Appendix 1- Guidance on preparing the modification tool

Purpose

This guidance explains how to complete the Modification Tool prior to submission to the Research Governance Team (RGT) for review and authorisation.

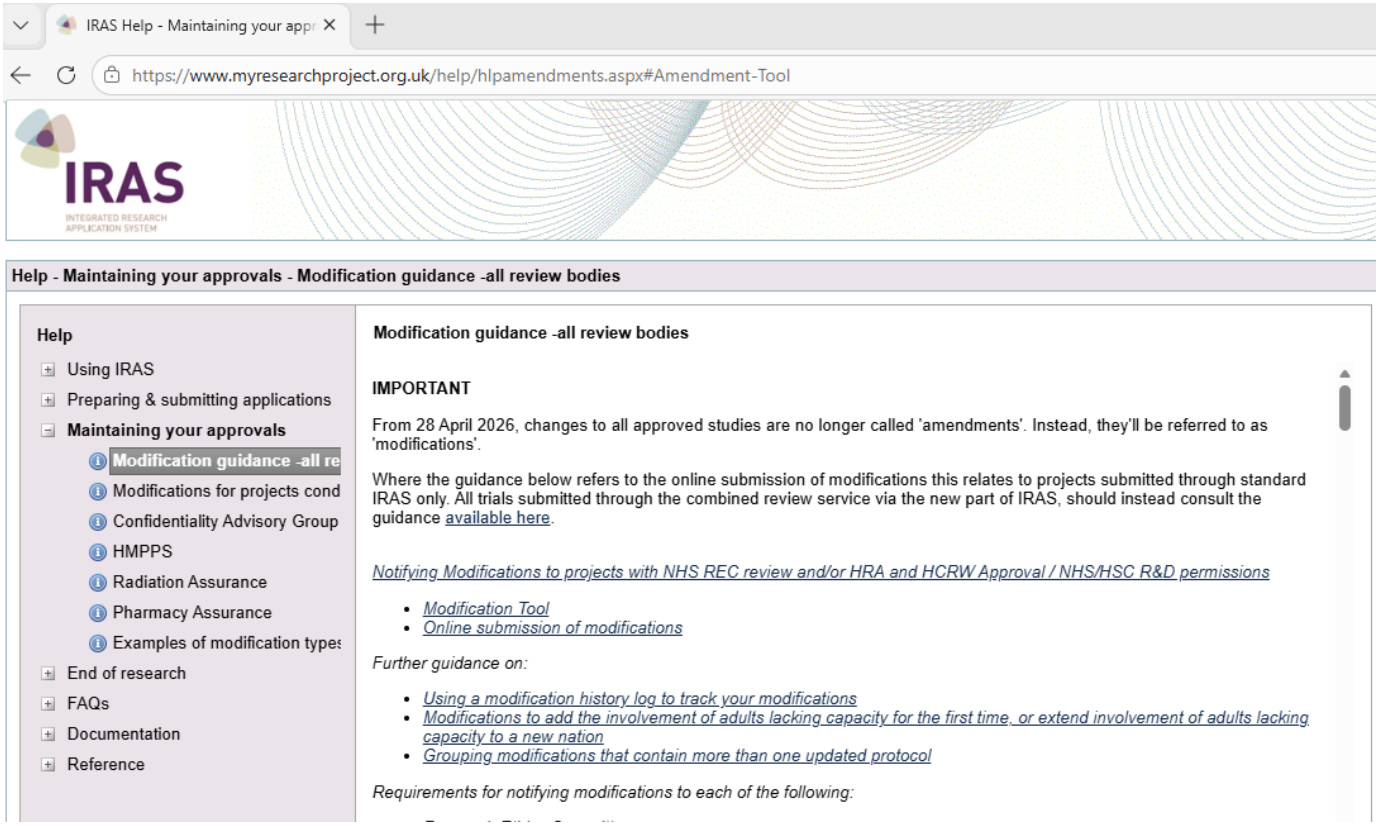
Overall process

- The study team completes the Modification Tool and prepares supporting documentation.
- The completed Tool and supporting documents are submitted to the Research Governance Team (RGT) for review.
- The RGT reviews the submission and, where appropriate, authorises the Modification Tool.
- The study team submits the authorised Tool via the IRAS Portal and informs sites as required.

