosure of illegal actions and what the consequences might be.</li> </ul>
<p>Debriefing</p>	<ul style="list-style-type: none"> <li>• Researchers should give details of how after data collection, information will be given/ made available to participants to inform them of the outcomes of their participation and the research more broadly.</li> <li>• Is the offer or breadth of the debriefing adequate?</li> <li>• Has the researcher offered to share findings with participants?</li> </ul>
<p>Research organisation and funding</p>	<ul style="list-style-type: none"> <li>• Are there any conflicts of interest or requirements/issues with a particular funder?</li> </ul>
<p>Other project-related risks</p>	<ul style="list-style-type: none"> <li>• If not included elsewhere, have risks been adequately addressed?</li> <li>• Researchers are asked how they will limit research risks by anticipating potential problems.</li> <li>• They are advised that where they are carrying out fieldwork in the UK or overseas they should be aware of the institutional guidance and policies.</li> </ul>
<p>Benefits and knowledge transfer</p>	<ul style="list-style-type: none"> <li>• Researchers should state how the research may be of general benefit to participants and society.</li> </ul>
<p>Supporting documents</p>	<ul style="list-style-type: none"> <li>• These should include all governance related documents e.g. indemnity, funding, external approvals/permissions, risk assessments etc. All listed, present, with version numbers and dates, and referenced?</li> </ul>

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# Appendix 2: Risk assessment matrix

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## Appendix 2: Risk assessment matrix

**NOTES:** The assessment of risk may be one of those areas where some degree of overlap between research governance and independent ethics review might occur. Institutions might themselves allocate a clear division of labour between governance and ethics, and indicate areas where some assessment in both spheres of activity should be allowed. For example, an ethics review of a research proposal would be remiss if clear risks to researchers might be anticipated, or seen as potentially arising, and the REC made no observations or comment about it.

The decision to take such risks must lie with the researchers and the employing institution – hence while the REC might state an opinion about such risks, thereby assisting the researchers' risk-taking decisions. It must remain up to the employer to approve the research going ahead – after all they hold the 'duty of care' for the researcher and, presumably, their insurance indemnity cover. In a similar vein, staffing issues (health and safety, working space, resources) are clearly of governance concern, but if a REC review finds something that concerns them, they should be in a position to state an opinion about it and its relevance to the project. Hence the following risk matrix does separate ethics and governance – the line of accountability has to be decided at an institutional level.

## Appendix 2: Risk assessment matrix

Project Title:		Proposer/ proposers:	Principal Investigator (PI) and collaborator/Research Associate (RA) – list names	Date:	...of completion of this risk assessment form
Reference No.:					

	Potential Risk Factors	Probability of Risk Arising (H/M/L)	Impact (H/M/L)	Risk Indicators	Control Mechanisms	Named Risk Lead
<b>Participants</b>	Harms – physical, emotional or social  Stressors  Inconvenience and discomfort  Invasions of privacy/ breaches of confidentiality  Incidental disclosures raising concerns such as safeguarding  Incidental findings impacting on the physical or mental health of the individual  Personal expense – out of pocket expenses such as travel  Unfair/discriminatory inclusion/exclusion					



## Appendix 2: Risk assessment matrix

	Potential Risk Factors	Probability of Risk Arising (H/M/L)	Impact (H/M/L)	Risk Indicators	Control Mechanisms	Named Risk Lead
<b>Financial</b>	<p><b>Funder/ commissioner problems:</b></p> <p>Funder insolvency?</p> <p>Failure to deliver promised funds?</p> <p>Last minute budget changes – under-funding?</p> <p>Matched funding not available?</p> <p>No infrastructural support?</p> <p>Funding delays in monies being delivered?</p> <p>Funder linking funding to deliverables.</p> <p>Change in funder contact persons</p> <p>Dispute re adequacy of deliverables</p>	<p><b>Estimate:</b></p> <p>High</p> <p>Medium or</p> <p>Low</p>	<p><b>Estimate impact:</b></p> <p>High</p> <p>Medium or</p> <p>Low</p>	Information from any source accounting for risk	<p>Outline proposal already submitted and approved</p> <p>Clear criteria for deliverables</p> <p>Cautionary notes minuted and recorded</p> <p>Regular meetings with funders/ advisors</p> <p>Regular progress meetings with project team</p> <p>Progress reporting to funder</p> <p>Audited oversight of institutional financial management</p>	Named person with responsibility

