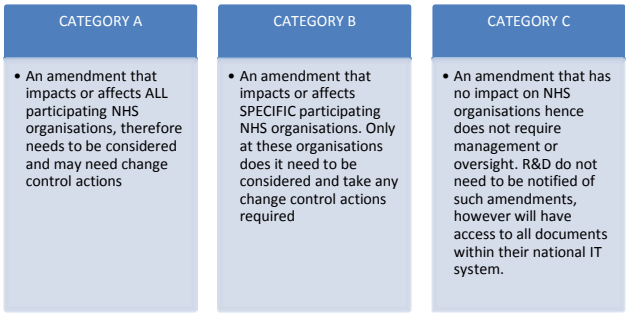
Guide for Researchers

UK process for handling UK study amendments

A revised UK study amendment handling process is being introduced across the UK in November 2014. The purpose is to reduce the number of study amendments that NHS organisations need to review for continuing NHS Permission, thereby speeding up the timelines of amendments that do need review. The scope of the revised UK process covers commercially- and non-commercially-sponsored studies[1].

The process is recommended to run in parallel to regulatory review and harmonises across all four UK nations, the principle of a 35 calendar day default approval of amendments for NHS organisations and introduces the categorisation of amendments into Category A, B, or C, The new process will benefit both researchers and NHS organisations by reducing over-processing and minimising unnecessary delays to the implementation of *Category C* amendments.



Key principles

- Applies to both substantial and non-substantial amendments[2] as categorised by the Sponsor.
- The 35 calendar day period starts on receipt of a full amendment submission (i.e. amendment form, letter and revised documents).
- Where required, regulatory approval must be in place before an amendment can be implemented. The only exception to this rule is an urgent safety measure.
- Subject to regulatory approval, *Category C* amendments can be implemented immediately.

For *Category A and B* amendments, NHS organisations have a maximum of 35 days to raise an objection, otherwise the amendment can be implemented after the 35 day period. NHS organisations are however encouraged to complete the review earlier where possible.

What must I do?

- Complete a Notice of Amendment Form giving details of the revised documents and impacted sites.
- Submit this Form and amended documents to the lead nation Coordinating Function (via IRAS for NIHR CRN Portfolio England or via email for other nations and non NIHR CRN Portfolio England). We strongly recommend this happens in parallel to the applications to other regulators.

The Sponsor/CI is responsible for providing details of the amendment, *including copies of revised documents*, to all participating Investigators and study teams.

What happens once I submit my application?

The Lead Coordinating Function will confirm to the Sponsor (delegate/CI):-

- whether the submission is complete
- the amendment category A, B or C
- the implementation date.

Details of the amendment will be made available to participating R&D offices in the UK, where necessary- for impact review and contract revision as required (agreement of which should not delay implementation

Contact the lead nation Coordinating Function for advice.

[1] There are differences in the processing of single site studies across the UK.

[2] As defined by REC, examples of substantial and non-substantial amendments can be found on the HRA website.

Endorsed by:

Contact us

For further guidance please contact the coordinating centre for the lead nation.

For England NIHR CRN Portfolio Studies
NIHR Clinical Research Network NIHR CSP

http://www.crn.nihr.ac.uk/can-help/funders-academics/gaining-nhs-permissions/

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For England non NIHR CRN Portfolio studies

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