

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

1. EXPECTATION. Quality Enhancement Research Initiative (QUERI) expects all research projects it sponsors to be carried out according to the plan presented in the approved proposal. Approval 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. 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.
- b. All requested modifications must be submitted electronically Via email to Linda.McIvor@va.gov and a copy to John.Midolo@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.
- c. Project modifications are viewed on an ongoing basis. Incomplete project modification requests will not be reviewed and will be returned to the Principal Investigator.
- d. Requestors must send the project modification request with the modifications cover page electronically in a PDF file to: vhacohsrdpm@va.gov. Project modifications will be reviewed on an ongoing basis, provided all necessary documentation has been included in your request.
- e. The following paragraphs address issues related to specific types of requested modifications.

(1) **Increase in Time.** Investigators are expected to complete project work within the approved-funding period and to notify QUERI early regarding any significant delay. Formal approval is required to extend a project-completion date, 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 less than 6 months. If a project will not be completed by the end date, the PI must submit a modification request to extend the end date.

(a) Project Final Reports are due within 90 days of the project's official end date. In rare circumstances, an extension of the due date can be requested. Requests for additional time to prepare the Final Report must be submitted to the assigned Scientific Program Manager (SPM)

through the Associate Chief of Staff (ACOS) for R&D. A “Request for Modification” is not required for this purpose.

(2) **Change in Objectives.** Approval must be obtained to add, delete, or significantly alter the objectives of a funded project. The written request must provide a detailed explanation of the proposed change, its rationale, and implications. A fundamental change in study design is not permitted unless prior approval has been obtained. It is the responsibility of the PI to provide IRB clearance for each site and OMB briefs, if they apply.

(3) **Change in Methods**

(a) Approval must be obtained to change any key component of the approved research plan. This includes, but is not limited to: sampling plan, source(s) of data, addition of another “arm” or comparison group, data collection instrument(s), data collection method(s), or analysis plan. A fundamental change in study design (e.g., elimination of a control group, use of retrospective instead of prospective data, etc.) is not permitted unless prior approval has been obtained.

(b) The request for approval of methodological changes must include a clear description of how the proposed change differs from the methodology described in the approved proposal, why a change is needed, and how the proposed change will resolve the problem. The request must be supported with sufficient information to allow a comprehensive scientific review. As an example, if a modification affects prior patient accrual expectations, the request needs to include a replication and comparison to the power analysis used in the original, funded proposal, after appropriate adjustment for effect size, etc. It is the responsibility of the PI to provide IRB clearance for each site, OMB briefs if they apply, and a DSMB Data Analysis Plan if the project is a Randomize Clinical Trial and multisite. If an additional site is being added, please reference section 4.

(4) **Adding Study Site**

(a) A request for the addition of a study site may not be made without the approval of the Director, QUERI. The request for the addition of a site must include a clear description of why an additional or replacement site is required and how the proposed change will benefit the project. The request must be supported with sufficient information to allow a comprehensive scientific review. It is the responsibility of the PI to provide the site name, IRB, and the R&D clearance for each site, OMB briefs, if they apply; and a DSMB Data Analysis Plan, if a project is a Randomize Clinical Trial.

(5) **Change in Location**

(a) QUERI projects are awarded to the medical facility where the PI is employed at the time of the award. If the PI or co-PI transfers to another VA facility, the project remains at the original facility until approval is secured for transferring the project to the new facility.

(b) A request for transfer of a project 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 PI moves to another VA, and no longer wants to conduct research, the PI must provide written authorization agreeing to transfer the project to a new investigator. Approval of the change in PI must be obtained from the Director, QUERI before the new PI can assume responsibility for the project.

(6) Change in PI (or Co-PI) Employment Status

(a) If the VA employment status of the PI or Co-PI 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 (see preceding subpar. 2e(5)).

(7) Change in Key Personnel

(a) The Principal Investigator (PI) and Co-PI (if one) are responsible for carrying the funded project through its completion. A change in PI or co-PI 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 of Department of Veterans Affairs (VA) Central Office also is required to change any other project participants who are responsible, in whole or in part, for the design, execution, or management of the project, and for any change in their time commitment to the project. Medical centers must provide a CV of the new participant(s) and other supporting documents to permit HSR&D to assess their qualifications, competing commitments, etc.

NOTE: For a funded project involving a mentor (e.g., Career Development) expects that the time commitment and geographic proximity of the awardee and mentor remain as presented in the approved project. If either the awardee or mentor seeks a decrease in time commitment or transfer to another facility, formal approval must be obtained.

(8) Change in Budget

(a) QUERI approval must be requested in writing for any budget change. The request must contain a clear explanation as to why the awarded budget was inadequate. QUERI does not generally approve a budget increase of more than 20 percent of the originally approved project budget. PI must provide a summary budget (including degrees) and budget justification (a sample summary budget can be found: <http://www.hsrresearch.va.gov/funding/sample-budget-table.xls>)

(b) A request for an increase in budget must include a description of efforts taken locally to address the budgetary deficiencies, including use of local QUERI, HSR&D, R&D, or other resources.

(c) If funds need to be transferred to the next fiscal year, a project modification must be submitted even if the total amount requested stays the same.

**REQUEST FOR MODIFICATION OF QUALITY ENHANCEMENT RESEARCH
INITIATIVE SERVICE-FUNDED 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: MM/DD/YY To: MM/DD/YY, XMonths)
- b. ___ Objectives
- c. ___ Methods
- d. ___ Location (site: _____)
- e. ___ Key Personnel (Name: _____ Degrees: _____)
- f. ___ Budget (Total amount of increase: FYYY_\$ _____ , FYYY \$ _____)

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)

PROJECT MODIFICATION CHECK LIST

Type of project modification	Supporting documentation required and implications
Project Extension	<ul style="list-style-type: none"> • Must provide justification • Must provide summary budget pages • Must provide Gantt Chart • IRB may have to also be extended-PI must provide approvals
Change Objective	<ul style="list-style-type: none"> • PI must provide justification • IRB may be required • Check for possible OMB issues
Methods	<ul style="list-style-type: none"> • PI must provide justification • Fundamental change in study design is not permitted • Check for possible changes in: IRB, OMB, and DSMB (if RCT) requirements
Add Study Site	<ul style="list-style-type: none"> • PI must provide justification • Site name • IRB approval(s) • If project is a RCT and multisite, then it must report to the DSMB
Change in Location	<ul style="list-style-type: none"> • Letter from releasing VAMC and the accepting VAMC
Personnel	<ul style="list-style-type: none"> • PI must provide justification • Provide name and educational degrees • We do provide salary support for MD, Pharma, PT or RN (a clinical waiver can be used for Title 38 employees) • 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