UK Research Ethics Committee (REC) Policy Document

28th April 2026

V 1.0

Contents

1. Scope and purpose

This UK REC policy document satisfies the requirement in the Care Act 2014, that: “the Health Research Authority (HRA)—

> (a)must publish a document (called “the REC policy document”) which specifies the requirements which it expects research ethics committees it recognises or establishes under this Chapter to comply with, and
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> (b)must monitor their compliance with those requirements.”[1]

The HRA and Devolved Administrations work together to deliver a Research Ethics Service for the UK. For RECs that review Clinical Trials of Investigational Medicinal Products (CTIMPs), compliance with the Clinical Trials regulations is overseen by a collective group of the HRA and Devolved Administrations in a group known as the UK Ethics Committee Authority (UKECA).

However, RECs review a broad range of proposed research in health and care settings in the UK, for which the different nations have set up arrangements for specific organisations to undertake functions to effectively deliver the Ethics service. For some functions, these, by agreement, are undertaken by HRA on behalf of other nations. Whilst this document provides high level information on some of these functions, specific arrangements are detailed in bilateral agreements and this document is not intended to supersede the agreements in any way.

As detailed in the Care Act 2014, the HRA and each Devolved Administration co-operate fully with each other in order to deliver their respective functions relating to the regulation of assessments of the ethics of health and social care research, with the aim of co-ordinating and standardising practice in the UK relating to such regulation.

This UK REC policy document is a joint policy document of the Devolved Administrations, the HRA and the UKECA.

1.1. Scope

1.1.1. The principles, requirements and standards set out in this document apply to RECs reviewing research that relates to areas of responsibility of the Devolved Administrations and the HRA. This includes research involving users of services for which the UK Health Departments are responsible. It also applies where the law requires review by a REC and the Devolved Administrations and the HRA provide for that review.

1.1.2. The research sponsor has overall responsibility for ensuring that the research has REC approval, if needed, before the research begins. To inform a decision about whether a

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[1] Care Act 2014

project is research[2] and whether it needs REC review, see the on-line decision tools. The decision tools align to the principles contained within this document.

1.2. Purpose

1.2.1. This document provides information on when review by a REC is required.

1.2.2. The document sets out the context within which the RECs across the United Kingdom (UK) undertake their review of the relevant research. It is intended to be a guide for committee members, alongside more operational detail, which is set out in the UK Research Ethics Service (RES) Standard Operating Procedures (SOPs).

1.2.3. Members of the research community, including researchers, sponsors and Clinical Research Organisation (CRO) staff may also find this information helpful as a reference guide.

1.2.4. This document revises and replaces the previous policy document, known as Governance Arrangements for Research Ethics Committees (GAfREC).

1.2.5. This edition takes effect throughout the UK from 28 April 2026.

2. Introduction

2.1. Research is a critically important part of the Health and Social Care (HSC) in Northern Ireland and NHS and other care services across the UK. Research generates an evidence base upon which decisions about care provision can be made. This enables health and care services to improve the current and future health and well-being of the people they serve. Current evidence[3] suggests a positive association between the engagement of individuals and healthcare organisations in research and improvements in healthcare performance.

2.2. The Devolved Administrations and the HRA are committed to enhancing the contribution research can make. Research is essential for protecting and improving health and well-being, as well as for achieving advanced, innovative and effective care services.

2.3. Research can sometimes involve a degree of risk because researchers cannot predict outcomes with certainty. It may also involve additional burdens or intrusions for people taking part, which exceed those received if the individuals were receiving standard care.

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[2] Research is defined in Section 3 of the UK Policy Framework for Health and Social Care Research

[3] (PDF) If health organisations and staff engage in research, does healthcare improve? Strengthening the evidence base through systematic reviews

It is important that any risks are minimised and do not compromise the dignity, rights, safety and well-being of the people who take part. Robust governance arrangements are essential to ensure that patients, service users and the public can have confidence in, and benefit from, high-quality, ethical research.

2.4. The UK Policy Framework for Health and Social Care Research sets out principles of good practice in the management and conduct of research and the responsibilities for satisfying them. The UK REC Policy Document sets out principles, requirements and standards for RECs. The public has a right to expect the highest scientific, ethical and financial standards, transparent decision-making processes, clear allocation of responsibilities and robust monitoring arrangements.

2.5. RECs review proposed research to assess whether the risks and burdens associated with the research are outweighed by the benefits and that the proposed research is ethical. The REC seeks assurance that any anticipated risks, burdens or intrusions will be minimised for the people taking part in the research and are justified by the potential benefits for the participants or for people in the future.

2.6. RECs aim to protect the people who will take part in research, ensuring that their dignity, rights, safety and well-being are protected. This helps to promote public confidence about the conduct of research.

3. Research Ethics Committees (RECs)

3.1. What RECs do

3.1.1. The Research Ethics Service in the UK enables ethical research, through working with researchers and research sponsors. The REC review complements the researcher's and sponsor's own consideration of ethical issues raised by their research and their involvement of a range of perspectives and expertise at the design stage of their research. This includes patient and public contributors, service users, health and care professionals, methodologists, statisticians, data experts, etc.

3.1.2. A REC is formed of a group of volunteers from a range of backgrounds and professions, who are appointed to committees by each UK nation's Appointing Authority (see **Annex A**). The RECs review the ethics of proposed research in line with the relevant laws. They also review all research which is intended to take place in the HSC/NHS or certain social care settings across the UK. **Annex B** sets out the legal requirements for REC review.

3.1.3. The role of the REC is to help ensure that the proposed research conforms to recognised ethical standards, which includes respecting the dignity, rights, safety and well-being of the people who will take part.

3.1.4. The RECs operate as part of a wider system that aims to ensure that the principles applicable to research as laid out in the UK Policy Framework for Health and Social Care Research are applied, focusing on the safety and wellbeing of participants and the ethical conduct of research.

3.1.5. RECs are required to review research in line with relevant laws and regulations. The law will take precedence over ethical judgements. Although all research must comply with the law, if RECs are concerned that complying with the law in a particular situation will raise significant ethical concerns, they will draw researchers' attention to this.

3.1.6. RECs are expected to conduct their review of proposed research independently and impartially. This responsibility applies regardless of the researchers involved, the organisations funding the research, or the institutions where the research will take place. In situations where REC members have a conflict of interest relating to any proposed research study that is being reviewed by their committee, they are required to declare this and where necessary, refrain from participating in the review of the application.

3.1.7. Each nation ensures that REC review is undertaken according to the timelines[4] required, providing operational and administrative support to the RECs to facilitate the promptness of review and efficiency of their decision-making processes. Some of these timelines are set as part of regulatory requirements, meaning compliance to those timelines must be demonstrated.

3.1.8. If a research project requires REC review, that project can only start once a REC favourable opinion has been provided, along with approvals from any other relevant approval or regulatory body. Research sponsors and care organisations are responsible for ensuring that all approvals required are in place before any research related activity starts.

