

What is a Research Ethics Committee?

A Research Ethics Committee (REC) is an independent body whose responsibility is to verify that the safety, well being and human rights of subjects in a particular Clinical Investigation are protected.

When should a Research Ethics Committee be informed of a Medical Device Clinical Study?

Research Ethics Committee **approval** must be obtained **before** the **commencement** of a Clinical Investigation. In the UK, Research Ethics Committee Approval is required for all Clinical Investigations and Post-Marketing Surveillance Studies (PMS) which do not meet the defined criteria as outlined by the UK National Research Ethics Service (NRES).

Process for Obtaining Research Ethics Committee Approval

Research Ethics Committee approval consists of applying to a designated medical device main REC and the local REC for each participating investigational site. There are currently 13 RECs flagged for medical devices:

- Cambridge REC
- Huntington REC
- King's College Hospital REC
- Leeds West REC
- Lothian 2 REC
- Multi Centre REC for Scotland Committee A
- Northern & Yorkshire REC
- North Sheffield REC
- Royal National Orthopaedic Hospital REC
- South Birmingham REC
- South Manchester REC
- South West REC
- West Midlands REC

Site Specific Assessment

In addition to gaining REC approval from a main REC, Site Specific Assessment (SSA) should be conducted at each participating investigation site to grant investigation site approval. The main REC reviews the ethical aspects of the Clinical Investigation and the SSA addresses the local issues at that investigation site. The submissions to the main REC and the local REC for the SSAs may take place simultaneously. The main REC will not usually give approval until they have received a letter of no objection from one SSA. Approval for each investigation site will be issued by the main REC directly to the Coordinating Clinical Investigator and not by each investigation site. SSA is not required for PMS studies which fit the NRES criteria.

Research Governance Approval

In the UK, all research involving NHS patients requires local NHS management approval. This is achieved via the hospital's Research & Development (R&D) department.

Research Ethics Committee Submission

The REC application form (including a section combining SSA and R&D approval) can be found at www.myresearchproject.org.uk using the Integrated Research Application System (IRAS). Guidelines on completing the application form; details of specific requirements, documentation required for the application; submission deadlines and timescales for approval can also be found at this website. The following documents are usually required for submission:

- **Clinical Investigation Plan** including appendices or amendments (6 copies).
- **Clinical Investigator's Brochure**, including any amendments (3 copies).
- **Patient Information Sheet, Informed Consent Form and GP letter.**
- **Product leaflets, questionnaires and diary cards.**
- Details of **compensation** for subjects and any **insurance** or **indemnity** cover provided.
- Details of the **financial arrangements** between the Sponsor and the Clinical Investigator, other hospital departments or the subjects.
- **Curriculum vitae** of the Clinical Investigator.
- Completed IRAS **application form.**

Once an application is ready to send, the Central Allocation System should be contacted by phone (0845 270 4400) to receive a REC reference number and confirmation which main REC will be reviewing the Clinical Investigation documentation. At this time notification of the date of the REC meeting will be received. The REC reference number must be entered on the application form prior to submission.

Research Ethics Committee Approval

Research Ethics Committee approval is normally required before Competent Authority approval, but in the UK, both may be submitted in parallel. REC approval will take the form of a letter. However this may stipulate certain conditions to be met or further information to be supplied prior to giving approval. The timescale for a decision may be up to 60 days.