

# Health Services Research and Development

## Innovation Initiative Program RFA: High Risk, High Impact Health Services Research

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# New HSR&D Innovation Initiative RFA

RFA is part of an overall Innovation Initiative that will provide

- Planning/startup funds for **innovative, high risk, high-impact research** that contributes to:
  - **Meaningful real-world transformations** in Veteran care & health outcomes
  - **Significant contributions to field of health services research.**
- Supports research that:
  - Challenges or seeks to **shift current research or clinical practice paradigms**
  - Typically **not funded through the established or traditional IIR** mechanism where innovative high-risk ideas may not be favorably scored

# Background: Development of the Innovation Initiative RFA

Steps leading to Innovation Initiative RFA—by **Dr. Jolie Hahn** of Tampa VA

- Utilized rapid mixed-methods approach involving representative and snowball sampling to collect data for assessing information related to funding innovative high risk, high impact studies.
- Data from 5 focus groups, 10 individual interviews, 3 follow-up interviews
- Participants- 12 VA scientists; 3 VACO operational administrators; 1 representative from the VA Center for Innovation, and 1 from Diffusion of Excellence; 4 VA HSR&D and 7 RR&D program managers; 18 COIN Leadership; 9 innovation experts from the Institute of Advanced Discovery and Innovation; and 2 NIH program administrators.
- An environmental/literature scan also conducted

# Defining Innovation

- Innovation may be defined as:
  - Creating or adopting new strategies, theoretical models, or research methods from other disciplines to health care systems
  - Incorporating novel sources of data for new insights or to enable new interventions
  - Eliminating long-standing regulatory or policy obstacles to enable and test new clinical practices
  - New ways of engaging hard-to-reach patients
  - New partnerships to deliver services more effectively to Veterans
  - Fundamentally new ways to deliver established services
  - New ways of implementing or scaling current interventions

# Defining Innovation

- Poses higher risk than traditional risk but in return offers greater rewards or earlier pay-off
  - Often less pre-existing data to support, thus poses higher risk
  - Impact in some situations cannot be pre-determined
  - Can create disruptive changes, opportunities for *different standard* of practice
- New, original or unusual process or product
  - Exciting, inspiring, and creative
  - Novel concepts, approaches or methodologies, or interventions
  - Adoption of an existing process or product in new or unusual way
- Results in impact
  - Addresses problem in terms of prevalence, severity, urgency, cost, etc.
  - Potential to produce significant lasting change
  - Broader improvements in VA healthcare system rather specific subpopulation

# What Does HSRD Hope to Achieve through the Innovation Initiative RFA?

HSR&D seeks high risk, high impact ideas that will achieve:

- **Major practice or health systems transformation vs. incremental changes**
- **Larger impact vs. modest change** in clinical or population health outcomes
- Improvements which have a **broader impact on and are applicable to the general population** and are not targeted to a specific subpopulation
- **Movement of health services research in new directions**

# What Does HSRD Hope to Achieve through the Innovation Initiative RFA?

- Development of technological advances or applying new technologies to new areas
- Novel methods for organizing, financing or delivering health or other social services for Veterans and their families/caregivers
- New ways of implementing or scaling current interventions

HSR&D is **not** interested in:

- One-off studies that propose testing new technologies in well-established areas
- Technologies that would require FDA approval

# Priority Areas

- ***Accelerate innovative research in key priority areas:***
  - Suicide Prevention
  - Opioid Misuse/Pain Management
  - Access to Quality Care
  - PTSD/TBI
  - Long Term Care Services and Support

# Collaboration with VA and Non-VA Entities

- Collaboration and service to **VA health system partners**
  - VA program offices
  - Regional VA (VISN) leadership
  - Innovation Groups (e.g. Innovators Network, Diffusion of Innovation Hub)
- Collaborations with non-VA entities
  - Other Federal agencies (e.g., NIH, CDC, HRSA, SAMHSA)
  - other Health Systems

# Innovation Initiative RFA

## Phased Approach

	Phase 1	Phase 2
Application	3-page Concept Paper	Full Proposal
Number Funded	Up to 10	Up to 3
Duration	Up to 18 months	Up to 5 years
Funding	Up to \$200,000 per proposal	Up to \$500,000 per year
Evaluation	Progress during Phase 1 will be assessed using the timelines and benchmarks developed by the awardee and approved by HSR&D	Progress during Phase 2 will be assessed using the timelines and benchmarks agreed upon by the investigator, HSR&D, and partner

# Innovation Initiative RFA Phase I Review Process

## *Phase I*

- Three page concept papers will be:
  - ***Double blinded*** to reduce biases or conflicts of interests by **reviewers** and **funding officials** during the Phase I reviews.
  - Review and decisions for funding completed by April 2019

# Innovation Initiative RFA Phase I Review Process

## ***Specialized Review Panels comprised of:***

- Experts and champions of innovation—“Big Thinkers”
- Diverse and multidisciplinary group of experts
  - VA central program operations, on the ground clinicians and managers
  - Non-VA innovators from academics & other federal agencies, engineering and IT technology
  - Private industry (health plans research units, operations/program administrators)

# Examples of Review Questions for Concept Proposal

1. Does the proposed work challenge or seek to shift current research or clinical practice paradigms by utilizing novel approach?
2. Does the proposed work involve the creation of a new, original or unusual process or product?
3. Does the proposed work involve the adoption of an existing process or product in a new or unusual way that transforms current approaches?
4. Does the proposed work have a realized value or impact?
5. Does the proposed work offer new directions in promoting current treatments or practice?
6. Will the proposed work contribute to an area of practice or science where the field is ready for a change?
7. If the proposed work is high risk, is the risk proportionate to the reward?
8. Does the proposed work focus on broader care improvements?
9. Does the proposed work address a significant problem?