3.2. Establishment and management of RECs

3.2.1. RECs established and operating in accordance with the principles, requirements and standards set out in this document are recognised and authorised by the Department of Health (Northern Ireland)[5], the Scottish Ministers, the HRA and the Welsh Ministers. Where RECs are established for review of CTIMPs, these standards are recognised and

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[4] REC review for CTIMPs must be completed within 30 days of a valid application, in line with The Medicines for Human Use (Clinical Trials) Regulations 2004 (SI 2004/1031), as amended by the Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2025 (SI 2025/538). Timelines will apply to all other full applications for REC review.

[5] Delegated to the Public Health Agency (PHA)

authorised by UKECA (see **Annex C** for more on the role of UKECA and its membership).

3.2.2. Together, these RECs and the Appointing Authorities and/ or REC operational leads, which co-ordinate the development and management of their operations, form the UK Research Ethics Service. (See **Annex A** and **D** for more on the role of these organisations).

3.2.3. In general, any REC across the UK Research Ethics Service may carry out the review required. Specific RECs within the Research Ethics Service may be recognised, or otherwise designated, for review of certain types of research proposal, according to legal, policy or operational requirements. Each organisation within the Research Ethics Service is accountable to the relevant Health Department as detailed below:

Organisation	**Remit**	**Accountability**
Chief Scientist Office & Scottish NHS Health Boards	RECs in Scotland	Scottish Government Health and Social Care Directorate
Health and Care Research Wales hosted by Powys teaching Health Board	RECs in Wales	Welsh Government's Health, Social Care and Early Years Group
Health Research Authority	RECs in England[6]	Department for Health and Social Care (England)
Office for Research Ethics Committees Northern Ireland situated in The Business Services Organisation	RECs in Northern Ireland	Department of Health Northern Ireland[7]

3.2.4. Appointing Authorities are the bodies that establish RECs, appoint and indemnify their members, seek their recognition from UKECA if the law requires it and monitor their performance. Note that the roles and functions of different Appointing Authorities are

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[6] The Health Research Authority performs some functions relating to management of the UK research ethics service outside of England (see annex E) when agreed at consultation at UKECA or these are listed in the respective agreements under devolved acts in each Nation and include engagement and oversight expectations.

[7] Research ethics policy in NI is delegated by Department Of Health NI to the Public Health Agency (PHA)

subject to variation across nations. The detailed responsibilities and functions of Appointing Authorities are listed in **Annex A**.

3.2.5. Each Appointing Authority must supply their REC members with a personal statement regarding the indemnity provided by the Appointing Authority and its conditions.

3.2.6. Each Appointing Authority identifies a named senior accountable person, who has responsibility for governance of the RECs on behalf of the Chief Executive or equivalent senior role in the organisation (unless the named officer is the Chief Executive). The Chief Executive (or equivalent) has overall accountability.

3.2.7. Every UK nation is also represented on UKECA, which is the body that recognises RECs for the review of CTIMPs.

3.2.8. The Appointing Authorities work together to maintain a consistent approach, on behalf of all Appointing Authorities, to the operations of all RECs within the UK Research Ethics Service. This helps to facilitate research that takes place across borders in the UK nations, reducing the need to duplicate reviews.

3.2.9. Note that the Appointing Authority for RECs in England, the HRA, performs some functions on behalf of the other Appointing Authorities, by agreement and in consultation with Devolved Administrations (see **Annex E**). It also acts in respect of some UK-wide functions and for the Devolved Administrations and UKECA.

3.3. Role and remit of RECs

3.3.1. RECs assess applications for an ethics committee opinion in relation to the research being proposed. The ethics committee will consider:

- Whether the anticipated benefits to participants and other individuals or groups outweigh the anticipated risks and inconveniences, taking account of:
  - The risks to any of the participants posed by the any interventions that might be investigated as part of the research
  - The nature of the intervention compared to normal care or usual service provision
  - The measures used to
    - seek and obtain informed consent for participation in the research
    - protect and promote the interests of participants and the general public (including by promoting transparency in research)

3.3.2. The REC may consider and give an opinion on any other issue relating to the research if:

  - The committee has been asked by the sponsor to consider the issue
  - It is, in the committee's opinion, relevant to the other matters considered by the committee in accordance with 3.3.1. above.

3.3.3. If the REC considers it appropriate to do so, they may consult a relevant expert reviewer, relevant committee or specialist group.

3.3.4. Where any conflicts of interest arise, REC members are required to declare this and if necessary, refrain from participating in the review of the application. This helps to retain the REC's freedom from pressures of:

  - Political or media influence
  - Lobby / pressure groups
  - Institutional affiliation including employing organisations
  - Trade union or professional body
  - Direct or indirect financial inducement
  - Coercion
  - Market forces
  - Research interests
  - Topic or discipline related bias

3.3.5. The responsibility for the design, conduct and reporting of research lies with the research sponsor and RECs will therefore expect the sponsor to provide assurances about the steps in place to ensure the scientific and ethical conduct of any proposed research.

3.3.6. REC members receive training and guidance, with SOPs in place in order to support them to deal with applications appropriately, identifying and considering the impact of relevant ethical issues as part of their review.

3.3.7. The RECs review information provided to them relating to proposed research, taking what is provided to them on trust and do not undertake any investigation into the veracity of the information. RECs review all applications with the interest of participants at the core of their consideration.

3.3.8. RECs seek assurance as part of their review that researchers and research sponsors have put in place appropriate and proportionate safeguards to protect people taking part in research. RECs act primarily in the interests of research participants. Interests of any other party are always secondary to the dignity, rights, safety and well-being of people taking part in research. RECs should balance the interests of the participants with the benefit to participants and the benefit to the public to inform the development of treatments, care and interventions in health and social care.

3.3.9. RECs are expected to consider both the risks and potential benefits for people taking part in research. RECs will also assess how sponsors approach the inclusion of participants in research. High quality research is vital for improving health and social care and it is widely accepted that different groups may respond differently to medical treatments and interventions due to genetic, social, and cultural factors. Some population groups are more likely to experience ill health and poorer quality of life yet are less likely to participate in research. RECs will therefore seek assurance that selection criteria for research studies do not unjustifiably exclude eligible participants. This could include potential exclusions on the basis of age, sex, gender, ethnicity, socio-economic status, culture, disability, marital status, pregnancy and maternity, religion or belief, or sexual orientation. RECs will take these considerations into account in reviewing the ethics of the proposals, including those involving people or groups under-served by research.

3.3.10. RECs must be assured about the planned ethical conduct and anticipated risks and benefits of any proposed research. RECs are not responsible for the conduct of research, but may ask a sponsor to provide progress reports, and may take action on the basis of new information provided.

3.3.11. REC decisions are independent of organisations undertaking or hosting the proposed research, including care providers. No interference is to be made with REC decision-making in order to maintain the impartiality of decision-making in line with the RES SOPs. The SOPs also set out the process for handling requests from external parties to bring information to the REC's attention, outside of agreed standard information needed for its review, whether received ahead of the review, or after the review in order to maintain impartiality.

