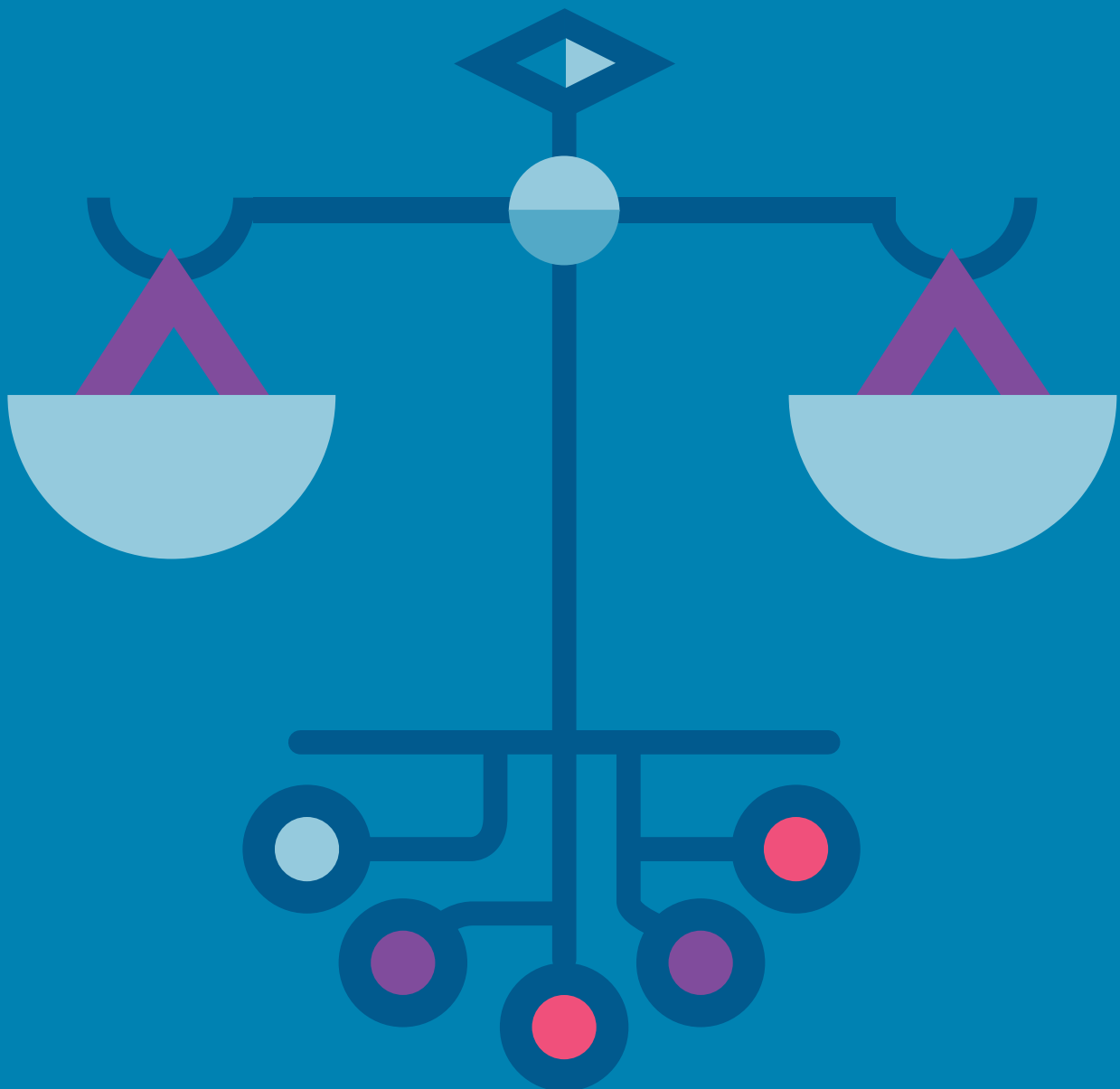

Research Ethics Support and Review in Research Organisations

Summary document



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Research Ethics Support and Review in Research Organisations

Summary document

Authors

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.