## Table 5. Deadline, Review and Award Dates

SUBMISSION CYCLES:	WINTER 2019
Release of Innovation Initiative RFA (Phase I: Planning Phase)- Concept Paper Submission) *	September 19, 2018
Innovation RFA Cyberseminar	October 11, 2018
Intent to Submit Window*	October 15, 2018 – November 1, 2018 (8:00pm ET)
First day to submit Phase I (Planning phase –submission of concept paper) applications to Grants.gov Early submission is strongly encouraged.	November 15, 2018
<p>Down to the Wire Submission Deadline to Grants.gov This deadline allows errors identified by Grants.gov, eRA, or the PI/SO during the two-business day examination period to be corrected. All changed/corrected applications must be submitted by this date.</p> <p><b>NOTE:</b> After this date the two-business day correction window CANNOT be used to identify errors and resubmit a corrected/changed application as a resubmission at this time would miss the eRA verification deadline.</p>	December 10, 2018

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<p>Verification Deadline in eRA * ‡</p> <p>Once verified, an application is considered final and no other version will be accepted for review.</p>		December 15, 2018
REVIEW AND AWARD CYCLES:		
Scientific Merit Review		February 2019
Administrative Review		March 2019
<p>Earliest Project Start Date for Phase I Planning</p> <p>Note: VA-ORD R&amp;D Services may not always be able to honor the requested start date of an application; therefore, applicants should make no commitments or obligations until confirmation of the start date by the awarding service.</p>		April 1, 2019

**For additional questions, please email:**  
[vhacoscirev@va.gov](mailto:vhacoscirev@va.gov)

In your email subject line, please include:  
**“Question on Innovation Initiative RFA”**

# HSR&D Innovation Initiative Program (Planning/Start Up Funds) HX-18-020

## RFA Questions and Answers

### Questions on the Phased Approach

**Q.** The drop off from the number of Phase I to Phase II awards is quite steep. Do you expect most of the investigators who are awarded planning funds to fail? If not, will there be another mechanism to provide funding to continue work on promising Phase I projects that do not make it into the top 3 (e.g., can they be reviewed along with merit awards to be continued with a more traditional timeframe and budget)?

**A.** For the Innovation Initiative, HSR&D is using a phased approach, which permits innovative high-risk ideas to be examined incrementally for potential success and feasibility. Projects funded for Phase I but not Phase II may complete for funding through other funding mechanisms.

### Questions on the Application Process

**Q.** Is the Intent to Submit (ITS) basically a blank page with title and topic only?

**A.** You will need to complete the Intent to Submit following the instructions outlined on page 9 of the RFA. Please note that all Intents to Submit must indicate which HSR&D priority area their proposal will address.

**Q.** Are letters of support allowed or encouraged?

**A.** As per Table 2 (page 11) in the RFA, letters of support should not be submitted as part of the application.

**Q.** Will this grant look for investigators that have a well-established research background, or are they considering investigators with little or no research experience but are seasoned clinicians?

**A.** This funding mechanism does not have any previous research experience requirements for investigators. However, during Phase II, applicants who receive the planning awards will undergo a rigorous IIR merit review process. As such, collaborating with more experienced researchers might be considered.

**Q.** Can an investigator submit more than one proposal to this RFA?

**A.** Yes, an investigator may submit more than one proposal to this RFA.

**Q.** Would it be okay for an investigator to submit on similar topic areas to both the Innovation RFA and the traditional HSR&D IIR in December 2018?

**A.** Yes, investigators may submit projects on a similar topic to both the Innovation RFA and the traditional HSR&D IIR in December as long as the project aims are different.

### Questions on Research Plans/Concept Papers

Q. If you have a group of collaborators on a program that has been designated a clinical program, can funds be used to pay for patient focus groups?

A. Phase I funds may be used to pay for patient focus groups; however, applicants should speak with their local IRB to determine if these focus groups are IRB exempt. Per page 13 of the RFA, activities conducted during the Planning Phase *should* not require IRB approval. However, if applicants wish to perform activities which require IRB approval during the Planning Phase, they should consider how this may adversely impact the project timeline.

Q. Will the inclusion of face to face meetings be viewed negatively? Would it be appropriate to include plans such as bringing together 12-15 people for 1.5 days?

