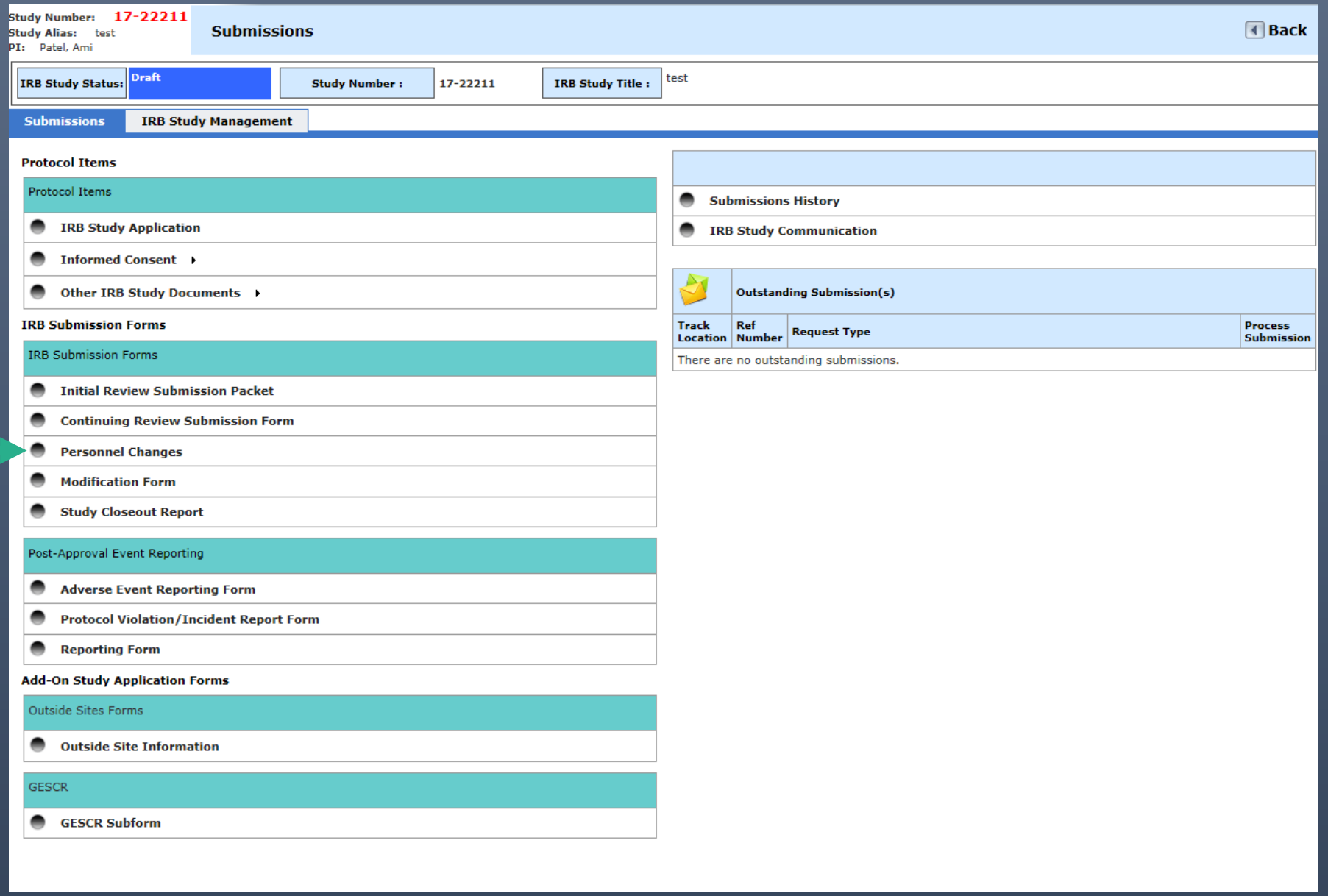
HOW TO:
COMPLETE THE PERSONNEL CHANGES FORM

UCSF

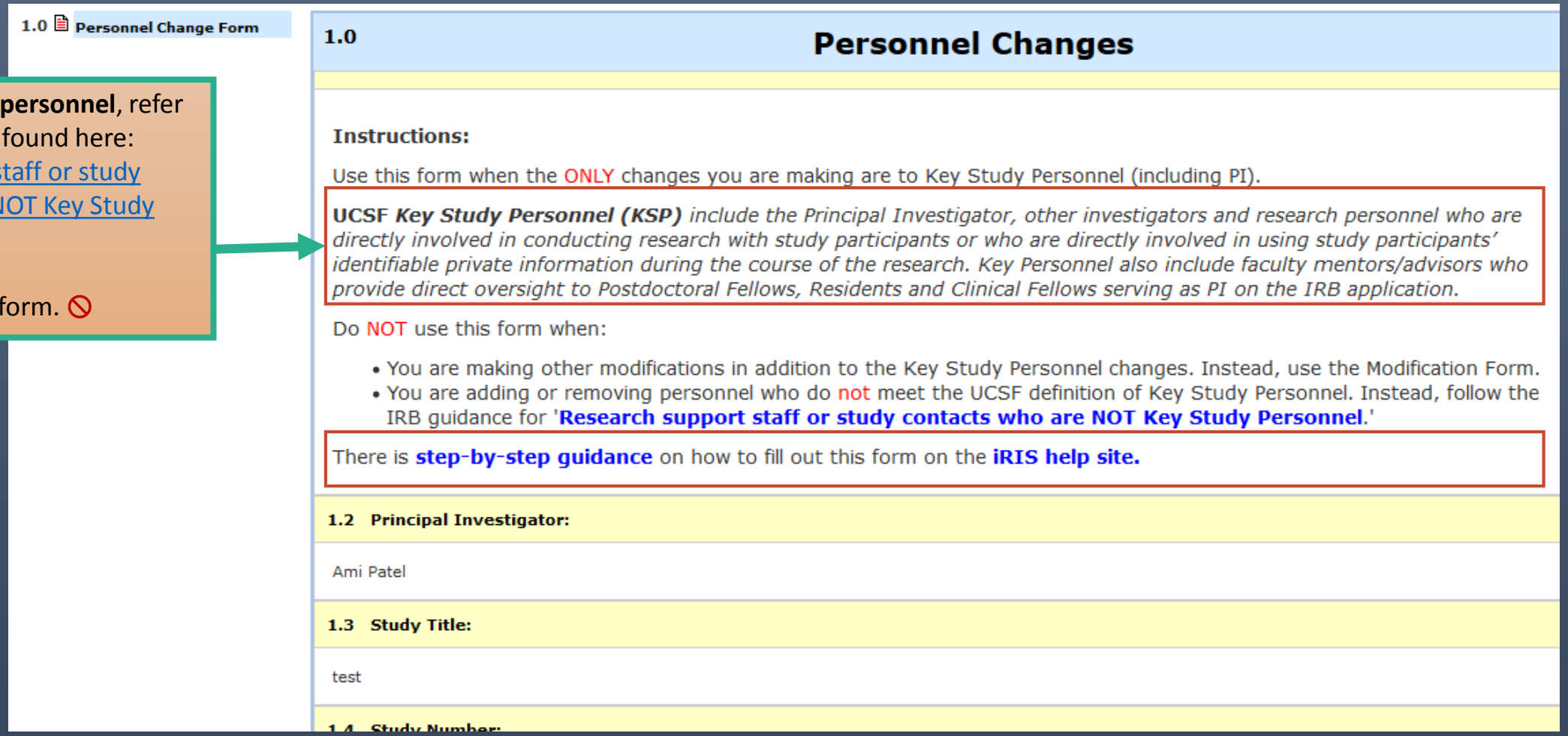
iRIS at UCSF

Locate Personnel Form

- ☛ Log onto iRIS.
- ☛ Locate the study.
- ☛ On study dashboard, locate and click on “Personnel Changes”



- For **non-key study personnel**, refer to the instructions found here: [Research support staff or study contacts who are NOT Key Study Personnel]
- Do not fill out this form. 🚫

