DEPARTMENT OF VETERANS AFFAIRS
Veterans Health Administration
Washington DC 20420

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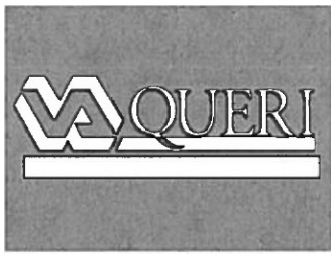
OFFICE OF RESEARCH AND DEVELOPMENT
PROGRAM ANNOUNCEMENT:



Quality Enhancement Research Initiative (QUERI)

Special Solicitation for Projects

Implementing Research into Practice to Improve Care Delivery

1. Purpose

The mission of the Veterans Health Administration (VHA) is to honor America's veterans by providing exceptional health care that improves their health and wellbeing. Research has a strategic role within VHA, focusing on clinical and system improvements designed to enhance the well-being of veterans. VHA seeks to increase collaboration between Research, Program Offices, and Operations with a particular emphasis on using the QUERI model to improve health care delivery. Proposals responsive to this solicitation will include efforts that:

a. Implement research findings and guidelines into routine practice.
b. Evaluate specific programs and strategies which were designed to improve VHA health care quality.
c. Develop evidence and insights about effective implementation and quality improvement approaches.
d. Create - through partnerships and collaborations with VHA leaders, managers, and policymakers at local, network, and national levels - sustainable tools, processes and infrastructure that support improved quality.

2. Background

VHA is devoting significant effort and resources to improve the quality and outcomes of its health care services. The Quality Enhancement Research Initiative (QUERI) promotes the systematic use of evidence as the basis of clinical decision-making to optimize patient outcomes and achieve ongoing system-wide quality enhancement. For details about the QUERI process and priorities for implementation research, see http://www.queri.research.va.gov/implementation/section_2/

The QUERI process has been applied to high-risk and/or highly prevalent diseases or conditions among veterans. Currently there are QUERI groups addressing Chronic Heart Failure, Diabetes, HIV/AIDS/HCV, Ischemic Heart Disease, Mental Health, Spinal Cord Injury, Stroke, Substance Use Disorders, and Polytrauma and Blast-related Injury. QUERI Centers include a collaborative group of health services and clinical investigators and VA operational leadership, in order to create a framework for national dissemination and sustainability. The QUERI Program is evolving away from a disease-specific orientation toward a broader scope of work that addresses improving care for patients with co-morbid conditions, creates durable partnerships between researchers and system leaders, and expands opportunities for researchers to participate in and evaluate the process of national implementation.

3. Coordination with VHA Leadership and Field

Projects responsive to this solicitation are recognized to be at the intersection of clinical practice, quality improvement, and traditional health services research. Projects typically require interaction with VHA Central Program Offices, Veterans Integrated Service Networks (VISNs), or VHA facilities and may include developing plans and mechanisms for the quality improvement activity to be undertaken by VISNs or health systems. Projects should demonstrate the early involvement of healthcare system leaders, managers, and policymakers in identifying key problems/questions to be addressed and designing evidence-based interventions that can be disseminated throughout VA and sustained beyond the lifespan of the project.

4. Project Features

This solicitation encourages comprehensive Service-Directed Projects (SDPs) that propose to implement improvement programs and evaluate their impact, as well as Rapid Response Projects (RRPs) that address particular focused needs in response to identified performance gaps. Specific instructions and recommended components for each type of proposal are described in the Appendices.

5. Eligibility

In order to apply, principal investigators must meet VA eligibility requirements including holding a VA appointment of at least 5/8 time at the time of appointment. While this solicitation is open to all eligible VA investigators, we strongly encourage applicants to explore collaboration and /or coordination with ongoing QUERI initiatives. Contact information for QUERI is available at http://www.queri.research.va.gov/about/contacts.cfm.

6. Funding

In planning project budgets, applicants are reminded to adhere to Office of Research and Development (ORD) guidelines regarding allowable use of funds for specific categories of expenses. Because implementation projects are funded with Medical Care (870) dollars, all funds must be obligated in the year that they are received.