Accessing the Modification Tool

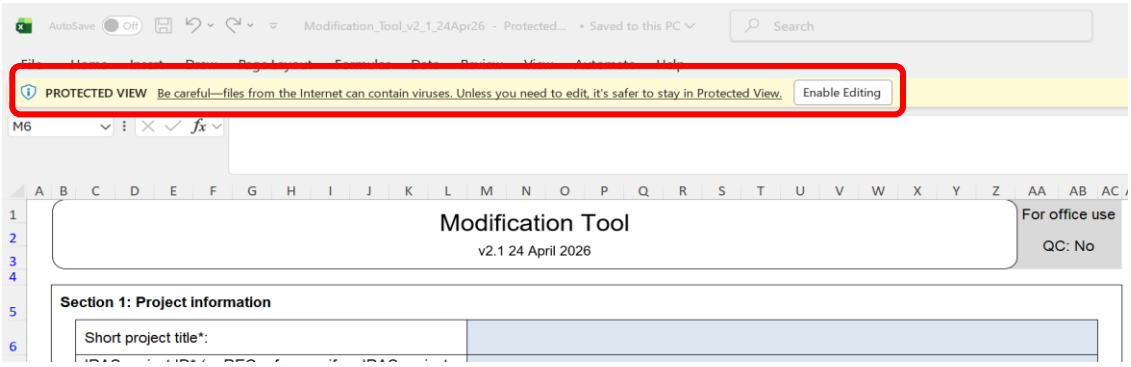
Ensure you use the latest version of the Modification Tool by downloading it from the IRAS website.

From the IRAS website, select <help>, <Maintaining your approvals>, <Modification guidance – all review bodies>, then scroll down to the section on the Modification Tool and select the link.

