Purpose. The Veterans Health Administration (VHA) Office of Research and Development (ORD) announces an opportunity for Department of Veterans Affairs (VA) medical facilities to compete for planning funds to inform service-directed research (SDR) projects supported by the Health Services Research & Development Service (HSR&D) in ORD to conduct randomized program evaluations of the impacts of new programs or policies that are planned for wide-spread implementation within VA. Detailed instructions for preparing and submitting applications are provided below.

Background. The U.S. Department of Veterans Affairs (VA) is undergoing a major reorganization to transform the way it provides services for its Veterans nationally. This transformation has already involved new policies such as the Veteran’s Choice Act that involve a dramatic shift in the delivery of VA health care services and evolution of the Veterans Health Administration (VHA)’s role as a payer in addition to provider of health care for millions of Veterans nationwide. This follows a period of other major national initiatives within VHA, including the national deployment of patient-centered medical homes, implementation of new telehealth and connected health programs, promotion of patient-centered care, and adoption of several specialty-care transformational initiatives, among others. Assessment of the impact of these programs is still ongoing, and in some cases is complicated by the lack of a strong, contemporaneous comparison group. Moreover, related VA priorities and modernization efforts (see Table below) bring forth additional opportunities for researchers to facilitate VA’s further transformation into a Learning Healthcare System. Specifically, the Learning Healthcare System as described by the National Academy of Medicine involves the alignment of science with clinical priority goals to conduct more rapid and efficient studies that leverage existing data to deploy and evaluate innovations and spread of effective practices. However, to date, many Learning Healthcare System initiatives have focused more on developing “Big Data” infrastructure, and less on implementation and evaluation of clinical programs/policies. VA is in a unique opportunity to take the concept of the Learning Healthcare System to the next level through the conduct of rigorous, time-sensitive studies that leverage Big Data to evaluate effectiveness and implementation of new programs/policies at the national level that address top VA priorities (or in some cases, de-implementation of low-value practices).

Table: VA 2017 Priorities

| Greater Choice for Veterans | Redesign the 40/30 Rule |
| Modernize our systems | Build a high-performing, integrated network |
| Focus resources more efficiently | Empower Veterans through transparency of information |
| Improve timeliness of services | Infrastructure improvements and streamlining services |
| Suicide prevention | EMR interoperability and IT modernization |
| | Strengthening of foundational services in VA |
| | VA/DOD/Community coordination |
| | Deliver on accountability and effective management practices |
| | Access to care and wait times |
| | Decisions on appeals |
| | Performance on disability claims |
| | Getting to zero |
Randomized program evaluations involve the systematic, but purposefully random, allocation of sites that will undergo a new practice or policy, or are in need of effective implementation strategies to deploy practices or policies shown to have evidence of effectiveness. A key advantage to randomization is that it provides the best opportunity to detect a true effect of a new practice or policy, since it reduces the potential influence of secular trends or systematic variation across sites, patients, and providers (for example, the possibility that sites that adopt a new program first are more committed or more experienced in delivering it – or conversely, motivated to do so by poor baseline performance). Identifying the true effect of a new practice or policy, as well as the most cost-efficient implementation strategy to promote the uptake and sustainability of effective practices/policies, can prevent wasted effort and expense on ineffective rollouts, and ultimately produce greater return on the resources invested. Randomization also allows an equitable opportunity for end-users to receive a new practice/policy where it is not possible to deploy to all locations simultaneously. These advantages led the Office of Management and Budget to strongly support randomized program evaluations through its Improve Government Performance Policy. This approach to data-driven decision-making has been referred to as “evidence-based policy” and reflects the recent passage of the Evidence-based Policymaking Commission Act of 2016 as well as the National Academy of Medicine’s Learning Healthcare System initiative, which advocates for better integration of randomized designs to evaluate new or augmented clinical practices or policies in health care systems. Within the VHA, such initiatives are institutionally sanctioned by leadership and evaluated with the purpose of determining whether they were implemented as intended, with an eye towards assessing effectiveness, impact, and ultimately, sustainability. Such an evaluation asks not only “does the program work?” but also “where does it work? What makes it work? and How can we make it work in the real world?” Examples of randomized program evaluations include the Oregon Health Insurance Experiment, VA Mental Health Operations Re-Engage evaluation, and the Head Start Impact Study. Randomized evaluation study designs can also range from effectiveness studies to hybrid-effectiveness-implementation studies that involve the testing of different strategies to promote the uptake and sustainability of practices/policies.