Service Directed Projects (SDPs): Investigators should indicate the estimated study budget and duration in their concept paper (described below). Projects should be designed to

produce useful findings in as short a timeframe as possible, including intermediate products (e.g., organizational assessments, gap analyses, toolkits for improvement) that can be shared with VA leaders prior to study conclusion. Investigators should adhere to budget guidelines for Investigator-Initiated Research projects funded by HSR&D. The budget limits are $350,000 per year or a maximum of 1.1 million dollars for a maximum of four years. Budgets exceeding the yearly or maximum budget limits will be approved only under exceptional circumstances. Approval to exceed budget limits must be obtained prior to proposal submission.

Rapid Response Projects (RRPs): Investigators may submit pilot projects, pre-implementation planning efforts (QUERI Steps 1-3), as well a small projects, that follow up on recently completed implementation efforts. Projects may also support development and initial testing of improvement tools, such as registries, clinician decision support tools, or education materials for patients and clinicians. Projects submitted by QUERI centers should be consistent with their strategic plan or be tied to a VHA Program Office initiative.

Depending on available funds, RRP projects from investigators not currently affiliated with QUERI Centers will be considered, provided they meet the following conditions:

1. If they are in an area related to a current QUERI center (for example, chronic heart failure), the proposal must be endorsed by the QUERI Center.
2. If they are not in a current QUERI area, they should be accompanied by a letter of support from the relevant VA program office (for example, Office of Nursing Services) and address a current implementation priority for that service.
3. Proposals should either support the strategic plan (if associated with an existing QUERI Center), address important cross-cutting issues regarding implementation for QUERI (for example, implementing a new electronic reminder), or have a definable value to implementation efforts of the clinical office endorsing the project. Proposals that represent early developmental work in an area not currently within the QUERI priority areas are not likely to get funded.
4. Proposals submitted independently of a QUERI Center should get prior approval from the QUERI office (Linda McIvor), based on review of a 1-2 page description of the project.

For all RRPs, areas of particular interest are as follows:

1. Ability to impact quality and/or outcomes in one or more VA healthcare facilities, via implementation of evidence-based clinical recommendations or practices.
2. Interventions and implementation research targeting recently separated military personnel from the OEF/OIF conflicts.
3. Projects focusing on how and why improvements are adopted and spread; not just whether implementations are adopted and succeed.
4. Quantitative and qualitative surveys of performance gaps for key conditions impacting health of veterans, including current QUERI conditions as well as emerging needs of the new veteran population (e.g., polytrauma and post traumatic stress disorder).
5. Qualitative and quantitative studies of organizational, provider, and patient characteristics that facilitate sustainability and spread of improvement.
6. Enhancing access to evidence-based care as well as continuity and coordination of care for new veterans entering the VA healthcare system.
7. Interventions directed towards patient self-management.
8. Implementation projects driven by consumer interest and need.

9. Interventions addressing access and equity issues by gender, social-cultural disparities and in rural communities.
10. Projects tied to Patient Care Services intervention rollouts or projects designed to inform policy.
11. Projects that include an economic component.

RRPs have a maximum budget of $100,000 and a maximum duration of one year.

7. Funding Decision

Implementation proposals (SDPs and RRPs) will be reviewed for the strength of the underlying evidence base, relevance to the veteran population, relevance to VHA, capability of applicant to meet intended outcome of proposed project, and potential contribution of proposed project to the field of implementation science and quality of life to veterans. Additional criteria for evaluation and review vary according to the type of study, but typically include:

a. Known gaps in performance within VHA,
b. Knowledge of the setting and context in which the performance gap occurs (e.g., needs assessment),
c. Presence of a needs or barrier assessment that determines the appropriate targets (e.g., patient, provider, micro-system, or macro-system) for intervention,
d. Feasibility and potential sustainability of the intervention,
e. Inclusion of methods, designs, and approaches (including quasi-experimental designs, qualitative methods, and formative and process evaluations) appropriate to the problem or issue,
f. An appropriate theoretical framework or model for system or organizational change,
g. Experience in using appropriate VHA information systems and data repositories, as well as knowledge of barriers, workarounds, and data quality issues,
h. Collaborations with system leaders, and
i. An evaluation component that includes an economic or business-case analysis to inform future decisions by VHA leaders (see http://www.queri.research.va.gov/economic-analysis.doc.)

As with all VA research, funding is contingent upon availability of funds.