3.3.12. RECs focus on the ethics of the proposed research, within the wider context. They are not expected to undertake detailed reviews of aspects that are conducted elsewhere or by other parties, taking assurance that this has been done. For example, they are not expected to reconsider the quality of the science of proposed research, as this is the responsibility of the sponsor and will have been reviewed by relevant experts. The REC will take assurances from the fact that the proposed research has an identified sponsor in place and that the appropriate level of scientific and/ or peer review has been undertaken.

3.3.13. Where others have a regulatory responsibility, RECs can expect to rely on them to fulfil it. If the law gives another body duties that are normally the responsibility of a REC according to this document, RECs do not duplicate them. For example, the Medicines and Healthcare Products Regulatory Agency (MHRA) has the primary legal responsibility for considering the safety of the research it regulates.

3.3.14. RECs can expect to rely on established mechanisms for ensuring the proper conduct of the research at individual locations. Organisations providing care that are subject to the UK Policy Framework for Health and Social Care Research are responsible for the management, governance and monitoring of the research they host. Other standard assurance processes, such as inspection or accreditation of locations by regulators, may also be adequate for the REC to be assured about the suitability of those locations.

3.3.15. The Appointing Authorities work across the Research Ethics service to ensure that relevant information is shared across RECs, for example in reviewing particular types of studies or where novel developments require further information with relation to ethical issues that might be raised as part of research studies.

3.3.16. The Research Ethics Service has agreed and established channels of communication with the relevant regulatory or enforcement bodies in order to exchange advice where needed (see **Annex F**). Where RECs need to seek advice or share information with other relevant bodies, or to advise if they have grounds to suspect that enforcement action is warranted by the relevant regulator/s, this is done through staff working with the RECs, normally employed by the Appointing Authority[8] or REC Operational Lead.

3.3.17. RECs may reconsider a favourable opinion in light of any pertinent information that subsequently comes to its attention. RECs may request changes to a study if new information becomes available. RECs are not expected to duplicate ongoing checks for which others are responsible. However, if the REC considers that it would not have reached a favourable opinion had it been given that information during its initial review, it should notify the relevant statutory enforcement authority, through REC operational lead staff. Where the law does not specify the responsibility for enforcement, the REC should notify the sponsor and chief investigator that its opinion is no longer favourable.

3.3.18. RECs must operate according to the law in the conduct of their reviews by following due process and complying with the RES SOPs.

3.3.19. A REC must not give a favourable opinion where it believes the research will break the law. It is not the role of the REC to offer an opinion on legal aspects of research proposals. The REC may however highlight to applicants where legal advice may be helpful to them in response to ethical considerations raised. Researchers, sponsors and locations where research is carried out remain responsible for making sure that the research is conducted in accordance with the requirements of law, relevant regulators and guidance as applicable.

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[8] Note that arrangements vary across UK nations

3.3.20. Some research requiring REC review may be suitable for expedited review, for example due to a public health emergency. RES SOPs detail the procedures for expedited review.

3.3.21. For transparency, RECs publish a summary of all research they have reviewed along with the outcome.

3.4. Composition of RECs

3.4.1. Each REC is made up of a range of people with individual expertise and experience, including registered health and social care professionals, research professionals, and a wide range of people with much broader experience, including members of the public who have experience using health and social care services and no professional knowledge of research or health and social care.

3.4.2. REC members are appointed to provide a broad range of perspectives on the committees, which scrutinise the rationale, aims and objectives of the proposed research to reconcile this effectively with protecting the dignity, rights, safety and well-being of the people who are likely to take part.

3.4.3. REC members are appointed independently of their employing organisation and are expected to reflect their own experience and ethical judgement on an individual basis, bringing sound judgement and personal experience to undertake the REC review, underpinned and supported by relevant training and RES SOPs.

3.4.4. All REC members are provided with training to understand research ethics and to understand the processes to be followed in reviewing research applications in line with the RES SOPs. Staff from the Appointing Authority or the REC operational lead support the committees.

3.4.5. The Research Ethics Service as a whole should reflect the diversity of the adult population of society. Appointing Authorities should take steps to encourage applications for membership from those who are under-represented.

4. Research that requires REC review

4.1. Requirements for REC review

4.1.1. REC review through the UK Research Ethics Service in line with this document is required by law under certain circumstances (see **Annex B**), or by policy when the research involves the health and social care services for which the UK Health Departments are responsible As a matter of policy, research that involves the services set out in the table below should have REC review through the UK Research Ethics Service. All research funded by any of the UK health or care departments that does not fall into the legal or policy requirements for REC review through the UK Research Ethics Service may request such review.

Nation	Health and/ or Social Care Department	Services
England	Department of Health and Social Care (England)	NHS care Social care where the research is funded by the Department of Health and Social Care (England) or the National Institute for Health and care Research (NIHR) or delivered through NIHR infrastructure including the Research Delivery Network.
Northern Ireland	Department of Health (Northern Ireland)	Health and social care
Scotland	Scottish Government Health and Social Care Directorate	NHS and adult social care
Wales	Welsh Government's Health, Social Care and Early Years Group	NHS and social care

4.1.2. As an overview, legislation requires REC review of research involving any of the following (note that some of these will also need review by other organisations or committees):

- People who lack the capacity to give informed consent to take part, or to keep taking part in the research
- Processing of confidential patient information without consent where this would otherwise breach confidentiality
- Material consisting of or including human cells, which has been taken from living or deceased individuals (see 3.1.3 for details)
- In Northern Ireland and Wales, patients (or information about them) in independent hospitals or clinics

- In Northern Ireland, residents or patients (or information about them) in private or voluntary sector nursing homes, care homes, dental practices, general practices, healthcare establishments and agencies; or the fire authority

- Exposure to ionising radiation as part of medical, biomedical, diagnostic or therapeutic research

- Medical devices that are not CE/ UKCA-marked (i.e. not compliant with European Directives) or CE/ UKCA-marked medical devices that have been modified or are being used outside of their intended purpose

- Investigational medicinal products

- Protected information from the Human Fertilisation and Embryology Authority register

4.1.3. REC review is required by law for research, where it involves any of the elements listed below.

- Storage or use of relevant material (as defined in the Human Tissue Act 2004) from the living, collected on or after 1 September 2006, where appropriate consent for the research is not in place from or on behalf of the donor; the researcher must not hold, or be reasonably likely to have access to, information from which the donor can be identified (England, Northern Ireland and Wales only)

- Relevant material from the living or deceased that is not held on premises with a licence from the Human Tissue Authority (HTA) for research (England, Northern Ireland and Wales only)

- Organs retained from a post-mortem examination carried out on the instructions of the Procurator Fiscal (Scotland only)

- Organs, tissue blocks or slides retained from a hospital post-mortem examination, or tissue blocks or slides retained from a post-mortem examination carried out on the instructions of the Procurator Fiscal, unless lawful authorisation has been given for use in research (Scotland only)

- Analysis of human DNA in cellular material, where appropriate consent for the research is not in place from or on behalf of the person whose body manufactured the DNA. The material must have been removed from a living person, the researcher must not hold in or be reasonably likely to have access to information from which the person whose body manufactured the DNA can be identified (UK wide).

