Ethics Submission

Trial Approvals Phase

Ethics Submission follows the CTA Submission station and precedes the R&D Submission station. The process occurs in parallel with CTA Submission and R&D Submission. Ethics Submission is a legal requirement which is relevant to all trials. This station is part of the 'trial approvals phase' group of stations.

Ethics Submission

The Health Research Authority (HRA) promotes and facilitates ethical research that benefits participants and wider society. A core function of the HRA is the Research Ethics Service (RES), which coordinates the ethics review of research projects.

All Clinical Trials of Investigational Medicinal Products (CTIMPs) and IMP/Device trials require ethics review. The amended Clinical Trials Regulations have changed the constitution and attendance requirements for Research Ethics Committees (RECs) reviewing CTIMPs. The HRA provides further information.

The Approval Process

For CTIMPs, the Combined Review process is used to obtain both a Clinical Trial Authorisation (CTA) from the MHRA and a favourable opinion from a Research Ethics Committee (REC). Applications are submitted through the Integrated Research Application System (IRAS). Revised processes and timelines aim to

support a more efficient and proportionate review. A step-by-step guide helps sponsors and, for CTIMPs, researchers submit their application via the new part of IRAS.

For IMP/Device trials, the MHRA provides specific guidance on submitting an application.

For ongoing trials submitted before 28 April 2026, transitional arrangements apply.

Trials Requiring Expert Advice

The MHRA and the REC may consult a relevant committee or specialist group on an application for clinical trial approval before issuing a decision. The MHRA provides details on when expert advice may be required.

Notifiable Trials

The amended Clinical Trials Regulations make provision for Notifiable Trials, which, if they meet the inclusion/exclusion criteria and other additional criteria (.PDF), will receive automatic MHRA approval within 14 days of validation, and should receive REC approval, or approval with conditions, within 30 days of validation.

Lapse of Approvals

Under the amended Clinical Trials Regulations, if a CTIMP recruits no participants within 2 years, its approval lapses. The sponsor must end the trial and notify in writing by that date; however, the sponsor may apply for extensions as described on the HRA website.

Public Involvement

RECs review the applicant's public involvement plans as part of the ethical review*. The HRA offers a checklist to ensure public involvement informs this process, along with guidance. The NIHR also provides comprehensive public involvement resources, training, and briefing notes.

* *Ethical approval is not required to conduct public involvement activities.*

Review of Gene Therapy Projects

Applications for ethical approval of a gene therapy trial must be made to the Gene Therapy Advisory Committee (GTAC), the national REC for gene therapy clinical research, in accordance with the Clinical Trials Regulations. Details of the GTAC application process are available on the HRA website.

Research Transparency

The HRA publish research summaries for all new studies approved by an NHS REC, typically within 90 days of the REC opinion being issued. Further information and access to published summaries are available on the HRA website.

Non-CTIMPs

Changes to the way non-CTIMP trial approvals are processed from 28 April 2026 are available on the HRA website. In addition, the HRA has published guidance that includes information on the duration of ethical approval.

Further Reading

- HRA: Step-by-step guide to using IRAS for combined review
- MHRA: Guidance for medicines trials requiring advice from expert advice from a specialist group or committee.
- MHRA webinar: Implementing the new Clinical Trial Regulations
- MHRA Guidance: Applying for approval in the UK
- Directory of Research Ethics Committees: A search function to help identify an appropriate REC for a particular study type and its meeting dates.
- Medical Research Council: Good Research Practice Policies and guidance that support the ethical conduct of clinical trials.