8. Format and Submission Instructions

SDP Concept Paper: The SDP application process requires submission of a Concept Paper describing the performance gap, evidence base, proposed intervention, research and evaluation design, key personnel, and estimated duration and budget. Concept papers should follow the format described in Appendix A. Concept papers will undergo a preliminary review by staff in ORD, PCS, OQP, and ION to determine appropriateness for the SDP funding mechanism and fit with VA priorities. The full SDP proposal should be submitted no later than 6 months after approval of the Concept Paper, and should address the comments, concerns, and suggestions made in the preliminary review.

SDP Applications: The recommended SDP proposal format and instructions for proposal submission are described in the Detailed Instructions are posted on the QUERI web page at http://www.hsrd.research.va.gov/queri.

RRP Applications: The RRP proposal format is abbreviated (see Appendix B) and uses electronic submission (via VA email) for most elements. The subject line of the email should indicate that it is an RRP proposal submission, and the name of the principal investigator. Each QUERI Center may submit up to four rapid response proposals each submission cycle. The Research Director, QUERI should send an e-mail to Linda.McIvor@va.gov indicating the number and titles of rapid response proposals being submitted for his/her QUERI Center.

9. Compliance and Reporting Requirements

Implementation projects are subject to the same human subject and privacy protections requirements as other ORD-funded projects. Because implementation projects address issues that often have great urgency, investigators are encouraged to initiate the compliance process as soon as possible (in contrast to the "just-in-time" approach that applies to traditional research studies). As with all research involving human subjects, funds are not disbursed until ORD receives documentation of IRB approval or waiver. Implementation projects frequently require access to protected health information in the electronic medical record (in which case approval by an IRB or privacy board is required), or to specially created limited data sets (in which case an appropriate Data Usage Agreement may be required by the data owner). Further information about privacy requirements may be found at:
http://www.virec.research.va.gov/HistoricalDocuments/VirecInsights/Insights-v04n2.pdf

SDPs and RRPs are subject to the same reporting requirements of other studies managed by HSR&D, including the submission of a final project report. Both SDPs and RRPs should be included in the annual reports of Centers of Excellence and QUERI Coordinating Centers according to their specific reporting requirements.

Because Medical Care (870) dollars cannot be carried over into subsequent fiscal years, changes to the protocol, budget, or participating sites that would require modification requests, as well as unanticipated delays (e.g., IRB delays) should be reported as soon as identified.

10. Inquiries

Specific guidance regarding SDP proposal development and RRP proposals may be obtained from Linda McIvor, Program Manager QUERI and Service Directed Projects, at Linda.McIvor@va.gov.

11. Due Date

SDP Proposals: An approved concept paper is required prior to submission of a full SDP proposal. Concept papers are accepted on an ongoing basis; please allow 4 weeks for review and feedback. Full proposals are reviewed three times per year. The due dates for SDP proposal submission are: January 2, May 1, and September 1.

Rapid Response Project Proposals: The submission deadlines for RRPs are the same as for SDPs: 5:00 p.m. ET January 2, May 1, and September 1. In the event that the submission deadline falls on a weekend or federal holiday, proposals will be due the next business day.

Joel Kupersmith, MD
Chief Research and Development Officer

A P P E N D I X A
INSTRUCTIONS FOR SUBMISSION OF SERVICE DIRECTED PROJECT CONCEPT PAPERS

The Concept Paper should be 2-5 pages in length (1.5 line spaced or double spaced, exclusive of references).

The investigator should:

1. Summarize the main objectives and specific clinical focus of the proposed project. Briefly describe (1) the clinical/quality issue(s) to be addressed (citing, as appropriate, data on the clinical condition's/problem's prevalence/incidence, mortality/morbidity, quality of life consequences, economic consequences, etc.) and (2) the evidence-based clinical recommendations/guidelines or other foundations for the improvement initiative.

2. Describe the proposed quality improvement strategy or program, citing appropriate literature and evidence supporting the hypothesized effectiveness of the proposed quality improvement approach.

3. Describe the intervention/evaluation design and methods to be used and the type(s) of analyses to be performed.

4. Describe existing or anticipated partnerships with VA operations or program offices.

5. List key personnel involved in the project, including key staff names, affiliations and the discipline or specialty of the P1 and co-PI (if applicable) and other key project participants. Describe the P1 and other project participants' past or current involvement in QUERI (e.g., member of a QUERI Coordinator Center or Executive Committee). Note: HSR&D encourages designation of a single PI; justification must be provided for a second co-PI.

