# 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).

4.1 Revise the application below to reflect all proposed change(s), if applicable:

📎 **Click here to attach the application.**

Click on the **Create Revised Application** ICON

Attaching Study Application ⊗

💬 Select the application that you would like to attach and then click Save Attachment   **Save Attachment**

Select	Show Rev.	Edit/ View	Form Name	Approved	Create a Revised Application
Already Submitted	📁	📝	WMed IRB Application (Version 1.1)	Yes	☑ **Add Revision**

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**

4.2 Modify or add new study document(s) here:

Attach both a clean copy **AND** a track changes copy of the revised **PROTOCOL, INFORMATION SHEET, RECRUITMENT MATERIAL, ETC.** to facilitate the IRB review. Please include in the name of the document if it is the clean or tracked version. (e.g., protocol v. 2.3- tracked changes, protocol v. 2.3- clean copy)
Note: When making a clean copy in Word, remember to go into Accept Changes and choose option "Accept All Changes and Stop Tracking". Also delete any comment boxes that may have been used.

Select or Revise Existing	Add a New Document	Add Multiple Documents				
Detach	Version	Title	Category	Expiration Date	Document Outcome	Checked Out	View Document
No Document(s) have been attached to this form.						

Select appropriate document category – click on:

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

Study Document Add Verification   X

What Category is the document you are Adding?

Please select the document Category: Protocol - track changes copy ▼

It looks like you may be uploading a revision of: Protocol - track changes copy.
Here are the existing documents for the Protocol - track changes copy category.
Please select the document you are making a revision of, or select "I want to add a new Document that has not been uploaded for this Study."

Select	Title	Version	Version Date	View Document
◉	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**

4.2 Modify or add new study document(s) here:

Attach both a clean copy AND a track changes copy of the revised *PROTOCOL, INFORMATION SHEET, RECRUITMENT MATERIAL, ETC.* to facilitate the IRB review. Please include in the name of the document if it is the clean or tracked version. (e.g., protocol v. 2.3- tracked changes, protocol v. 2.3- clean copy)
Note: When making a clean copy in Word, remember to go into Accept Changes and choose option "Accept All Changes and Stop Tracking". Also delete any comment boxes that may have been used.

		Select or Revise Existing	Add a New Document	Add Multiple Documents				

Detach	Version	Title	Category	Expiration Date	Document Outcome	Checked Out	View Document
❌	2.0	Awe and Wonder Information Sheet CLEAN 11.1.24	Other				26.06 KB
❌	2.0	Awe and Wonder Information Sheet TRACK 11.1.24	Other				27.01 KB
❌	2.0	2024.11.12_REDCap_HaymakerAweWonderPreRevised	Survey				41.85 KB
❌	2.0	Awe and Wonder Protocol CLEAN 11.1.24	Protocol - Clean Copy				221.40 KB
❌	2.0	Awe and Wnder Protocol TRACK 11.1.24	Protocol - track changes copy				221.81 KB

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.**

Christopher M Haymaker, Ph.D. as Principal Investigator
Do you Approve or Deny this submission?   ◉ **Approve**   ○ **Deny**

                 Save Signoff