

**MODIFICATION OF PROJECTS FUNDED BY THE
QUALITY ENHANCEMENT RESEARCH INITIATIVE (QUERI)**

1. EXPECTATION. Quality Enhancement Research Initiative (QUERI) expects all programs or projects it sponsors to be carried out according to the plan presented in the approved proposal. Approvals of requests for modifications involve situations beyond the control of the Principal Investigator. Once funding has started, investigators must obtain formal approval from the Director, QUERI, for any significant change in objectives, methods, budget, time, key personnel, or location. Requests for changes must be submitted in writing by the medical center Director, through the Associate Chief of Staff (ACOS) for Research and Development (R&D) to the Director, QUERI, in conformance with the following procedures. A project that is changed without prior approval is at risk of termination.

2. PROCEDURES FOR REQUESTING A MODIFICATION

- a. The following instructions pertain to QUERI Programs, Partnered Evaluation initiatives, or other independently-funded projects not affiliated with a QUERI program. NOTE: this process does NOT apply individual projects within QUERI field Programs
- b. To permit careful review, all modification requests must be submitted as soon as the need becomes apparent and, in all cases, prior to the effective date of the proposed change. Approval requires that a strong rationale be provided for the changes.
- c. All requested modification documents must be submitted electronically via email to vacoqueri@va.gov. The justification for every request must address in detail any implications for personnel, budget, timeline, and project feasibility (as applicable), and must include appropriate supporting documents, such as new budget pages, Gantt charts, curriculum vitae (CV), etc. Adequate information must be provided to permit reviewer(s) to determine why the change is necessary and to allow thorough evaluation of the request.
- d. Project modifications are viewed on an ongoing basis. Incomplete project modification requests will not be reviewed and will be returned to the Principal Investigator.
- e. Project modifications in budget CANNOT involve transfer of funds between fiscal years.
- f. **The following situations require a QUERI project modification request for approval:**

(1) **No-cost extensions to Program or Partnered Evaluation (but not for specific projects under the QUERI Program).** NOTE: Program or Partnered Evaluation Final Reports are due within 90 days of the project's official end date. Investigators are expected to complete program or project work within the approved-funding period and to notify QUERI early regarding any significant delay. A modification request is required if additional time is needed either to complete program or project work, or to complete the final report beyond the 90 day grace period, whether or not additional budget is also requested. All requests for additional time must be well justified, and the amount of time requested should be no greater than 6 months.

(2) **Change in Objectives or Methods to Overall Program (but not individual Program projects) or Partnered Evaluation.** Approval must be obtained for substantial changes to goals/objectives, methods, or procedures of funded **programs, partnered initiatives, or**

independent projects (but NOT for QUERI program projects). Changes that require a modification request include: a) fundamental changes to key study aims of programs, partnered evaluations, or independent projects not affiliated with QUERI programs, b) fundamental changes to the study design, including changes to use of comparison groups or systematic allocation of programs, partnered evaluations, or independent projects, or c) addition or deletion of sites or significant sources of data for projects considered research only (e.g., additional patient or provider survey cohorts or secondary data sources not originally included in the project)- see VHA Handbook 1058.05 for further details regarding research versus non-research, or quality improvement protocols. The written request must provide a detailed explanation of the proposed change, its rationale, and implications.

(3) Change in PI, or Location/Employment Status of PI

- a. QUERI programs or projects are awarded to the medical facility where the PI is employed at the time of the award. If the PI of a partnered evaluation or project, or corresponding PI of a QUERI program transfers to another VA facility, the program, evaluation, or project remains at the original facility until approval is secured for transferring the project to the new facility.
- b. A request for transfer of the Program or Partnered Evaluation PI between facilities must include written documentation from the medical center Director of each facility agreeing to the transfer. However, final approval rests with the Director, QUERI.
- c. If the Program or Partnered Evaluation requests a new PI, the current PI must provide written authorization agreeing to transfer the project to the new PI, along with the new PI's CV and proof of VA employment status (at least 5/8ths VA time). Approval of the change in PI must be obtained from the Director, QUERI before the new PI can assume responsibility for the project.