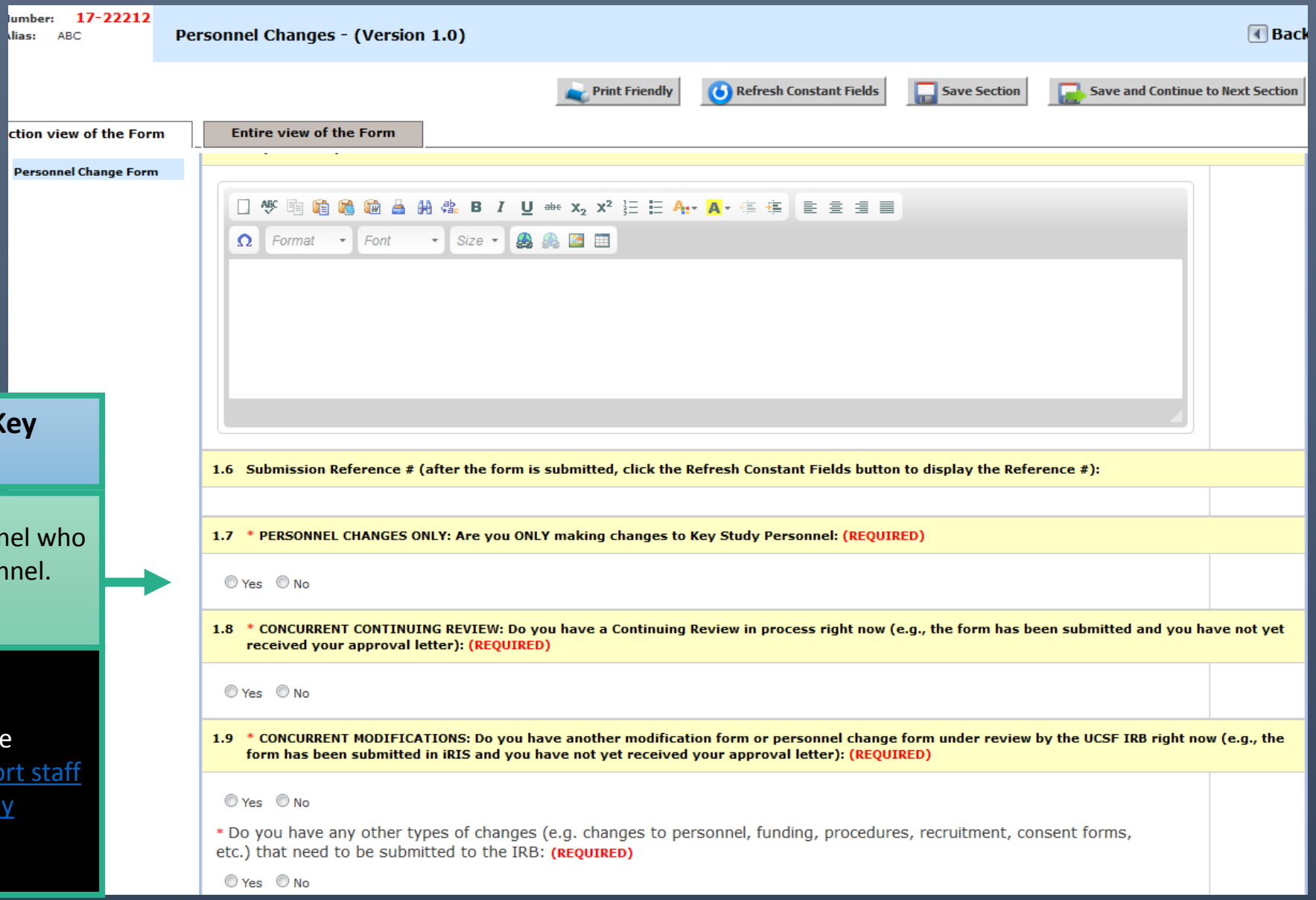


Are you ONLY making changes to Key Study Personnel?

Yes: You are adding or removing personnel who meets the definition of Key Study Personnel. Continue to next question.

No: Do not fill out this form. 🚫

For non-key study personnel, refer to the instructions found here: [Research support staff or study contacts who are NOT Key Study Personnel]

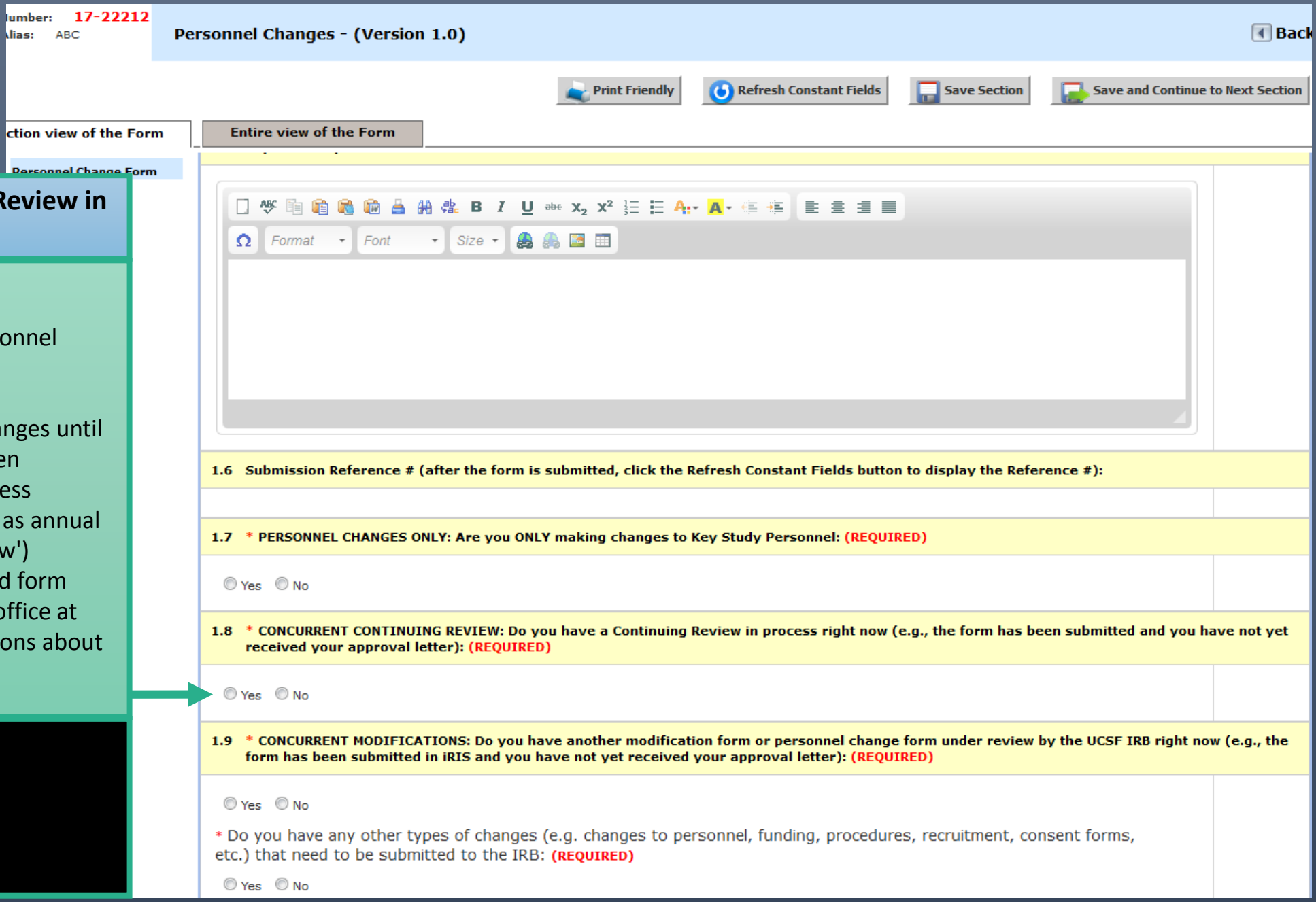


Do you have a Continuing Review in process right now?

Yes: Do **NOT** complete this Personnel Change form. 🚫

Please wait to submit these changes until your Continuing Review has been approved. The IRB will not process modifications at the same time as annual renewals (i.e., 'continuing review') because it causes document and form version problems. Contact our office at irb@ucsf.edu if you have questions about this policy.

No: Continue to next question.

