

TRISERVICE NURSING RESEARCH PROGRAM: EXPLORATORY RESEARCH AWARD INSTRUCTIONS

Purpose

The purpose of the Exploratory Research Award is to encourage and support military-relevant and military-unique preparatory investigations that have the potential to lead to larger, more comprehensive, and more expensive studies that are either on the same topic or follow from critical discoveries or advancements made by the preparatory investigation.

Exploratory studies may be conducted to accomplish one or more of the following:

- Explore an innovative concept or untested theory.
- Extend a previous discovery that addresses an important problem.
- Test a research design, research methods and procedures, and/or instruments.
- Test recruitment, randomization, and/or retention strategies.
- Estimate response and attrition rates.
- Generate preliminary data regarding variances, effect sizes, reliability and validity of measures, and/or outcomes that can be used to justify either a different TSNRP award or a research award from another Federal agency or program.
- Generate new hypotheses.
- Determine the financial or time costs of a research study.
- Identify critical research needs for an emerging topic within military nursing.

Award Amount

You may request funding of up to \$150,000 per year in direct costs, plus indirect costs as appropriate, for up to a 2-year performance period. The maximum award is \$300,000 in direct costs.

Application Forms

1. SF 424 (R&R), Application for Federal Assistance (also called the “Face Page”)

Complete highlighted areas, as appropriate

2. Project/Performance Site Location(s)

Provide the information for each site at which the research will be conducted. Depending on your study, you may have more than one performance site, which may not necessarily be your assigned duty station or academic institution.

3. Research & Related Senior/Key Person Profile

Provide the required (‘starred’) information for each senior/key person on the study.

Senior/key personnel are people who contribute substantively to the scientific development or execution of the study and devote measurable effort to the study, not occasional or as-needed effort. Ensure the mentor is included as key personnel.

Attach a biographical sketch for each senior/key person (limited to five pages for each person) using the PHS 398 Biosketch form (available at <http://grants.nih.gov/grants/forms/biosketch.htm>)

4. Research & Related Other Project Information

Complete all information, as appropriate. This form also requires the following documents which do not need to be submitted on any particular form. However, ensure the formatting requirements are followed as directed in the funding opportunity announcement.

- a. Project Summary/Abstract - Attach a Study Abstract that does not exceed one page and contains a summary of the proposed activity suitable for dissemination to the public. It should provide a complete overview of the entire study to a reader who might not read the rest of your grant application. Make sure to include the specific aims of your proposed study and describe the proposed design, rationale, and methods for achieving the study objectives and aims. Conclude this section with a relevance statement, describing how the proposed study is relevant to the body of military nursing science.
- b. Project Narrative – Attach a document that describes your **Research Plan**. Your plan will contain the following items in this order:
 - i. For revise/resubmit applications only: Introduction and response to reviewer table
 - ii. Specific Aims - **one page limit**

The following items are **limited to 12 pages total**, to include any figures or tables.

- iii. Background and Significance
- iv. Preliminary Studies/Prior Work
- v. Research Design and Methods

The following items do not have a specific page limit.

- vi. Protection of Human Subjects
- vii. Inclusion of Children
- viii. Vertebrate Animals
- ix. Consortium/Contractual Arrangements

i. Revise/Resubmit Table (only if needed)

A table with major reviewer comments/concerns/suggestions, changes made, and specific pages with relevant changes must be provided to summarize the revisions.

ii. *Specific Aims (one page limit)*

This item is the foundation on which the rest of your grant application is built. Specific Aims should present a direct relationship between your research questions or hypotheses, collected data, and data analysis.

iii. *Background and Significance*

Briefly describe the background that led to your proposed research study. Be sure to:

- Cite research literature that supports the significance of your research problem and identifies gaps your proposed study intends to fill.
- Describe the effect of the studies you cite on the concepts, methods, technologies, treatments, services, interventions, and outcomes that form the basis of your proposed study.
- Describe how your research will accomplish one or more of the identified purposes of the Exploratory Research Award.
- Include any economic impact that you expect the findings to have.

iv. *Preliminary Studies/Prior Work*

Highlight preliminary work that you (or your team) have done in the proposed area of study. Provide evidence demonstrating that your team has mastered the technical aspects of the proposed research/practice, including accessing the proposed sample population and pilot testing the proposed instruments.