Competing Interests

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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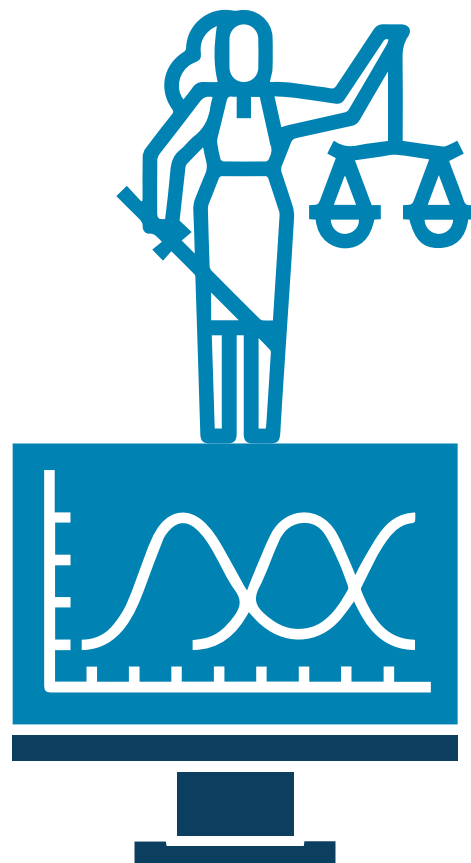
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Introduction

This document provides a concise summary of the key recommendations contained in the UKRIO/ARMA source document *Research Ethics Support and Review in Research Organisations*. The full document gives extended background and rationale with references. It should be consulted where changes in organisational practice are being considered on the basis of this guidance.

This summary version establishes the basic ground rule principles and overviews the implications of these for developing best practice in supporting high ethical standards in research.

The guidance is intended primarily for 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 of the role of their institution in supporting ethical practice.



Principles for the ethics and integrity of research

Key points

- The use of ‘principles’ in research ethics is well-established but it is important to be aware that there are various sets of principles in current use;
- The most widely used principles for research ethics are the ‘Belmont Principles’ (respect for persons, beneficence, non-maleficence and distributive justice);
- Research ethics as a field has widened considerably to include a number of different areas, each with their own parameters and principles, and forms a substantial component of ‘research integrity’ and ‘responsible research and innovation’ (RRI);

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, 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 20th 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), the UK Policy Framework for Health

and Social Care Research from the Health Research Authority (HRA), or the US Office of Research Integrity.

- 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.

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 Core Principles

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 a 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.
- 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 or that legal issues are managed effectively elsewhere in governance processes.
- 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.

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 effectively within defined timeframes, with appropriate analysis of risk and the associated proportionality of review, with mechanisms for 'fast-track' review in situations meeting clearly defined criteria.
- 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.]

RECs and governance

Key points

- Research ethics review should be distinct from research governance.
- Ethics and governance are both linked to different aspects of research integrity – ethics is primarily linked to good (ethical) professional research practice, governance to responsible research sponsorship, particularly its management.
- 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 since, 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 Core Principles



The pressure to 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 done 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.

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 the ways in which ethical review has been implemented in HEIs presents a challenge in 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 across institutions in order to assuage concerns that research may be held to higher ethics standard in one system than another, and to facilitate transfer of favourable REC opinions across institutions thus avoiding duplication of effort.

Research ethics committees cannot operate without a policy statement approved by an authoritative body of the institution that covers the rationale for their existence and a specified institutional commitment to upholding high ethical research standards.

Ethics committees should operate in accordance 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 review of all types of research.

A Standard Operating Procedures (SOPs) document will be required unless the constitution and terms of reference spell out matters of committee practice in adequate detail to ensure consistency and competency.

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.

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.

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.
- considering 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 unfavourably; 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 a REC relies largely on the degree to which research organisations are able to build appropriate structures and create a culture that recognises the central place of ethics review 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 required to make decisions – on the basis upon which ethical decisions can be made, using commonly agreed and shared ethics principles – and on 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 challenges not previously encountered 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 process. If necessary, different persons may need to deliver relevant training in the two areas.

Standard Operating Procedures

The role of a Research Ethics Committee

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 but raising other sensitive issues, for example with regard to the integrity of the environment.
- clear criteria identifying research which will be exempted from ethics review.
- 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, both in general terms and that of the local community.
- 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.
- 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, or at departmental level, the core principle of competence must still be upheld by ensuring that members have the necessary breadth of experience and skills.