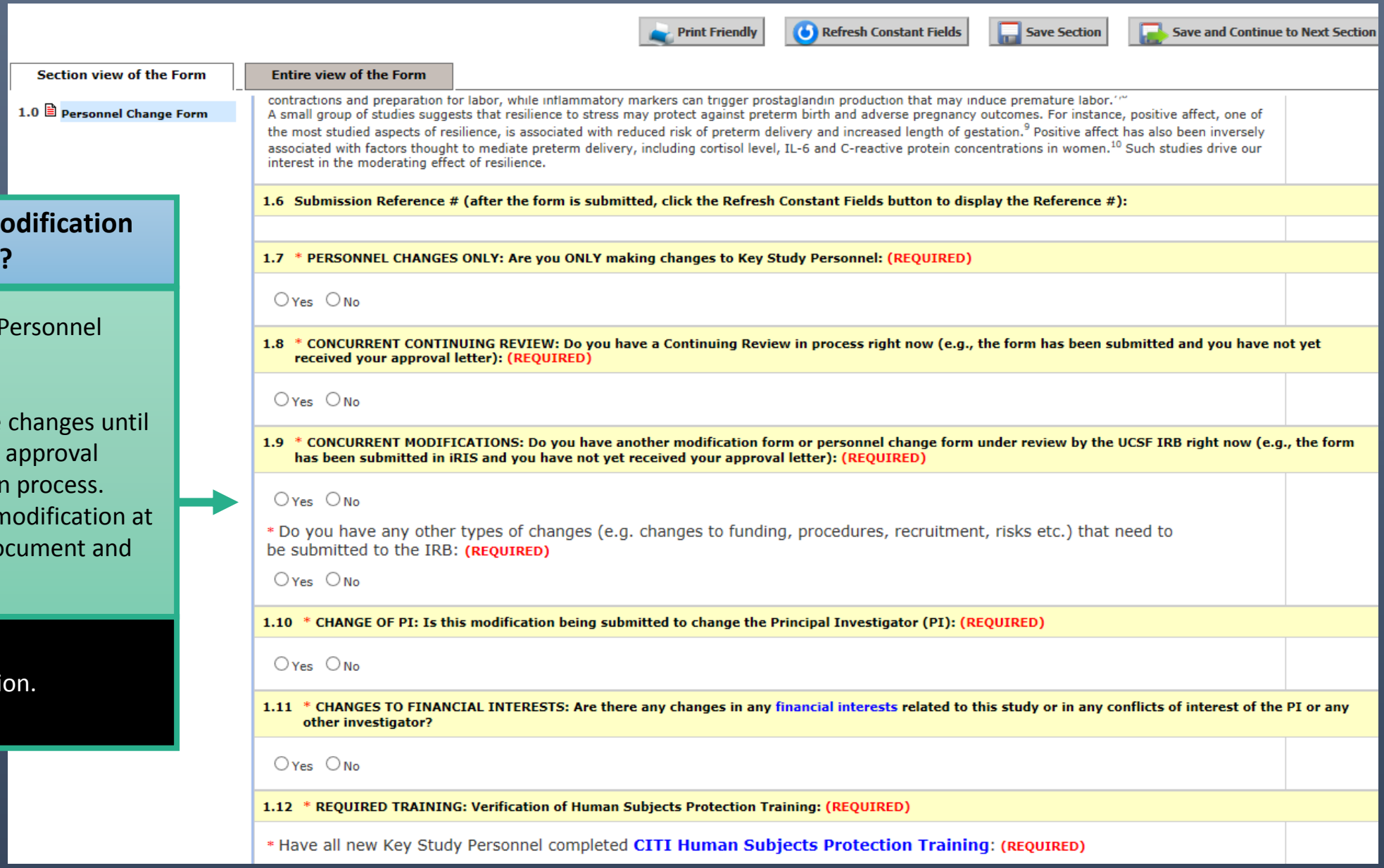


Do you have another modification or change request form?

Yes: Do **NOT** complete this Personnel Change form. 🚫

Please wait to submit these changes until after you have received the approval letter for the modification in process. Processing more than one modification at the same time can cause document and form version problems.

No: Continue to next question.

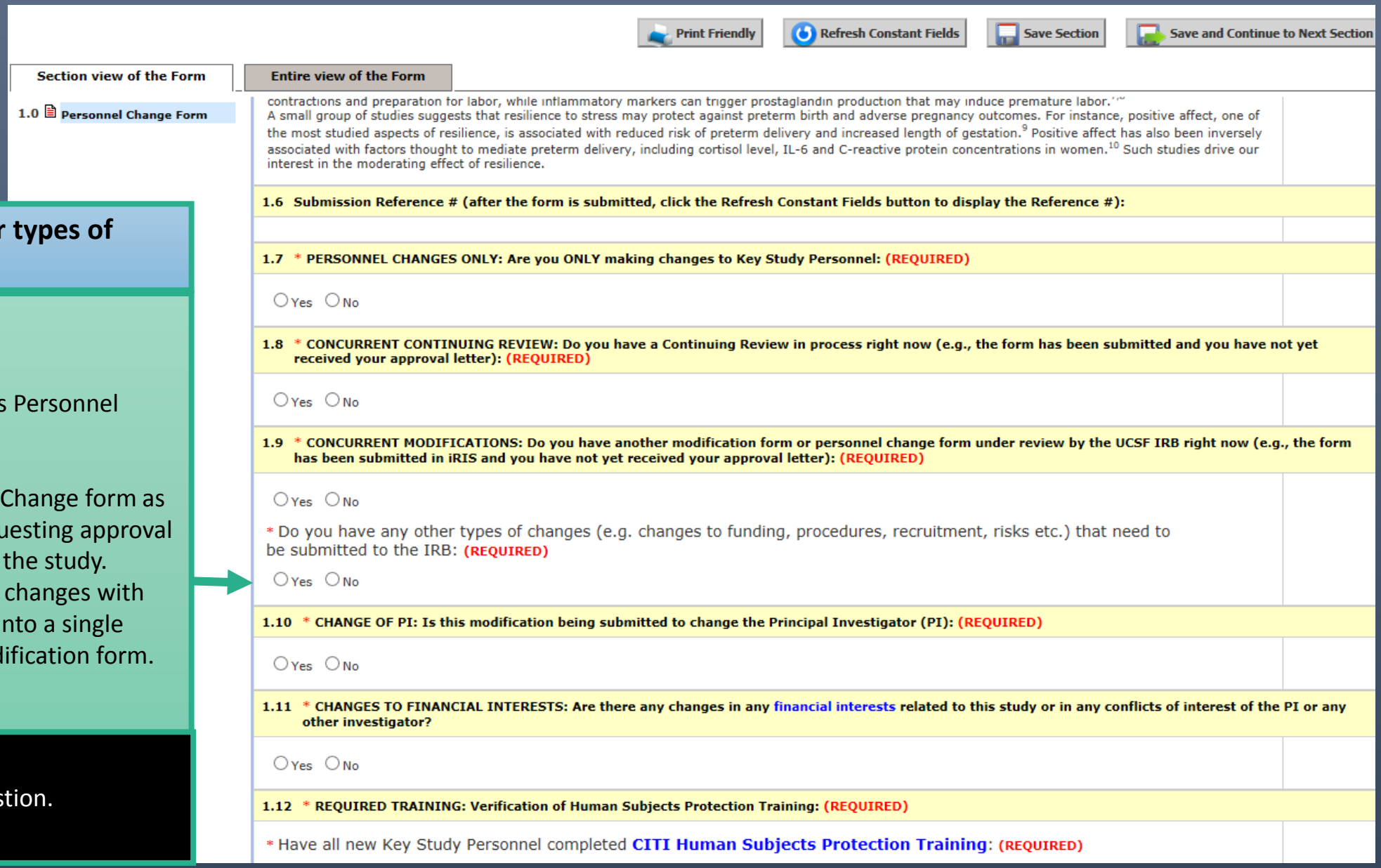


Do you have any other types of changes?

Yes: Do **NOT** complete this Personnel Change form. 🚫

Do not use the Personnel Change form as you indicated you are requesting approval to make other changes to the study. Please combine the other changes with these personnel changes into a single submission using the Modification form.

