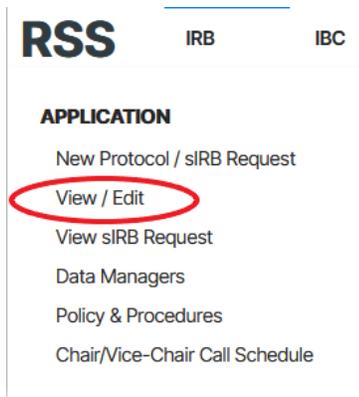


Submitting a Change Request

This document lays out how to submit a change request after an application is active. Changes can be made by anybody who created the application and/or is listed on the application and has an RSS account.

NOTE: If you are submitting change requests at the same time as a **continuing review**, be sure to click “RESET EDIT” **before submitting the continuing review**, otherwise the application will lock.

- 1) Log into RSS, go to IRB--- “**view/edit**” application--- and click the application you wish to make changes to.

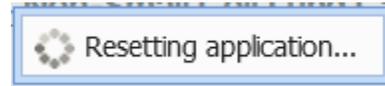


- 2) Towards the top of the application, you should see a button that says “**RESET EDIT**”. Click this.

****If you do NOT see this button**, send a message through the message portal asking for the application be reset to edit.



3) You will see the message “**resetting application**” as the page reloads. The page will refresh and you should now be in “**edit**” mode. If your application is in “**edit**” mode, you will see that reflected at the top (see bottom picture to the right).

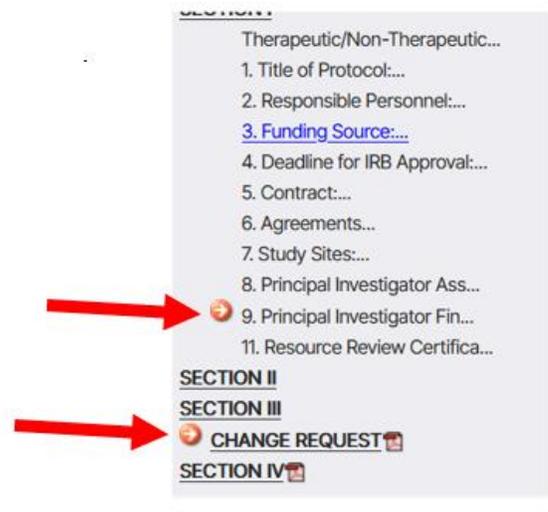


You can now make any changes you'd like to your application. You will make these changes the same way you completed your original application. Remember to hit “**SAVE**” often so you do not lose any changes before submitting.



NOTE: make sure you've reviewed the **CONSENT FORM** (if applicable) to make any necessary changes to match the application. **SEE THE STEPS FOR THIS PROCESS ON THE LAST PAGE OF THIS DOCUMENT.**

4) **Before you can submit any changes**, you must complete the “**CHANGE REQUEST**” form (see screen shots below) from the menu on the left side, complete any sections marked with an orange arrow, and **the PI must RE-SIGN** the application. **All orange arrows must be addressed before submitting.**



The change request form includes **5 additional questions**, some of which will require justification based on your answer. See the questions listed below.

1. Does the Clinical Trial Master Matrix require modification as a result of any of the changes in this study?

Collaborate/Comment (No comments exist)

Not Applicable

No

Yes

Attach a modified Clinical Trial Master Matrix that reflects the current version of the methods, procedures and commercial contract.

2. Are there new or modified recruitment materials?

Collaborate/Comment (No comments exist)

Yes

No

Not Applicable

List the recruitment material, whether it's new or modified, and provide justification.

Collaborate/Comment (No comments exist)

B I U S x₂ x² I_x Q t_a | Format - | Size -

3. Are there new or modified educational materials to give to subjects?

Collaborate/Comment (No comments exist)

Yes

No

Not Applicable

4. Was subject accrual halted pending IRB-approval of the Request for Change?

Collaborate/Comment (No comments exist)

Yes

No

Not Applicable

5. Will subjects be re-consented?

Collaborate/Comment (No comments exist)

Yes No

Are the subjects not being re-consented because a waiver of consent was approved by the IRB?