A. Reviewers will score all proposal activities (including face to face meetings) based on the justification and rationale provided in the proposal.

Q. During this Phase I Innovation award, we are not supposed to conduct human subjects research. Is it allowable to conduct new analyses using operations data under a quality improvement (QI) justification?

A. Analyses conducted under a QI justification would be appropriate; however, applicants should consult with their local IRB to ensure these activities are IRB exempt.

Q. One of the two main criteria is the impact the innovation could have; however, no preliminary data are supposed to be included in the research plan. We have data showing how big the impact would be. Are we only supposed to use data from other/published studies to demonstrate impact?

A. Although not required, preliminary data may be used to justify the potential impact of the innovation; however, preliminary data should not be used to provide background or rationale for the proposed strategy or intervention.

Q. In the Innovation planning grant RFA, it says that start-up activities should be IRB exempt. Would consulting with Veterans and providers about ways to adapt an innovation to VA still be considered IRB exempt? There would be no PHI.

A. Per page 13 of the RFA, activities conducted during the Planning Phase should not require IRB approval. However, if applicants wish to perform activities which require IRB approval during the Planning Phase, they may do so as long as these activities can be completed within the Planning Phase timeframe. Applicants should consult with their local IRB to determine what activities would be considered IRB exempt.

#### Questions on Blinding

Q1. I see that the review is blinded. What is the best way to refer to our operational partners? Is it permissible to indicate the office, without naming the partner's role?

A1. In the Research Plan section of the proposal, please refer to operational partners or program offices by their organization/office names, but do not identify specific individuals.

**Q.** Will reviewers only get the Research Plan to review, or will they also get the references? How will it be possible to blind citations?

**A.** Reviewers will only be critiquing the Research Plan (section 2a, as described on pages 12-13 of the RFA). This includes the Project Title, Aims/Objectives, Specific Questions to be Addressed, and Description of Activities. Citations may be included in the Bibliography and References Cited section, which will not be reviewed by reviewers.

**Q.** I understand that the 3-page Research Plan needs to be blinded. Does the ITS need to be blinded as well?

**A.** Instructions for submitting the ITS are outlined on page 9 of the RFA. No narrative or Research Plan is submitted as part of the Intent to Submit; therefore, there is no blinding required on the ITS.

**Q.** Should we blind the budget and budget justification?

**A.** Do not blind the budget or budget justification. Reviewers will not critique the budget or budget justification.

**Q.** How should we reference personal communication (that is, if some of the impetus for the project is based on knowledge gleaned through VA work activities and it is not yet published in peer reviewed journals, how should we cite this information without unblinding)?

**A.** Only section 2a, Research Plan, must be blinded. You may refer to personal communications in the Research Plan; however, do not include any personally identifiable information.

#### Questions on the Proposal Review Process

**Q.** Are biographical sketches and other support pages required? If so, will these be provided to the reviewers?

**A.** As per Table 2 on page 10-11 of the RFA, SF424 (R&R) Senior/Key Person Profile(s) is required. Please refer to page 15 of the RFA (box entitled "Important Notes" at the top of the page) for additional instructions. Biographical sketches will not be provided to reviewers.

**Q.** At what point in the decision process, will the team be considered? Is it advantageous to have a multi-disciplinary team? Multiple sites? Operations partners?

**A.** Use of multi-disciplinary teams, multiple sites, and/or operational partners is up to the investigator's discretion depending on the proposed idea/research plan, and may be included as part of the activities outlined in the proposal's Research Plan. If included in the Research Plan, applicants must ensure that no personal identifying information is included. Reviewers will independently critique the Research Plans based on the narrative provided by applicants.

**Q.** Who will be the members of the scientific review panel? Will they be researchers – in similar composition to other HSR&D Scientific Merit Review Boards (SMRB)? Or will this panel include operations leaders, innovation experts, topical experts in the five priority areas?

A. The review panels will be comprised of experts and champions of innovation. The panels will include experts from VA central program operations, and innovators from private industry, academia, other Federal agencies, engineering and IT.

**Health Services Research and Development (HSR&D) Innovation Initiative:  
*Funding Innovative High Risk, High Impact Health Services Research***

March 28, 2018

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## White Paper Aims

The aims of this White Paper are to:

1. Describe the goal of a more innovative research program, frame against current processes, barriers and results.
2. Define innovation and identify processes for successfully measuring innovative science.
3. Review funding mechanisms used by other funders to promote more innovative projects
4. Recommend funding processes for effectively supporting scientific innovation in Health Services Research on a competitive timeline.

**Goal Statement:** The goal of the Health Services Research and Development (HSR&D) Innovation Initiative is to support and promote high risk, high-impact research that contributes to meaningful improvements in Veteran care and health outcomes and substantial contributions to the field of health services research.