No: Continue to next question.

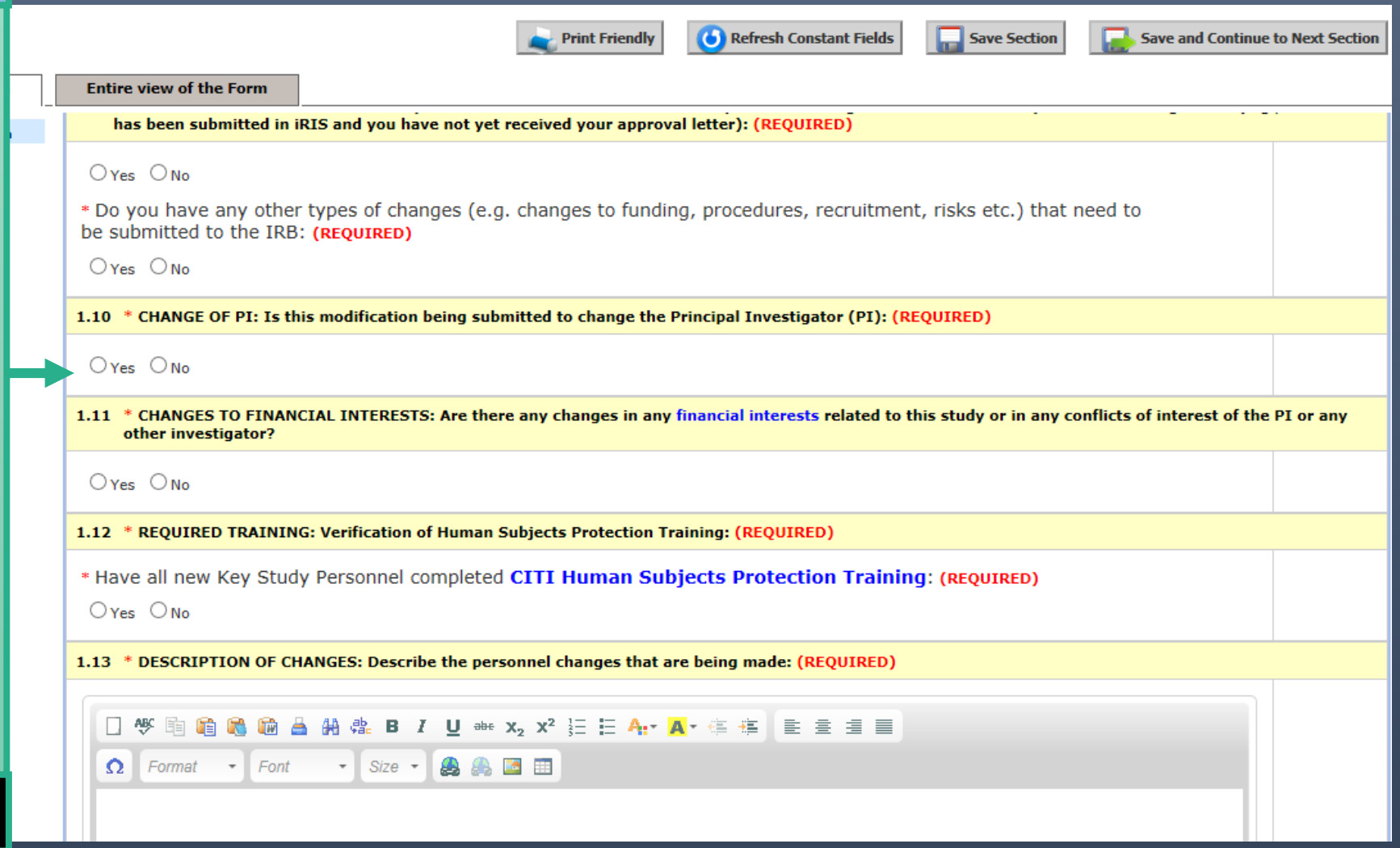


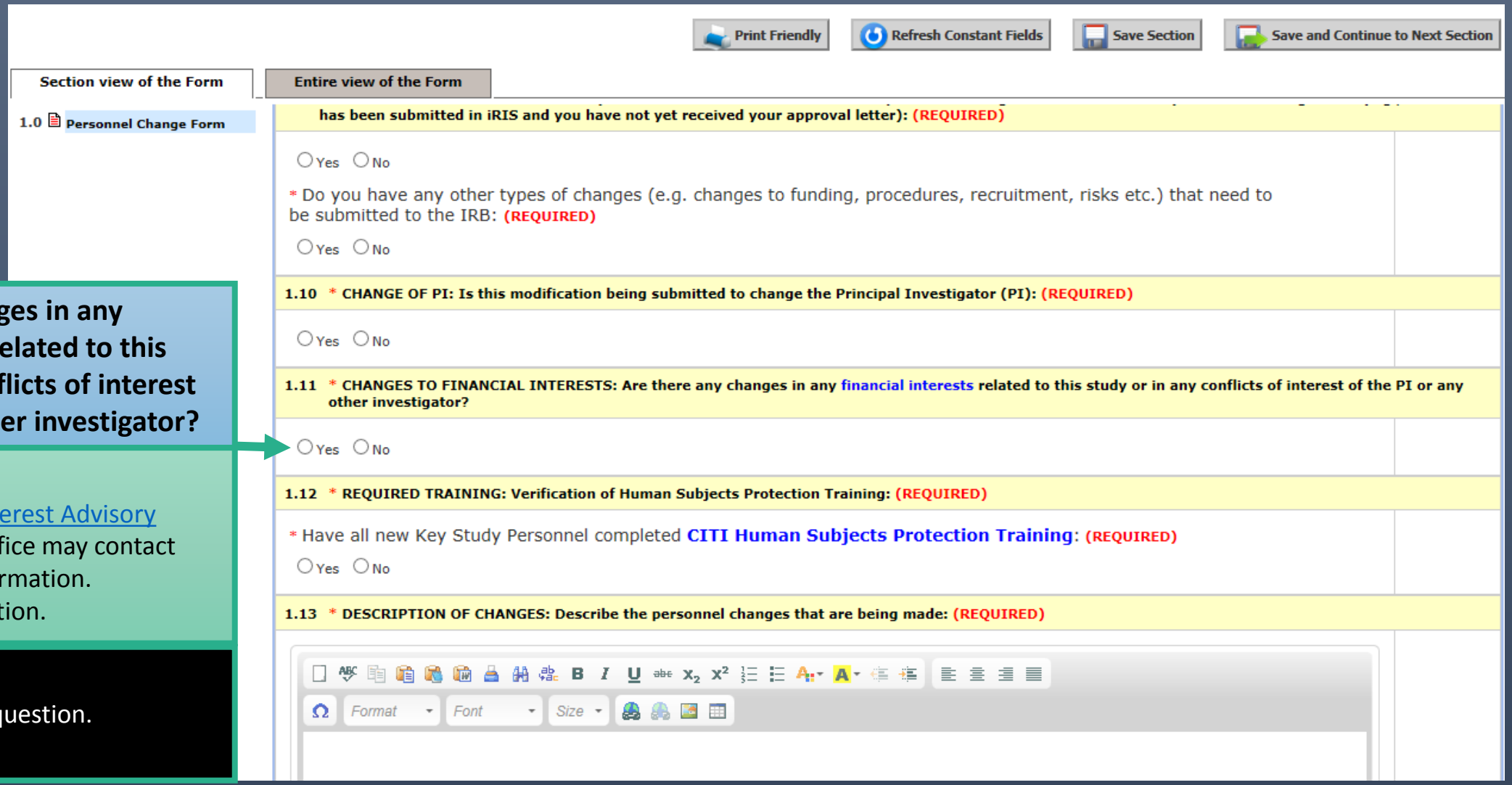
Is this modification being submitted to change the Principal Investigator (PI)?

Yes:

- Verify that the new PI's position corresponds with the selection under the follow-up question.
- Make sure to include documentation that the new PI will assume PI responsibilities for the study.
- Attach the following item in Section 1.14 below
  - IRB Application Form
- Attach the following item in Section 1.15 below
  - A letter signed by the outgoing PI requesting the change
  - Revised consent forms and other participant-contact documents that name the PI

No: Continue to next question.





