HOW TO:
COMPLETE THE PERSONNEL CHANGES FORM
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.

Instructions:
Use this form when the ONLY changes you are making are to Key Study Personnel (including PI).

UCSF Key Study Personnel (KSP) include the Principal Investigator, other investigators and research personnel who are directly involved in conducting research with study participants or who are directly involved in using study participants’ identifiable private information during the course of the research. Key Personnel also include faculty mentors/advisors who provide direct oversight to Postdoctoral Fellows, Residents and Clinical Fellows serving as PI on the IRB application.

Do NOT use this form when:
- You are making other modifications in addition to the Key Study Personnel changes. Instead, use the Modification Form.
- You are adding or removing personnel who do not meet the UCSF definition of Key Study Personnel. Instead, follow the IRB guidance for ‘Research support staff or study contacts who are NOT Key Study Personnel.’

There is step-by-step guidance on how to fill out this form on the iRIS help site.
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.

1.14 REVISED STUDY APPLICATION: (REQUIRED)

Please update the 'Grant Key Study Personnel Access to the Study' and 'Qualifications of Key Study Personnel' sections of the application to reflect the changes in personnel.

[Click here to attach the application.]

No Application has been associated with this submission.

1.15 REVISED DOCUMENTS AND CONSENT FORMS:

- Do you need to attach any revised consent forms: (REQUIRED)
  - [ ] Yes
  - [ ] No

- Do you need to attach any new or revised Study Documents: (REQUIRED)
  - [ ] Yes
  - [ ] No

1.16 ADDITIONAL INFORMATION: Are there any special processing requests or some additional information you would like to provide:

Note: The IRB tries to accommodate special requests but it's not always possible. Thank you for your cooperation!
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.
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 revised consent forms? (REQUIRED)
  - Yes
  - No

Click the ‘Select or Revise Existing’ button to attach revised consent forms. If you don’t need to attach any consent forms, change your answer to ‘No’ above to skip attaching consent forms.

* Do you need to attach any new or revised Study Documents? (REQUIRED)
  - Yes
  - No

* Type(s) of study documents: (REQUIRED)
  - New study document (i.e., letter of support for change of PI, CITI training certificates, PI eligibility form, etc.)
  - Revised study document (previous version has already been submitted to the UCSF IRB)

If you don’t need to attach any study documents, change your answer to ‘No’ above to skip attaching documents.

Attach revised consent forms (only appears if the answer to the preceding question is "yes")
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:
- New study document (i.e., letter of support for change of PI, CITI training certificates, PI eligibility form, etc.)
- Revised study document (previous version has already been submitted to the UCSF IRB)

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 us 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.

END OF FORM

Click ‘Save and Continue to the Next Section’ to get to the 'Signoff and Submit' screen.