The objective is to convince the reviewers that your team is prepared to undertake the proposed study and has a competitive advantage over other researchers or clinicians working in the same field.

Be sure to:

- Include relevant data from unpublished research or previous evidence-based practice.
- Describe what your preliminary data show and why the findings are significant to the proposed study.
- Report only research/evidence-based practice conducted by members of your proposed study team.

v. *Research Design and Methods*

Before describing the details of the methodology, first present the theoretical or conceptual basis of your research design.

Use enough detail (including methodology, statistics, controls, etc.) to clarify what will be done, how it will be done, who will do it, and how data will be interpreted, fully describing every step in the data collection procedures. Be sure to include details of the instrumentation, data collection procedures, and data analysis.

The **sample selection** that you describe should be realistic, especially if you are sampling a military population. Include:

- The parameters describing your population.
- The number of individuals available for sampling at each site.
- The results of a power analysis to justify the sample size used to answer your research question(s).
- Support letters demonstrating your access to settings and populations.
- Specific details of how you will identify and recruit subjects to your study.

Include a table that lists the reported **validity** and **reliability** for any tools, instruments, surveys, or other measures that you will use in your research study.

Finish with a thoughtful **dissemination plan**. This should explain the strategies that you will use to disseminate the results of your study to the military nursing community.

vi. Protection of Human Subjects

Use this section to describe any potential risks to your subjects caused by participation in your study and the actions that you and your team will take to minimize these risks. Include discussion of:

- Confidentiality.
- Coercion.
- Volunteerism.
- Data safety.
- Your monitoring plan.
- Health Insurance Portability and Accountability Act (HIPAA) compliance.
- Any other issue related to the protection of human subjects.

Consult the current U.S. Department of Defense (DoD) Service- and site-specific human subjects protection requirements and ensure that your plan for human protection meets those requirements. Research involving human subjects must be conducted in full compliance with all applicable Federal regulations and DoD policies.

Research taking place on DoD installations or using DoD beneficiaries must have the approval of all appropriate IRBs. Academic institutions' human use approval is not a substitute for the appropriate DoD IRB approval at the performance site. Because the Uniformed Services University of the Health Sciences (USU) is the grantor, its IRB will conduct a secondary review of your study, in addition to the review(s) conducted by your performance site(s) IRB(s). (**Note:** *If you plan on including vulnerable populations, your study will be subject to strict scrutiny; obtaining approval for your study may be a lengthy and difficult process.*)

Documented evidence of IRB approval of your research is not required with your grant application, but you must provide this documentation to TSNRP for each performance site if you receive an award.

(Note: Only an IRB can determine whether your research is exempt from human subject regulations.)

vii. Inclusion of Children

If your proposed research involves vulnerable populations, such as children, it must follow the additional protections and regulations described in Subparts B, C, and D of 45 CFR Part 46. A child is a person who has not attained the legal age for consent to treatment or procedures involved in your research under the applicable laws.

If your study involves children, describe:

- The rationale for selecting a specific age range of children.
- Planned procedures for protecting against or minimizing potential risks to the children. This plan must include a description of:
 - Your investigative team's expertise in working with children of the age(s) you include.
 - The appropriateness of the available facilities to accommodate the children.
 - The inclusion of a sufficient number of children to allow a meaningful analysis.

Also describe your process for meeting parental permission and child assent requirements, including:

- The circumstances under which you will seek and obtain consent.
- Who will seek and obtain consent and, if applicable, assent.
- The nature of the information that you will provide to prospective child subjects.
- The method for documenting consent.

viii. Vertebrate Animals

To conduct a research study using non-human vertebrate animals, your research site(s) must be accredited by the Association for Assessment and Accreditation of Laboratory Animal Care (AAALAC) International. Your research must also be in full compliance with all applicable Federal regulations and DoD policies for the use of vertebrate animals in research.