Are there any changes in any financial interests related to this study or in any conflicts of interest of the PI or any other investigator?

Yes: The Conflict of Interest Advisory Committee (COIAC) office may contact you for additional information. Continue to next question.

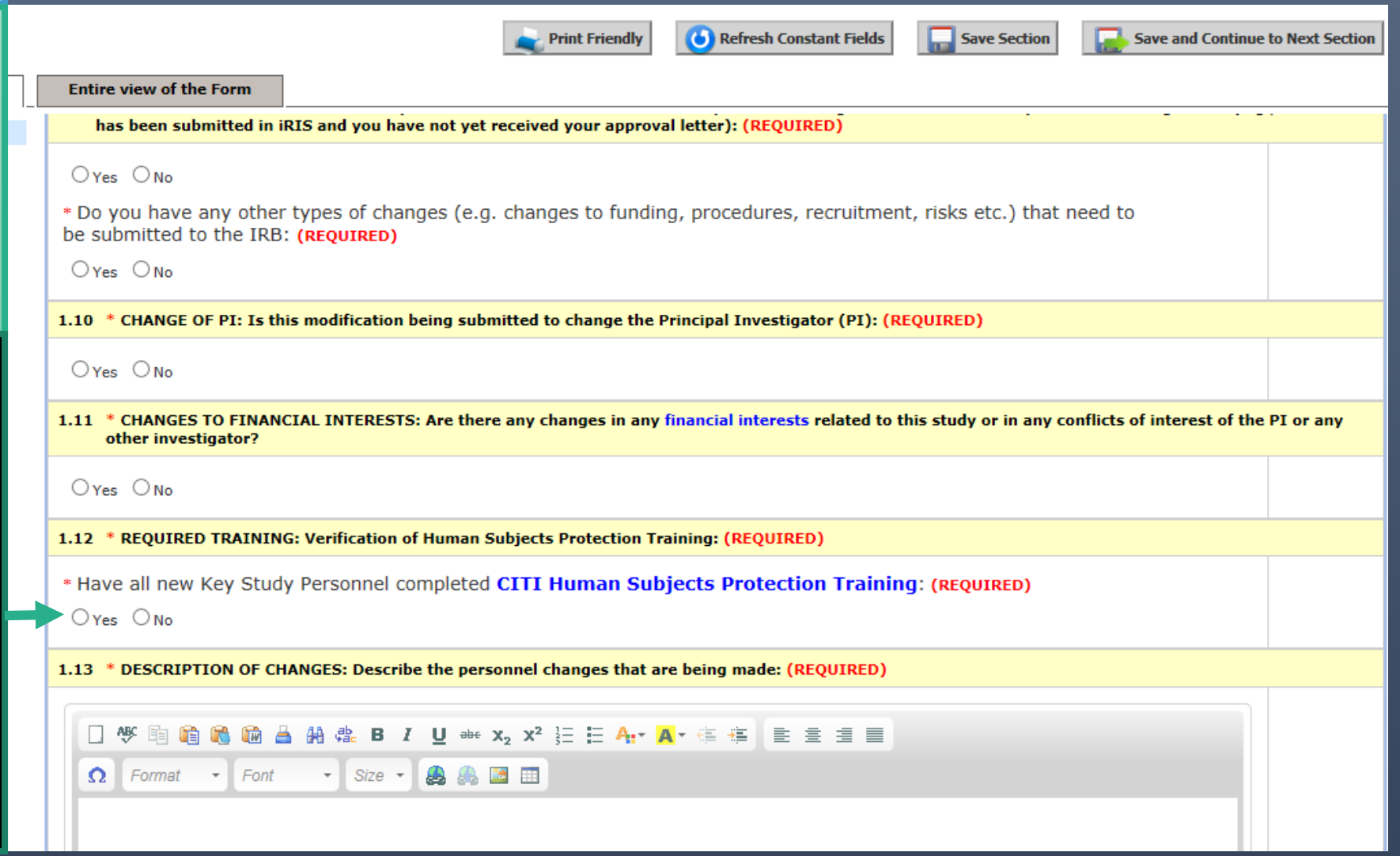
No: Continue to next question.

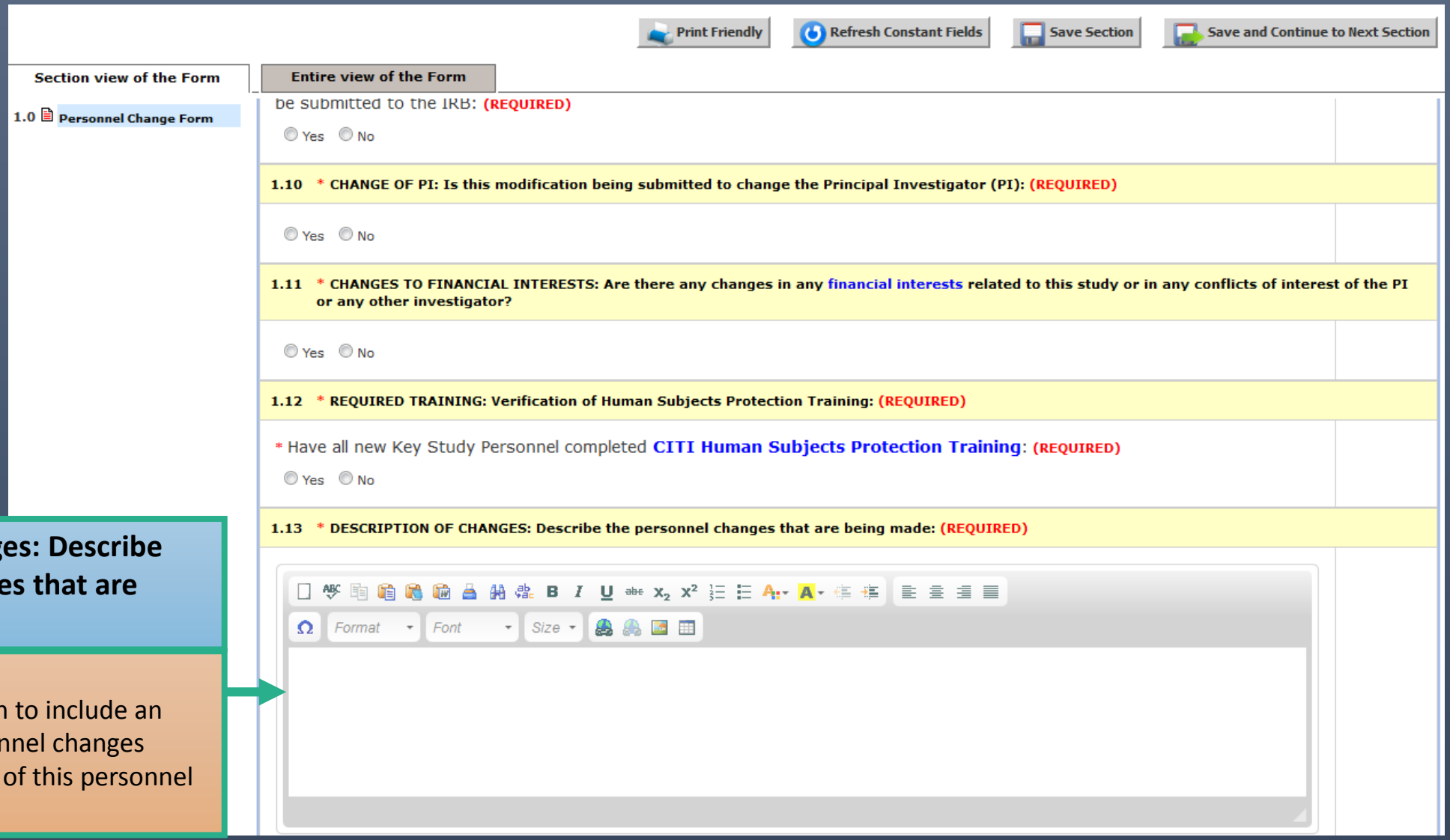
Have all the new key study personnel completed the required Human Subjects Protection Training?

Yes: To verify all Key Study Personnel has completed CITI Human Subjects Protection Training for study approval, check the following lists: UCSF CITI Completion list and the SFVAMC list.