6. State the expected project duration and estimated total cost.

Review Criteria

1. The Principal Investigator must be at least a 5/8 VA employee at the time of funding and eligible to conduct research in VA.

2. Concept papers will undergo a preliminary review by staff in ORD, PCS, OQP, and/or 10N to determine appropriateness for the SDP funding mechanism and fit with VA priorities.

3. The full SDP proposal should be submitted no later than 6 months after approval of the Concept Paper, and should address the comments, concerns, and suggestions made in the preliminary review.

4. **Transmission to QUERI Program**

The Principal Investigator should send electronic copies of the Concept Paper to: Linda.McIvor@va.gov.

Proposal and Concept Paper Submission Dates
The deadlines for full proposals in response to this solicitation are COB January 2, May 1, and September 1. If a deadline falls on a weekend or holiday, the deadline is the first business day following the deadline. Principal Investigators should notify Linda McIvor at Linda.McIvor@va.gov of Intent to Submit a proposal one month in advance of the submission deadline. Concept papers are accepted on an ongoing basis. Concept paper feedback and notification of acceptance will be provided approximately four weeks after receipt.

Contact Information
Please contact Linda McIvor (Linda.McIvor@va.gov), Program Manager, QUERI and Service Directed Projects with any questions regarding concept paper instructions or submission dates.

A P P E N D I X B
INSTRUCTIONS FOR SUBMISSION OF APPLICATIONS FOR RAPID RESPONSE PROJECTS

Implementation Rapid Response Projects (RRPs) are submitted in response to specific solicitations that will be emailed to the appropriate target audience, RRPs can include small pilots or demonstrations, pre-implementation assessments or planning efforts, and studies that follow-up on recently completed implementation activities. Projects may also support development and initial testing of improvement tools, such as registries, clinician decision support tools, or education materials for patients and clinicians.

Application Instructions

1. The Principal Investigator must be at least a 5/8 VA employee at the time of funding and eligible to conduct research in VA.

   a. Investigators interested in submitting a rapid response proposal for Chronic Heart Failure, Diabetes, HIV/HCV, Ischemic Heart Disease, Mental Health, Polytrauma and Blast-related Injuries, Spinal Cord Injury, Stroke or Substance Use Disorders must contact the Research Coordinator for the specified QUERI Center to determine if the proposal is consistent with the Center's strategic plan and if the Center is willing to sponsor the proposal as one of its submissions.

   b. Investigators interested in submitting a rapid response proposal for topic areas not covered by a QUERI Center, must meet the following criteria:
   1) The PI or co-PI must have previously received project funding from HSR&D or the QUERI program.
   2) The PI must have a doctoral degree from an accredited program.
   3) The project must be of high value to VHA and a letter of support from the appropriate VHA program office or VISN director must be included indicating how the proposed project will benefit VHA.
   4) Proposals submitted independently of a QUERI Center should get prior approval from the QUERI office (Linda McIvor), based on review of a 1-2 page description of the project.

2. Applicants should submit a plan **no longer than 10 pages** describing:
   a. How the project team will complete the work necessary to respond appropriately to the solicitation, and further support the work of ORD's Implementation efforts.
   b. Capacity to complete this work in a timely and high quality manner, as determined by availability of key personnel. Note: the total timeframe for the proposed project may **not exceed 12 months.**

3. All submitted materials not on forms must have margins of at least 1 inch on all sides, and be single-spaced.

4. Each submission must include a face page and an abstract page on forms 10-1313-1 and 10-1313-2. **Leave the space for social security number blank**.

5. Each submission may include one biographical sketch for each key personnel. Each biographical sketch is limited to 4 pages per person using forms 10-1313-5 and 101313-6 or 10-1313-5/6.

