Health Research Authority

Amendments

How is amendment handling changing for studies where the lead NHS R&D office is in England?

From 31 March, amendments for all English-led studies taking place in the NHS will be categorised on behalf of the NHS by the HRA in line with the UK Process for Handling UK Study Amendments. Amendments should no longer be submitted to NIHR CSP. The UK NHS categorisation process provides information to NHS sites about whether the amendment may require consideration prior to implementation, and is in addition to the definition of substantial or non-substantial for regulatory purposes.

How are amendments submitted for HRA Approval studies?

For studies led in England:

- Substantial amendments that require REC review are submitted by email to the REC that originally reviewed the study. The appropriate notice of substantial amendment form with relevant authorisations and supporting documentation are expected to be included in the email. The REC will review the amendment. If the REC is in Northern Ireland, Scotland or Wales AND the lead NHS R&D office is in England, please copy in hra.amendments@nhs.net.
- Non-substantial amendments or any amendments that do not require REC review should be submitted by email to hra.amendments@nhs.net using the non-substantial amendment form.

The HRA will categorise the amendment and inform the applicant within 5 days. The applicant should then send the amendment and the categorisation information to participating NHS organisations (study delivery team, R&D office, and LCRN where applicable).

For studies where the lead NHS R&D office is in Northern Ireland, Scotland or Wales there is no change to the handling of amendments. Compatibility arrangements are in place across the 4 UK nations. Amendments are categorised by the R&D permissions coordinating function of the lead nation and shared across participating UK nations.

How are amendments for studies set up using pre HRA Approval processes submitted?

Amendments for studies set up using pre-HRA Approval processes are submitted in exactly the same way as HRA Approval studies. Where the amendment introduces a new site for a pre-HRA Approval study the HRA Assessment Team will ask for the most up to date document set and the template agreements and costing information that will be used when working with the new site.

Detailed information for sponsors, investigators and NHS organisations participating in research is provided at the HRA website www.hra.nhs.uk and click through to ‘More about HRA Approval’. Queries can be sent to hra.approvalprogramme@nhs.net.