**Problem Statement – Current State and Barriers to Innovation:** All health systems, including VA, want innovative solutions to health care problems<sup>1</sup> and research programs should be an important source of this innovation. Unfortunately, the current research processes and infrastructure are often not conducive to supporting rapid innovation but are instead more likely to produce incremental improvements over an extended timeline.<sup>2</sup> Previous research paradigms have emphasized scientific rigor and established feasibility of completing the research, not less familiar ideas or disruptive advancements that often have some associated risk.<sup>3</sup> If research wants to contribute to more innovative solutions, the culture of the scientific community needs to change to reward research ideas that will challenge or seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or interventions. HSR&D leadership understands the need for greater innovation to address current health care problems and would like to implement changes in how research is currently being solicited, reviewed, funded, and carried out. Towards this goal, HSR&D is launching an innovation initiative including a new funding mechanism that supports research that has potential for high impact but which previously may have been perceived as too risky to fund.

**Problem with the current research review process:** In the current HSR&D research review process, proposals are reviewed and awarded based on the assessment of the importance, feasibility, innovation, and quality of the study design and research team. This process, however, often gives more weight to elements that are easier to assess such as experience of the study team, existence of prior data, and rigor of the study design rather than the level of innovation of the study question or the ultimate impact of the idea on health care outcomes, practice and policy. The substantial work involved in preparing a typical investigator-initiated research proposal, which usually involves one or two rounds of resubmission, may deter proposals that use unfamiliar interventions or methods or that are felt to be outside of the usual types of topics reviewed by panels. As

a result, research ideas that are pursuing a well-established pathway and building incrementally on our accumulated knowledge may stand a better chance of funding than ideas that break from traditional approaches, draw from different disciplines, have limited early data, or appear to pose a higher risk of failing.

Other factors that investigators see as potential risks in obtaining innovative research funds pertain to the limited number of mechanism for funding, the traditional perspectives of established reviewers, and 3-4 year funding cycles. These challenges also pose special risks and barriers for health services research aimed at improving clinical care, within the context of a rapidly changing learning health care system.<sup>3</sup> If research is to address the needs of a dynamic VA health care system, we need to build capabilities that will improve and/or adopt innovation closer to real time. The current HSR&D research model takes multiple cycles of scientific merit review to successfully obtain funding, undermining the relevance and value of the intramural research to quickly and continually improve delivery of health care. Another barrier to funding innovative health services research within the current system is that, although the current processes attempt to evaluate the potential significance of the research outcomes, the methods utilized to design studies and measure outcomes are not sufficiently flexible to support interventions that require adaptation in more dynamic and pragmatic real-world settings.

### **Assessing and identifying effective approaches to funding innovative high risk, high impact studies**

#### **Methods**

HSR&D utilized a rapid mixed-methods approach<sup>4</sup> using representative and snowball sampling to collect and collate data for assessing information related to funding innovative high risk, high impact studies. Information was collected for quality improvement purposes. Data were collected using focus groups (n=5), individual interviews (n=10), and follow-up interviews (n=3) to allow a breadth of descriptive data collection on relevant topic areas. Participants included Department of Veterans Affairs (VA) scientists (n=12); VA central office operational administrators (n=3); representatives from the VA Center for Innovation (n=1) and Diffusion of Excellence (n=1); VA HSR&D (n=4) and RR&D (n=7) program administrators and managers; innovation experts outside of VA from the Institute of Advanced Discovery and Innovation (n=9) and NIH program administrators from (n=2).

An environmental and literature scan was also conducted to review literature, publications, and correspondence relevant to innovation in research in the current climate. Search terms included: *innovation, what is innovation, adopting innovations, innovation implementation, disruptive innovation, innovation in healthcare, and innovation sustainability*. Search engines included: PubMed, OVID MEDLINE, Cochrane Systematic Reviews, Google Scholar, and the Joanna Briggs Institute Evidence Based

Practice Database. After a review of search results, 149 citations were selected for further review and inclusion. Published books were also examined using Google and Amazon, from which a collection of representative texts was selected. Data collected and collated from these sources were triangulated and ultimately produced the following findings and recommendations.

## Findings

### Definition and characteristics of Innovation

Based on various interviews and environmental and literature scans, several themes or concepts related to innovation arose. The most frequent response to the definition of innovation was that innovation is *novel* – *something new and different* - a new product, process, approach, and/or idea. The *novel* concept was considered “nova” if it had never been done before and was viewed by many as being “rare”. Often “novel” was also operationalized as the new/novel use of something, such as the application from one field to new field. A second common theme related to innovation was the notion that innovation should have a positive measurable *impact*. *Impact* could be defined as societal impact, affecting a significant portion of a population; improving quality of life in a notable way; having positive financial results including cost reductions and returns on investment or capital gains; and/or improving efficiency and performance. Lastly, the concept of *risk for failure* was associated with innovative research. Innovation was perceived as involving a *quantum leap* – a huge, sudden, change often requiring some level of risk. This differs significantly from the *incremental* approach traditionally used in current research which is associated with lower risk and potentially lower impact outcomes. The following list represents a sample of key characteristics of innovation that were frequently noted in the literature<sup>5</sup> and/or arose from the data collection:

- New, original or unusual process or product
  - should by nature be exciting, inspiring, and creative
  - challenges or seeks to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, or interventions
  - the adoption of an existing process or product in a new or unusual way
- Results in impact
  - addresses a significant problem or question in terms of its prevalence, severity, urgency, cost, etc., for VA and the general public
  - has the potential to produce a significant change to health care and impact on health, often by overcoming some existing barrier to change health or healthcare
  - focus is on broader care improvements in the VA healthcare system rather than within a smaller, specific subpopulation
  - contributes to an area of practice or science where existing strategies have been unsuccessful in producing meaningful improvement
  - produces a lasting change in guidelines for care in the VA

- offers new directions in promoting feasibility and/or sustainability of current treatments or practice
- Poses higher risk than traditional risk but in return offers greater rewards or earlier pay-off
  - Often less pre-existing data to support, thus poses higher risk
  - Impact in some situations cannot be pre-determined (due to lack of data but one can make certain cases where the impact might be preferable to the status quo – i.e. in areas where traditional approaches haven't paid off, where a new idea can get over an existing barrier to change, etc.)
  - High risk innovation can create disruptive and/or notable changes that present opportunities for setting a *different standard* of practice

### **Funding mechanisms that minimize barriers and encourage innovation**

Best practices of previous funding mechanisms within and outside the VA were also examined as part of the innovation analyses. Appendix 1 represents a sample of prior RFAs focused on innovation from external agencies including NIH and DoD, as well as VA, and includes information regarding funding mechanisms, a hyperlink to the example RFA, phased/benchmark funding status, and programmatic involvement. Though few funding mechanisms use all recommended features, prior funding for innovative research has the following **common** features.

#### 1. Identification of Priority Areas for Innovation

Although identifying criteria or targeting clinical conditions is not an inherent requirement of innovation, it may be helpful to provide a focused effort of innovation for priority areas. This approach is often necessary when resources are limited or if specific topic areas are particularly important. This approach can be supported by conducting a gap analysis & needs assessment to define the problem and gap in current solutions. The funding agency priorities and the priorities as identified by organizational leadership should be used to guide this process. This is also an opportune time to qualify restrictions, determine examples of what is and what is not desired, and identify details on factors of interest. In the case of HSR&D, these include the Secretary's and Undersecretary's priorities, gap analyses findings, and inputs from VSOs and clinical operations leaders.

#### 2. Implementation of a specialized panel and process

Feedback from several researchers and program administrators of innovation program suggested that a specialized review panel is essential in effectively identifying and funding truly innovative research. Traditionally reviewers and funders are accustomed to viewing safer, incremental lines of research and may weigh or emphasize issues related to feasibility or scientific rigor over innovation. What is needed is a specialized panel of reviewers that is sufficiently flexible and forward-thinking that allows a greater degree of risk in funding innovative health services research. In addition, it is also important to develop a specialized proposal review

process to establish an efficient timeline and procedure for rapidly evaluating and incremental funding innovative projects based on pre-defined bench marks and accomplishments.

3. Greater involvement of the funder to ensure continued support and progress

Several administrators from external funding agencies reported using a **cooperative agreement** approach in funding innovation research. Within the VA, the cooperative agreement model or an adaptation of one can ensure that HSR&D, the operational partners and the research investigators are actively and collaboratively engaged in the ongoing development and implementation of the project. This approach allows stakeholder groups to be actively engaged throughout the funding process to allow for seamless communication and cooperation that will facilitate, shared goal setting, monitoring, efficiency in troubleshooting, etc.

4. Phased funding to allow more ideas to be funded with smaller amounts of early funding to promote more risk taking with new ideas

Phased funding allows a “fail fast, fail often” approach by which funds can be allocated in phases to accommodate the complex nature of innovative research. A phased approach permits funds to be provided incrementally to assess feasibility and/or be used to establish processes into place (e.g. hiring, contracts, OIT, etc.). This approach to innovation permits a more rapid assessment of the progress and scientific rigor of each application at various time points throughout the course of the funded period. When using the phased approach, monitoring by the funding organization is essential by using such mechanisms as monthly calls, data blasts, and advisory council to monitor progress (managed by Scientific Program Manager). This approach is a scientific and fiscally prudent approach, compared to the current mechanism where the progress/success of a study is identified at the end of a longer period of funding during which the investigator has primary responsibility for ensuring the success of the project.

5. Pre-defined benchmark/milestones

Pre-defined benchmarks and milestones co-developed through a cooperative agreement facilitates the process of monitoring progress of a project and making decisions about continued funding over time. This approach also permits modifications as needed while still maintaining scientific rigor. Benchmarks and milestones should be operationalized by predetermined annual goals contingent on continued funding.

Examples of project milestones and benchmarks by funding year are represented below in Table 1 for a proposed 3-year funding solicitation.