## Appendix 2: Risk assessment matrix

	Potential Risk Factors	Probability of Risk Arising (H/M/L)	Impact (H/M/L)	Risk Indicators	Control Mechanisms	Named Risk Lead
Financial	Project budget overspend			<p>Regular (monthly) finance reports</p> <p>Regular reporting mechanisms to funder and institutional finance department</p> <p>Project management systems to control project stages</p>	<p>Designated budget holders (for all partner organisations)</p> <p>Monthly finance reports</p> <p>Budget projection modelling</p> <p>Sanctions for overspends</p> <p>Expenditure monitoring</p> <p>Finance procedures for each partner organisation followed</p> <p>Clear contingencies allowances indicated in budget</p>	Named person with responsibility
	Specific project-related sources of income generation			<p>Market research of potential income sources and likely returns</p> <p>Monitoring of income sources</p> <p>Evaluations of income generation proposals</p>	<p>Provide information to help assess potential</p> <p>Network with appropriate individuals/organisations</p> <p>Develop effective marketing strategy</p> <p>Pilot any proposed income generation</p>	Named person with responsibility
	Any partner organisations or individuals unable to meet deliverables due to financial difficulties			<p>Annual finance audits</p> <p>Yearly business plans</p> <p>Formal reporting mechanisms</p>	<p>Check partner organisations individual finance procedures</p> <p>Monitor partners' management meetings</p>	Named person with responsibility

## Appendix 2: Risk assessment matrix

	Potential Risk Factors	Probability of Risk Arising (H/M/L)	Impact (H/M/L)	Risk Indicators	Control Mechanisms	Named Risk Lead
<b>Legal/ Contractual</b>	Lack of appropriate working space for research project staff  Inadequate infrastructure support  Damage/costs to larger institution			Formal health and safety risk assessment undertaken  Project staff feedback  Disputes with staff unions, or need to address concerns of public representative bodies	Health and safety risk assessment action plan  Office space planned for and commissioned  Information Communications Technology (ICT) requirements implemented  Public relations and normal negotiating procedures in place	Named person or persons with responsibility
	Poor communication between research collaborators and/or partner organisations			Clear project meeting minutes – circulated reviewed  Independent advisors on project board  Stage reviews and authorisations to continue	Non-disclosure agreement signed by partner organisations  Project management system followed to check off project deliverables and ensure each stage signed off by key partners/ stakeholders  Standard reporting mechanisms in place ensuring external review of project processes  Regular internal project team meetings  Written agreement between partner organisations setting out terms and conditions for joint working accountabilities  Official research governance framework followed	Named person or persons with responsibility

## Appendix 2: Risk assessment matrix

	Potential Risk Factors	Probability of Risk Arising (H/M/L)	Impact (H/M/L)	Risk Indicators	Control Mechanisms	Named Risk Lead
<b>Reputation, delays and grievances</b>	Any potential for adverse publicity for the project			Stakeholder meeting minutes  Related local and national media stories	Proactive engagement with stakeholders & media throughout project  Establish and maintain strong formal and informal links with partner organisations  Develop effective marketing plan for any project products or outputs  Develop a project communication and dissemination strategy for project duration  Monitor live issues in public spaces related to project areas of interest	Named person or persons with responsibility
	Lack of commitment from any related professional/ service user/client organisations or groups			Summary project meeting minutes made available (Who collects? Who edits?)  Feedback from professional/ service user/client organisations or groups	Involve key stakeholders from the start of the project  Set up a stakeholder group with input, evaluation (and control?) over aspects of the project  Develop a project communication and dissemination strategy for project duration	Named person or persons with responsibility

## Appendix 2: Risk assessment matrix

	Potential Risk Factors	Probability of Risk Arising (H/M/L)	Impact (H/M/L)	Risk Indicators	Control Mechanisms	Named Risk Lead
<b>Reputation, delays and grievances</b>	<p>Loss of subject/ respondent or participant information</p> <p>Inappropriate disclosure of subject/ respondent or participant information</p> <p>Respondents/ subjects expressed dissatisfaction</p>			<p>Research ethics committee</p> <p>Database monitoring arrangements</p> <p>Feedback from respondents and/or research team member or members</p> <p>Complaints made by respondents</p>	<p>Comply with data protection legislation</p> <p>If 'anonymity' required: ensure personal data is non-identifiable to subject/respondent – code questionnaire immediately</p> <p>All subject data stored electronically is password protected</p> <p>Double-key encrypt sensitive data</p> <p>All other subject data stored in a lockable file</p> <p>Follow research governance guidance on the protection of subject information</p> <p>Implement any appropriate recommendations from the relevant research ethics committee or committees</p> <p>Research data regularly backed-up</p> <p>Clear specification of levels of data access for staff</p> <p>Two copies of research database stored securely</p> <p>Clear grievance route – indicated to subjects</p> <p>If 'non-anonymised' – clarify mutual expectations between researchers and participants</p>	Named person or persons with responsibility

