

Process for Submitting Amendments to the NHS REC/HRA

1. The study team/ applicant downloads and completes the HRA's amendment tool (Macro enabled Excel spreadsheet) available [here](#). Guidance on completion is provided on the first tab 'General Guidance'. Please leave rows 8 and 9 and all of Section 3 blank, as these will be completed by the Sponsor's Office.
2. The study team/ applicant emails the completed amendment tool to sponsorship@warwick.ac.uk, along with copies of any updated or new study documents. All documents should include the document revision date, version number and IRAS number in the document footer as this is required by the HRA.
3. The amendment tool and updated documents will be reviewed by the Sponsor's Office who will request clarifications/ further information if required. Once any issues have been addressed as necessary the Sponsor's Office will complete Section 3 'Declaration(s) **(including adding the sponsorship@warwick.ac.uk email address and study email resource account or study contact email address, separated by a semi-colon)** and lock for submission' and email a signed & locked PDF version back to the study team/applicant for online submission to the HRA.
4. The study team/ applicant can then proceed to submit the amendment online. Details of how to do this are available [here](#).
5. The 'Submission Guidance' tab of the Excel version of the tool provides further information about the next steps dependent on the categorisation of the amendment as automatically determined by the tool.
6. Following submission the applicant/ study team will receive an automated acknowledgement email confirming the submission has been successful. The Amendment Tool outputs include confirmation of the category of the amendment.
7. Category A and B amendments can be implemented after 35 days if there has been no objection from site/s (as long as any other regulatory approvals e.g. MHRA approval have already been received as required).
8. Non-substantial Category C amendments can be implemented immediately and without waiting 35 days (as long as any other regulatory approvals e.g. MHRA approval have already been received as required).
9. Category A and B amendments may be implemented sooner than 35 days where the NHS/HSC organisation has confirmed that the amendment may be implemented prior to this date (as long as any other regulatory approvals e.g. MHRA approval have already been received as required).
10. Once the applicant/ study team are ready to implement the amendment, final versions of the amended documents should be emailed to sponsorship@warwick.a.uk.
11. If the amendment involves the addition of a new research site, a new site agreement must be put in place. Applicants should contact the Grants & Contacts Team in R&IS (via siteagreements@warwick.ac.uk for WMS/ WCTU studies) in order to progress this.

12. If the amendment involves changes to a Principal Investigator at a research site, a variation to the site agreement may be required. Applicants should contact the Grants & Contacts Team in R&IS (via siteagreements@warwick.ac.uk for WMS/ WCTU studies) in order to progress this.