**Department of Veterans Affairs**

**VA Office of Nursing Service Pilot Grant Program Guidelines**

(This document can be accessed on the [ONS Internet Nursing Research](https://www.va.gov/NURSING/research/nursingresearch.asp) site)

1. **PURPOSE:**

This award is intended to support small, exploratory pilot studies that will contribute toward building a program of research. Priority is given to new investigators or those that are new to the VA. Consideration will also be given to mid-career and senior scientists. It is the expectation that data derived from this mechanism will be leveraged to obtain larger grants. We *strongly encourage* applicants to identify organizational partners i.e. Office of Nursing Services (ONS) and/or teams of PhD and DNP investigators. *Please note: Clinical trials are not eligible for this rapid response RFP.*

1. **Funds Available:** The budget for this award may not exceed $75,000 for the total funding period. Research funds must be obligated by September 2016 or spent by mid-September, 2016. Salaries of title 38 VA employees *may not* be included in the budget.
2. **Eligibility Information:**
	1. Principal investigators (PI) must be nurses, hold a VA appointment of at least 5/8 time and must possess a doctoral degree.
	2. Each principal investigator can submit only one proposal; the investigator may hold a secondary role in another submission.
	3. Documentation of support for the application from the Medical Center Director must be included as a separate attachment in all applications and included in the Appendix (as per instructions below). Proposals submitted without such documentation will be administratively withdrawn.
	4. Eligibility and scientific questions should be referred to Dr. Beverly Priefer at beverly.priefer@va.gov.
3. **DUPLICATE SUBMISSIONS:** A proposal submitted toONS Pilot Grants ***may not*** be *concurrently* submitted to any other VA-ORD Service (HSR&D- NRI, NRI Merit; RR&D; BLR&D, CLR&D).
4. **Intent to Submit**
	1. A letter of Intent is required for this funding opportunity. The purpose of this letter is to 1) determine that the proposed study is research and not a quality improvement or evidence based practice project; 2) ensure that the proposed study supports one or more of the Blueprint for Excellence strategies; and, 3) identify the number and composition of the scientific review group. The letter should be no longer than 2-3 paragraphs and include background, objectives, rationale for the proposed study, and the Blueprint for Excellence strategy(ies) the study supports. Send the Letter of Intent as an attachment in an email to Dexter.Willis@va.gov. by **COB November 2, 2015.** Applicants will be notified by **November 6, 2015** whether their LOI is approved or disapproved with the full proposal due **COB** **December 11, 2015.**
5. **Application And Submission Instructions:**
	1. Use instructions and templates (if attached) in the order listed in **“*Table I. Required sections and instructions.”*** *Each section should begin on a separate page. All documents should be collated and electronically submitted as* ***one*** *document or file*. Proposals not adhering to the instructions will be administratively withdrawn.
	2. Submission questions should be referred to Mr. Dexter Willis at dexter.willis@va.gov
6. **Approvals:**
	1. Awarded research funds **must be** obligated by September 2016. Investigators are encouraged to initiate all the appropriate approvals *as soon as possible*.
	2. Award funds will be sent to facilities when appropriate forms and approvals are provided e.g., human subjects’ training, Institutional Review Board and VA Research and Development Committee approvals, privacy protections, nurse executive and facility letters of support.
	3. One copy of these approval documents must be submitted electronically no later than Close of Business on **January 30, 2016** to Dexter.Willis@va.gov. Submissions received late will not be accepted for review.

**Table I. Required application sections and instructions.**

This table contains an overview of all required application sections and includes hyperlinks to templates (if available) and instructions (if available) for each section. **The application sections are presented below in the sequence that should be included in the grant**.

* Each section should start on a separate page and be labelled accordingly.
* If a template is to be used for the section, a hyperlink will lead you to the appropriate document. Absence of a hyperlink indicates that you should follow the instructions included in **Table I**. Please read the instructions carefully.

