

Listed below are the required documents to request a modification to PCORI contracts. Please provide the necessary supporting documents to your contracts administrator with your proposed change request.

REMINDER: If **any** modification(s) will result in a change to a budget category greater than 25%, the budget must be revised via an official contract modification (see budget revision below).

1. Scope of Work/Methodology/Research Plan Change

- Justification for requested change. The justification should include a narrative explaining how this change will affect the study. Any potential obstacle(s) should include a mitigation plan.
- New/Revised Scope of Work/Methodology/Research Plan
- Modified Milestone Schedule
- Revised Budget and Budget Justification (if applicable)

2. Key Personnel Change

- Justification for requested change. The justification should include a narrative explaining how this change will affect the study. Any potential obstacle(s) should include a mitigation plan.
- CV/Biosketch (for all new key personnel)
- Updated Conflict of Interest Form (Attachment C of the Contract)
- Revised Budget and Budget Justification (if applicable)

3. Subcontract Site Change

- Justification for requested change. The justification should include a narrative explaining how this change will affect the study. Any potential obstacle(s) should include a mitigation plan.
- CV/Biosketch (for all new key personnel)
- New Budget and Budget Justification for proposed site
- Statement of Work for proposed site
- Revised Budget and Budget Justification for the Prime (if applicable)

4. Change in Prime Institution

- Relinquishment Statement from old institution
- Confirmation of the Principal Investigator's new appointment (Letter of Appointment at new Institution)
- Explanation of the impact this transfer will have on the project
- Description of the new organizations research environment
- Revised research plan
- Revised Milestone Schedule
- Revised Budget and Budget Justification

Handout #1

- List of updated key personnel
- CV/Biosketch (for all new key personnel)
- Final invoice from old institution
- Final reports from old institution

5. Change in PI

- Justification for requested change. The justification should include the proposed start date of the new PI, and a narrative explaining how this change will affect the study. Any potential obstacle(s) should include a mitigation plan.
- CV/Biosketch (for new PI)
- If the original PI is continuing on the project and is moving to a new/existing subcontractor:
 - Appointment letter from the subcontractor where the PI is moving to
- Revised Budget and Budget Justification (if applicable)

6. Period of Performance

- Justification for requested change. The justification should include a narrative explaining how this change will benefit the study. Changes to the period of performance, must include a strong justification and benefit to the study.
- Revised Milestone Schedule
- Revised Budget and Budget Justification (if applicable)

7. Milestone(s)

- Justification for requested change. The justification should include a narrative explaining how this change will affect the study. A plan on how the study will continue on track should be included, if applicable.
- Revised Milestone Schedule

8. Budget Revision

- Justification for requested change. The justification should include a narrative explaining how this change will affect the study. Any potential obstacle(s) should include a mitigation plan.
- Revised Budget and Budget Justification