4.1.4. REC review as described in this document is required by policy if a specific research project involves people who are, or have been, users of HSC/NHS or social care services in the contexts of any of the following (unless any of the exceptions or other exclusions apply, as described in Section 4.2 – Exceptions):

- Potential research participants identified through their past or present use of the HSC/NHS or social care services or through information in their health or care records, including identification through use of digital intermediaries. This includes services provided under contract with the private or voluntary sectors; or identified through recruitment materials made available within HSC/NHS or social care services or where a health or social care professional directly involved in the individual’s care discusses the research with them.

- Potential research participants identified through information held about another individual who is, or was a user of these services.

- Research using previously collected tissue i.e. any material consisting of or including human cells[9], from which individual past or present users of these services are reasonably likely to be identified by the researchers either directly from that tissue or from its combination with other tissue or information in, or likely to be available to them.

- Research using health or care records of individual past or present users of these services, where identifiable confidential patient information is accessed at any stage for the purposes of research. This includes where identifiable confidential patient information is de-identified specifically for the research, or where confidential patient information is transferred outside HSC/NHS systems for linkage.

- Collecting tissue or information from users of these services.

4.1.5. REC review under this document is also required for:

- Xenotransplantation (putting living cells, tissue or organs from animals into people), which is recommended to take place in a controlled research context, carried out with a research protocol approved by a REC within the UK Research Ethics Service.

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[9] This includes those who have died in the last 100 years

- Health related research involving offenders, for which His Majesty's Prison and Probation Service (England and Wales), Scottish Prison Service and Northern Ireland Prison Service are responsible require review by a REC as well as compliance with their own approval procedures

- Research involving analysis of human DNA in acellular material, for example serum, processed plasma and processed semen, where appropriate consent for the research is not in place from or on behalf of the person whose body manufactured the DNA. The material must have been removed from a living person, and the researcher must not hold or be reasonably likely to have access to information from which the person whose body manufactured the DNA can be identified.

4.1.6. REC review is not required under this policy for:

- Research involving human biological material not consisting of or including cells[10], (unless it is required by law or where the research involves analysis of human DNA in acellular material, where it is not within the terms of consent for research from the person whose body manufactured the DNA or where the research also involves use of identifiable information about patients or service users).

- Research using previously anonymised human biological material, as this presents no outstanding issues with regards to research ethics.

4.1.7. Research projects involving human participants or their tissue or information may be undertaken on HSC/NHS or social care organisation premises by third party organisations. This could include, for example, contract research organisations or research units owned by universities or voluntary organisations. Where the proposed research falls within the scope as detailed in this section, REC review is required. Where the project only involves care organisations insofar as it involves use of or access to the organisation's premises or facilities, REC review is not required. Responsibility for considering and managing any risks relating to access to or use of the premises or facilities by visitors lies with the organisation concerned, with no involvement required from the Research Ethics Service.

4.1.8. Other provisions for REC review;

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[10] Guidance on identifying relevant material for the purpose of the Human Tissue Act 2004, i.e. material consisting of or including human cells, is published by the HTA - add link to www.hta.gov.uk

- RECs may agree to consider applications in respect of activities preparatory to research, for example the establishment of research databases or tissue banks, or pre-trial advertising and screening for healthy volunteers. By exception, they may also review research proposals that fall outside of the normal scope described above, capacity permitting. When they do this, they must follow the relevant steps in the RES SOPs.

- REC review is proportionate to the scale and complexity of the proposed research. Research proposals that present no materially significant ethical issues do not warrant consideration at a full meeting of the REC. As such, these studies will be reviewed in line with RES SOPs by a sub-committee of the REC. (Refer to section 7.1 on applying for REC review for further detail)

- Each research proposal is subject to review by no more than one REC within the UK Research Ethics Service, unless required by law or by the managed appeals process.

4.2. Exceptions

4.2.1. This document does not apply in England and Wales if social care research proposals are reviewed by a committee operating in accordance with the Economic and Social Research Council's (ESRC) Framework[11] for Research Ethics, unless any of the following apply:

  - The research involves HSC/NHS patients or users of HSC/NHS services as research participants
  - The research is a social care research project funded by the Department of Health and Social Care (England) or NIHR or delivered through NIHR infrastructure involving social care service users as participants
  - There is a legal requirement for review by a REC.

4.2.2. With these conditions, the ESRC's Framework for Research Ethics sets out principles, requirements and standards for review by university committees that are compatible with those set out in this document.

4.2.3. This document does not apply in Scotland for social care research proposals, and REC review is not required for social care research proposals, unless any of the following apply:

  - The study falls within scope of the Adults with Incapacity (Scotland) Act 2000, or has any other legal requirement for REC review

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[11] Research ethics guidance – ESRC – UKRI

- The study involves NHS patients, or a mixture of NHS patients and social care service users
- The study involves linking social care data with NHS data

4.2.4. RECs are not required or expected to consider applications that involve activities that are not research. This includes clinical or other non-financial audit, service evaluation and public health surveillance. Guidance on identifying whether a proposed project is classed as research can be found on the HRA website, which provides decision tools. REC members are not expected to give advice on non-research related activities.

4.2.5. This document does not apply to research reviewed by the Ministry of Defence Research Ethics Committee (MODREC). Where research approved by MODREC continues within the services for which the UK Health Departments are responsible, following transfer of participants into their care, it does not then require separate REC review under this policy. MODREC operates to standards set out separately by the Ministry of Defence, which are compatible with those in this policy.

4.2.6. Research recruiting staff working in HSC/NHS and care services (as participants) who are involved in research by virtue of their professional role does not require REC review under this policy. However, if the research falls under the legal requirements for REC review, for example also including patients or service users, REC review is required as described.

4.2.7. Research where participants have self-referred in response to an advertisement for a study conducted outside the HSC/NHS. This includes, for example, responding to a poster or advertisement for a study because they have a condition that was diagnosed by the HSC/NHS in the past but where the research is being conducted independently of the HSC/NHS. For example people with cancer which may have been diagnosed by the NHS but who respond to a poster or advertisement for a study outside of the HSC/NHS, or are identified from a cancer charity's contact list to be participants in a research project that is otherwise independent of the HSC/NHS does not require REC review.

4.2.8. Research involving only anonymous (also known as non-identifiable) information or data – that is, information which does not identify individuals and cannot reasonably be used to identify them from the perspective of those accessing it – including where information has been rendered anonymous by an intermediary before its onward release to the researchers, provided there is a legal basis for the anonymisation[12].

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[12] Anonymisation guidance Information Commissioner's Office March 2025

4.2.9. Research involving anonymised information released to researchers who work for an organisation acting as the sponsor or as a data processor for the sponsor, which may hold other information that, if combined, could identify individuals. Where there is no reasonable likelihood that such information will be combined or that individuals could be identified, the research does not require REC review.