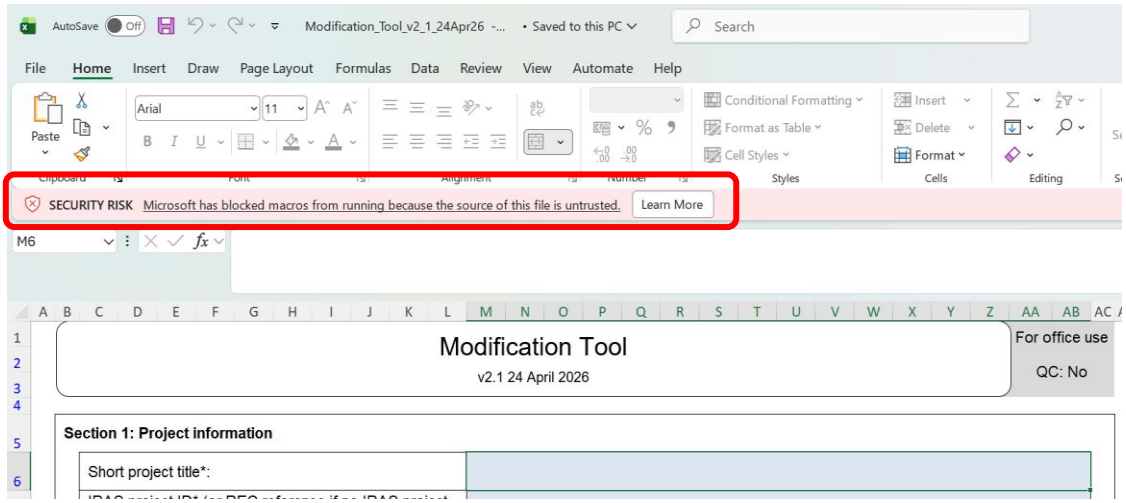


1. Save a copy of the Modification Tool locally.

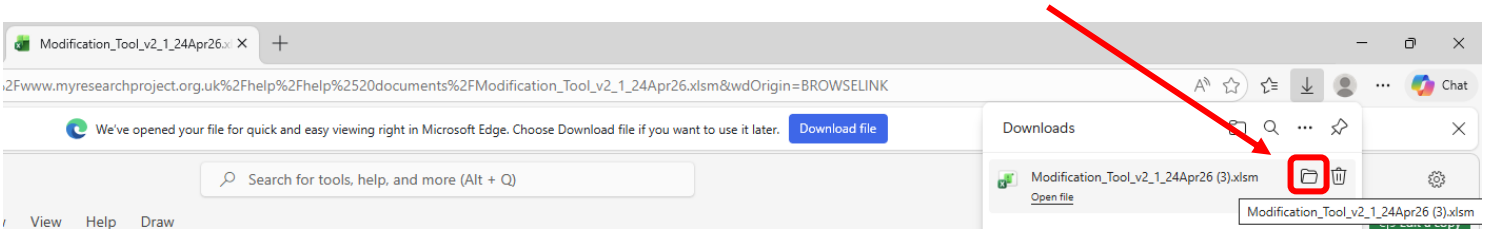
2. The first time the Modification Tool is opened after it's downloaded the below warning may come up requiring the "Enable Editing" button to be selected. If asked if the file is a "Trusted Document", select to confirm yes.



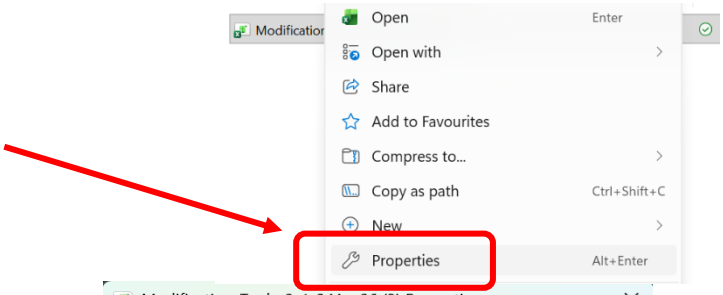
3. If the below "Security risk" warning is displayed, this means the macros in the file are blocked.



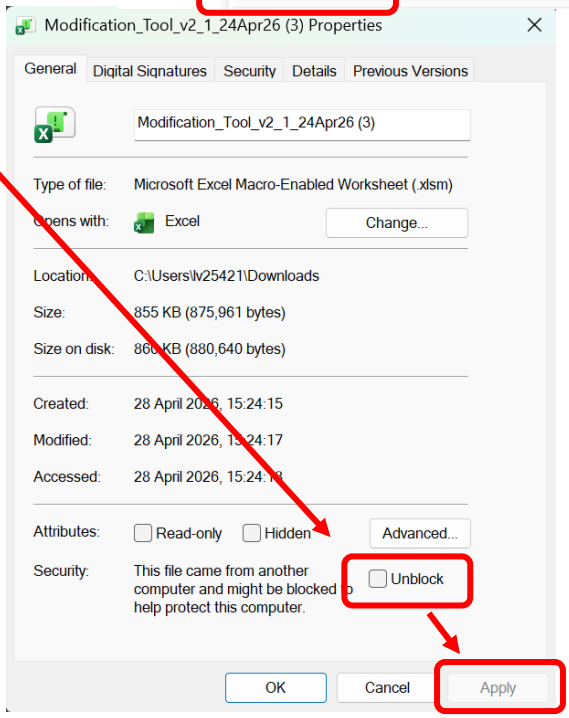
4. Re-download the Tool from IRAS, DON'T OPEN THE TOOL straight away. Find the Tool in your file explorer (or click on the icon circled below after it is downloaded).



5. Follow the Microsoft instructions here to unblock the macros in the Properties tab for the file.
    a. Right click on the Modification Tool file in the file explorer and select “Properties”



