

Frequently Asked Questions regarding the QUERI Program RFA (updated 5/5/15)

RFA link: <http://vaww.research.va.gov/funding/docs/HX-15-019.pdf>

For additional questions about submitting proposals please contact Linda Mclvor at Linda.Mclvor@va.gov

When are the Program applications due?

Full proposals are due in eRA commons on June 1, 2015; however, we strongly encourage you to submit by May 28th to ensure proposals go through error check in ERA commons.

How will the Program proposals be reviewed?

The QUERI program proposal will be reviewed as a single proposal that includes a description of the projects and implementation core (25 pages max). You will have room in the 24-page limit to describe the impact goal aims, the three projects (including the one QI project), and implementation core activities. Up to two additional projects can be proposed and the descriptions should be included as an additional appendix (4 pages maximum per project). There is a chance the review committee could approve your principal 3 projects, but then not approve additional projects.

Why the tight timeline with the RFA (June 1 submission date)?

In prior years, QUERI received its budget automatically as special purpose funds. Moving forward, QUERI's budget will need to be justified before the beginning of FY16 to ensure funds are aligned with updated VA national goals under the VHA's "zero-based budget" process. As a result, funding decisions will need to be made by early summer and eRA commons peer review process will be used to ensure a fair and transparent review.

How much of the condition-specific focus will be retained within QUERI?

VHA is changing due to the Choice Act, new priorities under the Blueprint for Excellence, and the reorganization, which have led the VA nationally to focus more on alignment of existing programs and work that involves more cross-cutting issues. The QUERI national evaluation results also indicated that cross-cutting QUERI topics were seen as more relevant to operations. Hence, existing QUERI programs and their affiliated operations partners will need to show how they are responding to these changes in order to stay relevant to VA national priorities. It will be especially critical for QUERI programs to bridge across operational partners and build coalitions to support a common goal, and focusing on a single disease can make this difficult. Moreover QUERI risks losing its funding if the set of programs proposed in the FY16 budget retain the same disease-focused areas without demonstrating how they are aligned with updated VA national priorities. A specific project within a QUERI Program application

can be disease-focused, especially if the disease represents an essential area of expertise and serves as an appropriate “index” condition that informs quality enhancement across a larger VA national priority goal. In addition, the Partnered Evaluation RFA that is primarily supported/co-funded by a specific partner (e.g., program office) may involve more directed evaluations of specific conditions or programs of interest to the partner.

Why is there a requirement for involving more than one program office/operations partner?

Yes- at least two separate program offices or operations partners need to be involved. Building coalitions across more than one partner can strengthen the QUERI program’s ability to address a VA national priority. Other program offices can provide resources or insight through different provider networks or treatment settings, data, logistics, policies, etc., thus producing synergies and learning for the QUERI program overall.

How are partnerships with VA operations supported through this RFA, and are there additional opportunities to leverage operations support?

The intent of the QUERI Program RFA is to support programs that serve as the implementation “engines” that collaborate across VA operations partners or program offices to help achieve VA national priority goals. To this end we encourage active partnerships with clinical operations that involve sharing of tangible resources including national data sources, provider networks, or additional supplemental funds that are leveraged to better serve VA national priority goals. Operations partners in turn benefit from QUERI programs who can help them further support and leverage their work towards achieving VA national priorities. Many operations partners that are supporting ongoing QUERI partnerships and VA national goals include but are not limited to:

- Quality, Safety, & Value (QSV, and Veterans Engineering Resource Center)
- Office of Analytics and Business Intelligence (OABI)
- Office of Health Equity (OHE)
- Patient Care Services (PCS)- e.g., Specialty Care, Social Work, etc.
- Patient-Centered Care and Clinical Operations (10N)
- Nursing
- Rural Health
- Connected Health
- Public Health
- Office of Academic Affiliations

Many program office directors are encouraging applicants to contact them to discuss potential partnerships. **Notably, the Office of Health Equity is considering additional supplements for approved QUERI programs that are aligned with key priority goals focused on regional health care equity improvement (e.g., VISN QI initiatives).** For more information on this opportunity with OHE please contact QUERI Program Coordinator Angela Whatley (Angela.Whatley@va.gov)

Why the focus on quality improvement (QI and program evaluation) in the new Program RFA?