**Purpose and Eligibility.** This call for planning proposals intends to support time-sensitive activities that lead to the successful submission of a Service-directed Research project for randomized program evaluation topics that involve implementation of a practice or policy at the national level, address one of the five VA priorities from the Table, and have a sponsoring VHA operational leader or program office to facilitate practice or policy deployment. The prior Randomized Program Evaluation call for proposals selected proposals for initial deployment in 2016 based on solicitation of topics from VA operations leaders (e.g., Veteran-Directed Home & Community Based Services, Predictive Model-Based Targeted Risk Mitigation for Opioids, Risk Stratified Enhancements for Suicide Prevention, Mobile Teledermatology). In contrast, this call for planning proposals intends to support SDRs that are initiated by investigators but represent evaluation of practices or policies ready for national evaluation or implementation that are endorsed and sponsored by an operations leader or program office at the national level. As with previous Randomized Program Evaluations, the clinical implementation of the program or policy including the randomization process is the responsibility of the relevant program office. The investigator applicant will be responsible for devising and executing the evaluation plan that provides a comprehensive assessment of the effectiveness of the practice or policy (or effectiveness of the implementation strategy or strategies promoting the practice/policy) on a relevant set of process, utilization, cost, and health outcomes, and for examining patient, provider, and facility level factors that may be associated with more or less effective implementation and program effectiveness. To achieve “arms-length” evaluation, principal investigators must not be affiliated with the sponsoring program office facilitating the evaluation. Applications may be submitted from any VA medical center with an active research program.

The HSR&D Merit Review Award Program is an intramural program to fund research conducted by VA-salaried investigators at VA medical centers or VA-approved sites. Each application must have at least one PD/PI who is eligible to submit a Merit Review application. A PD/PI shall hold a MD, PhD, or equivalent.
doctoral degree in a field relevant to the research proposed. For additional individual eligibility information, see HSR&D Parent Learning Healthcare Initiative Randomized Program Evaluation Review Process. Randomized program evaluation topics will undergo internal HSRD administrative review and external review by the Partnered Evidence-based Policy Resource Center (PEPReC), HSRD/QUERI’s resource center designed to provide timely, rigorous data analysis to support the development of high-priority policy, planning, and management initiatives and quantitative program evaluations to improve the quality and efficiency of VA health care. Planning proposals will be evaluated on their scientific rigor, availability and validity of data, randomization feasibility, likelihood of demonstrating a measureable effect, and clinical/policy importance.

**Mechanism and Funding.** Investigator applicants with approved planning proposals will receive funding in FY2018 for evaluation planning activities that can be conducted while the full proposal is being developed and reviewed and while an IRB approval is being obtained. Evaluation planning activities may include literature reviews, specification of study design, survey development, programming and analyses planning, and randomization planning with partners, and application for required research approvals. Up to $50,000 will be awarded per project for a 6-month planning period in FY2018, with the expectation that the full SDR proposal will be submitted in December 2017 or June 2018. If the full SDR proposal is selected for funding after review by a Scientific Merit Review panel, applicants will be funded for up to three years to conduct evaluation activities in collaboration with their operations partners. Up to $1,100,000 for up to three years will be available per project for the full SDR proposal.

**Planning proposals are due Tuesday, October 17, 2017 and should not exceed five pages (excluding cover page, letter of support, budget information), single spaced, 11 point Arial font, with at least 0.5 inch margins. Please do not include any additional Appendix items (e.g., survey instrument.) Send planning proposals as one combined pdf (no Adobe portfolios please) to VHA CO HSR&D HSR8 mailbox (COHSRDHSR8@va.gov).

Planning proposals should include the following sections:

1. **Cover Page (not included in page limit):** Include Principal Investigator (PI) name and contact information, Administrative Officer name and contact information, proposal title, keywords, list of key personnel with institution, location (city, state), academic affiliation, and project role, list of research sites, and operations partner and primary point of contact in that office.

2. **Background (~.5 page):** Briefly describe the clinical issues being addressed by the policy or program, gaps in current knowledge regarding the policy or program to be evaluated, and how the program is intended to improve specific outcomes.

3. **Specific Aims (~.5 page):** Describe the primary and secondary aims of the evaluation. Key questions include: Was the program successful in achieving the intended outcomes? What are the optimal implementation strategies for facilitating the uptake and sustainability of the practice or policy? Were there populations or sites with whom it was more or less successful? What factors are mediators and moderators of success? Was implementation consistent across different regions, facilities, and/or provider groups?