4.2.10. Where a research study does not require review by a health or social care REC under this document, review may be undertaken by research ethics committees established by universities or other institutions, as set out in the ESRC Framework for Research Ethics, where applicable.

4.2.11. Market research undertaken by professional market researchers, for example for public health research or on behalf of pharmaceutical or medical device companies does not require REC review under this policy. Where such research is undertaken, this would need to comply with the principles set out in the Market Research Society Code of Conduct[13], or with the Legal and Ethical Guidelines issued by the British Healthcare Business Intelligence Association (BHBIA). Unless otherwise required by law, REC review is not needed.

4.2.12. REC review is not required for public involvement activities related to the design of research studies or general public involvement or engagement activities that are not directly linked to specific research studies. However, when reviewing research proposals within their remit, RECs will consider, as part of their ethical considerations, whether researchers have undertaken appropriate public involvement in the design of research studies, based on the best practice principles for public involvement[14].

4.2.13. There are exceptional circumstances which mean that RECs can agree to review research excluded from the normal scope of review above, particularly where the REC agrees that a proposal raises material ethical issues. The sponsor, or other parties responsible for managing those issues remain liable for the assessment which informs that management.

5. REC composition and membership

5.1. REC composition

5.1.1. The RECs must be composed of sufficient members in order to ensure that each REC has a range of perspectives and experience to facilitate the ethics review process. For CTIMPs, this is in line with ICH GCP principles.

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[13] Code of Conduct | Market Research Society

[14] HRA best practice principles of public involvement - Health Research Authority

5.1.2. Members, who are volunteers, are appointed following an open, proportionate and fair process, compatible with the seven principles of public life[15] . Appointing Authorities in each UK nation are responsible for advertising opportunities to join RECs and placing those who have successfully applied onto the relevant committee. The volunteer appointment process is documented and is compliant with all relevant legislation.

5.1.3. Where a REC member has an interest in a research proposal or affiliation with a research organisation where impartiality and independence cannot be maintained, the declaration of interest process is followed. This involves the interest being declared and a decision made by the REC and REC chair about whether the member should leave the meeting for discussion of that particular research study. This is captured in the meeting minutes or in the meeting record as appropriate. An annual declaration of interest process is also in place for all members to state any potential interests or affiliations affecting their role as a REC member.

5.1.4. Each REC will be established and membership maintained by the Appointing Authority to ensure that the committee collectively has the qualifications and experience to review the ethics of proposed research. This includes lay members, who are not professionally involved in research.

5.1.5. Appointing Authorities will manage RECs so that there is a balance of experience in the membership of each committee to ensure quorum for meetings can be met and the appropriate review of research can be undertaken.

5.1.6. Each REC must have an appointed chair.

5.1.7. A quorate REC meeting is one attended by at least 5 members of the committee. The chair must be present to meet quoracy requirements, along with at least one lay member.

5.1.8. There may be instances where specific membership, composition or attendance criteria for certain types of studies are stipulated. Where this is the case, the necessary arrangements will be put in place and set out in relevant operational guidance.

5.2. Chairs, Vice Chairs and Alternate Vice Chairs

5.2.1. Each REC has a chair, a vice-chair and the option to appoint an alternate vice-chair. These roles are appointed by the relevant Appointing Authority. If all three are

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[15] The Seven Principles of Public Life - GOV.UK

unavailable, another member or an appointed chair, vice chair or alternate vice chair from a different REC will be appointed as an acting chair.

5.2.2. Candidates for the role of chair, vice chair and alternate vice chair are expected to have met the expectations detailed in the Volunteer Agreement, understand the role and remit of a REC, acted as a lead reviewer and have participated in subcommittee work, including modification and proportionate review subcommittee work. The Appointing Authority will set out the process for appointing, a chair, vice chair and alternate vice chair in a separate policy.

5.2.3. Chairs, vice chairs and alternate vice chairs are appointed for a specified period not exceeding five years. Chair, vice chair and alternate vice chair appointments may be renewed (and exceptionally extended) in the same way as member appointments. An acting chair’s appointment ceases when the chair, vice chair and alternate vice chair of that REC becomes available again or when their term as a member expires, whichever is sooner.

5.2.4. Chairs, vice chairs and alternate vice chairs may resign from the role at any time. They may continue as members of the REC, subject to the usual procedures of its Appointing Authority.

5.3. Referees

5.3.1. RECs may seek advice from specialist referees to gain an expert view on any aspects of a research proposal that would support a fuller understanding of the context of the proposed research to enable the ethical considerations to be fully reviewed. Only issues material to the ethical considerations of proposed research should require specialist referee input.

5.3.2. Referees do not count towards the quorum of the REC meeting, nor do they participate in the REC decision making process. The are only required to advise on the issues put to them. The advice is recorded in the minutes of the relevant REC meeting.

5.4. Observers

5.4.1. REC meetings are not public meetings. However, it is important that the UK Research Ethics Service is transparent and that members of the public can be assured of the role of RECs in UK research.

5.4.2. The REC operational lead staff will manage and co-ordinate requests for observations of REC meetings from a range of individuals. This includes individuals wishing to become members of a REC, members of the public, research staff or researchers. This list is not exhaustive.

5.4.3. REC chairs will be asked for agreement for potential observers to join meetings. There will be a clear expectation set out to observers that they do not play any part in the discussions or deliberations leading to the REC decisions. All observers will be required to sign a non-disclosure agreement in order to maintain confidentiality of the content of research proposals that the REC reviews.

5.4.4. Observers will not be able to access any paperwork associated with the research applications, receiving only the agenda for the meeting with joining details. The purpose of observations is to hear how the ethical considerations relating to research applications are identified and discussed by the REC.

5.4.5. Appointing Authorities and REC operational leads have the authority to pause observations if requests exceed available slots or for any other reason. They also reserve the right to refuse observers for particularly sensitive applications, for example commercially sensitive research.

5.4.6. Research applicants are asked if they are content for observers to be present at the meeting they attend. They have the right to refuse and when this happens, observers will be asked to leave the meeting.

5.4.7. Attendance will be agreed by the REC chair and the appropriate REC operational lead staff and they will be listed as part of the meeting attendees in the minutes.

5.4.8. Representatives of any relevant Appointing Authority or REC operational lead may attend and observe meetings at any time without prior notification.

5.5. Advice to applicants

5.5.1. REC operational lead staff should take steps to facilitate communication with their potential or active applicants. This includes advice about whether a proposed activity requires REC review, or the content, submission or review of an application. The point of contact will be the operational lead staff working with the REC. The REC chair may be approached to provide further advice or hold a detailed discussion with regards to the REC's review if necessary.

5.6. Delegation

5.6.1. A REC may appoint sub-committees consisting of its members. Sub-committees, committee chairs, vice chairs and alternate vice chairs and REC operational lead staff may exercise any of the REC’s functions on its behalf as appropriate and in accordance with RES SOPs. In particular, sub-committees may review and give an opinion on:

a. research proposals that present no material ethical issues
b. information further to earlier review in full committee
c. substantial modifications

5.6.2. If a REC issues a provisional opinion reached in full committee, it may delegate the responsibility for determining its final opinion to the chair, vice chair or alternate vice chair, a sub-committee of specified members or a member of REC operational lead staff as appropriate.