Review process

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.
- arrangements for requesting amendments and arrangements for dealing with appeals.

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

The employment of 'tiered review' systems is one way to maintain clear and consistent standards and permit differences in administrative implementation suited to different institutional needs without affecting the task of meeting review standards. If a tiered review system is employed, the operations must be set out clearly, and using some form of Standard Operating Procedures for such approaches is essential.

Procedures involving researcher declaration alone (often using a checklist), review by sub-committee (often involving research with few material ethical issues) and review by chairs' action should specify:

- 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.

Monitoring

Research organisations should establish appropriate procedures to monitor the conduct of research which has received favourable ethics review opinion until it is completed, and to ensure continuing review where the research design or the context in which it takes place (e.g. in times of political volatility), anticipates possible changes over time that might need to be addressed. Monitoring should be proportionate to the nature and degree of risk associated with the research. Requirements might include end of study reports for all studies and annual reports for those extending beyond a year.

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 require that the research be suspended or discontinued.

RECs should normally expect reports from researchers detailing any 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 might 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 a single institution differ in their opinions, as well as dealing with complaints.

The best way to achieve all of the above is to have a publicly available policy with reference to the basic commitments of ethical research and to conducting ethics review 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 SOPs 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.



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.



Criteria for ethics reviews

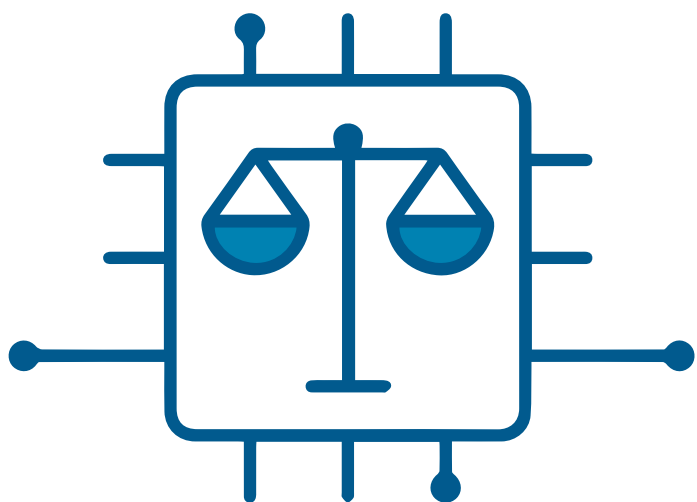
Criteria for ethics review

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.

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.



RECs and governance

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.

It is self-evident that the opinions of RECs should be well-reasoned, by drawing on moral theory or other recognised bases for ethical reasoning. Reviews should therefore be structured, consistent and balanced. This last point is particularly important as 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.

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, their role is not to check compliance with internal or external policy – again this is a matter for governance.



Appendices

Appendix 1: REC review panel checklist for applications

Title	<ul style="list-style-type: none"> • Short, clear and descriptive.
Abstract	<ul style="list-style-type: none"> • A summary of the main points of the research, written in terms easily understandable by a non-specialist and containing no complex technical terms.
Investigators	<ul style="list-style-type: none"> • Names and institutional attachments of all persons involved in the collection and handling of individual data and one person named as Principal Investigator (PI). • Research students should include a supervisor's electronic signature and comments as evidence of supervisor support.
Schedule	<ul style="list-style-type: none"> • Has the research been adequately planned so it will be carried out in a timely manner?
Methodology	<ul style="list-style-type: none"> • 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. • Are all documents for applicants worded appropriately?
Participants	<ul style="list-style-type: none"> • Give details of the population targeted or from sample will be obtained and how this sampling will be done. • Information on participants should include: <ul style="list-style-type: none"> • Age • Specific vulnerabilities • Cultural sensitivities • PREVENT safeguarding programme
Recruitment procedures	<ul style="list-style-type: none"> • Are there details of how potential participants will be identified/chosen and how they will be approached? • 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? • Have participants been informed of the time commitment expected of them and their right to decline to offer any particular information? • Have participants been given sufficient time to permit making an informed decision? • Are eligibility criteria clearly set out?

