

Regulatory approvals

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Interventional clinical or device trials are regulated by the Medicines and Healthcare products Regulatory Agency (MHRA) in the UK. Researchers are encouraged to use an existing and established international register such as ISRCTN or ClinicalTrials.gov to ensure that the public is aware of a trial before recruitment of the first participant. Trials involving sites specifically in EU countries must be registered in the EU Clinical Trials Register. Trials should be registered before applying to the MHRA for a clinical trial authorisation via the MHRA submissions portal and researchers must ensure that the registry is kept up to date and trial results are uploaded in the appropriate timeframe. This can be a complicated and trying process, and support should be sought from the investigators' employing institution. Editors of the major surgical journals now agree that all clinical trials should have been registered before an article relating to a trial can be published. All studies undertaken with NHS patients and/or carers will need HRA Approval and confirmation of capacity and capability from NHS sites. Studies involving animals require approval from statutory licensing authorities. In the UK this is the Home Office. Animal research should be based on ARRIVE guidelines (Animal Research: Reporting of In Vivo Experiments). Regulatory approvals

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