

Summary output resource

Research Ethics Committee (REC) Workshop: Reviewing Clinical (non-NHS) research

14 September 2026

Executive summary

UKRIO's new series of six workshops, hosted by Prof Simon Kolstoe, has been designed specifically for Research Ethics Committee (REC) members, REC Chairs and those professionals supporting RECs. The first of these sessions brought colleagues together to discuss ethics reviews in clinical (non-NHS) research, providing a dedicated, trusted space to discuss existing challenges, consider emerging issues and share approaches.

In the UK, the National Health Service (NHS) RECs (coordinated through the Health Research Authority (HRA)) review specific types of health and social care research to provide an independent opinion on whether the research is ethical. Determining which research is in or out of scope for NHS RECs can be challenging. This session explored the background of clinical research and the depth of governance surrounding this highly regulated area. The discussion highlighted the elements of research projects that determine when NHS/HRA review might be required, and when projects should be reviewed elsewhere, such as by a research organisation's internal REC.

This summary builds on the training session by bringing together key resources and further reading to serve as a useful reference for ongoing learning and application.

Quick guide

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Key message

Determining whether research requires NHS REC review is often highly technical and cannot be reduced to simple definitions or labels. Experience and professional judgement are frequently required to reach an appropriate decision.

Some projects, including audit, service evaluation, surveillance, quality improvement and patient involvement activities, would not normally require NHS REC review.

However, the absence of an NHS REC requirement should not be taken to mean that ethical issues are absent. Such projects may still raise important ethical, legal and reputational considerations and therefore warrant review through an organisational REC or other appropriate governance process.

Key training themes

1. Determining whether NHS REC review is required

Project categories often considered outside NHS ethics review requirements

For historical reasons, non-research or research-related activities are generally considered by the NHS not to require ethics review. Some of these activities include:

- Service evaluation
- Audit
- Patient and public involvement (PPI)
- Health surveillance
- Quality improvement
- Needs assessment
- Operational research
- Market research
- Wargaming exercises

Attendees explored other circumstances in which the need for ethics review may be debated, including projects using anonymous data, anonymised samples, research involving only staff or professionals or analysing historical records.

It was acknowledged that administrative burden, delays, regulatory complexity and negative perceptions of the ethics review process are perceived barriers to seeking ethics review.

Furthermore, a key theme of the discussion was that [the absence of a requirement for NHS research ethics review does not necessarily mean that ethics](#)

issues are absent, and consideration should be given to whether review by an organisational ethics committee may be appropriate.

The discussion drew on literature exploring challenges and critiques of ethics and governance review processes, including:

- [Entangled in an ethical maze](#) ¹
- [Research approvals iceberg: how a 'low-key' study in England needed 89 professionals to approve it and how we can do better](#) ²
- [The Case against Ethics Review in the Social Sciences](#) ³
- [Procedural Ethics vs Being Ethical: A Critical Appraisal](#) ⁴
- ['The ethics approval took 20 months on a trial which was meant to help terminally ill cancer patients. In the end we had to send the funding back': a survey of views on human research ethics reviews](#) ⁵

Lessons learned from COVID-19

The Coronavirus disease (COVID-19) pandemic highlighted weaknesses in existing approaches to classifying research and related activities, including:

- Blurred boundaries in classifying research, surveillance and service activities, creating uncertainty about the appropriate regulatory pathway.
- Difficulty applying existing HRA classification tools and guidance to rapidly evolving public health activities.
- A need for proportionate and rapid review processes.

In response, the HRA and Medical Research Council (MRC) revised the decision-making framework underpinning the HRA's research-classification tools to clarify the distinction between research and other activities.

Further reading can be found in the following paper, [Is my project research? Determining which projects require review by a research ethics committee](#) ⁶.

Updates to the HRA/MRC decision tools

The two tools that researchers must use for determining whether their projects require NHS REC review are:

- [Is my study research?](#) ⁷, the decision tool based on the [Defining research table](#).
- [Do I need NHS REC review?](#) ⁸, the decision tool that helps researchers determine whether their project requires NHS REC review.

The HRA [algorithm](#) can be used to complement the above tools.

If a project is not classified as research, NHS REC review is not normally required. However, other forms of governance or ethics reviews may still be necessary by sponsoring organisations (the organisation responsible for the research). The workshop emphasised that, rather than focusing solely on definitions or labels, organisations should ask:

"Is this the sort of project that requires research governance and ethics review, and if so, by whom?"

This reframing of the discussion is important in determining where legal, ethical and social accountability lies. It may be that the activity is covered elsewhere, and that accountability is already addressed through other mechanisms; for example, service evaluations are often regarded as part of clinical practice.

2. When NHS REC review is required by law

Legal implications of misclassification

The workshop emphasised that there can be legal consequences if projects are misclassified. Under the HRA decision tool, a "yes" response to certain questions indicates a legal requirement for NHS REC review.