Appendix 1: REC review panel checklist for applications

<p>Consent</p>	<ul style="list-style-type: none"> • 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: <ul style="list-style-type: none"> • PI contact details and an alternative contact. • Institutional email addresses should be used by default. • 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. • Is there information about how and to whom a complaint might be addressed? • Is there clear information about the processing and storage of data including evidence of compliance with the EU's General Data Protection Regulation (GDPR)?
<p>Where and when will the research be carried out and the data collected?</p>	<ul style="list-style-type: none"> • 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.
<p>Literature review</p>	<ul style="list-style-type: none"> • 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. • 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?
<p>Which guidelines will be followed?</p>	<ul style="list-style-type: none"> • Researchers should provide information on which guidelines will be followed. For example: BERA, BPS, BSA, SRA, MRS, SPA.

Appendix 1: REC review panel checklist for applications

<p>Data protection and information security</p>	<ul style="list-style-type: none"> • Has data protection and security been addressed adequately? • 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. • 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.
<p>Research data management</p>	<ul style="list-style-type: none"> • Have participants been given accurate information and given appropriate consent for the research data to be reused and/or published? • 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.
<p>Deception</p>	<ul style="list-style-type: none"> • 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. • Where used, any such deception should be fully justified. • Is there any indication that applicants might feel coerced, constrained, or otherwise induced to participate against their will?
<p>Risk of harm</p>	<ul style="list-style-type: none"> • 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? • 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. • Have participants been given information or contacts for emotional support if needed?

Appendix 1: REC review panel checklist for applications

<p>Incidental disclosures and findings</p>	<ul style="list-style-type: none"> • If there is a risk that disclosures raising concerns for the safety of participants or others, have relevant measures been explained? • 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. • If there is a risk of disclosure of illegal actions and what the consequences might be.
<p>Debriefing</p>	<ul style="list-style-type: none"> • 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. • Is the offer or breadth of the debriefing adequate? • Has the researcher offered to share findings with participants?
<p>Research organisation and funding</p>	<ul style="list-style-type: none"> • Are there any conflicts of interest or requirements/issues with a particular funder?
<p>Other project-related risks</p>	<ul style="list-style-type: none"> • If not included elsewhere, have risks been adequately addressed? • Researchers are asked how they will limit research risks by anticipating potential problems. • 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.
<p>Benefits and knowledge transfer</p>	<ul style="list-style-type: none"> • Researchers should state how the research may be of general benefit to participants and society.
<p>Supporting documents</p>	<ul style="list-style-type: none"> • 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?

Appendix 2: Risk assessment matrix

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
Participants	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
Financial	<p>Funder/ commissioner problems:</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>Estimate:</p> <p>High</p> <p>Medium or</p> <p>Low</p>	<p>Estimate impact:</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
Legal/ Contractual	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
Reputation, delays and grievances	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
Reputation, delays and grievances	<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:</p> <p>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
Methodological limitations	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
Resource	Changes in key project staff			<p>Recruitment processes</p> <p>Appraisal process</p> <p>Adequate staffing</p>	<p>Develop succession plan</p> <p>Ensure handover mechanism in place</p> <p>Involve other key members in partner organisations in project processes</p> <p>Ensure 'cover' arrangements for illness etc.</p> <p>Allow for contingencies in initial staffing needs appraisal</p>	Named person or persons with responsibility
	Appropriately qualified and experienced PI and other staff recruited to undertake project			<p>Recruitment process</p> <p>Appraisal process</p> <p>Liaison meetings with any partners sharing recruitment</p>	<p>Clear and appropriate training plan for researchers developed & implemented</p> <p>All human resources processes in place to manage the recruitment process</p> <p>Regular specified supervision undertaken, and as required, from project sponsor</p>	Named person or persons with responsibility
	Project overruns planned timeframe			<p>Project board meetings</p> <p>Feedback from PI at key project stages</p> <p>Evaluation against original project schedule</p>	<p>Project management systems used to manage project time frames</p> <p>GANTT chart developed and updated regularly to monitor timeframes involved for each task</p> <p>Project supervision undertaken by project board</p> <p>Timely updates to sponsor/funder</p>	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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