## Appendix 2: Risk assessment matrix

	Potential Risk Factors	Probability of Risk Arising (H/M/L)	Impact (H/M/L)	Risk Indicators	Control Mechanisms	Named Risk Lead
<b>Methodological limitations</b>	Project rejected/ subjected to amendment by research ethics committee			Feedback sought from research ethics committee  Feedback from stakeholders and advisors	Input from ethics advisor sought prior to submitting project proposal  Independent ethics advisor or advisory group if ethics issues warrant  Advice and input from institutional research director and research sponsor  Implement recommendations from ethics committee and resubmit if required  Stakeholder group approves project proposal	Named person or persons with responsibility
	Poor uptake of project outputs or deliverables (if appropriate)			Feedback from stakeholder steering group  Feedback from user panel  Monitoring of outputs and uptake  Feedback from any pilot phases	Develop project communication and dissemination strategy  Full involvement of stakeholder group and user groups throughout project  Marketing strategy developed for each project output  Evaluate pilot phases of project products and implement changes	Named person or persons with responsibility
	Project overruns planned timeframe			Project board meetings  Feedback from PI at key project stages  Evaluation against original project schedule	Project management systems used to manage project time frames  GANTT chart developed and updated regularly to monitor timeframes involved for each task  Project supervision undertaken by project board  Timely updates to sponsor/funder	Named person or persons with responsibility

## Appendix 2: Risk assessment matrix

	Potential Risk Factors	Probability of Risk Arising (H/M/L)	Impact (H/M/L)	Risk Indicators	Control Mechanisms	Named Risk Lead
<b>Resource</b>	Changes in key project staff			Recruitment processes Appraisal process Adequate staffing	Develop succession plan Ensure handover mechanism in place Involve other key members in partner organisations in project processes Ensure 'cover' arrangements for illness etc. Allow for contingencies in initial staffing needs appraisal	Named person or persons with responsibility
	Appropriately qualified and experienced PI and other staff recruited to undertake project			Recruitment process Appraisal process Liaison meetings with any partners sharing recruitment	Clear and appropriate training plan for researchers developed & implemented All human resources processes in place to manage the recruitment process Regular specified supervision undertaken, and as required, from project sponsor	Named person or persons with responsibility
	Project overruns planned timeframe			Project board meetings Feedback from PI at key project stages Evaluation against original project schedule	Project management systems used to manage project time frames GANTT chart developed and updated regularly to monitor timeframes involved for each task Project supervision undertaken by project board Timely updates to sponsor/funder	Named person or persons with responsibility



# Appendix 3: Audit tool aligned with core principles

## Appendix 3: Audit tool aligned with core principles.

The audit tool reflects the core principles section and has been added to enable institutions to audit themselves against these standards.

1. Standard not met
2. Standard met partially
3. Standard almost met
4. Standard fully met or exceeded

Independence	Grading 1-4	Evidence	Actions agreed
Ensuring that RECs include members from a wide range of disciplines and that RECs have members (which may include chairs) from outside the academic unit(s) covered by the committee.			
Establishing a constitution and terms of reference which guarantee each REC the freedom to make ethics judgements.			
Including representation from groups external to the institution in RECs and other processes. For example, this may involve service users, members of faith groups or delegates from industry.			
Having an overarching policy committee which sets consistent research ethics standards, monitors performance and provides a means to manage appeals against REC decisions.			

## Appendix 3: Audit tool aligned with core principles

Competence	Grading 1-4	Evidence	Actions agreed
Ensuring that REC membership includes ethics expertise across the range of research carried out by the institution.			
Recognising, through workload allocation or other compensations, that contributing to ethics review and other support processes is accepted institutional work..			
Establishing standard operating procedures that are regularly reviewed.			
Ensuring regular audits of formal review processes.			
Provide training to REC members and researchers.			

Facilitation	Grading 1-4	Evidence	Actions agreed
Ensuring that procedures balance duties of care with enabling and supporting ethical research and innovation.			
Providing training for researchers in ethics issues and in the policies and mechanics of ethics review, seeking to develop researchers' autonomy and skills in making reasoned ethics judgments.			
Progressing formal ethics review efficiently and rapidly, with appropriate analysis of risk and the associated proportionality of review, and mechanisms for expedited review.			
Achieving a good balance between the detail and the burden of completing applications for formal ethics review.			
Making opportunities available for researchers to seek informal advice on ethics issues.			

## Appendix 3: Audit tool aligned with core principles

Transparency & Accountability	Grading 1-4	Evidence	Actions agreed
Having a clear and easily accessible public statement of institutional policies and processes for maintaining high standards of research ethics.			
Ensuring that there is a named officer of the institution who is the primary contact for research ethics matters.			
Maintaining consistent records of research ethics review and support processes that are made publicly available in a timely manner, while protecting sensitive data.			
Making regular reports, at least once a year, evidencing REC performance in responding to applications for formal ethics review.			



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