Collaborate/Comment (No comments exist)

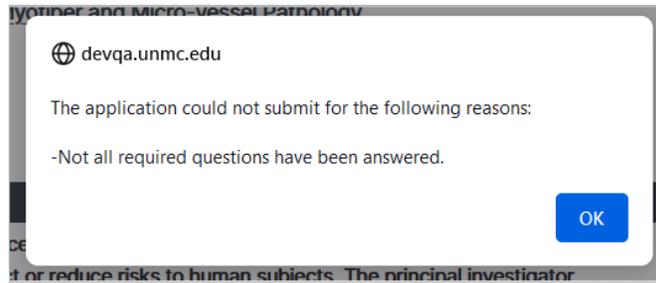
Yes No

Provide justification why re-consent is not required.

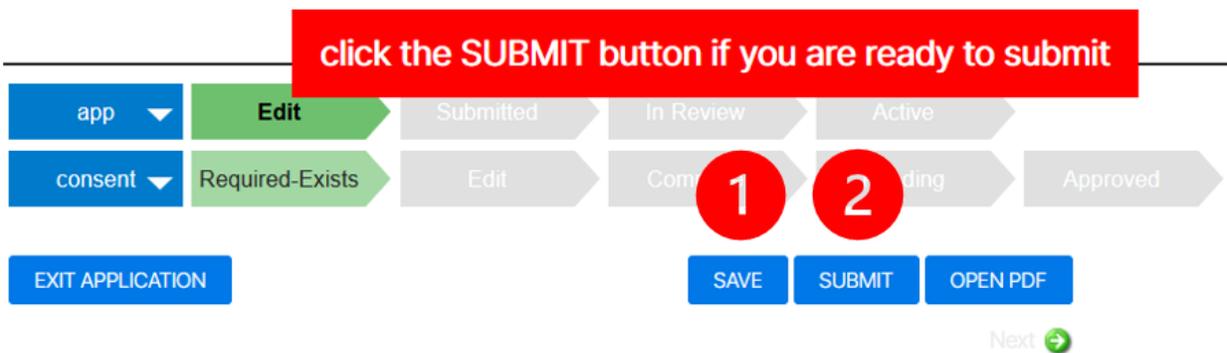
Collaborate/Comment (No comments exist)

B I U S x₂ x² I_x Q t_a | Format - | Size -

If you attempt to submit your change request without answering any of the orange arrow questions, including the justifications (as applicable), the following pop up will appear:



- 5) Once you've made all of the necessary changes, completed your change request section and the PI has re-signed the application, you are ready to submit. We always suggest clicking **"SAVE"** first and **"OPEN PDF"** if you'd like to double-check any changes. Once you're ready, click **"SUBMIT"**.

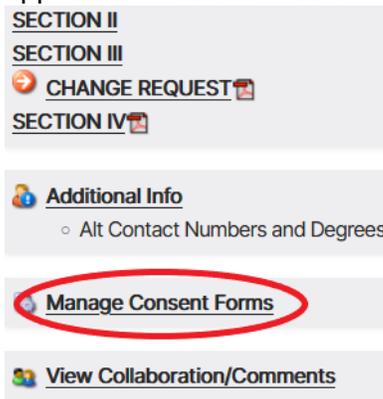


- 6) After you submit your changes, your application status is set to **"SUBMITTED"** and an email is sent to IRBORA.
- 7) Once the IRB/ORA approves your change(s), they will send an approval letter, the status of your application is set back to **"ACTIVE"** and your application will now be on the next version number.

Continue below to see how to edit a consent form.

EDITING A CONSENT FORM

- 1) Click “Manage Consent Forms” on the left side of the application you are editing. The application must be in edit in order for this to appear.



- 2) Select the “Approved Consent” form you would like to edit.



- 3) Click “edit” at the top of the page and make any necessary changes.



- 4) Click “complete” at the top when you are finished.



- 5) Click “close consent”. This will direct you back to the Application list. You may need to re-enter the application you were editing.

