

University Ethics Committee

Submitting an ethics application to an NHS Research Ethics Committee

If your research project involves the NHS it is very likely you will need some kind of NHS approval, such as ethics approval, Research and Development (R&D) approval, information governance approval or study registration.

This includes research with NHS:

- patients, their data or samples
- staff, their data or samples
- sites
- data extracted from or through clinical systems.

Even 'data only' studies, which do not involve direct contact with patients or staff, will often require approval of some kind.

The Research Ethics and Governance Manager in RKES can offer advice on sponsorship approval and how to complete the IRAS form and other NHS requirements, and should be contacted early in the procedure. NHS applications cannot be submitted without sponsorship approval so researchers should factor in time for this process when considering submissions.

Ethics approval is required from the NHS for most but not all investigations in which it is involved. Details of the circumstances in which NHS ethics approval is required, and information on the application procedure, can be found on the <u>Integrated Research</u> <u>Application System</u> (IRAS) website at www.myresearchproject.org.uk.

Investigations involving NHS staff or undertaken on NHS premises do not necessarily require NHS ethics approval. However, these studies are likely to require other NHS approvals together with University ethics approval. Please contact <u>ethics@strath.ac.uk</u> for more information.

Researchers are not required to submit a University ethics application as well as an IRAS application. Once NHS approval is in place, the UEC Convener will likely endorse the application on behalf of the UEC.

Non-research projects

Service evaluations, audits and similar involving the NHS may not require NHS ethics review, but will likely need to be registered or have R&D approval. The University considers that most service evaluations contain elements of research and so DO require University ethics review, please contact <u>ethics@strath.ac.uk</u> for more information.

Student research projects

The Health Research Authority (HRA) do not permit NHS Research Ethics Committee (REC) review of independent undergraduate and masters-level student projects. Students seeking experience in this area are encouraged to consider alternatives, such as getting involved with active projects or research programmes led by an experienced Chief Investigator.

You can read more about this on the <u>HRA's student research page</u>. : <u>https://www.hra.nhs.uk/planning-and-improving-research/research-planning/student-research/</u>

Approval types in more detail

NHS Research Ethics Committee (REC) approval

Work which is classed as 'research' will most likely require NHS ethical review (often also called Research Ethics Committee or REC review).

There are two types of NHS ethics review - proportionate review and full review:

- Proportionate review the proportionate review service (PRS) provides an accelerated, proportionate review of research studies that raise no material ethical issues. Studies that have no material ethical issues have minimal risk, burden or intrusion for research participants. Researchers do not need to know if their study is suitable for proportionate review in advance. The <u>Online Booking Service</u> asks a number of questions to establish if an application should be booked for a Full or Proportionate Review meeting. Upon receipt, the REC Manager undertakes a thorough pre-screen of the application to gauge its PR suitability.
- Full review any study not allocated to proportionate review will undergo a full review.

The HRA have two decision-making tools to help you decide whether you need NHS ethics approval:

- <u>Is my study research?</u>
- Do I need NHS REC review?

These tools are a good indicator of whether REC review is required but we advise that you always confirm this as sometimes a study not meeting these criteria can still require review. There is also a <u>document describing the algorithm</u> underpinning the 'Do I need NHS REC review?' tool which goes into more detail.

These tools also only give an indication of whether an NHS REC review is required - you may still need a University ethics review or NHS R&D or information governance approvals.

When might you not require an NHS REC review?

Studies involving NHS or social care staff

Studies that only involve NHS or social care staff, and not patients or service users only require NHS REC review if the research raises ethical issues.

Studies using data collected as a part of routine care or for research purposes

You will need NHS ethics approval for research using this type of data unless:

- the data has already been collected by a member of the patients' care team as part of routine care (without the intention that the data would be used for research) and individuals are not directly or indirectly identifiable to the researcher or any other parties involved with the research
- the data you receive is completely anonymised and already in the public domain
- the data you receive come under an existing ethics approval, such as a 'blanket' approval held by a data repository.

Data collected for a research purpose requires NHS ethics review even if collected by a member of the patients' care team or if the researcher will receive the data in anonymised form. If data are anonymised such studies will normally qualify for proportionate REC review.

The sponsor or researcher can also choose to request an NHS REC review for a study if they have any concerns, for example, around ethical issues, consent, or identification of individuals, though this is normally expected to only be in exceptional circumstances.

Studies involving social care

Where the study will take place only in Scotland, NHS REC review is not required for research in the social care setting, unless:

- the study involves adults unable to consent to themselves
- the study involves NHS patients or a mix of NHS patients and social care users.

Studies taking place elsewhere in the UK may require NHS REC review.

Guidance and other approvals

Seek guidance and confirmation from the relevant NHS boards' research and development department (or equivalent if social care). You can also obtain advice from an NHS REC or the University's Research Ethics and Governance Manager at ethics@strath.ac.uk.

NHS Research and Development approval

Studies involving NHS patients, staff or sites require NHS R&D approval, even if NHS ethics approval is not required. To obtain NHS R&D approval, you must apply via <u>IRAS</u>

Guidance on all aspects of the IRAS application system may be obtained from the Research Ethics and Governance Manager by emailing ethics@strah.ac.uk.