

How to Complete the Amendment Tool

As of June 2020, in order to submit an amendment, you have to complete a spreadsheet known as the **amendment tool**. This must then be submitted via an **online submission portal** (this is separate to IRAS but looks similar) when requesting an amendment to your research.

Please read 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>)

We recommend that you download a new amendment tool each time you submit an amendment to avoid the amendment tool becoming corrupt and not working properly.

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).

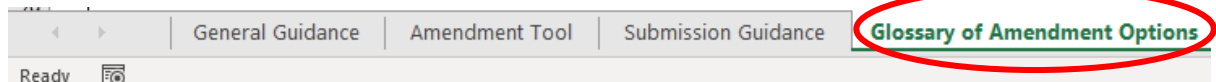
Please note that this is a 'smart document' meaning that additional sections will become visible as sections are completed and boxes are ticked. If you can't find something, it's likely that you have missed a box or answer in a previous section.

3. Populate all the project information in the fields at the top
4. The amendment reference should be your study 4-digit Sponsor reference number followed by the relevant amendment type (e.g. substantial (SA) or non-substantial (NSA)) and number i.e 0001_SA01 or 0001_NSA04. 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 must 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.
6. You then type in an overview of the amendment 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.

You must complete the details of the nations taking part in the study (row 77-79) in order for the rest of the amendment tool to open up.

75	amendment introduce details				
76		England	Wales	Scotland	Northern Ireland
77	Lead nation for the study:	Yes	No	No	No
78	Which nations had participating NHS/HSC organisations prior to this amendment?	Yes	No	No	No
79	Which nations will have participating NHS/HSC organisations after this amendment?	Yes	No	No	No
81	Was this a "single site, self sponsored" study in England or Wales prior to this amendment?	Yes		No	
86					

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. Please note this section will only appear once you have answered the questions relating to the nations involved in your study.



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):
- 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)
- Then complete the details; this is where you provide the detail about the change.
11. So, it should look like this....

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?*	Yes	No	No	No
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):	All		Some	
	Add another change			

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. Once you have exhausted all your changes, save the amendment tool in its Excel format and submit it to the Research Governance Office via Infonetica alongside any relevant supporting documents. A member of the Research Governance Office will review your amendment documents and will either request changes or will return both an unlocked and a signed and locked (PDF'd) version of the tool and give you permission to formally submit the amendment.
14. On the unlocked amendment tool, the final two rows on the Amendment Tool tab can be used to confirm the overall type and category of the amendment. Please also refer to the submission guidance tab for guidance on who needs to be notified on your amendment.

Overall amendment type:	Non-substantial, no study-wide review required
Overall Category:	C

