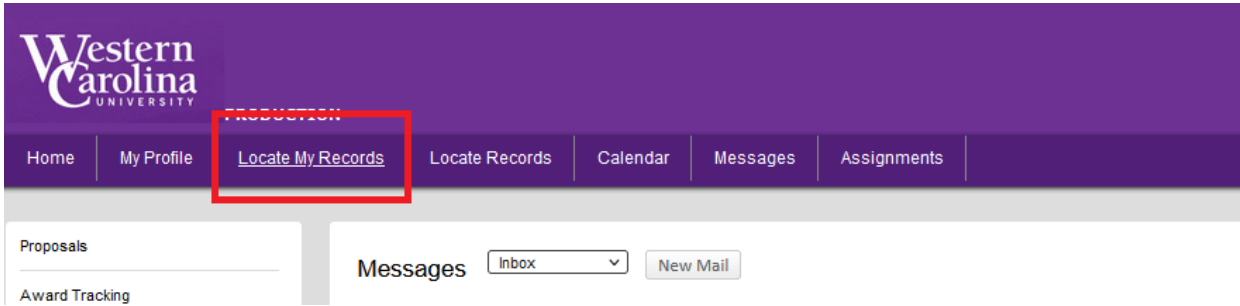


Submitting an Amendment/Modification to an Approved Project:

Login to InfoEd and select “Locate My Records” in the menu at the top.



All of the records that populate will be your protocols. Navigate to the protocol you wish to amend. Click the lined menu to the left of the record number.

▶	Temp-21-149	Compliance Protocol	Investigator, Pete	New Protocol Created for Pete Investigator on 04-Jun-2021 12:51 PM	In Development	English
▶	Temp-21-148	Compliance Protocol	Investigator, Pete	New Protocol Created for Pete Investigator on 04-Jun-2021 12:51 PM	In Development	English
▶	Temp-21-147	Compliance Protocol	Investigator, Pete	New Protocol Created for Pete Investigator on 04-Jun-2021 10:58 AM	In Development	English
▶	Temp-21-148	Compliance Protocol	Investigator, Pete	Effect of yoga on sleep	Approved	English
▶	Temp-21-148	Compliance Protocol	Investigator, Pete	IBC Test in June	Approved	English
▶	Temp-21-148	Compliance Protocol	Investigator, Pete	New Protocol Created for Pete Investigator on 01-Jun-2021 1:33 PM	In Development	English
▶	Temp-21-148	Compliance Protocol	Investigator, Pete	New Protocol Created for Pete Investigator on 28-May-2021 2:32 PM	In Development	English

From the menu, go to “Create New” and select “IRB Request for Modification.”

▶	Temp-21-148	Compliance Protocol	Investigator, Pete	New Protocol Created for Pete Investigator on 04-Jun-2021 12:51 PM	In Development	English
▶	Temp-21-147	Compliance Protocol	Investigator, Pete	New Protocol Created for Pete Investigator on 04-Jun-2021 10:58 AM	In Development	English
▶	Temp-21-148	Compliance Protocol	Investigator, Pete	Effect of yoga on sleep	Approved	English
▶	Temp-21-148	Compliance Protocol	Investigator, Pete	IBC Test in June	Approved	English
▶	Temp-21-148	Compliance Protocol	Investigator, Pete	New Protocol Created for Pete Investigator on 01-Jun-2021 1:33 PM	In Development	English
▶	Temp-21-148	Compliance Protocol	Investigator, Pete	New Protocol Created for Pete Investigator on 28-May-2021 2:32 PM	In Development	English
▶	Temp-21-136	Compliance Protocol	Investigator, Pete	IBC r/s DNA Research	Approved	English

A new screen will populate. Your approved application populates with a modification section at the top. Make sure the form is unlocked. Complete the section at the top by checking the appropriate box for your modification. Briefly explain the modification in the box provided.

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Save Lock Form Submit

MODIFICATION

This modification/addendum changes the original IRB application in the following ways: (Check all that apply.)

- Changes** the intended use of data collected.
- Changes** the known or potential conflicts of interests related to this research.
- Adds/deletes/modifies** participant population and recruitment
- Changes** approved informed consent/assent forms.
- Modifies** study procedures.
- Increases/modifies** risks to subjects enrolled in the study.
- Modifies** study confidentiality and safeguards.
- Modification** to research personnel

Check all the boxes that apply and briefly explain the modification in the box below.

*For any box checked in question 2, describe the modification/addendum here and modify the appropriate section in the rest of the form:

ADMINISTRATION

Required Human Subjects Training : Prior to submitting your application to the IRB, please make sure all personnel listed on the application have completed human subjects training. WCU's human subjects training can be accessed at www.citiprogram.org. Detailed instructions for registering, affiliating with WCU, and selecting the correct course can be found on the [IRB Website](#).

If your study will include tribal members from the Eastern Band of the Cherokee Indians (EBCI) or will occur on Cherokee lands (e.g. the Qualla Boundary or Snowbird community), approval may also be required by the EBCI Cultural IRB and/or EBCI Medical IRB. No research may be conducted on EBCI Tribal Lands without explicit approval from the EBCI Cultural IRB and/or EBCI Medical IRB.

Then go through your application and update the areas that are being modified. If you are adding more personnel, navigate to the personnel section and add the individual. If you are adding or updating a data collection instrument, navigate to that section of the application and add the new instrument. The same is true for deleting information. Anything you change will be captured by the system. The reviewer will see what the previous version of the application was, as well as all of your changes.

When you are finished with your edits, navigate to the very top of the form. Click the “Lock Form” box. Then click “Submit.” Your modification has been submitted to the Compliance Office.

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Save Lock Form Submit

MODIFICATION

This modification/addendum changes the original IRB application in the following ways: (Check all that apply.)