Health Research Authority

Setting up new NHS sites in England

Setting up new sites for studies set up through pre-HRA Approval processes

From 31 March 2016, all studies that have started or completed existing approvals processes but want to set up new NHS sites in England will need to complete the set-up of those sites through HRA Approval systems. Moving all new and existing studies to the same system from 31 March means that there will be a single system for setting up NHS sites in England.

What is HRA Approval?

HRA Approval is the new process for the NHS in England that brings together an assessment of governance and legal compliance, with an independent REC opinion provided through the UK research ethics service. HRA Approval replaces the process of NHS Permission (also known as R&D Approval) from each participating organisation in England.

How are NHS sites opened in England for studies processed through pre-HRA Approval processes?

After 31 March 2016, if an application for an NHS participating organisation in England has not yet been submitted for review under previous systems, it will be set up in accordance with the HRA Approval site level processes. This means that the HRA will issue HRA Approval for the NHS organisations in England to provide assurance that the study is legally compliant, and the NHS organisation can then assess, arrange and confirm its capacity and capability to take part in the study.

Applicants who wish to set up new NHS sites in England are asked to:

- Send an email to hra.approval@nhs.net with title “IRAS XXXXXX – request for pre-HRA Approval study to come under HRA Approval”.
- List and attach the current approved document set – this includes template agreements (where applicable) and for, commercial studies, the validated Industry Costing Template. Applicants will have this document set readily to hand and it enables a list to be confirmed in the HRA Approval letter.
- Non-commercial studies should include a template Statement of Activities and Schedule of Events for each site type being added to the study. If your lead NHS R&D office is outside England please email hra.approval@nhs.net for advice. Please note that single site studies taking place at NHS sponsor site (or an agreed partner University) do not require Statements of Activity or Schedule of Events templates.
- Confirm if the study has previously applied to NIHR CSP or to a national coordinating function in Northern Ireland, Scotland or Wales.
- The HRA Assessment Team will very briefly review the study and issue a HRA Approval letter to enable applicants to set up the new site. Where the study has an existing UK study wide review this will be taken into account.

There are important changes to the arrangements for setting up NHS sites in England. Applicants should review the information about setting up NHS sites in England. All study documents and amendments for NHS sites in England should be provided to the local research team and copied to the relevant NHS R&D office (and the Local Clinical Research Network for NIHR CRN portfolio studies). Contact details are available at http://www.rdforum.nhs.uk/content/contact-details/.

To add new sites that are not listed on Part C of the original NHS R&D/REC forms, please make an amendment to the study – guidance is available in IRAS. Detailed information for sponsors, investigators and NHS organisations is on the HRA website www.hra.nhs.uk, and queries can be sent to hra.approvalprogramme@nhs.net.