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| **Grant Sections** | **Suggested Page Limit and instructions** |
| Cover Page including Project/Performance Site Locations (as needed) | **One page** [Use Cover Page template](https://www.va.gov/nursing/docs/research/ONS_Application_Cover_Page.docx)  |
| References Cited | **Not to exceed** **one** **page**Read [Reference instructions](https://www.va.gov/nursing/docs/research/references_bibliography.pdf)This section must follow the required **font** and **margin** specifications. |
| Project Summary Abstract | **Not to exceed** **40 lines of text**Read [Project Summary/Abstract instruction](https://www.va.gov/nursing/docs/research/project_summary_abstract.pdf)This section must follow the required **font** and **margin** specifications. |
| Project Narrative (Relevance to Veterans Health Issues) | **Maximum of** **10 lines** **of text**Read [Project Narrative instructions](https://www.va.gov/nursing/docs/research/project_narrative_instruction.pdf) This section must follow the required **font** and **margin** specifications. |
| Specific Aims | **One page**See [page 5](#aims) of this documentThis section must follow the required **font** and **margin** specifications. |
| Research Plan  | **Four pages maximum**See [pages 5](#plan) of this documentThis section must follow the required **font** and **margin** specifications. |
| Human Subjects, Vertebrate Animals, | **Complete if checked “yes” to Question 15 or 16 on the Cover Page.** **No page limit** See [Table 3](#Tbl3) below for instructionsThis section must follow the required **font** and **margin** specifications. |
| Appendix – Director letter of support, Other letters of support | **One page per letter**See [Table 4](#Tbl4) below for instructions. This section must follow the required **font** and **margin**. |
| Biosketches of senior/key personnel | **Four page maximum** **per biosketch**. Use [Biosketch Template](https://www.va.gov/nursing/docs/research/biosketch_template.pdf) See [instructions and an example biosketch](https://www.va.gov/nursing/docs/research/BiosketchSampleInstructions.pdf) from the NIH website:  |
| Current and Pending Support (PI) | Read [Support Instructions](https://www.va.gov/nursing/docs/research/OtherSupportInstruction.pdf)See example: [ONS Other Support Instructions](https://www.va.gov/nursing/docs/research/ONSotherSupportSample05-01-15-2.doc) |
| Budget with summary table | See instructions and use template included in [Budget Guidelines](https://www.va.gov/nursing/docs/research/Budget_Guidance.pdf) Use [Summary Budget Table template](https://www.va.gov/nursing/docs/research/BudgetSummaryTable.docx)  |
| Budget Justification | Read [Budget Justification instructions](https://www.va.gov/nursing/docs/research/budget_Justification.pdf) |

* 1. **Format:**
		1. **Page Limits**: The application narrative is limited to 5 pages, *excluding* references (limited to one page).
		2. Font
			1. Use an **Arial, Helvetica, Palatino Linotype, or Georgia typeface,** a black font color, and a font size of **11 points or larger.** A Symbol font may be used to insert Greek letters or special characters, but the font size, font typeface, and color requirements still apply.
			2. Type density, including characters and spaces, must be no more than 15 characters per inch.
			3. Type may be no more than six lines per inch.
		3. **Page formatting**
		4. All pages should be numbered in the bottom right-hand corner, showing principal investigator’s last name and the page number.
		5. **Appendices are limited to** Director’s Letter of Support (if applicable).
		6. Proposals must be submitted as **one consolidated pdf or word file** and electronically transmitted to Dexter.Willis@va.gov .
		7. Not conforming to this format will result in ***administrative withdrawal*** *of* *the application*.