As detailed in Section B of the [algorithm](#), the questions are designed to identify research that falls within the scope of legislative frameworks requiring NHS REC review. Importantly, these questions apply irrespective of whether any potential research participants are patients or service users within the services for which the UK Health Departments are responsible. This is a consideration that is often misunderstood when assessing the need for NHS REC review.

Several legislative frameworks were identified that may trigger a legal requirement for NHS REC review where the research project falls within the scope of the legislation.

Clinical trials legislation

[The Medicines for Human Use \(Clinical Trials\) Regulations 2004](#)⁹ as amended by the [Medicines for Human Use \(Clinical Trials\) \(Amendment\) Regulations 2025](#) set out the requirements of how clinical trials of investigational medicinal products (CTIMPs) are approved, conducted, monitored and reported¹⁰.

For reference, the following [algorithm](#) can be used to assist whether the project meets the definition of a CTIMP. Where a study is identified as a CTIMP, NHS REC review is required by law.

Mental Capacity

The [Mental Capacity Act \(2005\)](#) ¹¹, alongside related legislation in the devolved nations ¹², was highlighted to contain specific provisions governing research involving adults (people aged 16 and over) who lack capacity to consent, and where the research is not a CTIMP. Therefore, if the research involves adult participants who lack capacity to consent for themselves, NHS REC review is legally required.

Human Tissue

The [Human Tissue Act 2004](#) ^{13,14}, together with related legislation in the devolved nations, was discussed in relation to research involving storage and use of relevant material.

NHS REC review is legally required in certain circumstances, including where relevant material is stored without an appropriate Human Tissue Authority (HTA) licence, where proposed research is outside the scope of donor consent, or where human DNA is analysed without appropriate consent.

Definitions and examples of relevant material are available in the [HTA Guidance](#). The HTA is a regulatory body that helps ensure human tissue is used safely and ethically with proper consent ¹⁴.

Ionising Radiation

With reference to [The Ionising Radiation \(Medical Exposure\) Regulations 2017](#) ¹⁵, NHS REC review is required for projects that involve exposure to ionising radiation. This includes the following procedures (though not an exhaustive list): CT scans, DXA scans, general radiography, interventional imaging, mammography administration of radioactive substances (e.g. for nuclear medicine and PET/CT), radiotherapy or dental radiography.

However, research involving procedures such as Magnetic Resonance Imaging (MRI) or ultrasound investigations are not in scope as these do not involve ionising radiation ¹⁶.

Medical Devices

[The Medical Devices Regulations 2002](#) ¹⁷ is administered by the Medicines and Healthcare products Regulatory Agency (MHRA), which regulates medical devices and medicines in the UK. Where a medical device is not UKCA- or CE-marked ⁱ, or where it is intended to be used for a medical purpose outside the scope or intended purpose of its UKCA or CE marking (i.e. modified or off-label use), NHS

ⁱ UK Conformity Assessed (UKCA) and Conformité Européenne (CE) markings indicate that the manufacturer declares the product complies with applicable regulatory requirements, including relevant safety, health and environmental protection requirements ²⁹.

REC review is required and MHRA notification may be required, subject to any applicable exemptions.

See the relevant [guidance](#) and accompanying [flow chart](#) to determine whether MHRA notification is required. The workshop highlighted a commonly misunderstood flowchart process, specifically question 3: “Is the device being used for a medical purpose in the study?”.

Whether a device is being used as a research tool rather than for a medical purpose significantly affects the applicable regulatory route. Considering the device’s intended use in the study and consulting the MHRA guidance is advised.

For further support, sponsors or researchers can email info@mhra.gov.uk with an annotated flow chart, showing and explaining the decision pathway ¹⁸.

Control of Patient Information (COPI)

The workshop discussed [the Health Service \(Control of Patient Information Regulations\) 2002](#) (COPI Regulations) ¹⁹, made under Section 251 of the National Health Service Act 2006 ²⁰. These provide a legal framework for the use of confidential patient information without consent, such as for medical research or public health activities. Bound by regulations, such research (processing confidential information of patients or service users by researchers outside of the care team without consent) requires NHS REC review.

It was noted that compliance with data protection legislation requirements does not automatically mean that all confidentiality requirements have been met, even in cases where UK GDPR may permit researchers to process such data. Two key provisions were noted:

- Regulation 3 of COPI permits the processing of confidential patient information for certain public health purposes, including disease surveillance, monitoring and control.
- Regulation 5 of COPI may permit the use of confidential patient information for medical research purposes without consent, subject to the relevant requirements and approvals. Applications are reviewed by the [Confidentiality Advisory Group \(CAG\)](#), which provides advice to the HRA to inform the approval decision. NHS REC review is also required.