QUERI's funding source (medical services/administration) puts us in a unique position to conduct quality improvement (non-research) studies, which cannot happen under research-funded programs such as HSR&D. VHA may also need additional support for time-sensitive implementation and evaluation efforts under the transformation to improve quality, especially towards reducing variation across regions and to ensure programs/practices are deployed effectively. QI protocols do not require IRB approvals and can be launched more efficiently.

Why is QUERI suspending the investigator- initiated RFAs (SDPs, RRP's)?

QUERI funding comes from special purpose (i.e., medical services/administration and not research) dollars, which are used specifically for supporting clinical services including quality enhancement. A separate type of funding supports medical research. Recently, QUERI's support for investigator –initiated projects was seen as research and not quality enhancement, and hence, not appearing responsive to VHA needs. In addition, QUERI funds under zero-based budgeting will need to be allocated to the field by the beginning of FY16 in order to prevent funds from being swept during the fiscal year, thus limiting the ability to accept “rolling” proposal applications. QUERI programs will receive additional funding to support rapid response and specific project activities.

Are there other opportunities to apply for funding for implementation research?

Yes- HSR&D portfolios have been expanded since last year to [include implementation-focused projects](#). In addition, new RFAs will be released from ORD that will include implementation-focused research areas around the Learning Healthcare System (e.g., measurement science, operations research, provider behavior, randomized program evaluation). For investigators who are already working with a single operations partner, QUERI released a second RFA (Partnered Evaluation Initiative) that can provide additional funding for partnered evaluations that are primarily supported by a single operations partner and focus on the application of rigorous evaluation methods. See the [ORD website](#) or contact Angela Whatley for additional details.

How many Programs can a site have?

Sites can apply and potentially receive more than one program, and programs can involve project leads from one or more sites

How many projects does a program require?

The Program must have a minimum of 3 projects, where one must be a local or VISN level QI project. The goal of the QI project is to support alliances with the regional facilities and networks. The other 2 projects can be research, investigator-driven

projects ranging from \$100,000-\$400,000 each per year. The Program can propose up to 2 additional projects for up to \$200,000 per year for a maximum of 5 projects total.

Will the 3-5 projects proposed by the QUERI Program be managed through QUERI central office?

No, the projects will be managed as Locally Initiated Projects in the field. The QUERI Program proposal will be submitted in eRA by the Program PI and if approved will be entered into RAFT (CO accounting system) and HSR&D ART. The projects will be described in the proposal but will not be entered separately into eRA.

Can more than one project be a QI project?

You are encouraged to have more than one QI or non-research project since QUERI is funded with operations dollars. However, be sure to route projects as research if they involve substantial new data collection, systematic allocation, or study questions that are not primarily directed by the operations partner. Please refer to VHA Handbook 1058.05 for more information on whether a project falls under research or QI status.

Is it correct to assume that the budget may vary considerably year to year, as the QI projects will wrap up within a year?

We expect to fund each Program at least \$800K consistently, assuming adequate process in the work across projects. Programs will be reviewed and renewed annually so investment in new focus areas or projects are welcome and counted towards Program impacts.

If the QI projects are to be completed in a year, should we suggest a portfolio of QI projects in the additional projects?

You can- and you should tie them to the Implementation Core goals as well as the overall impact goal.

Concerning the additional projects 4 and 5, do they appear on the specific aims page?

Yes- then refer readers to the appendix for additional information.

Can we discuss projects 4 and 5 in the body of the application as they relate to our Program Impact Goal?

Yes- in the specific aims (overall program goals section) and if relevant the implementation core sections

Are Multiple PIs allowed, and does the overall Program lead need to be the implementation core PI?

Yes- multiple PIs are allowed per program application. At least one PI leads the Implementation Core and be the corresponding PI. This also allows for all program core and project funds to be transferred to the lead implementation core PI. Note that the ART ITS and the VACO Finance system can only accept 3 PIs. The PIs must be registered in eRA Commons and assigned the PI role in that system.