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**Table 2. Instructions for Research Plan (First line of new Page)**

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| **Sections** | **Instructions** | **Suggested Page Limit**  |
| Specific Aims | Concisely state the goals of the proposed research and summarize the expected outcome(s), including the impact that the results of the proposed research will exert on the research field(s) involved. Succinctly list the specific objectives of the proposed research. *Be sure to include how this pilot study will be used in future studies.*  | 1 |
| Research Plan  | The Research Plan should include sufficient information needed for evaluation of the project, independent of any other document. Be specific and informative, and avoid redundancies. The Research Plan is limited to 4 pages.Do not repeat the Specific Aims in the research plan.In general, the Research Plan should contain the following: a description of the Background and Significance to the Field, and Research Design and Methods **(See below)** | 4 |
| Research Plan Continued (specific subsections) | **Background**Briefly sketch the background leading to the present application, critically evaluate existing knowledge, and specifically identify the gaps that the project is intended to fill. Provide evidence addressing:1. The scientific rationale and theoretical framework for the proposed research. Discuss relevant research, completed or underway, inside and outside VA.2. The context in which the study will be conducted and results applied.3. How or why this study will succeed in answering questions that have eluded other researchers (e.g., better design, larger sample, longer follow-up, etc.)**Significance**1. State concisely the importance and health relevance of the research described in this application by relating the specific aims to the broad, long-term objectives. If the aims of the application are achieved, state how scientific knowledge or clinical practice will be advanced. How will results from this study be used for a future submission.2. Consider how common, serious, or urgent is the problem this research addresses?3. What are the potential contributions of the proposed research? For example, how will the proposed research extend knowledge and/or contribute to improved quality, effectiveness, or efficiency of VA health care or the health of eligible Veterans? How will it enhance health care management or clinical decision-making? How does this research represent a unique opportunity for VA?4. Describe the audiences for the results of the research and how might they use the information or product(s)?**Research Design and Methods**Describe the research plan, including the basic study design, sampling plan, control or comparison groups, methods for data collections and analysis, and specific techniques and measures. Specify the kinds or sources of data to be used, how hypotheses will be tested, aggregate and subgroup analyses, and provisions for ensuring data quality and adherence to the study protocol. Address:1. How is the study design suited to the specific research question(s) and population? What are the advantages and disadvantages of this approach? Describe any new methodologies to be used and why they are preferred over existing methods. Discuss potential problems and limitations to the proposed methods and/or procedures and possible alternative approaches to achieve specific aims.2. If the study uses “usual care” as either the baseline or as a comparison group, usual care must be defined.3. Where will the study take place? Why is this setting or geographic location appropriate? Will the results be applicable to other places or populations?4. What are the characteristics of the study population? How will the sample be selected and what steps will be taken to secure and retain the needed number of subjects (and controls, if applicable)? What steps will be taken to ensure adequate representation of women and minorities? What is the estimated sample size and how was it derived? What assumptions were made regarding the magnitude of the expected treatment effect? At what level of power can inferences be drawn?5. Identify and define the dependent and independent variables and explain their selection. How will the major variables be measured and how will they be linked in the analysis? Comment on the reliability, validity, and appropriateness of the proposed measures for the study. 6. What is the data collection strategy and timeline? What are the potential problems in collecting data and controlling data quality? How will these problems (e.g., missing data, respondent drop-out, interviewer bias) be addressed?7. What is the strategy for data analysis? Outline the planned analyses, indicating which variables will be used in which analyses and the order in which analyses will be done (do not merely name proposed statistical tests). What are the strengths and limitations of this analytic strategy? Include power calculations if appropriate. Power calculations should be described in terms of clinical significance, if appropriate, as well as statistical significance. Since this is a pilot grant power may not be relevant.**Project Management Plan**Describe:1. The project management plan and timeline. Present the project timeline in Gantt Chart format 2. Estimate and describe project activities. 3. The role and tasks of each member of the research team and how their work will be coordinated.4. Any proposed collaboration with institutions or investigators outside the PI’s facility and how the work will be coordinated. Include a description of the role of consultants, contractors, and other non-VA employees (if applicable). |  |

**Table 3. Instructions for Human Subjects or Vertebrate Animals (select either human or vertebrate animals as appropriate ). Label as appropriate (First line of new Page)**