4. **Methods/Evaluation Plan (~2 pages):** This section should describe how you intend to accomplish the aims described above. The evaluation plan should specify the study design, data sources, study population, number of sites, and analysis strategies. Identify specific outcomes and independent variables of interest and indicate how you intend to construct the variables and the source(s) of the data. Explain any potential obstacles and solutions (e.g. data availability) that may arise.

5. **Partnerships/Data Sources (~.5 page):** Describe prior experience with partnerships with VHA program offices and describe how investigators will collaborate with partners. A letter of support (not
included in page limit) from a sponsoring program office/operations partner is required that details the practice/policy to be implemented, randomization method, and ongoing commitment to evaluation.

6. **Deliverables and Timelines (~.5 page):** Describe planned intermediate and final deliverables and their timelines associated with evaluation questions in 1-3 month intervals.

7. **Research Team and Relevant Experience (~.5 page):** In this section describe the key participants (co-investigators and organizations) and their relevant experience in collaborating with relevant VA operational partners, conducting program evaluation, and evaluation and implementation methods.

8. **Management Plan (~.5 page):** Describe the project management plan including roles and tasks of each member of the investigative team and how the work will be coordinated with all involved parties. Describe local resources available at your facility that will contribute to your team’s ability for success, including any proposed collaboration with institutions or investigators outside the principal investigator’s facility.

9. **Budget and Justification for Planning Phase (2-3 pages NOT included in 5-page limit):** List anticipated expenses for the planning phase, including evaluation planning support and administrative support for IRB submission. The budget should include up to $50,000 in fiscal year 2018 funds (with an earliest start date of 1/1/18 and a latest possible end date of 9/30/18). See [Sample Summary Budget table](#) and [Example Budget Justification](#).

### Key Dates for the HSR&D Randomized Program Evaluation SDR Review Process:

- **September 19, 2017:** Call for planning proposals released
- **October 11, 2017:** SDR RFA released
- **October 17, 2017:** Planning proposals due via email COHSRDHSR8@va.gov
- **November 1, 2017:** Planning proposal funding decision announcement
- **November 15, 2017:** Revised planning budgets and JIT documents due
- **January 1, 2018:** Earliest date planning funds will be available
- **September 30, 2018:** Latest end date for planning phase

**Only Applicants with Approved Planning Awards may apply to the HSR&D SDR RFA**

- **December 8, 2017*:** SDR proposals due in eRA commons
- **March 2018:** Scientific Merit Review for SDR proposals
- **May 2018:** Earliest SDR funding date

*Approved Planning proposals must submit full SDR proposals within the next two consecutive HSR&D proposal cycles (e.g., December 2017, June 2018). SDR proposals not submitted by the June 2018 cycle will have to submit a new application for planning funds.

**General Criteria for Review and Scoring of Planning proposals**

1. **Conceptualization of the problem:** Understanding of the clinical program and its goals, and how they relate to needs of Veterans and priorities of VHA. Relevance of evaluation to the operations partner and to VHA overall priority goals (e.g., greater choice, modernizing systems, focus resources more efficiently, improving timeliness of services, suicide prevention).
2. **Methods and Measurement**: Are the study design and study population/analysis strategies well-specified and appropriate to the program and its aims? Are the clinical, utilization/cost, provider, and patient outcomes well-described and justified by the insights they will provide on the effectiveness of the program? Are implementation strategies based on current knowledge from implementation/quality improvement science? Are underlying mechanisms such as individual, provider, and system factors identified and measurable? Evaluations that include primary data collection using qualitative or mixed-methods to assess mechanisms of implementation outcomes and contextual factors across provider/treatment settings, and that use established quality-safety data (e.g., SAIL, Mental Health Scorecard) are highly encouraged.

3. **Measures**: Validity and feasibility of proposed secondary data sources, primary data collection measures/surveys, subject identification, and degree to which proposed work is integrated and achievable with the evaluation timelines. Are measures relevant to partner-driven evaluation request, taking into account potential subject burden in the context of these national evaluation efforts? Are contingencies and alternative data collection strategies identified and addressed?

4. **Partnership Experience**: Experience with partnered evaluations in VA, relevant experience with the appropriate operations partner, and operations partner’s experience with randomized evaluations.

5. **Qualifications of Team and Management Plan**: Qualifications and experience of PI and collaborators in health services and policy evaluation; Degree to which timeline and management plan are realistic; and to what extent evaluation results will be actionable at the VA leadership levels.