Include the following information in this section if your study involves the use of non-human vertebrates:

- A detailed description of the proposed use of the animals.
- A justification of the animals' use, of the species of animal, and of the number of animals of each species.
- A description of the proper veterinary care for each species and the per diem rate for their care.
- Procedures for ensuring that discomfort, distress, pain, and injury will be limited to that which is unavoidable in conducting your research.

- A description of the use of analgesic, anesthetic, and tranquilizing drugs or comfortable restraining devices, when appropriate, to minimize discomfort, distress, pain, and injury to the animals.
- A description of any method of euthanasia that you will use and the rationale for its selection. State whether this method is consistent with the recommendations of the American Veterinary Medical Association Guidelines for the Euthanasia of Animals. If the method does not accord with the guidelines, justify your choice of the euthanasia procedure.

If you receive a TSNRP Award, the **Institutional Animal Care and Use Committee** (IACUC) at each research site must approve your study. Because USU is the grantor for TSNRP awards, its IACUC will conduct a secondary review of your study as well. You must provide documentation of each IACUC's approval to TSNRP to receive your monetary award.

ix. Consortium/Contractual Arrangements

Explain the programmatic, fiscal, and administrative arrangements to be made between your Applicant Organization and any consortium organization(s). Include letters of collaboration and budget plans for each contractual agreement (including PHS 398 budget pages for both the initial budget period and the entire proposed period). Place the letters of collaboration in an appendix to your grant application.

Some military treatment facilities will require a **Cooperative Research and Development Agreement** (CRADA) between themselves and your grantee organization. This is an agreement between a government agency and a private company or university to work together on research and development. Before selecting a performance site(s) for your study, you should find out whether your grantee organization has a CRADA in place with the specific facility that you are considering using. The process to create a CRADA can take several months. You may need to include this process in your project's timeline.

- c. Bibliography & References Cited – Attach a document that contains a list of references from your Project Narrative. Use a consistent style of your choice for the bibliography — one that includes the article and journal or book titles, volume number, page numbers, and year of publication in the bibliographical references.
- d. Facilities & Other Resources – Attach a document that describes the resources at each performance site that are available for the proposed study. Reviewers will use this information to assess the capability of the organizational resources available to perform your study. Consider the following:
 - Identify the facilities that will be used for the study (e.g., laboratory, clinical, research animals, computer[s], office). If appropriate, indicate capacities, pertinent capabilities, relative proximity and extent of availability to the study. Describe only those resources that are **directly applicable** to the proposed study.

- Provide any information describing the Other Resources available to the study (e.g., machine shop, electronic shop) and the extent to which they would be available.
 - Describe how the scientific environment that would contribute to the probability of success (e.g., institutional support, physical resources, intellectual rapport). In describing this environment, discuss ways in which the study will benefit from unique features of the scientific environment or subject populations or will employ useful collaborative arrangements.
 - Describe the Applicant Organization's investment in the success of the principal investigator (e.g., resources for classes, travel, and training; collegial support, such as career enrichment programs, assistance and guidance in the supervision of trainees involved with the study, and availability of organized peer groups; logistical support, such as administrative management and oversight, and best practices training; and financial support, such as protected time for research with salary support).
 - If there are multiple performance sites, describe the resources available at each site.
 - Describe any special facilities used for working with biohazards or other potentially dangerous substances, if applicable. (**Note:** Information about select agents must be described in the Project Narrative.)
- e. Equipment – this information is provided as part of the budget document, and **is not required on this form**.

5. Research & Related Budget

Provide the required information for the initial (12-month) budget, adding a budget period for each additional 12-months.

- a. Senior/Key Person - In this section, list each person involved in your proposed study, beginning with you (the PI). Also include any individuals who will not receive compensation. Designate each person's role on the study, avoiding any duplication of roles or responsibilities.