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| **Sections** | **Instructions** | **Suggested Page Limit**  |
| Human Subjects, Vertebrate Animals, | This attachment is required if you checked the box marked “Yes” for Question 15 on the Cover Page. Since VA proposals usually require IRB approval or exemption, “Yes” should be checked and this attachment included. **Address only the requested issues.**This section covers the information regarding the Protection of Human Subjects. In this attachment, the following four headings should be used and fully described. 1. Risk to Subjects* *Human Subjects Involvement and Characteristics*. Describe the proposed involvement of human subjects in the work outlined. Describe the characteristics of the subject population, including their anticipated number, age range, and health status. Identify the criteria for inclusion or exclusion of any subpopulation. Explain the rationale for the involvement of special classes of subjects, such as pregnant women, prisoners, institutionalized individuals, or others who may be considered vulnerable populations*.* **Indicate whether all subjects recruited for the study will be Veterans or whether non-Veterans will also be included. Justification must be provided for use of non-Veteran subjects in VA funded research projects.**
* *Sources of Materials*. Identify the sources identifiable living human subjects in the form of specimens, records, or data. Indicate whether the material or data will be obtained specifically for research purposes, or whether use will be made of existing specimens, records, or data. Justification must be provided for use of biological samples from non-Veteran subjects.
* *Potential Risks*. Describe the potential risks to subjects (physical, psychological, social, legal, or other) and assess their likelihood and seriousness to the subjects.

2. Adequacy of Protection from Risk* *Recruitment and Informed Consent*. Describe plans for the recruitment of subjects and the process for obtaining informed consent. Include a description of the circumstances under which consent will be sought and obtained, who will seek it, the nature of the information to be provided to prospective subjects, and the method of documenting consent. **NOTE: Do not submit the informed consent document.**
* *Protection Against Risk*. Describe the planned procedures for protecting against or minimizing potential risks, including risks to confidentiality and data security, and assess their likely effectiveness. Where appropriate, discuss plans for ensuring necessary medical or professional intervention in the event of adverse effects to the subjects.

3. *Potential benefits of research to subjects and others*. Discuss the potential benefits of the research to the subjects and others. Discuss why the risks to subjects are reasonable in relation to the anticipated benefits to subjects and others.4. *Importance of knowledge to be gained*. Discuss the importance of the knowledge to be gained as a result of the proposed research. Discuss why the risks to subjects are reasonable in relation to the importance of the knowledge that reasonably may be expected to result.5*. Data and Safety Monitoring Plan.* (If applicable) Describe the plans for monitoring the safety of participants and the accuracy and integrity of the data. Describe steps to ensure adequate subject recruitment and enrollment, including if necessary, replacement of study sites.6. In addition, the inclusion of women, minorities and/or children must be addressed. Children may not be included in VA-approved research conducted by VA investigators while on duty, or conducted at VA facilities or approved off-site locations, unless a waiver has been granted by the Chief Research and Development Officer | None |
| Vertebrate Animals | **An attachment addressing the following five key points is required if you checked the box marked “Yes” for Question 2 on the Other Project Information Component (Are Vertebrate Animals Used?)** Address only the requested issues.When research involving vertebrate animals will take place at other performance site(s), provide this information before discussing the five points. Although there is no specific page limitation, be succinct.1. Provide a detailed description of the proposed use of the animals. Identify the species, strains, ages, sex, and numbers of animals to be used in the proposed work.2. Justify the use of animals, the choice of species, and the numbers to be used. If animals are in short supply, costly, or to be used in large numbers, provide an additional rationale for their selection and numbers.3. Provide information on the veterinary care of the animals involved.4. Describe the procedures for ensuring that discomfort, distress, pain, and injury will be limited to that which is unavoidable in the conduct of scientifically sound research. Describe the use of analgesic, anesthetic, and tranquilizing drugs and/or comfortable restraining devices, where appropriate, to minimize discomfort, distress, pain, and injury.5. Describe any method of euthanasia to be used and the reasons for its selection. State whether this method is consistent with the recommendations of the Panel on Euthanasia of the American Veterinary Medical Association. If not, present a justification for not following the recommendations. | None |

