Developers guidance

Step 6: Medical device clinical investigation approvals

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This is required guidance

It is legally required and it is an essential activity.

From:

- Health Research Authority (HRA)

This Guide covers:

- England



A clinical investigation of a technology is defined as research by the HRA and HCRW and needs approval. You will need to follow the steps described in Step 5.

Clinical investigation of a non-CE or non-UKCA marked device

If you plan to do a clinical investigation for a non-CE or non-UKCA marked device, you will need approval from a REC.

How to get a medical device clinical investigation approval from a REC

Step A: Notify the MHRA

You must notify the Medicines and Healthcare products Regulatory Agency (MHRA) before you begin a clinical investigation.

Submit an MHRA devices application to the MHRA. When this is confirmed to be valid, you can submit your application for review on the HRA's Integrated Research Application System (IRAS). IRAS is a single system for applying for the permissions and approvals for health, social and community care research in the UK. The IRAS form explains what information you need to provide specifically for these types of investigations. See help and guidance on IRAS.

Email: mhracustomerservices@mhra.gov.uk with 'MHRA/HRA Coordinated assessment pathway' in the subject line.

Step B: Submit a REC application

Once the MHRA confirms your application as valid, you can submit your REC application on IRAS.

If confidential patient and service-user information is being processed without explicit (common law duty of confidentiality) consent then, as part of your application on IRAS, you will need to apply also to the CAG (further guidance on how to do this can be found here).

CAG will provide independent advice to the HRA on whether your request for access to the confidential information should be approved based on its assessment criteria. Read the CAG's pre-application assessment before formal submission of an application, which will help you decide whether an application to CAG is an appropriate route.

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Updates will be provided (including possible requests for additional information) and a possible meeting with the REC who will do the review. You will then be notified of the decisions, usually by the main email address you have provided and/or that of your sponsor representative.

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