5.6.3. Responsibilities of REC chair, vice chair and alternate vice chair may be delegated to REC operational lead staff where the matters are within their remit, in accordance with SOPs. In particular, REC operational lead staff may check evidence provided by applicants in response to requests for further information and issue letters confirming the REC’s opinion.

6.0 Expectations of membership

6.1. A Volunteer Agreement outlining the expectations of appointment for REC members is required to be put in place and updated regularly. This includes:

- Duration of appointment
- Renewal policy
- Process for resignation
- Process to be followed if a member who is a registered professional becomes disqualified
- Policy relating to declaration of interests

6.2. REC members are appointed to be part of the service for up to five years, but can resign at any time. Members may stay on for another term of five years, subject to agreement with the Appointing Authority. After this time, they will be required to join a different REC if their membership extends for longer than a ten year period. By exception, the Appointing Authority may extend a member’s term while new members are appointed, to ensure continuity of service.

6.3. Former members may be reappointed to the same REC no sooner than one year after the end of their last term, or to another REC without interval.

6.4. When a member is appointed to a chairing role (as a chair, vice chair or alternate vice chair), their 5 year term will begin at the point of appointment in the chairing role. In line with the approach in 6.2, the term can be extended for another five years in the chairing role. By exception, the Appointing Authority may further extend the term of a chairing role to ensure continuity of service.

6.5. REC members can attend meetings of other RECs as a co-opted member. This is encouraged as it provides opportunities to learn from other REC's reviews.

6.6. Members can simultaneously be part of more than one REC at a time, with the approval of the Appointing Authority.

6.7. Each REC has 10 full meetings each year. Members are expected to attend as many full meetings as possible, as well as participate in proportionate review and sub-committee meetings.

6.8. REC members are volunteers and are not paid for their role as part of the Research Ethics Service. RECs may not charge an application fee or seek any other financial contribution or donation for considering a research proposal for which their review is required. Members receive no payment for contributing to the review of applications at scheduled meetings or for attending such meetings.

6.9. Expenses incurred during the course of a REC members' duties are reimbursed. These may cover travel, subsistence and care arrangements, but do not cover loss of earnings.

6.10. REC members are required to complete specific training modules to ensure that the approach to reviewing research is consistent across the Research Ethics Service and that members have the right information to support their reviews. Members also participate in ongoing training required in order for them to undertake their role.

6.11. REC members have a duty to maintain confidentiality regarding applications, meeting deliberations and any other information about research applications that they have access to.

6.12. Each Appointing Authority provides indemnity cover for their REC members.

6.13. The meetings and proceedings of RECs and their sub-committees are conducted in accordance with the RES SOPs.

7.0. Requirements of REC review

There is a standard process for applying to a REC for review of proposed research.

RECs review applications in accordance with standards as set out in the RES SOPs.

7.1. Applying for REC review

7.1.1. The application process is set out in guidance for applicants. The REC will take on trust the information provided to them.

7.1.2. The REC and staff from the Appointing Authority/ REC operational lead who supports the REC are able to offer advice and guidance to potential and active applicants. This includes answering queries about whether REC review is required, the application process and the review process.

7.1.3. There is a managed process for allocating REC applications to an appropriate REC, which takes into account what will be convenient to the applicant as far as possible.

7.2. Outcomes from REC review

7.2.1. RECs are required to provide an initial outcome with 30 days of receiving a valid application. If further information is required from the applicant, the REC then has 10 days from receipt of that information to issue its final outcome.

7.2.2. A REC can give one of the following as a decision following review of a research proposal or review of further information:

- Favourable opinion
- Favourable opinion subject to conditions
- Unfavourable opinion

7.2.3. A REC gives a favourable opinion if it is assured that there are no significant outstanding ethical issues relating to the proposed research. REC members receive training and guidance about the issues that they should consider. The training and guidance reflect recognised standards for ethical research, including the Declaration of Helsinki and all applicable legal requirements.

7.2.4. A REC gives a favourable opinion subject to conditions when further information or clarification is required. Applicants will have the opportunity to provide further information to meet the request of the REC, upon which the final opinion will be confirmed.

7.2.5. A REC gives an unfavourable opinion where there are significant and unresolved ethical issues.

Annex A: Functions of Appointing Authorities (all RECs)

An Appointing Authority is an organisation or organisations within each UK nation, that has the responsibility for setting up RECs, appointing members and overseeing the delivery of the Research Ethics Service for the RECs within their remit. For RECs that review CTIMPs, Appointing Authorities operate and work on behalf of UKECA to enable the discharge of its functions. An Appointing Authority:

a. establishes, on the advice of the relevant REC operational lead, RECs to act for the whole or part of their geographical area under its jurisdiction, ensuring there is sufficient provision to meet the demand for REC review; Where the REC will review CTIMPs, the Appointing Authority will seek UKECA recognition of the REC;

b. establishes, on the advice of the relevant REC operational lead, RECs to act in relation to such descriptions or classes of research as are appropriate;

c. varies, on the advice of the relevant REC operational lead, the extent to which its RECs may act under (a) and (b);

d. seeks recognition from UKECA of its RECs if the law requires it;

e. on the advice of the relevant REC operational lead and in collaboration with other Appointing Authorities where appropriate, abolishes RECs it has established, merges them with other RECs and nominates, if required, successor RECs when RECs cease to operate or are abolished or varied under (c) or have their recognition revoked;

f. appoints, with support from the relevant REC operational lead, the members of its RECs in accordance with the UK REC Policy, other operational guidance and the law to ensure that its RECs have the required composition;

g. indemnifies members of its RECs to relieve them of personal liability in respect of their opinions of the ethics of research;(the organisations providing the indemnity for members varies across UK nations)

h. facilitates the provision of funds for members' volunteer expenses and other associated costs for RECs

i. appoints the chairs, vice chairs and alternate vice chairs of its RECs, extends their tenure of appointment and terminates their appointment in accordance with its termination and resignation procedures, the requirements of the UK REC Policy and the REC standard operating procedures;

j. approves, working in consultation and collaboration and with advice from the relevant REC operational lead, standard operating procedures for the regulation of the proceedings and business of its RECs;

k. approves, with advice from the relevant REC operational lead, variations to, or revocation or suspension of, the standard operating procedures of its RECs; and

l. monitors the extent to which its RECs adequately perform their functions, through appropriate performance monitoring notification of their accreditation status and other mechanisms for quality assurance provided by the Research Ethics Service. Quality assurance and accreditation is undertaken by the HRA on behalf of all nations (see Annex E)

The distribution of functions may vary between nations and some of these functions may be performed by REC operational leads (see Annex D) on behalf or instead of Appointing Authorities.

