For England and Wales, HRA/HCRW Approval central governance review takes place (if needed).

For Northern Ireland, each participating HSC organisation will undertake the governance review (if needed) alongside their local assessment

England, Wales or Northern Ireland

Scotland (single centre studies)

Scotland (multi-centre studies)

**What happens if the participating organisation is in…**

Amendment implemented or rejected by each organisation



Complete and submit Amendment Tool

**If needed**

**Share amendment**

Sponsor emails amendment to R&D, local delivery team and (if applicable) RRDN

Participating organisation completes local assessment

Participating organisation completes local assessment and governance review

Sponsor emails amendment to R&D and local delivery team

Sponsor emails amendment to local delivery team

Participating organisation completes local assessment and governance review

Coordinating function shares amendment with R&D

**Long description for diagram**

Initially applicants will complete the amendment tool and submit their amendment.

For studies with participating organisations in England, Wales or Northern Ireland, once the amendment is submitted the sponsor should share the amendment, by email, with the participating organisation R&D offices, local delivery teams and (if applicable) the regional research delivery network (RRDN). Participating organisations will then perform any local assessments (if required for the amendment) whilst the amendment is undergoing any required regulatory reviews/assessments. Once these are complete the participating organisation will then either reject or implement the amendment.

For single centre studies in Scotland, once the amendment is submitted the sponsor should share the amendment, by email, with the R&D offices and the local delivery team. The participating organisation will then perform any local assessments (if required for the amendment) and a governance review. Once these are complete the participating organisation will then either reject or implement the amendment.

For multi-centre studies in Scotland, once the amendment is submitted the sponsor should share the amendment, by email, with the participating organisations local delivery team. The national coordinating function in Scotland will share the amendment with R&D offices. Participating organisations will then perform any local assessments (if required for the amendment) and a governance review. Once these are complete the participating organisations will then either reject or implement the amendment.