

How to Submit an Amendment – all studies

The amendment process has changed (as of June 2020): there is now a spreadsheet to fill in called the **amendment tool** and an **online submission portal** that you need to use (this is separate to IRAS but looks similar) – details are described in full on the HRA website and the IRAS help sections on amending your approvals:

- HRA: <https://www.hra.nhs.uk/approvals-amendments/amending-approval/>
- IRAS help:
<https://www.myresearchproject.org.uk/help/hlpamendmentsresearch.aspx>

Please read the information on the links above and the instructions below in full (they should tell you everything that you need to know).

1. Open up the amendment tool spreadsheet (**download the latest version** from here: <https://www.myresearchproject.org.uk/help/hlpamendments.aspx#Amendment-Tool>)
2. Once it is open, there should be a little pop up at the top that says ‘enable content’ > you need to click on ‘enable content’ > then yes (otherwise it won’t work)
3. Populate all the study information in the fields at the top
4. The amendment reference needs to be written in full – for example “Substantial amendment 01”; if you do not know what the amendment reference is, please email rgosponsor@le.ac.uk
5. The date will be whatever you choose it to be but this date **must** match the date of all the amended documents (i.e., if you change the protocol to v2.0 29/01/2021 then the date of the amendment will also be 29/01/2021 – this makes the document control of the paperwork much easier to follow); the date needs to be entered in the format requested (DD/MM/YY) but it will auto-change to DD MONTH YYYY.
 - a. Substantial Amendments = a change in version numbers to the **next whole number** (i.e., v1.3 will become v2.0, v4.0 will become v5.0)
 - b. Non-Substantial Amendments = a change in version numbers to the **next decimal number** (i.e., v1.3 will become v1.4, v4.0 will become v4.1)
 - c. The dates of all the amended documents must match
 - d. The footers and filenames must match; we recommend the following format: Sponsor Ref (IRAS Number)_Doc Title_vX.X_DD-MM-YYYY (you can also add ‘TRACKED CHANGED’ (or ‘TC’) or ‘CLEAN’ to the end of the filename to make it easier to identify documents)

6. You then type in a bit of information about the changes to the study in the big text box – this just needs to be top line statements and a justification/rationale for the changes, the detail is entered in Section 2
7. Then it's just a series of Yes and No responses to all the next questions
8. When you get into **Section 2 Summary of Changes** please first review the **'Glossary of Amendment Options'** tab of the spreadsheet. This gives you a list of all of the different changes that can be selected from the drop down boxes.
9. Under Change 1 select the relevant type of change from the drop down box, for example (this is a random example, not one specific to your study):
 - a. Study Design,
10. Then the next drop down, the appropriate sub-change should be selected from the options, for example: Samples - significant changes (e.g. to the arrangements for removal, storage or use of samples under the relevant legislation on Human Tissue)
 - a. Then complete the details; this is where you provide the detail about the change.
11. So, it should look like this....

Section 2: Summary of change(s)				
Please note: Each change being made as part of the amendment must be entered separately. For example, if an amendment to a clinical trial of an investigational medicinal product (CTIMP) involves an update to the Investigator's Brochure (IB), affecting the Reference Safety Information (RSI) and so the information documents to be given to participants, these should be entered into the amendment tool as three separate changes. A list of all possible changes is available on the "Glossary of Amendment Options" tab. To add another change, tick the "Add another change" box.				
Change 1				
Area of change (select)*:	Study Design			
Specific change (select - only available when area of change is selected first)*:	Samples - significant changes (e.g. to the arrangements for removal, storage or use of samples under the relevant legislation on Human Tissue)			
Further information (free text - note that this field will adapt to the amount of text entered):				
Applicability:	England	Wales	Scotland	Northern Ireland
Where are the participating NHS/HSC organisations located that will be affected by this change?*	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Will all participating NHS/HSC organisations be affected by this change, or only some? (please note that this answer may affect the categorisation for the change):	<input checked="" type="radio"/> All		<input type="radio"/> Some	
Add another change: <input type="checkbox"/>				

12. You then repeat this process for the different types of changes you have made to the study, its documents, the investigators, etc as per all things you identify on the glossary tab; to get another Change box you need to tick the 'Add another change'.

13. *** CTIMP trials (see below)**

14. Once you have exhausted all your changes, save the spreadsheet and send it to rgosponsor@le.ac.uk for review and signing along with the tracked changes and clean versions of all the documents that have been amended.

- a. NB. when you attach the amendment tool to an email it will get an ! in its picture, this is normal, please carry on with the steps below.

15. We will review all of the documents and if necessary send back queries, but eventually we will return a signed and PDF'd version of the amendment tool to you.
16. You then need to log into the [online portal](#) to [submit it](#) (this is a short YouTube video on how to do that). *** CTIMP trials (see below)**
17. The PDF'd amendment tool and the tracked and clean versions of the documents should be uploaded to the portal.
18. The portal will send you an automated email to confirm submission.
19. Then you await the approvals and contact the R&I department(s) as per normal about the amendment.
20. The amendment can be implemented once we have received Trust C&C and we have issued Sponsor Green Light (we will tell you at Step 15 whether or not there is any exception(s) to this).

***Additional Instructions for CTIMP trials**

Please note that as of 25 March 2021 the European Commission "Annex 2" form will no longer be required when notifying amendments to the MHRA. The MHRA will now accept a copy of the completed Amendment Tool when notifying them of amendments to a single CTIMP. The Annex 2 form, which is available on the MHRA website, can still be completed and submitted to the MHRA for 'bulk' amendments (where the same change affects multiple studies simultaneously).

Therefore, if you do need to use the Annex 2 form, please follow the instructions below.

13. [Download the 'Annex 2' form.](#)
 - a. Enter the information in B4 'Sponsor's protocol code number, version and date' – this should be the information of the **currently approved** version of the protocol (not the version you are submitting).
 - b. Please insert the Sponsor details in both D1 and D2 (requests for the Competent Authority and the Ethics Committee, respectively) – this enables us to sign both the amendment tool and the Annex 2 form at the same time reducing the requirement for you to obtain signatures from multiple people.
 - c. We will return a PDF'd version of Annex 2 at Step 15.
 - d. You will make your submission via the new [MHRA portal](#) (if you need to register for this portal, please contact rgosponsor@le.ac.uk). You may also need to use the CESP portal for trial sites outside the UK.

Please continue to follow the rest of the instructions above.