**Table 1: Examples of Project Milestone/Benchmark by Funding Year**

Funding Year	Milestone/Benchmark Examples
Year 1	Hiring Completed

	Contracts Initiated
	Recruitment Initiated (0-25%)
	Regulatory Approvals Received
	OI&T Tasks Accomplished
<b>Year 2</b>	Recruitment Goals Met (50%)
	Data Collected and Managed
	Data Analytics initiated 3
<b>Year 3</b>	Recruitment Goals Met (100%)
	Data Collected and Managed
	Data Analyzed
	Results Summarized
	Preliminary Reports Developed and Disseminated
	Publications/Presentations Accepted
	Tangible Products Produced and Disseminated (e.g. Innovators Network, Diffusion Hub)

6. Provide successive opportunities for additional funding for ideas that succeed

A shorter funding timeline was discussed by various key informants in the innovation field along with more intermittent updates and products throughout the award period. This approach of having more frequent updates aligns with the VA becoming more of a learning health care system where research can provide information, tools and products that can be implemented in clinical practice to address ongoing care needs of Veterans. In addition to a phased performance-based approach as discussed previously, the idea of providing successful projects the opportunity to compete for transition funds to implement or scale up effective interventions, products and procedures. Emphasis will be placed on these funded projects lending themselves to other existing mechanisms of innovation and collaborations beyond HSRD/ORD, such as the VHA Innovation Ecosystem, Diffusion of Excellence, and Innovators Network.

**Discussion**

**Implications for VA**

HSR&D’s goal is to create an application, review and funding strategy that will facilitate a more efficient and effective process to award innovative health services research that will have significant impact on the quality of services for Veterans. A more dynamic and iterative process may reduce the time between conceptualization and implementation. Funding mechanisms can be implemented in a way to facilitate more interactions among the funded research team, operational programs and the funder so they can co-create goals, processes, and outcomes, monitor progress, and maximize resources. The recommended cooperative approach is amenable to rapidly producing rigorous, yet fiscally resourceful research and products that can expedite the dissemination and implementation pipeline at a more rapid and efficient pace.

## Recommendations

The following considerations and recommendations represent a synthesis of the practices used in previous RFAs that were recommended by expert informants within and outside the VA for funding high impact, high risk innovative research.

**Characteristics of Innovation for Special Consideration:** Four key common elements of innovation were identified during the course of the assessment process which will guide the funding of high impact, high risk innovative studies. They are:

- (1) Novelty – New ideas have less pre-existing information/pilot data and thus inherently carry a higher risk of failure than established foundations of knowledge; novelty may exist in applying ideas from outside fields to healthcare. Applying proven health care interventions to a slightly different patient population or different setting, however, does not constitute true innovation. Novelty may also be represented by application of new data to an existing problem (for example, using social media to identify changes in health status).
- (2) Potential for Important Impact – When examining innovative approaches, it is more difficult to estimate impact but there are qualitative ways to project potential impact. This is relevant to: (a) topic areas that previously have not seen much progress; (b) approaches that are generalizable to multiple conditions; and (c) when there is opportunity to overcome a major barrier to progress, or when there is potential for major change in how care is structured or delivered;
- (3) Risk – Risk does not make an idea innovative but innovative ideas inherently carry more risk because their newness means there is less existing data from which to predict success. The current barrier to conducting and funding innovation is that investigators and funders are risk averse. There are limited mechanisms to support innovation, but they are infrequently used in research, translation and achieving impact. It is critical to create a shared meaning of “innovation” and cultivate a research climate where it is permissible to allow some degree of “risk” of failing. Risk taking is an essential element in supporting innovation.
- (4) Accountability – To balance the allowance of uncertainty, risk and failure, it is imperative for funding processes be performance-based, incremental and iterative. Innovative proposals should lay out a plan for regularly reassessing progress and likelihood of success along the way to allow iteration and recalibration as both the investigator and funder learn more about an innovative idea.

**Develop Specialized Review Panel:** Based on feedback and information from relevant stakeholder interviews, the following recommendations were proposed:

- 1) conduct off cycle special RFA that will emphasize the uniqueness of the innovation

award from traditional funding mechanisms;

- 2) establish separate and appropriate review criteria that emphasize innovation, higher risk compared to risk associated with traditional research, and potential higher impact;
- 3) develop and conduct special review processes such as small (3-4) specialized panels, one which predominantly consists of members from outside the VA (in 3:1 ratio) to bring in new perspectives and ideas; and
- 4) develop a review panel that consists of a cross fertilization of members to include: (a) subject matter expert, internal or external to the organization; (b) experts in innovation; (c) methodologists; and (d) end users (e.g. Veterans, clinicians, operations/program administrators). A critical step in preparing the panel will be to provide materials in advance, training, and group exercises to develop shared perspectives, in this case on the scope and definition of “what is innovative?” Reviewers should use specific criteria to evaluate proposals that are unique to the goals of the Innovation RFA, as seen in Table 2: Questions to be addressed in concept proposal.

