



## Personnel Modification Guidance

### Instructions

Follow the applicable instructions on How To Submit a Modification, either in HSER, or via email for paper studies, online here: <https://irb.upenn.edu/homepage/how-to-submit/modifications>.

1. Make the necessary changes on the Personnel Page to add personnel or remove them as applicable.
2. Click the red Remove button to remove personnel, if applicable. 
3. Click the green Add or Set buttons to add personnel. 

### Completeness Checks

1. When adding new personnel, please note the following:
  - A. Did you add all Penn staff to the Personnel Page? Double check to avoid the submission being returned to you.
  - B. If a Penn study team member is not selectable in HSER, you need to request an ERA account and research affiliation for this individual. This is often the case for students. The HSER support team can assist you with this process. Please complete the Qualtrics Form linked below. Please contact your associated department Business Administrator to obtain the department's 4-digit Responsible ORG code and confirm the individual's employment status before contacting the IRB for assistance.  
[https://upenn.co1.qualtrics.com/jfe/form/SV\\_1FVGNnePNawraiW](https://upenn.co1.qualtrics.com/jfe/form/SV_1FVGNnePNawraiW)
  - C. Ensure that they have completed the required **CITI Human Research Training curriculum**. Please see <https://irb.upenn.edu/citi> regarding CITI training requirements. **NOTE: Good Clinical Practice and Responsible Conduct of Research training are not the correct curriculum** and do not fulfill IRB requirements.
  - D. **Please note that it takes 24 hours after completion of CITI training for it to feed from Workday to HSER.** If you cannot wait 24 hours, you must upload the individual's completion report into the Additional Documents section on the Confirmation Page of the HSER application.
2. When changing the PI, please note the following:
  - A. If the study has been determined to be greater than minimal risk by the IRB, the PI must be a Penn faculty member.
  - B. If the study is minimal risk (as determined by the IRB), the PI must be a Penn faculty or staff member. Students may not serve as PIs.
  - C. Include a cover letter *signed by both the outgoing and incoming PIs* that documents the transfer of responsibilities. **NOTE: If the old PI has left the institution and their signature cannot be provided, document this in your cover letter. In lieu of the outgoing PI signature, please obtain signature from the Department Chair.**

3. If you are proposing adding individuals who are not Penn staff, please note the following:
  - A. You should first review the engaged in human research guidance online here to determine if the individual is engaged in research:  
<https://irb.upenn.edu/homepage/how-to-submit/initial-submission/is-irb-review-required>.
  - B. If the individual is engaged in research, review <https://irb.upenn.edu/homepage/how-to-submit/single-irb/irb-reliance-agreements> and consult with Patrick Stanko on whether an agreement is required.
  - C. **The IRB does not recommend sponsoring Penn Keys for non-Penn staff** unless all other options have been exhausted and they require access to HSERA or other Penn systems.
  
4. If you are proposing adding Penn Medicine personnel from Chester County, Princeton Health, or Virtua Health:
  - A. Ensure these personnel have completed paper COI forms from:  
<https://irb.upenn.edu/homepage/formsandtemplates>. Attach these with your submission. Questions may be sent to Kim Craig at [kcraig@upenn.edu](mailto:kcraig@upenn.edu).
  - B. If the research will be conducted in NJ, review the NJ state law guidance:  
<https://irb.upenn.edu/homepage/how-to-submit/initial-submission/focused-initial-submission-guidance>.
  
5. If you are proposing adding non-Penn Medicine or Penn Dental personnel (e.g., a student from School of Arts and Sciences or a nursing student from Penn nursing) to a Penn Medicine or Penn Dental study:
  - A. Ensure these staff have the appropriate HIPAA training completed, per Penn Medicine/Dental policies.
  - B. Make efforts to ensure that Penn Medicine/Dental patient PHI is not leaving the covered entity.