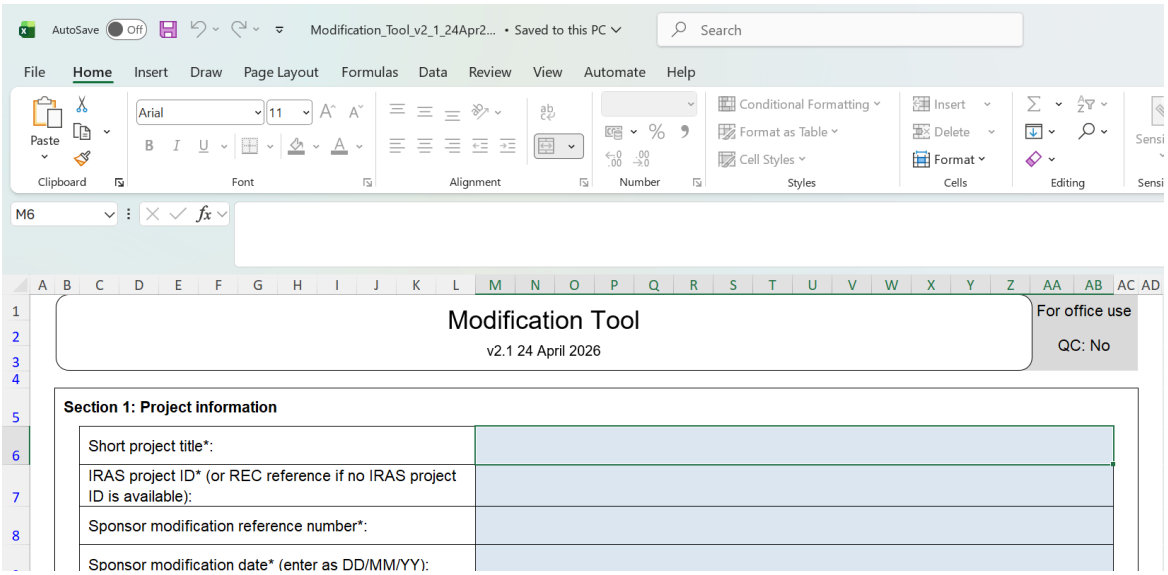
    b. In the ‘General’ tab, select ‘unblock’, and then ‘apply’.



6. Open the Modification Tool, click “enable content” if the warning “macros have been disabled”. The Tool can now be used.

Completing the Modification Tool

Complete section 1 of the Tool and ensure all mandatory fields (marked with an asterisk) are populated; this generates the questions that need to be answered in the rest of the Modification Tool.



Complete information about the first change:

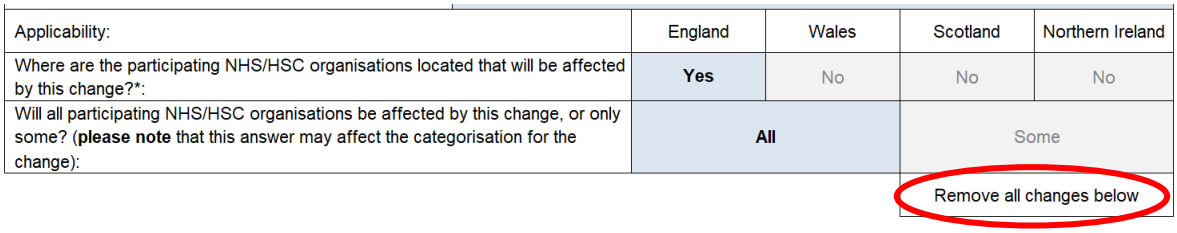
Section 2: Summary of change(s)

Please note: Each change being made as part of the modification must be entered separately. For example, if a modification 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 modification tool as three separate changes. A list of all possible changes is available on the "Glossary of Options" tab. To add another change, click the "Add another change" box.

Change 1	
Area of change (select)*:	
Specific area of change (select - only available when area of change is selected first)*:	
Further information: explain what the change is, why the change is being made and any possible impact on participants/carers (free text - note that this field will adapt to the amount of text entered):	

1. Select the area of change from the drop-down menu.
2. Select the specific change from the next drop-down menu.
3. Complete the ‘Further information’ free text box and the applicability of the change.

If more than one change is required repeat the process using the boxes for Change 2, 3, 4, etc. The Tool will support a maximum of ten changes. If only one change is required, select the 'Remove all changes below' button (see screenshot below).



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	
			Remove all changes below	

Change 2	
Area of change (select)*:	
Specific area of change (select - only available when area of change is selected first)*:	

Section 3 must be completed by the Sponsor, or a person with explicit delegated authority from the Sponsor, i.e. an authorised delegate. Modifications must not be submitted without prior authorisation from, or on behalf of, the Sponsor. For the avoidance of doubt, the authorised delegate for studies Sponsored by the University of Bristol is a member of the Research Governance Team.

Requesting review of the modification

The Modification Tool can now be sent to the Research Governance Team by email, along with the to-be-modified documentation, which should have tracked changes. Once review is complete, the RGT will return an authorised Modification Tool to for submission via the IRAS Portal. This requires a different login to the system through which the initial IRAS application was submitted; there is more information on the IRAS webpages.