No: If the PI lacks current CITI Human Subjects Protection Training, your submission can be reviewed, but **CANNOT** be approved until the PI completes or renews the CITI training. Please complete the training for study approval.

All Key Study Personnel, including non-PI KSP, must complete CITI Human Subjects Protection Training before participating in any study activities.



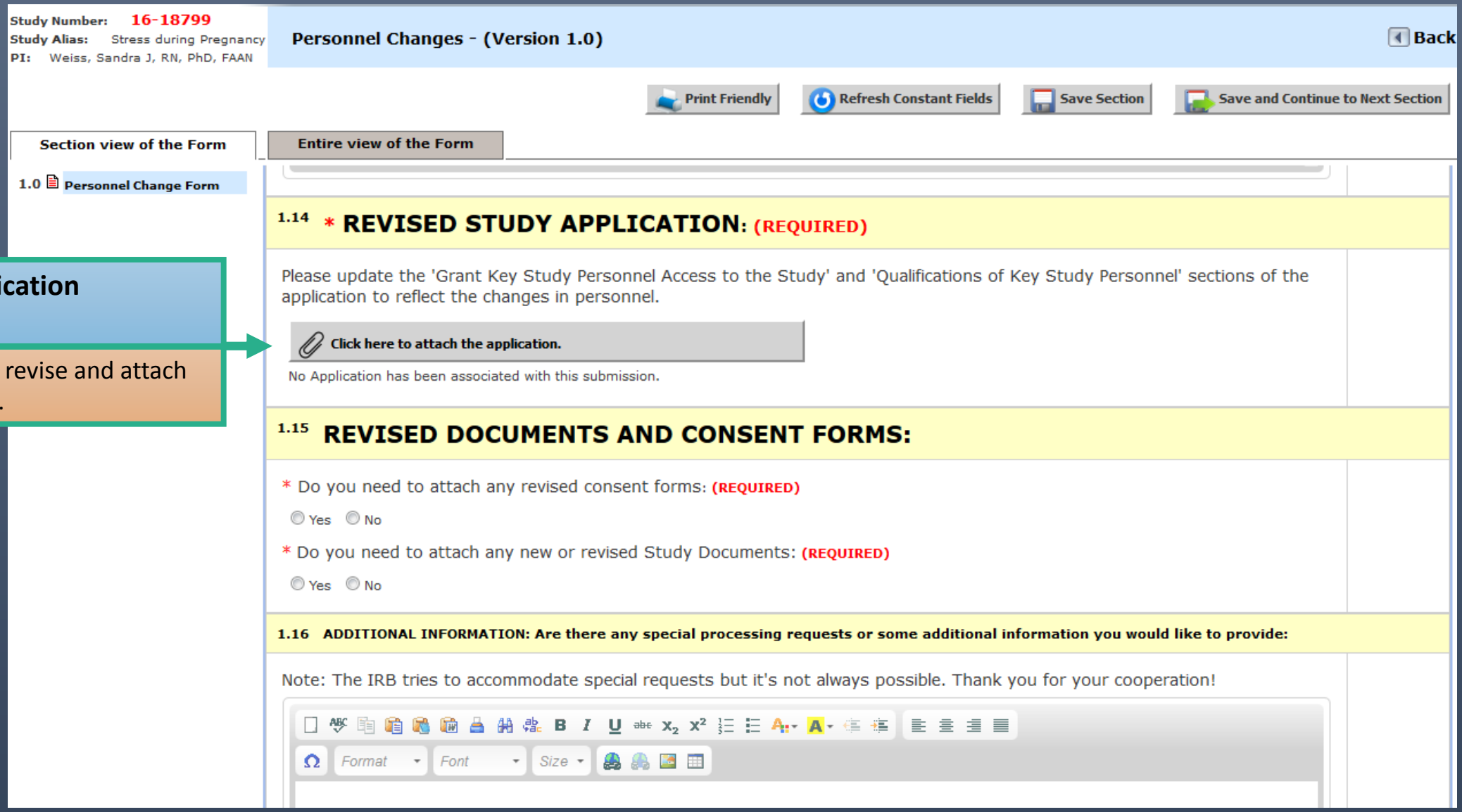


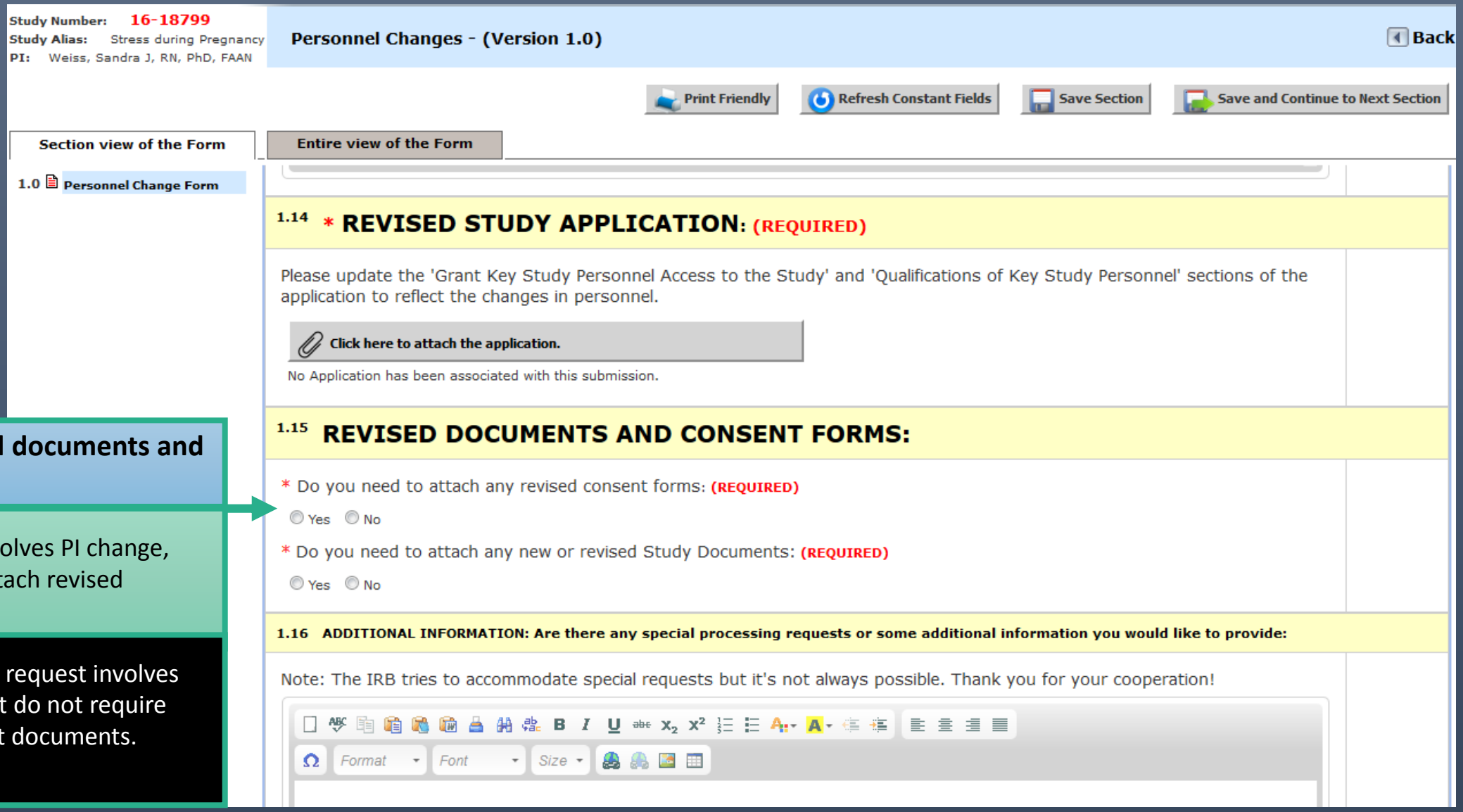
Description of Changes: Describe the personnel changes that are being made:

☛ Note: Use this section to include an itemized list of all personnel changes being requested as part of this personnel change request.

Revised Study Application (Required):

☛ Click the gray bar to revise and attach your Study Application.