Human Fertilisation and Embryology

The [Human Fertilisation and Embryology \(Disclosure of Information for Research Purposes\) Regulations 2010](#) ²¹ are also relevant when determining whether NHS REC review is required by law. Research involving the use of disclosable protected information on the [Human Fertilisation and Embryology Authority \(HFEA\)](#) register without consent requires NHS REC review.

Importantly, NHS REC review may be required by policy even where it is not required by law. The HRA decision tool, supported by Section C of the algorithm, identifies such circumstances in which review requirement applies.

3. Different approaches to ethics and governance review

Ministry of Defence Research Ethics Committee (MODREC)

Within MODREC, it was noted that the definitions of research and related activities are broadly aligned with those used by NHS RECs. MODREC was also described as broadly equivalent to an NHS REC and can therefore review CTIMPs and other studies meeting the criteria for NHS REC review.

Where MODREC review is required, a separate NHS REC submission would not normally be expected. This could apply to MOD-funded research and studies involving MOD-employed staff or personnel, including military doctors or clinicians as participants in the study.

UK Health Security Agency (UKHSA)

The workshop reflected on the UKHSA's approach to ethics review. Attendees heard that [UKHSA](#) adopts a pragmatic approach whereby, if a project needs NHS REC review or has already been reviewed by a university REC, then the Agency is generally willing to accept that review rather than require an additional review process.

It was noted that the UKHSA Research Ethics and Governance Group (REEG) is also interested in reviewing certain service evaluations and audits, particularly where vulnerable populations are involved, where there is potential for additional distress or anxiety, or where public health issues are involved, such as those related to COVID-19. This extends beyond the traditional remit of research ethics review and illustrates that activities not classified as research may nevertheless raise important ethical considerations that warrant formal review.

Professional and organisational accountability

What is “business as usual (BAU)”?

Some activities may not require ethics review, because they fall within established professional roles and are governed by existing professional standards and accountability frameworks. Examples included:

- Clinical practice regulated by professional regulators and bodies, including the [Academy of Medical Royal Colleges](#), [General Medical Council](#), [Health & Care Professions Council \(HCPC\)](#) (who regulate 15 health and care professions), and other relevant bodies.

- Chartered professions and professional bodies operate under established codes of conduct and have their own frameworks for professional and ethical standards. As such, many BAU activities may be considered service evaluation, routine practice, or other forms of non-research activity.

For activities outside these regulated areas discussed above, ethics review requirements in the UK are typically determined by the sponsoring organisation's governance policies. However, regardless of any review requirements by professional or regulatory bodies, the research sponsor remains legally accountable for all activities. Any review process should be proportionate to the level of risk and avoid unnecessary duplication of oversight.

4. The range of ethical issues that can arise

Background into Research Ethics and defining research

The workshop explored the historical development of research ethics, including:

- The distinction between research and clinical care, recognising the [Hippocratic Oath](#) ²² as an ancient code of medical conduct.
- The early milestones in research ethics and informed consent development via the unethical experiments of [Dr Albert Neisser](#).
- The influence of the [Nuremberg Code](#) ²³ and [Declaration of Helsinki](#) ²⁴.
- Contemporary definitions of research used by the [UK Policy Framework for Health and Social Care Research](#) ²⁵ and OECD's [Frascati Manual 2015: Guidelines for Collecting and Reporting Data on Research and Experimental Development](#) ²⁶. The OECD guidelines describe research and development through five key characteristics: novelty, creativity, uncertainty, systematicity, and transferability and/or reproducibility. It also distinguishes between basic research, applied research, and experimental development.

Reputation, public trust and scrutiny

The workshop stressed the importance of public confidence in research, highlighting the risk of sensationalist or inaccurate media coverage and the significance of considering how research may be portrayed by newspapers, online news outlets and social media platforms. Evidence of an ethics review can be a necessary defence, regardless of the outcome of the NHS decision tools. This is one important reason for internal (organisational) ethics reviews.

Researchers and research sponsors should assess whether their work complies with established standards of good research practice and whether it is ethically

justifiable, legally compliant and socially responsible. They should also consider how the work may be perceived by relevant stakeholders, including professional peers, participants, affected communities and the wider public.

In addition, organisations should be satisfied that the governance arrangements supporting the activity are robust, proportionate and capable of withstanding reasonable public and professional scrutiny. Given the importance of public trust to research progress, the potential impact of a project on that trust should be considered as part of decision-making.

Where appropriate, this may justify additional safeguards, such as by ethically reviewing non-research activities.

Other standards for research ethics and integrity

[The Concordat to Support Research Integrity](#) is the UK's governing document on research integrity, including requirements on specific aspects of research integrity such as research culture, research ethics and governance of research projects. It is a 'framework by which the UK research community, and those collaborating with them, can support the trustworthiness of UK research' ²⁷.