**Table 2: Questions to be addressed in concept proposal**

1. Does the proposed work challenge or seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, or interventions?
2. Does the proposed work involve the creation of a new, original or unusual process or product? Please explain.
3. Does the proposed work involve the adoption of an existing process or product in a new or unusual way? Please explain.
4. Does the proposed work have a realized value or impact to the existing VHA Health Care structure and/or to Veterans’ quality of health? If yes, please explain the impact or value of the proposed work and how will it be measured.
5. Does the proposed work offer new directions in promoting feasibility and/or sustainability of current treatments or practice? Please explain.
6. Will the proposed work contribute to an area of practice or science where the field is ready for a change (e.g., where there is a need, where there is dissatisfaction with the current state of the science)? Please explain.
7. If the proposed work is high risk, is the risk proportionate to the reward? Please explain.
8. Does the proposed work focus on broader care improvements in the VA healthcare system rather than within a specific subpopulation? Please explain.
9. Does the proposed work address a significant problem or question in terms of its prevalence, severity, urgency, cost, etc., for VA and the general public? Please explain.

**Develop Modified Process for Reviewing Proposals:** The HSRD Innovation Award Overview (see Figure 1) represents a phased approach and timeline by which awards will be solicited, reviewed, awarded, and monitored throughout project funding. Based

on previous efforts, rapid review cycles can be completed from RFA release to award between 6-11 months. HSR&D anticipates that the Innovation Initiative will take approximately 10 months. The use of a phased approach, however, may permit a preliminary examination of findings and products throughout the process. The initial **screening phase** which we anticipate will elicit about 100 applications uses a rapid process (2-3 page application) that focuses solely on the concepts of innovation, risk and impact leading to notable improving in the delivery of care for Veterans. The recommended timeline for the innovation initiative for the screening phase is four months from RFA release to the time the concept papers are awarded (See Table 3: Review Timeline). Applications will undergo a **blinded screening review** to reduce any biases or conflicts of interests during the screening and ensure that the focus of the review will be primarily on the innovation concept. It is anticipated that up to 10 applications that show the most promise in terms of innovative ideas and potential impact will be awarded between \$75K to \$100K to test out the feasibility of their ideas and/or plan for the full submission. This feasibility testing/planning phase will likely take between 6 months. At the end of this phase, awardees will submit a full proposal (10-15 pages) for a **non-blinded** review to determine whether they receive full funding (\$500K-\$750K/year for up to 3 years) to complete their study. From the full proposal submissions, 2-3 applicants will receive final full funding to begin their projects. Awardees will be assessed bi-annually/quarterly, for subsequent year funding based on the benchmarks jointly established by the investigators and funder.

**Table 3: Innovation Award Timeline**

<b>Task</b>	<b>Deadline Date</b>
Release RFA	August 1
ITS/LOI Opens	August 15
ITS/LOI DUE	August 22
Invite Reviewers	August 1 – September 1
Develop Panels	September 5
ITS Spreadsheet Meeting	September 20
Begin Reviewer Guidance Document & Critique Template revision	September 20
Start First Contact Process for Application Receipts	September 20
First Day to Submit Concept Paper (2-3 pages)	September 26
Down to the Wire Submission Deadline	October 3
Concept proposals DUE for review	October 5
Verification Deadline in ERA [If using ERA]	October 5
SPM finalize application-panel assignments	October 9
Complete panel assignments in ERA (by COB) [If using ERA]	October 10
Start involved Personnel Sheet, PreCOI, & Ethics email to reviewers	October 11
Send out proposals for review	October 15
Review Concept proposals with feedback	November 1
Last day to submit non-complaint score (email PDF scores)	November 2
Scores Released	November 15
Award planning funds/Invite Full Proposal	December 1
Startup activities	December 1 – May 1
Begin Reviewer Guidance Document & Critique Template revision	March 10
Start First Contact Process for Application Receipts	March 10
First Day to Submit Full Proposal	March 15
Down to the Wire Submission Deadline	March 20

Full proposal Due for Review	April 1
Verification Deadline in ERA [If using ERA]	April 1
SPM finalize application-panel assignments	April 4
Review/Administrative Review	April 10
Last day to submit non-complaint score (email PDF scores)	April 11
Scores Released	April 15
Announce Award Recipients	April 30
Project Start Date	May 1

**Figure 1. Award Overview**



## REFERENCES

1. Sensmeier, J. E. Disruptive innovation and the changing face of healthcare. *Nurs. Manag.*2012;43:13.
2. Riley, W. T., Glasgow, R. E., Etheredge, L. & Abernethy, A. P. Rapid, responsive, relevant (R3) research: a call for a rapid learning health research enterprise. *Clin. Transl. Med.* 2013;2:10.
3. Bindman, A. B., Pronovost, P. J. & Asch, D. A. Funding Innovation in a Learning Health Care System. *JAMA.*2018;319:119–120.
4. Creswell, J. 2007. *Designing and conducting mixed methods research.* SAGE Publications.
5. Poirier, V. *et al.* Thoughts on Improving Innovation: What Are the Characteristics of Innovation and How Do We Cultivate Them? *Technol. Innov.*2017;18,319–330.