Enter the number of months that each person will spend on the study. **This number must be greater than zero and cannot be "as needed" or another non-number.** Use only the column labeled **Cal. Mnths** (calendar months) for each individual, unless the person in question has different appointments throughout the calendar year. If the person will have one appointment during the academic months and another during the summer months, complete the columns labeled **Acad. Mnths** (academic months) and **Summer Mnths** (summer months) with the months during each period that the individual will spend on your research; leave the calendar month column blank.

Enter the **Base Salary** for any personnel on the study who are neither Federal employees nor active duty military personnel; this should remain blank for active duty and Federal employees. You may not use a TSNRP grant award to pay salaries to active duty personnel or Federal employees. For each such individual involved in your research study, leave the funds requested.

Indicate the salary requested for each person listed in the column labeled **Salary Requested**. Regardless of the number of months that each individual will devote to the research study, indicate only the amount of salary for this budget period for each individual.

In the column labeled **Fringe Benefits**, list the benefits for each individual that are included with his or her salary. Your Applicant Organization will provide you with this information.

Total the amounts listed in the **Salary Requested** and **Fringe Benefits** columns in the column indicated.

- b. Other Personnel - Provide the names and organizational affiliations of all consultants not involved in consortium/contractual arrangements. Include any consultant physicians in connection with patient care and persons who are confirmed to serve on external monitoring or advisory committees. Include the number of days of anticipated consultation, the expected rate of compensation, travel, per diem, and other related costs for each consultant. You will describe each consultant's services in the Budget Justification.
- c. Equipment Description – list each piece of equipment exceeding \$5,000. All other equipment (less than \$5,000) is considered 'materials and supplies' and included on the other direct costs.
- d. Travel - A maximum of \$2,000 per award may be budgeted for travel to scientific conferences or meetings for the purpose of dissemination. (Note: Dissemination activities typically occur in the last year of the proposed study.)
- e. Participant/Trainee Support Costs – Include any incentive costs that would be provided to those that participate in the study. This includes any inpatient or outpatient care costs directly required due to participation in the study (not part of their usual healthcare).
- f. Other Direct Costs
 - The maximum allowable cost for computer equipment and software is \$3,000.
 - In most cases, TSNRP awards do not pay for Cooperative Research and Development Agreement (CRADA) or IRB fees. However, if required, a one-time maximum of \$2,500 may be budgeted for IRB/CRADA fees.
- g. Budget Justification – Attach a single file with the following information included in the budget justification, which does not require any particular form. However, ensure the formatting requirements are followed as directed in the funding opportunity announcement. You must justify your request for:
 - The inclusion of each senior/key personnel listed on the study. Describe each individual's specific function. Include any "to-be-appointed" positions.
 - The inclusion of any consultants, other than those involved in consortium/contractual arrangements. Describe the services that each consultant will perform. Include the number of days of anticipated consultation.
 - Required equipment (exceeding \$5,000).

- Travel. List each travel request and travel cost separately. This travel should be necessary for the completion or outcomes dissemination of the research that you propose. Any international travel for dissemination purposes must be fully justified and clearly benefit both TSNRP and the U.S. military nursing community.

For each travel request and for each individual, list:

- Purpose of the travel.
- Potential destination.
- Estimated round-trip airfare or car mileage.
- Estimated hotel prices.
- Estimated per diem costs.
- The registration fee, if applicable.

If you plan to take multiple trips, you may create a table for this section and include it as an appendix to your grant application.

- Participant Costs
- Materials and Supplies: For supplies that total less than \$1,000, list each category of supplies that you will purchase with the award along with the total cost for the category. If the total is greater than \$1,000, list each item and cost in that category individually. The maximum allowable cost for computer equipment and software is \$3,000. Computer equipment or software should be based on the needs of the study and should be well justified.
- Any significant increase in budget between subsequent years of your proposed study.
- Inclusion of active duty, Reserve, or National Guard personnel. For each study team member (including the PI) who is an active duty, Reserve, or National Guard member, provide details about his or her deployment or permanent change of station/assignment dates and the plan for continuing his or her research role in the event of deployment or assignment away from the performance site. If you are an active duty, Reserve, or National Guard applicant, include another nurse scientist who has agreed to continue the research in the event that you are away for more than 3 months and describe the contingency plan. Include a letter of support from this person as an appendix to your application.
- Other Expenses: Itemize any other direct costs that you anticipate in your research study, such as:
 - Animal maintenance (cost of care per animal and number of care days).
 - Publication costs.
 - Equipment rental.
 - Communication costs.
 - Transcription costs.
 - Advertising costs (to recruit study participants).