**Table 4. Instructions for Appendix (First line of new Page) Each letter should be on separate page**

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| **Sections** | **Instructions** | **Suggested Page Limit**  |
| Appendix – Directors letter, letters of support | A signed copy of the letter of support from the Medical Center Director must be submitted as a separate document in the Appendix and must include the following:● A statement that the Director understands the impact of the proposed research on the facility’s organization and that he/she endorses the project.● Where the research will be conducted, if any off-site waivers are included with the application, and that the VA space described in the application and necessary support of the VA facility will be available.If a clinician PD/PI’s appointment is to start at the time of funding, the VA medical center Director’s memorandum must contain a statement indicating that the PD/PI will be given a VA-paid clinical appointment of at least 5/8ths time.**Proposals submitted without this attachment will not be accepted for review**. | **One page per letter** |
| Letters of Support (see below) | All memoranda/letters should be scanned and submitted as part of the total application packet. Please DO NOT send separate original hard copies or email PDF copies of Letters of SupportLetters of support are required from:1. Participating institutions and persons from a site other than that of the submitting PI (i.e., letters of support are NOT required from participating persons within the same center/institution as the submitting PI). Each participating or affected organizational element, institution, collaborator, and consultant must provide a letter of support, whether or not they are VA or Non-VA employees. The letter must indicate concurrence of the affected person or institution with their specific role or contribution as described in the application, their willingness to fulfill the duties described in the application, and their rate/charge for consulting services, if applicable.  | **One page per letter** |

**APPLICATION REVIEW**

1. **Criteria**

The review criteria described below will be considered in the review process.

1. **Review and Selection Process**

**Overview**

Applications submitted in response to this RFA will be reviewed through a two-tier system. The first level of review will be performed by past and present members of the Nursing Research Field Advisory Committee. These members will comprise a scientific review group, The SRG is an Advisory Group charged to evaluate the scientific and technical merit of applications. The SRG *does not* make funding decisions.

The second level of review will be performed by ONS Directors, based not only on considerations of scientific merit, as judged by the SRG, but also on the relevance and responsiveness of the proposed study to the mission and program. Final funding decisions are made at the discretion, and approval, of the Chief Nursing Officer of ONS.

**Not Discussed/Unscored**

The initial scientific peer review of research applications may include a process in which only those applications deemed by the reviewers to have the highest scientific merit will be discussed and assigned priority scores at the scientific review meeting. Before the scientific review meeting, each reviewer assigned to an application will provide a preliminary score for that application based on the review criteria described below. The preliminary scores will be used to determine which applications will be or will not be discussed or assigned a priority score at the meeting (streamlined). This process allows the reviewers to focus their discussions on the most meritorious applications.

If an application is not discussed, the PI will receive the written comments from the reviewers assigned to the respective PI’s application.

Each applicant (PI) will receive the written comments from the reviewers assigned to the respective PI’s application.

SRG members are instructed to evaluate research applications by using the review criteria described below and assigning a single, global score for each scored application. The score will reflect the overall impact that the proposed research could have on the field.

**Criteria for Review and Scoring of the Proposal**

The following criteria are considered during scientific merit review:

**Responsiveness to Research Priorities**. ONS will give special funding consideration to proposals that are responsive to program priorities, i.e. that address the blueprint for excellence, identify operational partners, PhD/DNP collaborations. Investigators must indicate what Blueprint for Excellence strategy the proposal addresses. The Blueprint for Excellence strategies can be found at <http://www.va.gov/HEALTH/docs/VHA_Blueprint_for_Excellence.pdf> Reviewers will evaluate whether the justification provided by the investigator adequately supports identifying the proposal as responsive to the Blueprint for Excellence strategies.