6. Budgets must be submitted on VA forms 10-1313-3 and 10-1313-4. Note that if the project crosses fiscal years, each fiscal year should have its own budget pages. **Total funding cannot exceed $100,000** unless a waiver has been granted prior to submission**.**

7. Letters of support will be accepted.

8. **All applications must be received via electronic mail by the due date indicated in the solicitation, in one single MS WORD file or PDF. Paper submissions, or submissions sent in multiple files will not be reviewed.**
9. ORD research forms can be downloaded at
http://www.research.va.gov/funding/process/forms.cfm

Review Criteria
Applications will undergo peer review by an ad hoc committee. The research team will be notified of the funding decision within eight weeks of submission.
To be eligible for this solicitation, projects must:

1. Impact quality and/or outcomes in one or more VA health care facilities, via implementation of evidence-based clinical recommendations or practices

2. Include formative and summative evaluation designed to identify barriers and facilitators to change. Where appropriate, there should be sufficient cost analysis to inform future resource allocation decisions (http://www.queri.research.va.gov/economic-analysis.doc)

3. Involve active partnership of researcher's with clinicians, managers, and leaders at VAMC, VISN, or VACO levels

Contact Information
For questions:
Linda McIvor, MS, MHS
Tel. 202-461-1516
E-mail Linda.McIvor@ va.gov

A P P E N D I X C
QUERI SERVICE DIRECTED PROJECTS
PROPOSAL REVIEW CRITERIA

Adequacy of Response to Previous Reviewer Comments

- ❑ Did the applicant address the issues raised by the reviewers of the concept paper or previously reviewed full proposal (if this is a resubmission)?

Project Goal(s) and Questions/Hypotheses

- ❑ Is the project's overall goal(s) described in light of the quality enhancement (QE) or performance problem(s) the project is targeting?
- ❑ If the project aims to address an intervening barrier or factor *contributing* to the quality problem (but not *directly causing* the quality problem), does the proposal explain how the project will contribute to the solution of the overarching quality problem, and why a direct solution is not possible?

Background of Context

- ❑ Does the proposal provide an adequate literature review and evidence-based clinical recommendations/guidelines or other foundations supporting the hypothesized effectiveness of the proposed quality improvement approach?
- ❑ Is there an adequate description of current practices, determinants, barriers and facilitators?

Significance

- ❑ Does the proposal adequately describe the clinical/quality issue(s) to be addressed, including as appropriate data on the clinical condition's/problem's prevalence/incidence, mortality/morbidity, quality of life consequences, economic consequences, or other significant considerations.
- ❑ Is the proposed work grounded in theoretical and empirical evidence on <u>organizational change and/or provider behavior</u>?
- ❑ Will the proposed work contribute to policy, practice and/or the science of Implementation?
- ❑ Will lessons learned from the proposed project be generalizable to other Implementation efforts?
- ❑ Are the specific research questions/hypotheses clearly stated and appropriate?
- ❑ Is the project aimed at creating a learning organization focused on the translation of research into practice?

Methods

- ❑ Is an overall conceptual framework for the approach provided, citing specific sources and justifying the selection of the source(s) and framework for the specific quality problem and intervention approach planned?
- ❑ Are the design and methods appropriate given the stated project goals?
- ❑ Does the work involve a clearly articulated process or formative evaluation?

- ❑ If an intervention is being implemented, is it adequately described (e.g., are components specified, is it apparent who will administer the intervention and to whom it is targeted) and justified?
- ❑ If applicable, are intervention components described that will perform the functions listed below?
  - o Communicate the legitimacy (e.g., evidence base) of recommended practices (to facilitate their acceptance by the target clinicians, managers, patients, and/or other stakeholders),
  - o motivate clinician, manager, patient willingness to change via presentation of evidence of a quality/performance problem or via other means
  - o establish, disseminate and reinforce professional (patient) norms favoring the recommended practices and countering current (non-adherent) practices and conveying the advantages of the preferred practices over current practices,
  - o create or strengthen external expectations and interest in improved quality (among professional, policy, public, special interest, and/or other groups),
  - o educate clinicians, staff, patients regarding desired/expected roles, practices and professional behaviors,
  - o enhance clinician/staff/patient knowledge regarding the desired clinical practices and/or enhance skills in performing desired practices,
  - o create conditions facilitating and favoring desired practices in routine care, including financial, administrative and other conditions,
  - o redesign other aspects of the delivery system and organization to facilitate improved practices,
  - o implement the desired care model or organizational arrangements and the behavior/organizational change efforts in a manner adapted to the target practice settings, to maximize success,
  - o monitor and continually refine implementation of the new practices, including actions needed to remove any barriers that may arise.
- ❑ Is the overall research design, including issues such as the experimental unit (facility, clinic, team, clinician, or patient) and other major design features justified?
- ❑ Are the variables, measures and data collection methods/plans adequately described?
- ❑ If relevant, is detailed information on methods to study current practice patterns and their determinants provided?
- ❑ If applicable, is a description provided of plans for monitoring implementation and progress of the quality enhancement effort, and refining the effort based upon this ongoing monitoring?
- ❑ Are decisions to attend to certain features of the implementation effort but not others or to exclude a formative evaluation altogether justified?
- ❑ Impact (summative) evaluation: overall plan. Are plans for measuring the quality enhancement program's impacts on key structures, processes and outcomes of interest addressed?
- ❑ Are plans for identifying and recruiting all relevant participants, including clinicians, other staff (managers, support staff), patients, patient family members or caregivers, etc., discussed and any human subjects issues addressed?
- ❑ Are the participating project sites, site recruitment processes, and timeline adequately discussed and justified? Listed below are some elements that reviewers may wish to consider:
  - o Randomization protocol
  - o Usual care condition