**Appendix 1. Innovation Initiative Previous RFA Examples**

Organization	RFA	Funding Type	Review Process	Phased Funding	Funder Involvement
W/in & Outside NIH	Rapid Review R01s <a href="https://grants.nih.gov/grants/guide/pa-files/PAR-15-346.html">https://grants.nih.gov/grants/guide/pa-files/PAR-15-346.html</a>	R01	<ul style="list-style-type: none"> <li>Rapid Review process (See attached article Riley et al 2013)</li> </ul>	N/A	N/A
NIH	U01 <a href="https://grants.nih.gov/grants/guide/rfa-files/RFA-OD-17-004.html">https://grants.nih.gov/grants/guide/rfa-files/RFA-OD-17-004.html</a>	Collaborative	<ul style="list-style-type: none"> <li>Not innovative/rapid review of funding</li> </ul>	N/A	High degree of programmatic involvement beyond normal dictation of program officer
NIH	Eureka <a href="https://grants.nih.gov/grants/guide/rfa-files/RFA-MH-14-214.html">https://grants.nih.gov/grants/guide/rfa-files/RFA-MH-14-214.html</a>	Innovative, high risk/high reward research funded	<ul style="list-style-type: none"> <li>Two level review process</li> <li>Panel trained to fit the announcement                             <ol style="list-style-type: none"> <li>TRiage - 100 apps into 6 broad areas (36 remote reviewers)</li> <li>15 apps to each reviewer, chose top three</li> <li>In person review of subset panel assigned all remaining 18 applications to rank good, better, best</li> <li>Ultimate numerical values, with feedback (can be boiler plate, per regulation)</li> </ol> </li> </ul>	N/A	
NIH- (NIDDK, NIMH)	PAR <a href="https://grants.nih.gov/grants/natural_disasters.htm">https://grants.nih.gov/grants/natural_disasters.htm</a>	Policy change Natural Experiments	<ul style="list-style-type: none"> <li>Expedited review process on reduced cycle</li> <li>Skeleton review panel</li> <li>Rolling review</li> </ul>	N/A	N/A

		nt – natural disaster				
NIH	UG3-UH3 <a href="https://www.ninds.nih.gov/taxonomy/term/1720/all">https://www.ninds.nih.gov/taxonomy/term/1720/all</a> ; <a href="https://grants.nih.gov/grants/guide/rfa-files/RFA-CA-17-038.html">https://grants.nih.gov/grants/guide/rfa-files/RFA-CA-17-038.html</a>	High risk, high reward	<ul style="list-style-type: none"> <li>• Review both phases together – total review</li> <li>• PI doesn't comeback in for review, but makes benchmarks and then goes on to phase 2</li> <li>• May not fund any/all components of phase 2</li> <li>• Can use same panel, asynchronously on conference call</li> <li>• Option of another form of same RFA</li> <li>• Can do expedited review on UH3 component</li> <li>• Can use same panel, asynchronously on conference call</li> </ul>	Phased approac h	Puts burden on staff – critical for research management	
NIH	Limited Competition RFA (rare)  <a href="https://grants.nih.gov/grants/guide/rfa-files/RFA-TR-17-002.html">https://grants.nih.gov/grants/guide/rfa-files/RFA-TR-17-002.html</a>	e.g. Long- term follow up	<ul style="list-style-type: none"> <li>• Can use "X02" pre-application review process</li> <li>• Can use UG3/UH3 model (as seen in link to RFA example)</li> <li>• When have group has been doing previous work</li> <li>• Program staff encourage PI to apply</li> <li>• e.g. 5-10 year follow up work when PI/group did original work</li> </ul>	N/A	N/A	
NIH	ARRA funding  <a href="https://recovery.nih.gov/">https://recovery.nih.gov/</a>	Stimulus funds - have to be funded within the fiscal year	<ul style="list-style-type: none"> <li>• First pass yes/no</li> <li>• Only review triaged subset</li> </ul>	N/A	N/A	
DARPA	Dept. of Defense Advanced Research	High risk	N/A	Time limited	High degree of programmatic	

Project Agency					involvement beyond normal dictation of program officer
DOD	N/A	N/A	<ul style="list-style-type: none"> <li>• Request LOI</li> <li>• Use QUAD chart to triage</li> <li>• Invite full proposal from subset</li> </ul>	Phased Approach	N/A
RRD	N/A	Innovation	<ul style="list-style-type: none"> <li>• Program staff encourage PI(s) to apply</li> <li>• Held consortium review by experts in field</li> <li>• 3-month compressed review cycle</li> </ul>	Phased Approach	High degree of programmatic involvement beyond normal dictation of program officer
RWJF	E4A <a href="https://www.rwjf.org/en/library/funding-opportunities/2015/evidence-for-action-investigator-initiated-research-to-build-a-culture-of-health.html">https://www.rwjf.org/en/library/funding-opportunities/2015/evidence-for-action-investigator-initiated-research-to-build-a-culture-of-health.html</a>	Evidence for Action	<ul style="list-style-type: none"> <li>• Applications are accepted on a rolling basis</li> <li>• Applicants notified within 6-8 weeks of their LOI submission</li> <li>• Invited full proposal stage with 2 months to submit</li> <li>• Full proposal funding decisions will generally be made within 6-8 weeks of the submission deadline</li> </ul>	No explicit range	N/A