Significance. Does this study address an important problem? Reviewers assess the scientific significance and theoretical foundation of the stated goals, objectives, and specific research questions and/or hypotheses. Reviewers consider the proposed research in relation to information and/or pilot data that the investigator provides regarding prior work (by self and others), as well as information from other sources that relates to the scientific significance and likely contribution of the proposed work.

Reviewers will be specifically asked to comment on the following questions:

* Does the proposed research support/advance the health and healthcare of Veterans?
* Address an important and priority scientific question/area?
* Have potential for contribution to scientific literature?
* Address critical barriers to progress in the field?
* When applicable, comment on:
	+ Magnitude of scientific innovation to be achieved, likelihood of new knowledge
	+ Impact on health, especially outcomes, prevalence of problem to be addressed
	+ ROI to system, policy relevance

**Approach.** Reviewers assess the appropriateness of the research design and specific methods proposed for conducting the research. Reviewers evaluate the adequacy of data for the proposed study. For primary data, reviewers consider the adequacy of the proposed data collection instrument(s) or the plan for developing and testing new instruments, as well as the feasibility and appropriateness of data collection procedures. Secondary data issues to be considered include: appropriateness, availability, accuracy, and completeness of data. Applicants proposing to use existing databases need to provide evidence of familiarity with these, and an awareness of the availability, idiosyncrasies, and limitations of the data. For all types of data, reliability, validity, and adequacy of quality control procedures are important issues.

The following list contains some of the elements that reviewers consider, as applicable to a particular project, and in accordance with their particular expertise:

* Study design (e.g., retrospective versus prospective, experimental, quasi-experimental, etc.).
* Analytical approach (quantitative, qualitative, mixed methods).
* Theoretical model and conceptualization of key components.
* Population and sample, sampling plan, and/or comparison groups.
* Statistical power. Power calculations should be described in terms of clinical significance, if appropriate.
* Key variables, operational definitions, and their measurement.
* Data analysis plan.
* Data collection issues, including respondent burden.
* Definition and feasibility of any intervention.

Reviewers will be specifically asked to comment on the following questions:

* Is the overall research plan well-reasoned and appropriate to the aims of the study?
* Incorporate current scientific/theoretical bases?
* Use appropriate research design/methods for addressing hypothesis/research question?
* Demonstrate feasibility?
* When applicable, comment on:

Adequacy of methods to answer question with enough specificity to advance knowledge:

* Data quality
* Appropriately constructed or identified control group for intervention studies
* Accuracy of power calculations based on prevalence/incidence of condition of population

**Impact and Innovation**. Is the project original and innovative? Will there be a substantial gain in knowledge? Will the finding advance the field? To what degree will this study impact the lives of Veterans?

Reviewers will be specifically asked to comment on the following questions:

* Is the potential impact on advancing the health and health care of Veterans substantial?
* Risk worth the reward with early pay-off?
* Challenges or re-directs current research models and/or intervention paradigms?
* Addresses novel concepts, methods, interventions and/or gaps in state-of-the-science?
* When appropriate, comment on:
	+ Likelihood of uptake of findings or recommendations
	+ Study orientation toward implementation
	+ Appropriate involvement of relevant clinical or operational partners in proposal development

**Investigators and Environment**. Reviewers evaluate the overall organization and management of the project to evaluate whether the initiation, conduct, and completion of the proposed research is feasible. Factors that may be considered are:

* Distribution of roles and responsibilities across project staff;
* Justification of Full-time Employee Equivalent (FTEE) allocations for each project year;
* Plans for coordinating multiple participants, tasks, or sites;
* Reasonableness of the timeline showing important benchmarks and products; and
* General feasibility of the management plan.