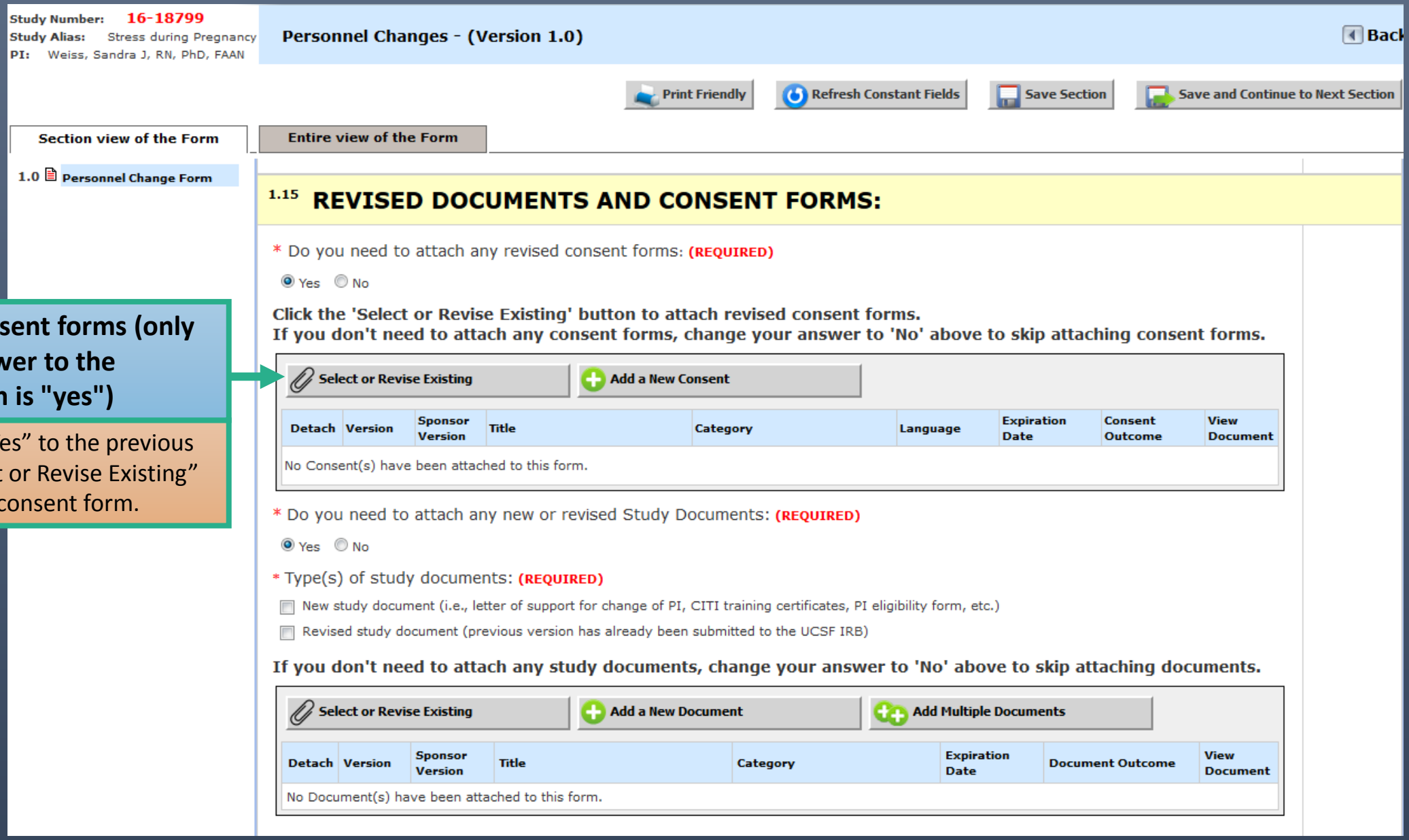




New and/or revised documents and consent forms:

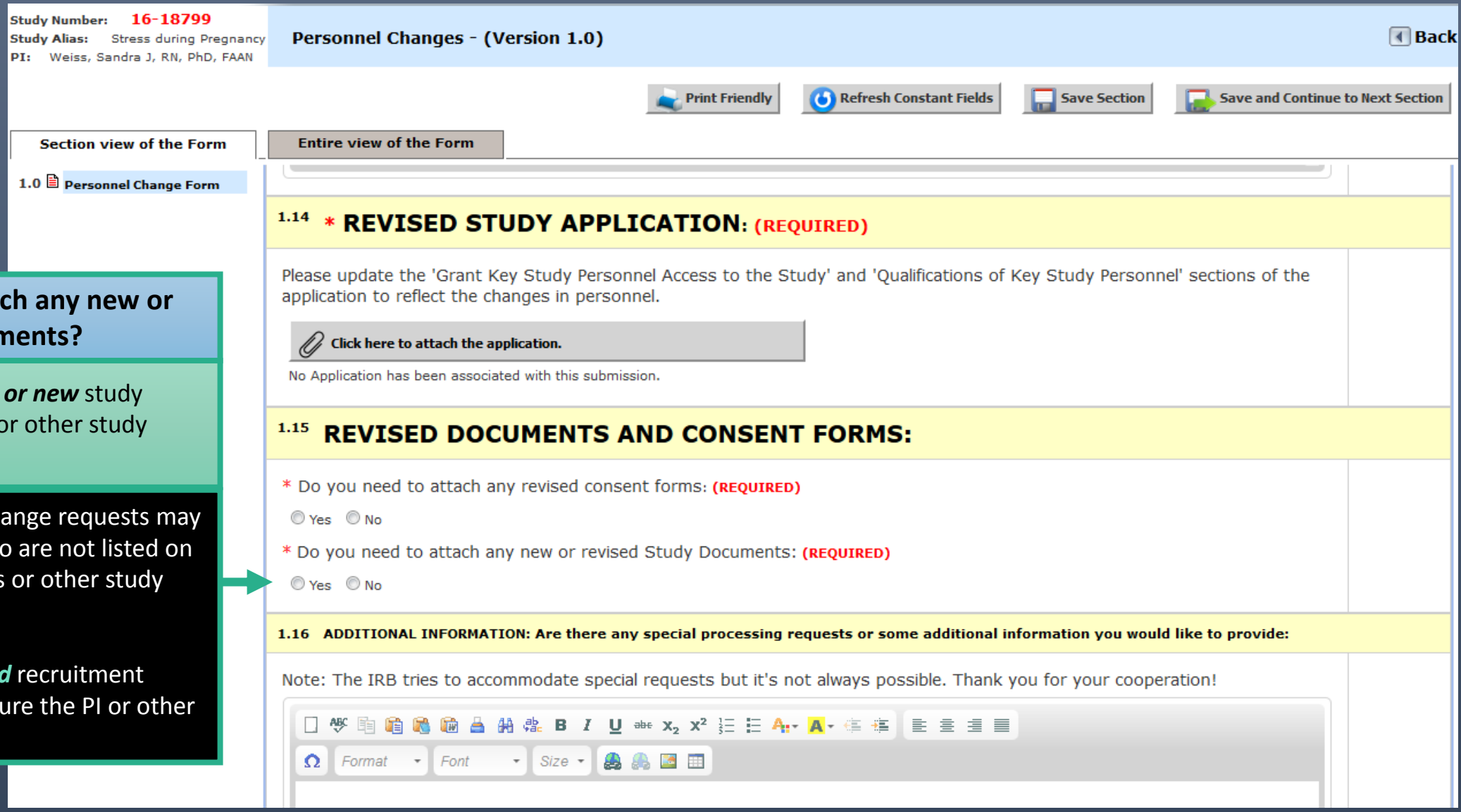
Yes: If your request involves PI change, this should be 'yes'. Attach revised consent document(s).

No: Select "No" if your request involves personnel changes that do not require changes to the consent documents.



Attach revised consent forms (only appears if the answer to the preceding question is "yes")

☛ If you indicated “Yes” to the previous question, click “Select or Revise Existing” to attach the revised consent form.

