

Criteria and Instructions for Requesting an HSR&D Administrative Project Modification

The Office of Research and Development (ORD) expects all research projects it sponsors to be carried out according to the plan presented in the approved application. Requests for modifications should be rare, involving situations beyond the control of the Principal Investigator (PI). In accordance with VHA Handbook 1200.2 (Research Business Operations), PIs with the concurrence of their Associate Chief of Staff (ACOS) for R&D, must obtain formal approval from the appropriate Service Director (Biomedical Laboratory (BLRD), Clinical Science (CSR), Health Services (HSR), or Rehabilitation (RRD)) for any significant changes in project duration, budget, aims, methods, site(s), or key personnel after their application has been reviewed and selected for funding.

Blackout dates: August and September. All current fiscal year requests with a budget or extension, must be submitted by August 1 due to closing of financial databases.

Project modification budgets should only list current and future fiscal years and should be submitted as fiscal years rather than project years (JIT budgets). Budgets should use the HSR&D Summary Budget Table and must include the budget justification. The Summary Budget Table or Recruitment Table may be requested by emailing vhacohtsrdpm@va.gov.

I. No-Cost Extension

An awardee may apply for a no-cost extension to the award end date with or without redistribution of funds (see paragraph III.). The awardee is encouraged to request a project modification as soon as the need for the extension is anticipated and not at the end of the funding period.

Reasons for requesting a no-cost extension include, but are not limited, to:

- PI changes station and is unable to perform research until new facilities are set up and committee approvals have been obtained.
- PI had to relocate research facilities to another location at the same site
- Delay in hiring research staff
- Delay in executing contracts or obtaining critical equipment or supplies

Required documents to be submitted with a no-cost extension request include:

- A revised Quad Chart.
- An updated summary recruitment table, if this is an HSRD funded human subject study and recruitment is impacted
- A revised budget if a redistribution of funds is requested.

II. Cost Extension

Cost extensions are considered only in rare situations, and only if efforts taken locally to address the budgetary deficiencies (e.g. use of locally unobligated and carry over funds) have been insufficient.

Reasons for requesting a cost extension include, but are not limited, to:

- A clinical trial (e.g., has not achieved target enrollment) where a short extension may ensure success
- Catastrophic event that damages facilities (e.g., flooding, fire, earthquake)
- A supplement to the current project (e.g., develop an implementation)

Required documents to be submitted with a cost extension request include:

- A revised budget (summary budget worksheet and budget justification narrative)
- A revised Quad Chart.
- An updated summary recruitment table, if this is an HSRD funded human subject study and recruitment is impacted
- If a supplement, a narrative of the proposed supplemental aim.

III. Redistribute Funds

Redistribution of funds (can be requested without a change to the award end date) are considered only in rare situations as it has a negative impact on our budget and minimizes the number of new award starts in the years involved. The awardee is encouraged to request a project modification as soon as the need for the redistribution is anticipated and not at the end of the funding period.

Reasons for requesting a redistribution of funds include, but are not limited, to:

- Significant change in key personnel that has impacted recruitment
- Failure of a significant piece of equipment required to conduct the study
- Catastrophic event that damages facilities (e.g., flooding, fire, earthquake)

Required documents to be submitted with a request for redistribution include:

- A revised budget (summary budget worksheet and budget justification narrative)
- An updated summary recruitment table, if this is an HSRD funded human subject study and recruitment is impacted

IV. Change in Aims, Methods, or Key Personnel/Effort, and/or Budget

Funds are awarded for the study to be conducted as reviewed and approved. Significant changes to any key component of the research plan as proposed in the approved application therefore must be approved by the funding Service. The Services reserve the right to require review of modification requests by external expert(s).

Significant changes might include, but are not limited, to:

- A revised aim necessitated by recent research findings that impact the conduct of the proposed study
- A change in methods that requires new analyses or additional key personnel, or is in response to an ethical concern raised by a review committee
- An alteration to inclusion/exclusion criteria to ensure adequate participant recruitment
- A change of 25% or more (cumulative) in the level of effort for the PI or other senior/key personnel designated in the application
- Publication costs not covered in original funded budget. Publication costs of up to \$3,000 will be considered.

Required documents to be submitted with a change in aims, methods, key personnel/effort, and/or budget request include:

- If adding new senior/key personnel, provide their CV or Biosketch, as well as their Current & Pending Support
- A revised budget (summary budget worksheet and budget justification narrative), if applicable
- A revised Quad Chart.
- An updated summary recruitment table, if this is an HSRD funded human subject study and recruitment is impacted

V. Change in Study Site(s) and/or Site-PI

Additional or replacement study sites and site investigators (site-PIs) are considered if the modification request provides sufficient justification that the change will enhance successful, on-time, and on-budget completion of the project.

Reasons for requesting additional or replacement study sites and site-PIs include, but are not limited, to:

- A clinical trial where a new or replacement site may ensure success (e.g., trial has not achieved target enrollment).

Required documents to be submitted with a change in study site(s) and or site-PI request include:

- Provide CV or Biosketch of proposed site-PI, as well as their Current & Pending Support
- A revised budget (summary budget worksheet and budget justification narrative).
- A revised Quad Chart.
- An updated summary recruitment table, if this is an HSRD funded human subject study and recruitment is impacted

VI. Change in PI

In rare cases, a request to transfer an ongoing Merit Review award from the current PI to a new PI at the same VA station may be considered. A change in PI cannot be requested for a Career Development or Research Career Scientist Award.

A change in PI will be considered in the following cases:

- PI drops below 5/8ths VA
- PI leaves VA
- PI relocates to a different VA, but chooses to leave project at the initial VA
- PI retires

Required documents to be submitted with a change in PI request include:

- Proposed PI's CV or Biosketch, as well as their Current & Pending Support
- A revised budget (summary budget worksheet and budget justification narrative)

- Written agreement between current and proposed PIs addressing intellectual property (if applicable). Contact the VA Technology Transfer Program (TTP) with questions.
- A revised Quad Chart.
- An updated summary recruitment table, if this is an HSRD funded human subject study and recruitment is impacted

VII. PI Station Transfer

Projects are awarded to the VA medical facility where the PI is employed at the time of the award, so a modification must be requested if the PI transfers to a new location. The request is made by the new station and should be submitted at least 90 days before the anticipated move date.

- New station must be able to support the project (e.g., patient population/animal facility, research space, equipment, committees) as proposed in the approved application.
- For Career Development awards, the new station must have appropriate mentor(s)

Required documents to be submitted with a PI station transfer request include:

If any of the research will be performed off-site, attach an off-site waiver request

- For Career Development Awards, provide a new mentoring plan and the Biosketch of the new onsite mentor(s)
- A revised budget (summary budget worksheet and budget justification narrative)
- A revised Quad Chart.
- An updated summary recruitment table, if this is an HSRD funded human subject study

VIII. Change in Eighths of PI

If the VA employment status of a PI drops below a 5/8 paid appointment, an eligibility waiver must be obtained from ORD, or an eligible VA investigator must replace that PI. Changes in eighths for Career Development Awardees or Senior/Research Career Scientists must be accompanied by a corresponding request to modify the award budget.