[Research Ethics Support and Review in Research Organisations](#) is a joint publication by the UK Research Integrity Office (UKRIO) and the Association of Research Managers and Administrators (ARMA) to support the research community in achieving high standards of research ethics review. The revised 2026 version is to be published shortly.

5. Complex and practical issues discussed

Capacity, dementia and longitudinal studies

Attendees raised common issues and concerns regarding longitudinal studies that may recruit participants with mild or moderate dementia who initially have capacity but lose capacity during the study. The concern was that such a study would have initially been reviewed at a university (or research organisation) REC, whereas, as aforementioned, when participants lack capacity, an NHS REC is required to ethically review that project.

Useful takeaways were noted, such as that capacity management needs built-in monitoring throughout the study, not just at recruitment.

- Capacity is not a simple yes/no concept and capacity can fluctuate.
- Capacity assessments need to be undertaken by appropriately trained staff.
- UK law assumes capacity unless evidence suggests otherwise.

- If participants lose capacity in such a study, they generally cannot continue under that approval route.

Researchers, in consultation with relevant research ethics, integrity and governance professionals, may need to seek NHS/HRA approval if, during the course of the research, the provisions of the Mental Capacity Act become relevant.

Research involving NHS Staff

The absence of a requirement for NHS REC review does not necessarily mean that no review or approval is required by the HRA. Research governance responsibilities may still apply, and this is where confusion often arises.

Considering that:

- Research involving NHS staff as participants may be exempt from NHS REC review.
- It may still require governance review. Using NHS resources, privileged information or recruiting NHS staff through NHS systems will sometimes require HRA approval.
- A common source of confusion is the distinction between ethics review and governance review.

Integrated Research Approval System (IRAS) is a portal used for numerous review processes, not just ethics review. IRAS defines a 'staff study' as a:

- Non-interventional research project;
- that identifies potential research participants from pools of NHS and Health and Social Care (HSC) organisations, in their capacity as NHS/HSC employees – recruited because of their employment status as part of the NHS/HSC workforce;
- alongside no participant recruitment of NHS patients, carers or family members ²⁸.

Recruitment through non-NHS pathways

The workshop considered situations where researchers recruit participants through non-NHS routes rather than NHS pathways.

Key messages included:

- Alternative recruitment routes are not inherently unethical.
- Many countries conduct health research without NHS-like systems.
- The critical issue is whether research design is scientifically justified.

- Study design should be scientifically and ethically justified, rather than driven primarily by attempts to avoid particular governance or review requirements.

International research

Issues were raised regarding complex projects involving UK research organisations, NHS patients, overseas research sites, foreign ethics systems and multiple approvals. International projects may require:

- Research Organisational / University ethics review
- NHS/HRA review
- Local ethics approval
- Gatekeeper permissions

When reviewing international research, REC members and supporting staff may encounter broader questions concerning cultural contexts, local ethical norms, power dynamics in global research partnerships or questioning the legitimacy of Western ethics committees reviewing overseas research.

The decolonisation of ethics review is a movement in academic research to improve research integrity. Readers interested in these issues may wish to consult UKRIO's report on the topic, [Ethical issues in international and interdisciplinary collaborations](#).

Borderline cases and classifications

Issues were raised regarding circumstances in which projects may be classified as surveillance rather than research. Factors within a proposal that may indicate a project constitutes research include:

- The collection of additional biological samples
- DNA sequencing
- The introduction of an intervention beyond routine practice
- The randomisation of participants to different treatments
- An intention to generate generalisable knowledge

A key takeaway was to [always examine objectives, outputs and intended use of findings, rather than project labels](#).

Researchers can contact the HRA Queries Line via email (queries@hra.nhs.uk), in scenarios where they are unsure of the tool's result or have complex questions. If the sponsoring organisation is uncomfortable with the classification of a project

and the subsequent regulatory routes, as it is their legal responsibility, they should also contact the HRA.

Seeking this reassurance strengthens good practice in research and upholds organisational reputation. Furthermore, workshop participants reflected that in concerning scenarios where harm, disputes, or other adverse events arise, organisations may be required to demonstrate the strictest compliance to any relevant governance and approval processes in order to meet legal or insurance requirements, proving paramount to support potential insurance claims.

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Acknowledgement

UKRIO would like to thank all participants for their attendance and contributions to the workshop. The workshop was designed by Prof Simon Kolstoe, and this summary has been prepared by UKRIO based on the discussion.

Transparency Statement on AI Use

During the preparation of this summary, UKRIO used Microsoft Copilot (Version 1.25094.120.0), operating under Enterprise Data Protection, to assist in the identification and summarisation of themes from an audio transcript of the discussion. All outputs were reviewed, edited and verified by UKRIO staff, who retain full responsibility for the accuracy, interpretation and content of this publication.