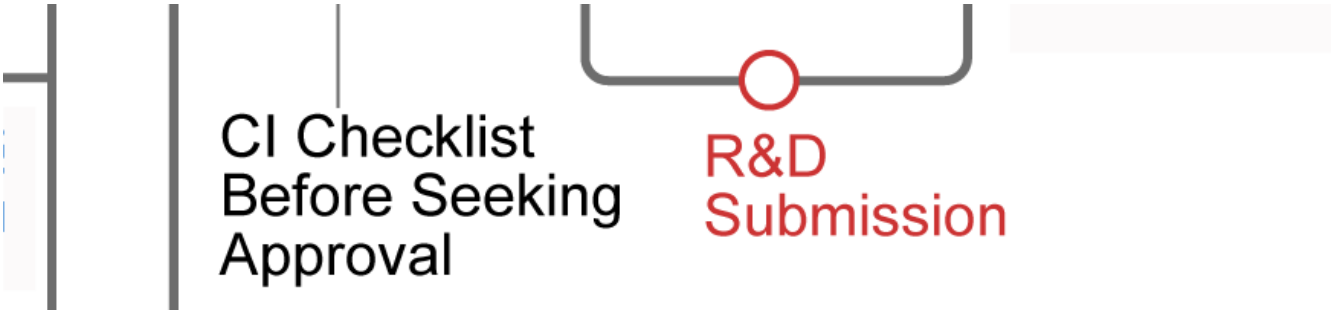
Routemap

R&D Submission



Trial Approvals Phase

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

Clinical trials conducted on the premises of an NHS organisation, with NHS patients or with NHS staff, require permission from the local NHS R&D office. Coordinated systems for NHS R&D review are in place across the UK. The system available will depend on where the lead NHS R&D office is based (the part of the UK where the Chief Investigator is located).

HRA and Health and Care Research Wales (HCRW) Approval are the processes for applying for approvals for all project-based research in the NHS taking place in England or Wales. Detailed guidance on the application process for HRA approval can be found here. In Scotland, the Permissions Coordinating Centre offers a coordinated process for obtaining Scotland-wide NHS R&D Permission for all NHS research studies. In Northern Ireland, Local HSC Trust Site Set Up is described here (.PDF).

The UK Local Information Pack is the UK-wide mechanism for setting up participating NHS/HSC organisations. It is used for all studies with participating NHS/HSC organisations.

Non-NHS Sites: Where studies do not involve the NHS (i.e., patients, their data, tissues or NHS resources) then application for NHS permission is not required. In addition, the investigator should be aware of any local policies relating to the gaining approval from their non-NHS sponsor/host organisation and requirements for non-NHS SSI Forms to be provided to the REC.

Patient Identification Centres (PICs): PICs are organisations from which clinicians or clinical units refer potential participants to a research team based in another organisation, for assessment and possible recruitment to a study. The IRAS webpages provide guidance on the arrangements for setting up PICs via the system that is in operation in the part of the UK where the PIC is based.

The Research Passport and Honorary Research Contracts: Researchers who have no contractual arrangements with NHS organisations hosting research and who want to carry out research in the NHS (that affects patient care or requires access to NHS facilities) may require a research passport. If the research only requires access to patient identifiable data and does not have a direct impact on quality of care, then only a Letter of Access may be required. To facilitate the process of obtaining Honorary Research Contracts or Letters of Access, the Research Passport scheme has been developed. An HR Good Resource Pack and other guidance can be found on the IRAS webpages.