HOW TO SUBMIT A MODIFICATION REQUEST

Log into iMedRIS

Once logged in you will land on the Study Assistant page.

Go to the All Studies section on the bottom half of the page and locate the study to be modified.



Click on the Forms Icon

In the Modification Request Form section - click on Start a new Submission Icon.



Click on Save and Continue to Next Section in the upper right-hand corner after completing each section.

Section 2.0: Select the type of determination assigned to project: Active-Exempt, Active -Non-Exempt Expedite Review, Active – Non-Exempt Full Board Review. The status can be found on the study assistant page.

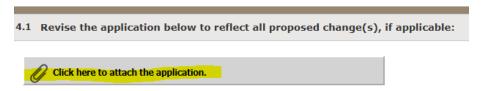


NOTE: A modification request cannot be submitted for projects that were given a Non-Human Research determination. If changes are made and there are questions about whether these activities are research involving human subjects, please submit a new request for IRB determination.

Section 3.0: Provide a summary of the proposed changes.

Section 4.0: Application and Document Revisions

Update the application if applicable (e.g. changes in the number of subjects, data collection date revisions, changes to data storage, study procedures, etc).



Click on the Create Revised Application ICON



You will be asked to confirm that you want to create a revision

Update the applicable sections of the application – in section 13 – click

Save and Continue to Next Section

Section 4.2

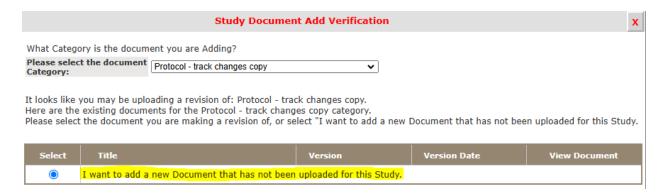
Attach both a clean and track changes version of documents being revised or upload new document (e.g. Protocol, Information Sheet, Recruitment Material, etc). The revised documents should have an updated date.

Click on Add a New Document



Select appropriate document category – click on:

I want to add a new Document that has not been uploaded for this Study.



Click on Proceed with Document Upload in lower right-hand corner.

On the study document upload page – update the document version number if applicable – make sure the version date matches the document date. Complete the process for each document.

Once all revised documents are added - click on Save & Continue



The next step is to signoff and submit – click on Sign Off and Submit

The final page is the submission routing signoff. On the bottom of the page click on **Approve and then Save Signoff.**