NOTE:

- The Program encourages a team science approach so it is encouraged to name more than one PI who will lead the Implementation Core as well as have each PI lead a separate project.
- Each PI must be a full-time VA employee (5/8ths) and can lead no more than one additional project.
- One of the projects must be led by a clinician (i.e., clinical degree with a license—medical doctor, clinical psychologist, or a nurse) or at least one PI lead for a program with multiple PIs must be a clinician.
- Program PIs will be recognized in NIH Grants.gov, but non-program PIs who are leads of individual projects will not be recognized in Grants.gov.

Are there additional requirements for personnel (e.g., implementation scientists)?

Program proposals should also have sufficient implementation expertise beyond the PI roles (e.g., at least 50% effort of an implementation expert in addition to the PI to work across projects). The implementation expert role can be split between 2-3 individuals.

Does the implementation scientist need to be an investigator or can staff fill this role?

A staff member should have expertise in implementation would be acceptable; staff members with implementation expertise are welcome especially those with extensive experience in the operationalization of implementation studies or partnered research.

Should this person/people have a title like "Implementation Research Coordinator"?

It is up to the program and there is no specific expectation especially since we might also potentially have folks from complementary disciplines filling that role (e.g., health systems engineering, policy analysts, etc.) so it would be important through the monthly calls to ensure a wider tent but a common expectation that they work towards evidence-based implementation strategies supported by the literature

Are letters of support required from local co-investigators and staff for the QUERI Program grant submission?

No, you do not need letters of support from local co-investigators and staff. Letters of support are required from paid consultants and from the operational partner leads confirming involvement in the QUERI Program application.

For our letters of support from Senior Partners, should we combine support for individual projects (listing the resources provided) with the overall letter of support for the QUERI Program or have separate letters for each project and QUERI program?

Combined letters are fine.

Do we only need a Director's letter from the site where the corresponding PI is located, not from sites with co-PIs?

Correct- just one Directors letter from the corresponding PI's site.

What unit of organization counts as 1 organizational partner?

Operations partners are considered separate if they have their own VA operational budget and are listed as a separate organizational "box" in the VA organizational chart.

Can a partner be a co-investigator?

Yes, as long as the individual has the relevant experience for the role.

What are the budgetary limitations for this RFA?

Each QUERI program can propose up to \$800,000 per year, and there is the opportunity to ask for additional funding if more projects are proposed (up to \$200,000 may be approved for each project for up to two additional projects, with a maximum budget of \$1.2 million if five projects). The Program can last for up to five years subject to satisfactory progress. Note that project start and end dates can be staggered as the Program can be proposed for up to five years.

How much can be budgeted for travel?

Include in your budget up to \$30,000/year in addition to the \$800,000 for travel

What is the budget limit per project?

The project budgets can vary but projects should have a budget of at least \$100K and no more than \$400K each per year, for up to four years each. Some projects might cost more because they involve primary data collection for example, and some of the methods being developed in the implementation core might also cost more or less depending on what is being developed across projects. It would be good to cross-pollinate personnel wherever possible to ensure synergy.

For the two additional projects, is the budget for each fixed at \$200,000 for year, or could the two projects split up \$400,000 per year unevenly between them?

We set the budget at \$200,000 per year for each, as the review committee might only approve one of them. Note QUERI may offer implementation supplements as a separate RFA in the future if you want to build on them (or else you can use core budget funding from the \$800K to support additional projects).

How should the budget be organized in the Program application?

The budget (SF424) should come from the Corresponding PI's Medical Center, but include personnel and other expenses from all participating medical centers. Budgets separated by medical center will be requested using VA forms 1313-3 and 1313-4 at the time of funding decision. Also, include a single budget justification listing all personnel and expenses. In the justification, the PIs should be listed first, starting with the Implementation Core lead (who is required to be PI or one of the PIs if multiple PIs); then list Co-Is, and staff. Under each personnel item describe their respective roles and expertise in the Implementation Core and for each of the projects. Budget breakouts by individual projects are not required. Whenever possible, Co-Is and staff members should have roles across the projects and Implementation Core. Other expenses associated with each project should be listed in the corresponding section.