Annex B: Legal requirements for research ethics committee review

Any updates to this list will be published at www.hra.nhs.uk. Unless otherwise stated, all legislation cited refers to the latest available version, as amended by subsequent enactments.

	Extent of legal requirement for research ethics committee review			
Legislation	**England**	**Northern Ireland**	**Scotland**	**Wales**
Adults with Incapacity (Scotland) Act 2000 §51	No	No	Yes	No
Adults with Incapacity (Ethics Committee) (Scotland) (Coronavirus) Amendment Regulations 2020	No	No	Yes	No
Health Service (Control of Patient Information) Regulations 2002, as amended by the Care Act 2014	Yes	No	No	Yes
Human Fertilisation and Embryology (Disclosure of Information for Research Purposes) Regulation 2010	Yes	Yes	Yes	Yes
Human Tissue Act 2004	Yes	Yes	Yes (§45)	Yes
Human Tissue Act 2004 (Ethical Approval, Exceptions from Licensing and Supply of Information about Transplants) Regulations 2006	Yes	Yes	No	Yes
Human Tissue Act 2004 (Persons who Lack Capacity to Consent and Transplants) Regulations 2006	Yes	Yes	Yes	Yes
Human Tissue (Scotland) Act 2006 §40, 48	No	No	Yes	No
Human Tissue Act 2004 (supply of Information about Transplants) Regulations 2024	Yes	Yes	No	Yes

	Extent of legal requirement for research ethics committee review			
Legislation	**England**	**Northern Ireland**	**Scotland**	**Wales**
Approval of Research on Organs No Longer Required for Procurator Fiscal Purposes (Specified Persons) (Scotland) Order 2006	No	No	Yes	No
Independent Health Care Regulations (Northern Ireland) 2005	No	Yes	No	No
Independent Health Care (Wales) Regulations 2011	No	No	No	Yes
Ionising Radiation (Medical Exposure) Regulations 2017	Yes	No	Yes	Yes
Ionising Radiation (Medical Exposure) Regulations (Northern Ireland) 2018	No	Yes	No	No
Medical Devices Regulation 2002	Yes	Yes (Partially)[16]	Yes	Yes
EU Medical Devices Regulation (Regulation 2017/745)	No	Yes	No	No
In vitro Diagnostic Medical Devices Regulation (Regulation 2017/746) (EU IVDR)	No	Yes	No	No
The Medicines for Human Use (Clinical Trials) Regulations 2004 (SI 2004/1031), as amended by the Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2025 (SI 2025/538)	Yes	Yes	Yes	Yes
Mental Capacity Act 2005 §30-34	Yes	No	No	Yes
Mental Capacity Act 2005 (Appropriate Body) (England) Regulations 2006	Yes	No	No	No

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[16] UK MDR 2002 does not govern placing devices on the Northern Ireland market: The UK MDR 2002 continues to apply in Great Britain, but for Northern Ireland, EU MDR and IVDR take precedence. UK MDR 2002 only has residual relevance for transitional EU exit provisions, regulatory oversight and enforcement mechanisms linked to UK law (for example, penalties, MHRA powers, device registration).

Mental Capacity Act 2005 (Appropriate Body) (Wales) Regulations 2007	No	No	No	Yes
Mental Capacity Act 2005 (Loss of Capacity During Research Project) (England) Regulations 2007	Yes	No	No	No
Mental Capacity Act 2005 (Loss of Capacity During Research Project) (Wales) Regulations 2007	No	No	No	Yes
Mental Capacity Act (Northern Ireland) 2016	No	Yes	No	No

	Extent of legal requirement for research ethics committee review			
Legislation	**England**	**Northern Ireland**	**Scotland**	**Wales**
Mental Capacity (Research) Regulations (Northern Ireland) 2019	No	Yes	No	No
The Mental Capacity (Research) Regulations (Northern Ireland) 2019 (as amended)	No	Yes	No	No
Residential Care Homes Regulations (Northern Ireland) 2005	No	Yes	No	No

Annex C: Functions of the UK Ethics Committee Authority (UKECA) for RECs reviewing CTIMPs

Under the Medicines for Human Use (Clinical Trials) Regulations 2004 (SI 2004/1031), as amended by the Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2025 (SI 2025/538), UKECA is defined as “the body responsible for establishing, recognising and monitoring the ethics committees” and consists of the Health Research Authority, the Welsh Ministers, the Scottish Ministers and the Department of Health in Northern Ireland.

The functions of UKECA may, by agreement, be undertaken by any one of the named entities, on behalf of others; or undertaken independently.

In the UK, functions of UKECA are discharged to various people, teams or organisations, which vary across the UK. This includes REC operational leads, which work with RECs to support the review of research applications and the Appointing Authorities, which set up (establish) and appoint members for all RECs including RECs that fall under the remit of the Clinical Trials regulations. These organisations will also provide practical arrangements to support REC membership, including management of member recruitment, training and provision of incidental expenses as appropriate.

The Health Research Authority also performs some functions on behalf of the UK Ethics Committee Authority (UKECA) (see Annex E). The following functions remain the responsibility of UKECA for the purposes of Clinical Trials Regulations:

a. establishing or recognising research ethics committees (RECs) to act for the entirety of the geographical extent of its jurisdiction or such areas thereof as it considers appropriate as part of the UK wide Research Ethics Service
b. establishing or recognising RECs to act in relation to such descriptions or classes of research as it considers appropriate;
c. varying the extent to or relation in which RECs act under (a) and (b);
d. appointing members and chairpersons (by agreement, discharged to Appointing Authorities or other relevant organisations.
e. abolishing or revoking the recognition of RECs which it has established or recognised;
f. monitoring the extent to which RECs adequately perform their functions, including through annual reporting ;
g. approving standing orders and standard operating procedures for the regulation of the proceedings and business of RECs; and
h. approving variations to or revocation or suspension of orders or procedures made or adopted under (f).

Annex D: Research Ethics Committees operational lead function (all RECs)

The REC operational lead of the Research Ethics Service in each nation is responsible for day to day management of the operation and performance of RECs. The REC operational lead:

a. makes arrangements on behalf of Appointing Authorities for the appointment of such operational and other staff for their research ethics committees (RECs) as it considers necessary to enable them to perform their functions;
b. may fund RECs through, or on behalf of, their Appointing Authorities a sum in respect of each financial year equal to the amount of expenditure which it considers may be reasonably incurred by the RECs in that year for the purpose of performing their functions;
c. may pay RECs through, or on behalf of, their Appointing Authorities such travelling and other allowances as it may determine;
d. collaborates with Appointing Authorities on their behalf to establish sufficient provision for REC review, according to a common operational structure so that applications are directed to an appropriate and convenient REC;
e. ensures on behalf of Appointing Authorities that an appropriate system is in place for REC members so as to achieve business continuity, the development and maintenance of expertise within each REC and the regular refreshment of debate;
f. supports Appointing Authorities in ensuring standard practice and a consistent approach, for the benefit of researchers and RECs alike; and
g. handles appeals against the unfavourable opinions of RECs on behalf of their Appointing Authorities.