Reviewers will be specifically asked to comment on the following questions:

* Is the research team appropriate?
* Have a track record for success?
* Have the knowledge/background and resources (e.g., equipment, staff, mentorship for early stage investigators) to ensure timely and successful project completion?
* Capitalize on unique expertise or opportunity?
* When appropriate, comment on:
	+ Implementation expertise of study team
	+ Qualifications for mixed methods or qualitative analyses

**Investigator Qualifications.** Reviewers assess the expertise of each investigator and each major consultant, including professional credentials, institutional position, role in the project, expertise (especially as reflected in publications), and relevant experience. All reviewers assess the combined strength of the team in relation to the objectives of the project and determine whether it encompasses all needed skills and competencies.

**Study Participants**. Reviewers evaluate the risk/benefit ratio of the study, analyzing whether the study places human participants at risk of physical or psychological harm and evaluating the adequacy of provisions to minimize risk, protect participants’ privacy and the confidentiality of their records or responses, ensure informed consent, and minimize respondent burden. In considering human study participant issues, reviewers may question the decision of an IRB and may impose a stricter standard (see VHA Handbook 1200.05).

**Inclusion of Women and Minorities**. VA mandates that all research proposals reviewed and funded by ORD include women and minorities in their study populations to the extent possible. ONS reviewers are responsible for considering the adequacy of representation and to assess whether investigators have made a substantive effort to include women and/or minorities in each research proposal.

**Facilities and Resources**. Reviewers evaluate the adequacy of facilities and resources to carry out the proposed study. The proposal must include evidence of support from the applicant's VA facility, support from any additional study site(s), and documentation of any agreements with consultants, or commitment of non-VA resources to the study.

**Budget**. Project budgets need to be appropriate to the proposed work, sufficiently detailed, and well-justified. Reviewers assess the reasonableness of the project timeline and costs allocated to major budget categories. Personnel costs, and whether proposals are staffed appropriately, are key considerations. Prior to any funding decisions, all proposals under consideration will undergo administrative review of budgets by ONS staff. Items that appear to be outliers, and large amounts for equipment, travel, or subcontracts are scrutinized. This review ensures that VA funds are not used for any unauthorized purposes, such as patient care, salaries of Title 38 employees, and that the proposed budget is well justified.

**Importance of the Problem Addressed**. Reviewers assess the importance of the problem or question that the proposed research seeks to address, in terms of its prevalence, severity, urgency, cost, etc., for VA and the general public. The importance of the problem is assessed independently of the investigator’s approach.

**Contribution to VHA**. Reviewers consider the expected contribution of findings of the proposed research to improving the quality, effectiveness, or efficiency of health care in VA, or its potential to improve the health status of Veterans. This includes consideration of the adequacy and sustainability of the investigator’s plans for translating findings into practice.

**Disapproved Proposals**. A proposal may be disapproved if the SRG determines that the proposed study is unethical, is unlikely to yield useful information, or is not relevant to VA’s mission.

* Proposals that are disapproved are not given a numerical score.
* Studies disapproved for ethical considerations may not be carried out in VA space, with VA resources, even if the project is funded by another agency

**Appeals.** The appeals process is intended to ensure that the scientific review of all proposals is fair and equitable. It is not intended as a means to resolve differences in scientific opinion between the applicant and the reviewers, to adjust funding decisions, or to circumvent the peer review process. (See VHA Handbook 1204.01, Paragraph 7.f.)

If a PD/PI submits a revised application and an appeal of the previous application is subsequently sustained and funded before the revised application is reviewed, the revised application will be administratively withdrawn. If the revised application receives a fundable score and the appeal is sustained and fundable, only one of the two projects will be funded.

Note: Applicants are encouraged to revise and resubmit their ONS pilot grant, if allowed, or submit a new ONS pilot grant while an appeal is under review.

