Routemap

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) facilitates ethical research that is of potential benefit to participants. The Research Ethics Service (RES) is a core function of the HRA. Whilst the majority of research conducted within the NHS requires ethical review, there are some exceptions that can be identified by using the HRA Decision Tool.

In the UK, applications should be made using the Integrated Research Application System (IRAS) (see also IRAS station for more information).

For CTIMPs and combined trials of an investigational medicinal product and an investigational medical device (IMP/Device trials), there is now a single application for both Clinical Trial Authorisation and Research Ethics Committee (REC) opinion. Applications for combined review are prepared and submitted in a new part of the Integrated Research Application System. The HRA website contains information on the combined review process.

Patient and Public Involvement (PPI)

Ethics Committees will consider a researcher's plans for public involvement as part of the ethical review process. Specific ethical approval does not need to be sought when involving the public in trial design and management activities. The Health Research Authority (HRA) has developed a statement to provide further clarity.

Ethical Approval of Projects Involving Gene Therapy and certain other types of research

Applications for ethical approval of a gene therapy clinical trial must be made to the Gene Therapy Advisory Committee (GTAC) which is the national REC for gene therapy clinical research according to regulation 14(5) of The Medicines for Human Use (Clinical Trials) Regulations 2004. Details of the application process can be found on the HRA pages for the Gene Therapy Advisory Committee.

The MRC hosts The Experimental Medicine Toolkit and resources supporting research using health data and human tissue samples.

Research summaries

Since 2014, the HRA have been publishing research summaries of all new research approved by a NHS REC, usually within 90 days of the REC opinion. Further information can be found on the HRA web pages.

Further reading:

- HRA: Research Ethics Service (RES).