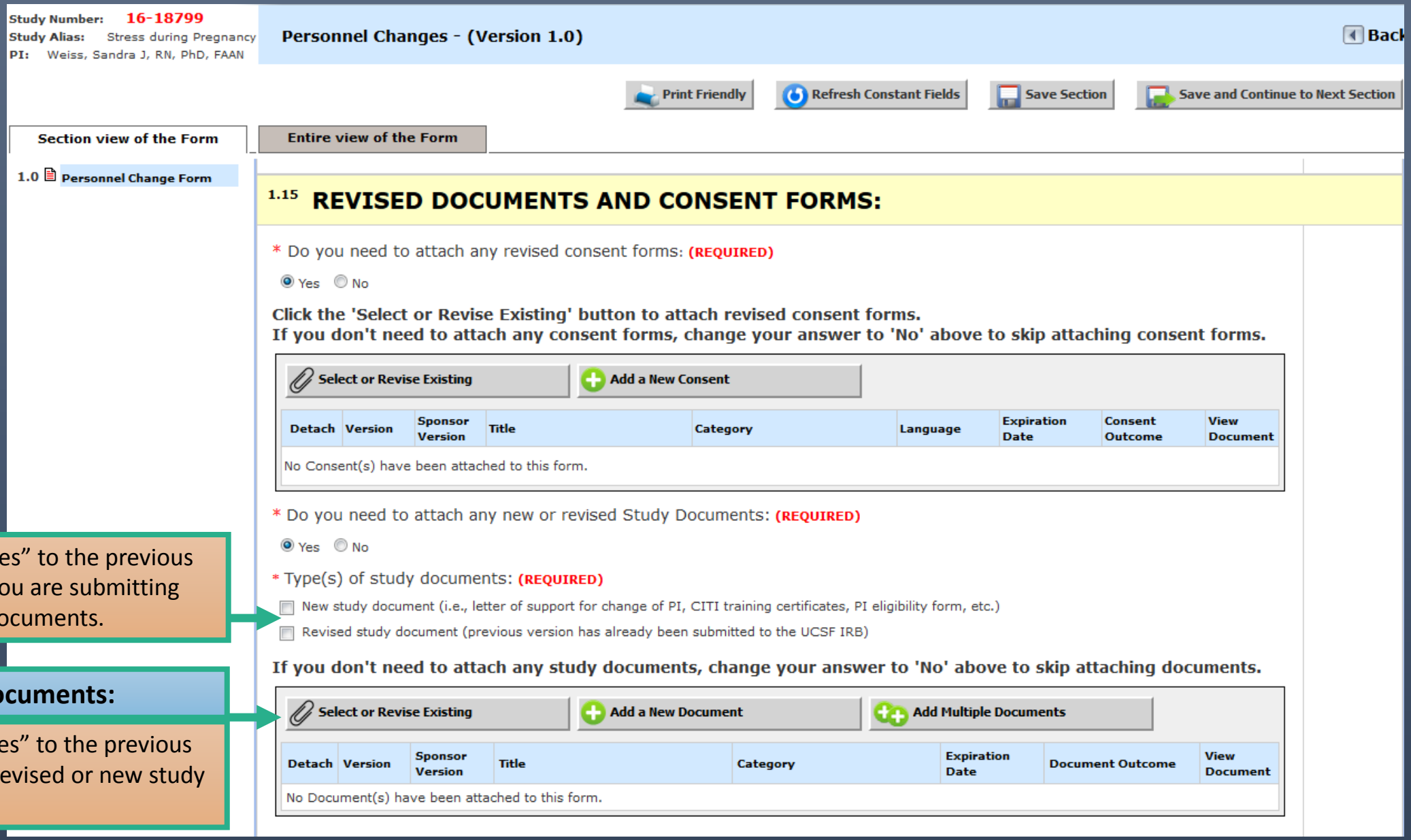


Do you need to attach any new or revised Study Documents?

Yes: Attach any ***revised or new*** study materials listing the PI or other study personnel.

No: Some personnel change requests may involve only people who are not listed on recruitment documents or other study materials.

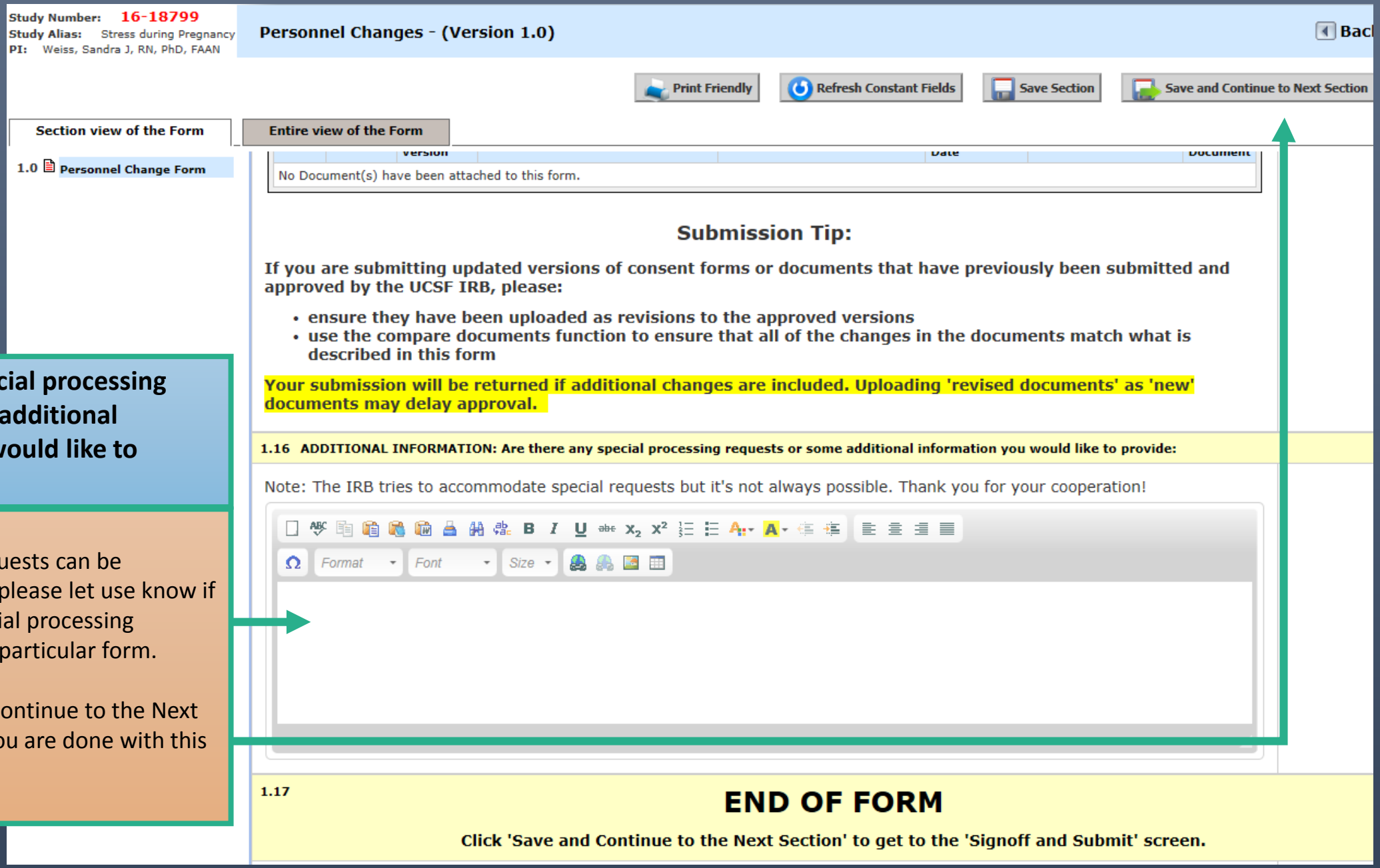
Check ***current approved*** recruitment documents and make sure the PI or other personnel are listed.



☛ If you indicated "Yes" to the previous question, indicate if you are submitting new and/or revised documents.

Type(s) of study documents:

☛ If you indicated "Yes" to the previous question, attach any revised or new study documents.



Are there any special processing requests or some additional information you would like to provide?

- While not all requests can be accommodated, please let use know if there is any special processing requests for this particular form.
- Click “Save and Continue to the Next Section” when you are done with this form.