- Assurance of patient safety
- Sustainability

- ❑ Are the general analytical approaches for quantitative and qualitative data to be collected as part of the diagnostic analysis, formative evaluation and impact/summative evaluation appropriate?
- ❑ Is an Economic Analysis appropriate to VA decision makers (e.g., cost consequences, as opposed to traditional cost-effectiveness) included?

Project Organization and Management

- ❑ Are the investigators clearly qualified to lead the proposed project?
- ❑ Is there a sound plan for project management and leadership?
- ❑ Are the necessary team members identified and are their qualifications, skills, and expertise appropriate for their designated roles within the project?
- ❑ Does the project team include individuals with expertise in organizational change and management research?
- ❑ Is it clear that the investigators have access to the data required for successful completion of the proposed work?
- ❑ If existing databases are to be used, is evidence of familiarity with these databases (and awareness of their idiosyncrasies and limitations) included in the proposal?

Adequacy of Evidence-Base Supporting Implementation *at This Time*

- ❑ Does the proposal clearly demonstrate the existence of an adequate evidence-base, in the form of published research and/or guidelines, to warrant Implementation at this time?
- ❑ Are there known or potential risks to patients if implementation is <u>delayed</u>?
- ❑ Is it clear that implementation is not being rushed (therein creating potential patient risk)?
- ❑ Is there a critical level of need and/or urgency for implementation at this time?
- ❑ Does the implementation plan appear to target a viable system or organization (e.g., it may only be feasible to implement an intervention at a single unit – with VISN support – as a *step* toward implementing VAMC- and/or VISN-wide)?
- ❑ Is there sufficient supplemental evidence to support implementation if a substantial body of effectiveness data has not as yet been published (e.g., cumulative efficacy data, practical/clinical evidence, etc.)?

Involvement of Key Stakeholders

- ❑ Is there evidence of commitment, including tangible resources, at all necessary levels (e.g., provider, unit, facility, VISN)?
- ❑ Are the needs of veterans clearly represented in the project plan either by direct or indirect veteran involvement in process evaluation?
- ❑ Is there a plan for continued feedback from all stakeholders?

Contribution to the Veterans Health Administration

- ❑ Does the proposed work have the clear potential to improve the quality, effectiveness and efficiency of health care in VA and the health status of veterans?
- ❑ Does the proposed work hold the promise of rapid clinical and organizational improvement?
- ❑ Is there evidence that the activities planned for implementation would be <u>sustainable</u> beyond the life of the proposed project?

- ❑ Is there potential for expansion throughout VHA if the implementation is successful at the level proposed within the scope of the project (e.g., if implementation is to take pace within a single unit, is there potential for expansion throughout on or more VISN(s))?

Budget Efficiency
- ❑ Is the budget well justified?
- ❑ Does the budget reflect VISN support (e.g., in-kind support, equipment, facilities)?

Evaluation Plan
- ❑ Does the proposal include a well-structured evaluation plan?
- ❑ Is the evaluation plan unbiased and appropriately tailored to the goals of the proposed work?
- ❑ Will mechanisms be in place to continue to track the success of the implementation efforts after the funding period?
- ❑ Will spread and rollout (i.e., to other sites, clinics, VISNs) be tracked?

Dissemination / Implementation Plan
- ❑ Evaluate how and when research results will be disseminated and implemented