(4) Change in PI Employment Status

- a. If the VA employment status of the PI (or any PI listed in a QUERI program with multiple PIs) drops below a 5/8 paid appointment, an eligible VA investigator must replace that PI.
- b. The ACOS for R&D is responsible for notifying QUERI of a change affecting PI eligibility within 2 weeks of receipt of this information. This notification must be accompanied by a request for approval of a new PI and supporting information.

(5) Change in Key Personnel

- a. A change in any PI of a program, partnered evaluation, or other independent project (not affiliated with a program) may not be made without the approval of the Director, QUERI. Supporting information submitted with any request to change a PI must be accompanied by a letter from the current PI indicating the PI's agreement to relinquish responsibility for the project to the proposed new PI and a letter from the new PI accepting responsibility for the project.

- b. Approval from the Director, QUERI is also required to change any other project participants who are responsible, in whole or in part, for the design, execution, or management of the program, evaluation, or project. Medical centers must provide a CV of new participant(s) and other supporting documents to permit HSR&D to assess their qualifications, competing commitments, etc.

(6) Change in Budget

- (a) NOTE: QUERI funds CANNOT be transferred to the next fiscal year. QUERI approval for any changes in budget must be applicable to the current fiscal year and must be requested in writing for any budget change, and a clear justification for the budget change must be included. QUERI does not generally approve a budget increase of over 20% unless it can be clearly justified. The PI must provide a summary budget (including degrees) and budget justification.
- (b) Budget templates are provided in the attached file. *In the budget form be sure to list all personnel including Site PIs.*

A slide deck highlighting the budget process is available:

<http://vaww.research.va.gov/funding/docs/BudgetSubmission.pdf>

A cyberseminar explaining the slide deck is also available here:

<http://vaww.research.va.gov/funding/ord-021116.cfm>

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**REQUEST FOR MODIFICATION OF QUERI PROGRAM, EVALAUTION, OR
OTHER INDEPENDENT PROJECT**

SAMPLE FORMAT OF COVER PAGE

1. Identifying Information

- a. Project Number _____
- b. Project Title _____
- c. Name of Principal Investigator _____
- d. Principal Investigator's Department of Veterans Affairs (VA) Facility _____
- e. Principal Investigator's Telephone No. _____

2. Request for a change in: *NOTE: Check all that apply.*

- a. ___ Time (From: _____ To: _____ , ___ Months)
- b. ___ Goals, Objectives, or Design (research OR quality improvement)
- d. ___ Location/data sources for **research** protocols only (Describe site/data: _____)
- e. ___ Key Personnel (Name: _____ Degrees: _____)
- f. ___ Budget (Total amount of increase: FY___ \$ _____ , FY___ \$ _____)

3. Preferred effective date of requested change _____

(Signature of Principal Investigator) (Date)

(Signature of Center of Excellence or Research Enhancement Award
Principal Investigator (if applicable)) (Date)

(Signature of Associate Chief of Staff for Research and Development) (Date)

(Signature of Medical Center Director) (Date)

**MODIFICATION CHECKLIST FOR QUERI PROGRAM, PARTNERED
EVALUATION, OR INDEPENDENT PROJECT**

Type of project modification	
Project Extension	<ul style="list-style-type: none"> • Must provide justification • Must provide summary budget pages • Must provide Gantt Chart
Change Objectives or Design	<ul style="list-style-type: none"> • PI must provide justification • Check for possible OMB, IRB, QI approval requirements • Is NOT required for projects within QUERI Programs
Change in Study Site/Data	<ul style="list-style-type: none"> • Research protocols only • PI must provide justification • Site name • IRB approval(s) • If project is a RCT and multisite, report to DSMB if applicable
Change in Location	<ul style="list-style-type: none"> • Letter from releasing VAMC and the accepting VAMC
Key Personnel	<ul style="list-style-type: none"> • PI must provide justification • Provide name and educational degrees • For change in PI: <ul style="list-style-type: none"> ○ Must provide letter from PI relinquishing responsibility to new PI ○ Provide letter from new PI accepting responsibility ○ Letter from releasing VAMC and the accepting VAMC ○ CV for new PI ○ Biosketch ○ New budget
Budget	<ul style="list-style-type: none"> • PI must provide a summary budget table • Budget justification