The distribution of functions may vary between nations and some of these functions may be performed by Appointing Authorities or other organisations (see Annex A).

Annex E: Health Research Authority functions related to the UK Research Ethics Service (all RECs)

In addition to its functions as the Appointing Authority for the Research Ethics Service for England (see Annex A), by agreement and through consultation with the Devolved Administrations, the Health Research Authority:

a. develops and manages a national training programme for REC members and REC operational lead staff and provides resources to support this training;
b. develops, implements and maintains standard operating procedures for RECs and provides advice and support to RECs on procedural issues;
c. develops a quality assurance programme to encourage a consistently high level of service to applicants, including accreditation of RECs, based on regular monitoring and audit of their operation and performance;
d. provides and supports information systems for all nations to utilise to monitor and manage applications and membership.
e. provides guidance and advice to assist RECs in their work and encourage consistency of approach to common issues in research ethics;
f. provides advice on the practical implications of implementing legislation, policy and guidance across the UK;
g. acts for UKECA to provide a national mechanism for operational advice and assistance to RECs recognised for the purposes of Clinical Trials Regulations and to receive, on UKECA's behalf, the REC annual report;
h. acts for UKECA to handle appeals against the unfavourable opinions of RECs in respect of clinical trials of investigational medicinal products;
i. acts for UKECA to transfer to a successor REC the functions of a REC that has ceased to operate or that has been varied, abolished or had its recognition revoked.

Annex F: Enforcement authorities

Any updates to this list will be published at www.hra.nhs.uk.

		Jurisdiction			
Activity	**Relevant Body**	**England**	**Northern Ireland**	**Scotland**	**Wales**
Protection of service users from unsafe or inappropriate care	Care Quality Commission	Yes	No	No	No
Human Embryo Research	Human Fertilisation and Embryology Authority	Yes	Yes	Yes	Yes
Licensed storage of relevant materials for research purposes	Human Tissue Authority	Yes	Yes	No	Yes
Research exposure to ionising radiation	IR(ME)R Inspectorates[23] (Each nation has its own IR(ME)R Inspectorate. This is a function of the Care Quality Commission in England and of the Department of Health (Northern Ireland), the Scottish Ministers and the Welsh Ministers in Northern Ireland, Scotland and Wales.)	Yes	Yes	Yes	Yes
Clinical investigations of medical devices	Medicines and Healthcare Products Regulatory Agency	Yes	Yes	Yes	Yes
Clinical trial of investigational medicinal products	Medicines and Healthcare Products Regulatory Agency	Yes	Yes	Yes	Yes

Annex G: Management information about research ethics committees

The Appointing Authority should maintain up to date information, about the following:

a. the REC's name and contact details;
b. the type of REC, including details of any recognition by UKECA and/or designation by the Research Ethics Service for review of certain types of research proposal;
c. details of the chairs, vice chairs and alternate vice chairs if applicable, as well as staff working with the REC;
d. details of the membership of the REC, including for each member their occupation, lay status where applicable, initial date of appointment, and where applicable the date on which the term of membership expired or the member resigned;
e. the current register of members' interests;
f. the attendance record of each member during the year;
g. a list of full meetings held during the year, including their dates and the number of members attending;
h. the training record of each member; and
i. a list of the applications reviewed during the year, including the final decision reached on each application and the time taken to complete the review (or the current status of the review).

In the case of clinical trials of investigational medicinal products, the Medicines for Human Use (Clinical Trials) Regulations 2004 amended by the Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2025 states that where an ethics committee gives an opinion in accordance with this regulation, it must publish the conclusion of that opinion, whether favourable or unfavourable. This is done via the HRA website.

Each Appointing Authority will have guidance in place in terms of how documentation in relation to membership and research applications is managed, archived and destroyed.

Glossary

Anonymous / (effectively) anonymised information

Information that has undergone an anonymisation process and, in line with the Information Commissioner's Office Anonymisation Guidance (March 2025), has been assessed as no longer reasonably identifiable in context, and is therefore treated in law as anonymous (that is, effectively anonymised) information.

Appointing Authority

The organisation or organisations that have responsibility for establishing RECs, appointing and indemnifying members, seeking recognition from UKECA if required by law, and monitoring REC performance.

Clinical Trials of Investigational Medicinal Products (CTIMPs)

Any investigation in human participants, other than a non-interventional trial, intended to discover or verify the clinical, pharmacological or other pharmacodynamic effects of one or more medicinal products (as defined in regulation 2 of the Human Medicines Regulations 2012); to identify any adverse reactions to one or more such products, or to study absorption, distribution, metabolism and excretion of one or more such products with the object of ascertaining the safety or efficacy of those products.

Declaration of Helsinki

The World Medical Association developed the Declaration of Helsinki as a statement of ethical principles for medical research involving human participants following the atrocities by physicians conducting unethical medical research during the Second World War. Since the World Medical Association first adopted the Declaration of Helsinki in 1964, researchers, ethics review committees, and governments around the world now rely on the document's high-level enduring principles to guide fundamental ethical considerations and decision-making.

Devolved Administrations

Governments of Scotland, Wales, and Northern Ireland responsible for health and social care services in their nations.

HSC

Health and Social Care, the name for health services in Northern Ireland

Human Tissue Act 2004

UK legislation governing removal, storage, and use of human tissue for research and other purposes.

IR(ME)R

Ionising Radiation (Medical Exposure) Regulations.

NHS

National Health Service, the name for health services in England and Wales and health and social care services in Scotland.

Proportionate Review

Streamlined review process for research proposals presenting no material ethical issues, conducted by a sub-committee of the REC.

Quorate Meeting

A REC meeting attended by at least five members, including the chair and one lay member, as required for valid decision-making.

Research Ethics Committee (REC)

Independent group of volunteers reviewing research proposals to ensure ethical standards and participant protection. Note this term specifically relates to the UK Research Ethics Service and should not be interpreted as referring to any other body that reviews the ethics of research.

Research Ethics Service (RES)

UK-wide system comprising RECs and Appointing Authorities enabling ethical review of research proposals.

REC Operational Lead

Staff responsible for supporting REC operations, managing applications, coordinating meetings, and advising applicants. The staff who work with RECs day to day. The organisations that host these staff may vary across nations.

Sponsor

Individual, company, institution, or organisation who takes responsibility for the initiation, management, and financing of a clinical trial or research project.

Standard Operating Procedures (SOPs)

Detailed instructions developed by the HRA and the Devolved Administrations to ensure consistency in REC processes across the UK, including application review and decision-making. Common working practices promote efficiency and enable RECs to work together as part of a consistent Research Ethics Service. Published standards enable transparent accountability. SOPs take account of applicable laws and national guidance and advice as well as reflecting relevant internationally recognised principles and standards.

UK Ethics Committee Authority (UKECA)

Statutory body that covers functions as detailed in Annex C, is responsible for recognising RECs for CTIMP review and overseeing compliance with Clinical Trials Regulations.