

Revised process for handling amendments to NIHR CSP studies

The process for handling amendments for studies that have gained approval through the National Institute for Health Research Coordinated System for Gaining NHS Permission (NIHR CSP) has been revised. The revised process sets out a clear timeline and consistent approach for handling amendments and will improve the facilitation and tracking of the process for the Chief Investigator (CI) and sponsor. Please refer to the table below for further details.

Principle	Trusts have a maximum of 35 days after a CI/sponsor has submitted an amendment to raise an objection otherwise the default is that it can be implemented at each site where an objection has not been raised subject to regulatory approval.
Scope	<ul style="list-style-type: none"> • This process is for all studies which gained their <u>initial</u> approval through NIHR CSP. • The process covers substantial and non-substantial amendments.
Key points	<ul style="list-style-type: none"> • The 35 day timeline starts on submission of a complete amendment application (i.e. amendment form/letter and revised documents). The date of implementation is confirmed by the Lead CLRN by e-mail. Trusts however are encouraged to acknowledge amendments before this limit. • No amendment, other than a safety amendment, may be implemented until the relevant regulatory approvals are in place. • A complete amendment application should be submitted to the Lead Comprehensive Local Research Network (CLRN), this is the CLRN which processes the original NIHR CSP application and is normally where the CI is based. • It is recommended that this process is conducted concurrently with the application for ethical approval. The 35 day timeline however is irrespective of whether conducted in parallel or subsequent to the application for ethics approval (or other regulatory approval). • The CI/sponsor retains responsibility for alerting all investigators at site(s) of the amendment and providing the respective documents. • Copies of all regulatory approvals must be forwarded to the Lead CLRN before implementation.
Further information	<ul style="list-style-type: none"> • The full process can be downloaded from the NIHR CSP publications section of the NIHR CRN Coordinating Centre (CC) website. • For further information on the amendment process please contact your local CLRN (see interactive map). Further information is also available from NIHR CRN CC.