**Additional Review Criteria**

In addition to the above criteria, the following items will continue to be considered in the determination of scientific merit and the priority score:

**Protection of Human Subjects from Research Risk:** The involvement of human subjects and protections from research risk relating to their participation in the proposed research will be assessed according to the following criteria: (1) Risk to subjects; (2) Adequacy of protection against risks; (3) Potential benefits of the proposed research to the subjects and others; (4) Importance of the knowledge to be gained. Plans for the recruitment and retention of subjects will also be evaluated. Use of non-Veteran subjects must be justified.

**Inclusion of Women, Minorities, and Children in Research:** When human subjects are involved in the proposed research, the Scientific Review Board will also evaluate the adequacy of proposed plans to include subjects from both genders and all racial and ethnic groups (and subgroups), as appropriate for the scientific goals of the research.

Research involving children is restricted in VA-approved research and must not be conducted by VA investigators while on official duty, or conducted at VA facilities or approved off-site locations, unless a waiver has been granted by the Chief Research and Development Officer.

NOTE: Congressionally-mandated research programs that involve children are exempt from this policy.

If such a waiver is approved, the involvement of children as subjects in research must be in compliance with all applicable Federal regulations pertaining to children as research subjects (see VHA Handbook 1200.05, Appendix D).

**Care and Use of Vertebrate Animals in Research:** If vertebrate animals are to be used in the project, the adequacy of the plans for care and protection of vertebrate animals will be assessed for the following: (1) Detailed description of the proposed use of the animals; (2) justification for the use of animals and for the appropriateness of the species and numbers proposed; (3) adequacy of proposed veterinary care; (4) appropriate procedures for limiting pain and distress to that which is unavoidable; and (5) appropriate methods of euthanasia.

**Additional Review Considerations**

**Budget and Period of Support:** The appropriateness of the proposed budget and the requested period of support in relation to the proposed research may be assessed by the reviewers. The priority score should not be affected by the evaluation of the budget.

**Administrative and National Policy Requirements**

**Research Integrity**. ONS is committed to the highest standards for the ethical conduct of research. Maintenance of high ethical standards requires that VA medical centers and investigators applying for, and receiving, ONS Pilot Grants have appropriate procedures to preclude the occurrence of unethical research practices. All research data must be retained for 5 years after completion of a research project.

The PD/PI and others associated with the research must subscribe to accepted standards of rational experimental research design, accurate data recording, unbiased reporting of data, respect for the intellectual property of other investigators, adherence to established ethical codes, legal standards for the protection of human and animal subjects, and proper management of research funds.

Deliberate falsification or misrepresentation of research data will result in withdrawal of an application, possible suspension or termination of an award, and potentially, suspension of the application, possible suspension or termination of an award, and potentially, suspension of the investigator’s eligibility to submit proposals to HSR&D.

**Acknowledging VA Research Support**. By accepting an ONS Pilot Grant, the PI agrees to properly acknowledge VA affiliation and support in all public reports and presentations (see VHA Handbook 1200.19). Failure to acknowledge VA affiliation and support may result in termination of the award.

**Intellectual Property Rights**. By accepting this pilot award agrees to comply with VA policies regarding intellectual property disclosure obligations and Federal Government ownership rights resulting from the proposed work (see VHA Handbook 1200.18).

**Other Responsibilities and Expectations**:

Investigators funded for pilot projects are expected to submit a VHA Nursing Research Initiative application or other federal grant application within a year after completion of the study.

A one page interim report is due to Mr. Dexter Willis electronically by August 1, 2016

A final report is due to Mr. Dexter Willis electronically by July 1, 2017

1. **Program Schedule:**

|  |  |
| --- | --- |
| Submit Letter of Intent (LOI) | COB Nov 2, 2015 |
| Approval/Disapproval of LOI Notification | COB November 6, 2015 |
| Submit proposal electronically | COB December 11, 2015 |
| Funding Decision | December 31, 2015 |
| Electronic submission of required forms, approvals, and support letters       ……   | COB January 22, 2016 |
| Obligate or spend funds | September 2016 or facility policy |
| Submit one page final report | COB July 1, 2017 |

20-Oct-15