The grant instructions say to list senior key personnel (page I-78). Do support staff members need to be listed?

Staff should be listed (anyone you expect to pay off of QUERI funding from the Program Project funds you receive each year).

Is IRB review /approved required before beginning Program work?

No- initial work on implementation core activities should be considered administrative and should not involve research or clinical work to require IRB review. IRB approval will only be required for any projects that are considered research and IBA approvals should be handled locally since projects will be considered locally initiated projects. At least one of the projects must be QI.

When are QUERI program projects considered Quality Improvement (QI) vs. research?

Whenever possible, projects should be considered non-research, or QI, and it is required that the local (i.e., VISN) project is QI, in order to support VHA in more rapidly implementing research into practice (Blueprint for Excellence Strategy 7h/QUERI Strategic Goal 1).

A letter from a program office or local facility or VISN partner is required to designate the project as QI (See [VHA Handbook 1058.05](#), and the [list](#) of program offices designated to provide QI letters). The letter should explain that the project meets the Handbook's criteria for QI, including: 1) the project is designed and implemented for internal VA purposes (i.e., findings are intended to be used by and within VA or by entities responsible for overseeing VA and not inform activities beyond VA i.e. not generalizable), 2) the project is not designed to produce information that expands the knowledge base of a scientific discipline or field, and 3) the project does not involve collecting new data that are not needed for internal operations purposes but would otherwise produce information that expands the knowledge base. Also, if the proposal is an evaluation of the Veterans Choice Act OR if done to directly inform VA practice or policy then it would be considered non-research or QI.

If you plan on testing implementation strategies across sites, the project MAY be considered QI if the program office is directly involved in the allocation of the implementation strategies. However, if your study team is directly involved in the allocation of implementation strategies then it is likely research.

A project is clearly research if you will be collecting a lot of "new" data from patients and providers; data that are not meant to be data that directly inform clinical practice or improvement, or that would inform clinical care directly.

In addition, the QI project must not be construed to generalize to other healthcare settings. If your proposal is meant to inform other US healthcare settings and that is spelled out in your protocol, it would be considered research.

However, keep in mind that a project can also be a combination of QI and research; it depends on who is rolling out the clinical intervention or implementation strategy. If, for example, a Central Office partner is responsible for rolling out a clinical or implementation strategy then the process could still be considered QI, even if done in a

randomized fashion. However, if you overlay additional data collection of variables beyond measures needed to directly inform clinical practice (e.g., organizational surveys, provider assessments, etc. that collect new data not routinely used to inform clinical care), then that portion would be considered research and should be reviewed by an IRB. Overall, when you apply to the IRB be very clear about what aspects of your proposals will be considered research.

Is the 4-page limitation for references for the proposal lifted (as it was for COINs)?

The limitation is lifted. You can have more than 4 pages of references.

What will the composition of the review committee be?

It will be a mix of individuals with research and/or operations backgrounds.

Is there a Just-in-Time (JIT) process to receive initial Program funds?

There is no formal JIT process for QUERI Programs. However, the following forms will be needed prior to funding disbursement:

1. QI approval letter from operations partner or local site/VISN for QI project (see VHA Handbook 1058.05 for additional information)
2. Budget pages for October 1- September 30, 2016: VA forms 1313-3 and 1313-4 for each medical center receiving funding

The following items will also be required prior to October 1, 2015:

1. A list that includes the contact information and corresponding CVs or resumes of proposed Program Strategic Advisory Group Members. Final approval of members will be made by QUERI national leadership.
2. Completed Quad Chart that includes an outline of Program goals, projects, and timeline (see attached template).
3. Documentation of OMB exemption ONLY if any of the projects includes surveys of patients or non-VA providers (Contact Linda McIvor for a copy of the form)
4. Documentation of organizational survey (OASC) approval ONLY if any project involves surveying VA employees from >1 VISN (Contact Linda McIvor for a copy of the form)