Note: Provide the hours and rates for all equipment rentals and services that you list.

Consortium/Contractual Costs

Each participating consortium/contractual organization must submit a separate detailed budget for both the initial budget period and the entire proposed research period.

Consortium arrangements may involve personnel costs, supplies, and other allowable costs, including F&A costs. Contractual costs for support services, such as laboratory testing of biological materials, clinical services, or data processing, are occasionally sufficiently high to warrant a similar categorical breakdown of costs.

For each budget from a participating consortium/contractual organization, leave the **Consortium/Contractual Direct Costs** category blank and use the **Subtotal Direct Costs** category to total the consortium direct costs. When F&A costs are requested by a consortium organization, enter those costs in the **Consortium/Contractual F&A Costs** category for each supplementary budget. Provide the F&A cost base and rate information in the budget **Justification** section. The **Total Direct Costs for Initial Budget Period** category can be used for the consortium/contractual Total Costs (Direct Costs plus F&A).

If you will be conducting a multisite study, each additional site beyond that at which you will work must enter into a consortium/contractual arrangement with you and with your Applicant Organization. This is a formalized agreement whereby you and one or more other organizations that are separate legal entities carry out a research study. Each of these other organizations must have a lead associate investigator (AI) who will be in charge of the study at his or her site. Under the agreement, you must perform a substantive role in conducting the planned research and not merely serve as a conduit of funds to another party or parties. These agreements typically involve a specific percentage of effort from the consortium organization's lead AI and a categorical breakdown of costs, such as supplies and other allowable expenses, including F&A costs. Provide the details of any consortium/contractual arrangements in your Research/Study Plan.

6. Attachment Forms

- a. Timeline – Provide a detailed timeline that delineates how your study will progress. This timeline should include major tasks and milestones as well as the time periods within which you will accomplish them. The timeline should include IRB processing. (Note: If you plan to study vulnerable populations or use multiple performance sites, IRB processing will take longer.)
- b. Letters of Support – Include letters of support on letterhead from:
 - Commander, director, supervisor, or manager of the military installation, medical facility, department, or unit that might be affected by any aspect of your research. These letters should demonstrate that you and your research team have access to the population and facilities you need to conduct the study. (*Examples:* a letter of support

to access a military treatment facility or other clinical site; a letter of support to access data in a secure database or data registry.)

- Associate investigators.
 - Consultants. These letters should include the scope of the consultants' work and responsibilities, level of commitment and percentage of effort, and duration of the commitment.
 - Site commanders (if relevant).
- c. Additional Information – Provide any additional material relevant to your grant application but not suited for the main body of the grant application, such as:
- Copies and/or detailed descriptions of data collection tools, instruments, surveys, or other measures.
 - Letters of permission for the use of any instruments not in the public domain. Using instruments not in the public domain requires the **authors' permission**. If you are using any such instruments, include letters from the authors or their legal representatives granting you permission for their use.
 - Informed consent document.
 - HIPAA authorization form.
 - Published papers that you've authored showing preliminary research, pilot data, or history of previous research.

Further Questions

This is the first year these forms have been used for TSNRP proposals, and it is expected there will likely be some unanticipated difficulties. If there are any further questions that have not been fully addressed by these instructions, please contact Lt Col Jennifer Hatzfeld via email at jennifer.hatzfeld@usuhs.edu or by telephone at 301-319-0596. Answers to frequently asked questions will be posted to the TSNRP Call for Proposal web page at <https://www.usuhs.edu/tsnrp/call-for-proposals> and may be a helpful resource. We appreciate your patience as we transition to this new system.